ACORDA THERAPEUTICS INC
Form 10-K
February 29, 2016

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, 2015

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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, 2015, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was $706,885,171. 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, 2015 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, 2016, the registrant had 45,749,265 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 2016 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2015. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

Part III, Item 10, Directors, Executive Officers and Corporate Governance.

Part III, Item 11, Executive Compensation.

Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Part III, Item 13, Certain Relationships and Related Transactions, and Director Independence.

Part III, Item 14, Principal Accounting Fees and Services.

ACORDA THERAPEUTICS, INC.

2015 FORM 10-K ANNUAL REPORT

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This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: The ability to complete the Biotie Therapies Corp. transaction on a timely basis or at all; the ability to realize the benefits anticipated from the Biotie Therapies transaction and the Civitas Therapeutics, Inc. transaction, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the ability to successfully integrate Biotie Therapies' operations and Civitas's operations, respectively, into our operations; we may need to raise additional funds to finance our expanded operations and we may not be able to do so on acceptable terms; 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, or the products that we would acquire if we complete the Biotie Therapies transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator Biogen 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 function and improve the lives of people with neurological disorders. We market three U.S. Food and Drug Administration (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 five Orange Book-listed patents providing protection for Ampyra up to 2027. Ampyra also has Orphan Drug designation, which gives it marketing exclusivity in the U.S. until January 2017. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described below under “Company Highlights – Ampyra/Fampyra Patents and Legal Proceedings” and in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights.

We have an industry leading pipeline of novel neurological therapies addressing a range of disorders, including MS, Parkinson’s disease, chronic post-stroke walking deficits (PSWD), epilepsy and migraine. Our goal is to help patients to a better future, while building a leading neurology company with a portfolio of innovative products. Our pipeline includes the following three late stage programs:

- CVT-301, an inhaled formulation of levodopa, or L-dopa, using our proprietary ARCUS technology, in Phase 3 development for the treatment of OFF periods in Parkinson’s disease;

- Plumiaz, a proprietary nasal spray formulation of diazepam, in Phase 3 development for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures; and

- A program evaluating the use of twice-daily (BID) dalfampridine to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD), and exploring a once daily (QD) formulation of dalfampridine for use in this program.

We are expecting important clinical milestones in 2016 for all three of these late-stage programs, including the completion of a pivotal trial for the CVT-301 program this year, and we plan to file New Drug Applications for both the CVT-301 and Plumiaz programs in 2017. We project that these two therapies, if approved, could generate combined peak annual U.S. net revenue of more than $700 million. Also, in 2016 we expect to perform an interim analysis in our Phase 3 trial of dalfampridine for chronic post-stroke walking deficits. This analysis, combined with results from our development efforts on a once-daily formulation of dalfampridine, will establish the next steps for the program.

In January 2016, we announced that we had entered into an agreement to acquire Biotie Therapies Corp. for a cash purchase price of approximately $363 million. Subject to completion of the acquisition, which we

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expect to occur in the third quarter of 2016, we would acquire worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. A2a receptor antagonists have the potential to be the first new class of drug for Parkinson's disease in over 20 years. We believe that tozadenant would be complementary to our other Phase 3 product for Parkinson's disease, CVT-301, because while tozadenant is aimed at reducing overall OFF time, CVT-301 is aimed at rapid improvement of OFF periods when they occur. We project that, if approved, tozadenant could generate peak annual U.S. net revenue of more than $400 million. Further expanding our pipeline, if we complete the acquisition we would also obtain global rights to SYN120, an oral, 5-HT6/5-HT2A dual receptor antagonist for Parkinson's-related dementia, in Phase 2 development with support from the Michael J. Fox Foundation. Also, Biotie receives double digit royalties from sales of Selincro, a European Medicines Agency (EMA)-approved orally administered therapy for alcohol dependence therapy. Selincro has been introduced across Europe in 29 countries by Biotie's partner, H. Lundbeck A/S, a Danish pharmaceutical company specializing in central nervous system products. Selincro is not approved for use in the U.S. and is not under development for use in the U.S.

Concurrently with the announcement of the Biotie transaction, we announced two separate financing transactions. The first was a private placement of 2,250,900 shares of our common stock for an aggregate purchase price of approximately $75 million. We paid discounts and commissions of $2,250,900 in connection with the private placement, which settled on January 26, 2016. We intend to use the net proceeds from the private placement to fund, in part, the acquisition of Biotie described above. If the acquisition is not consummated for any reason, we will use all of the net proceeds from the private placement for general corporate purposes. We also announced a commitment from JPMorgan Chase, N.A. for an asset-based credit facility for up to $60 million. The closing of this credit facility transaction is expected to occur in the first quarter of 2016.

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 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, using our own specialty sales force, and had net revenue of $436.9 million for the year ended December 31, 2015.

Since the March 2010 launch of Ampyra, more than 110,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. As of December 31, 2015, 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. Our First Step program provides eligible patients with two months of Ampyra at no cost. During 2015, on average more than 70% of new Ampyra patients enrolled in First Step. The program is in its fifth year, and data show that First Step participants have higher

compliance and persistency rates over time compared to non-First Step

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patients. Approximately 50% of patients who initiate Ampyra therapy with the First Step free trial program convert to paid prescriptions.

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial 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. 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 is marketed as Fampyra outside the U.S. by Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen, 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 anticipates making Fampyra available in additional markets in 2016. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a $25 million milestone payment from Biogen in 2011, which was triggered by Biogen's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be $15 million, due when ex-U.S. net sales exceed $100 million over four consecutive quarters.

In October 2015, we presented 5-year post-marketing safety data for dalfampridine extended release tablets in MS at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. The data presented continue to be consistent with those reported in double-blind clinical trials, with incidence of reported seizure remaining stable over time.

Ampyra/Fampyra Patents and Legal Proceedings

We have five issued patents listed in the Orange Book for Ampyra, 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 USPTO, this patent will extend into 2027.

- The second is U.S. Patent No. 5,540,938, 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, this 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, this 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.

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- 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 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.

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 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 certain claims of these patents. In response to the filing of these ANDAs, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. These lawsuits have been consolidated into a single case. The court has scheduled a Markman hearing on March 7, 2016, and has set a five day bench trial starting on September 19, 2016. 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 Notices. 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 statutory 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. In October and December 2015, we entered into settlement agreements with two of the generic drug manufacturers, Actavis Laboratories FL, Inc. and Aurobindo Pharma Ltd., respectively. These settlements do not resolve pending patent litigation that we brought against other ANDA filers, described in this report.

In May 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (“Sun”) advising that they had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun challenged the validity of four of our five Orange Book-listed patents for Ampyra, and they also asserted that generic versions of their products may not infringe certain claims of these patents. In response to the filing, we filed a lawsuit against Sun in the U.S. District Court for the District of Delaware alleging multiple counts of patent infringement. In October 2015, we entered into a settlement agreement with Sun to resolve this patent litigation. The settlement with Sun does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

In September 2015, we received a Paragraph IV Certification Notice from Par Pharmaceutical, Inc. (“Par”) advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Par challenged the validity of four of our five Orange Book-listed patents for Ampyra. In response to the filing of the ANDA, in September 2015 we filed a lawsuit against Par in the U. S. District Court for the District of Delaware asserting infringement. In January 2016, we entered into a settlement agreement with Par to resolve this patent litigation. The settlement with Par does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

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.

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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. In August 2015, the U.S. Patent and Trademark Office Patent Trials and Appeals Board ruled that it would not institute inter partes review of either of these patents. In September 2015, however, the hedge fund filed two motions for reconsideration to the U.S. Patent and Trademark Office Patent Trials and Appeals Board, requesting that the denial to institute these two IPRs be reversed.

In September 2015, the same hedge fund filed four separate IPR petitions with the U.S. Patent and Trademark Office. These new IPR petitions challenge the same two patents that were the subject of the February 2015 IPR petitions and also U.S. Patent Nos. 8,354,437 and 8,440,703. The challenged patents are four of the five Ampyra Orange-Book listed patents. We have opposed the requests to institute these IPRs, and if one or more is allowed to proceed, we will oppose the full proceedings and defend our patents. The 30 month statutory stay period based on patent infringement suits filed by us against ANDA filers is not impacted by these filings, and remains in effect.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), 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. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

The ANDA and IPR litigation and legal proceedings discussed above are further described in Part I, Item 3 of this report.

CVT-301, CVT-427 and ARCUS Technology

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 periods of Parkinson’s disease, or PD. Our acquisition of Civitas also included rights to Civitas’ proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a leased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. CVT-301 is an inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods 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 for the treatment of Parkinson’s disease is oral levodopa, but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects as Parkinson’s disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease. 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 allows delivery of significantly larger doses of medication than are possible with

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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 periods in Parkinson's disease. We expect results from the efficacy trial in the fourth quarter of 2016, and pending timely recruitment for clinical trials, our goal is to file a new drug application, or NDA, in the U.S. in the first quarter of 2017. We are projecting that, if approved, annual peak net revenue 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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS delivery system. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority 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. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in a nasally-delivered formulation. However, based on available data, we believe that nasally-delivered triptans generally have an onset of action similar to orally administered triptans. In December 2015, we initiated and completed a Phase 1 clinical trial of CVT-427 for acute treatment of migraine. We expect to provide an update on this program by the end of the first quarter of 2016.

Plumiaz

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity, also known as seizure clusters or 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. In May 2015, we announced that we completed discussions with the FDA, and are advancing development of Plumiaz. Based on these discussions, we are conducting three clinical trials for Plumiaz, which we have initiated and are currently enrolling. We are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. If approved, we project peak annual U.S. net revenue of more than $200 million.

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 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. As part of the trial design, we are planning to conduct an interim analysis of the trial data in the third quarter of 2016. This analysis, combined with the results from our development efforts on a once-daily formulation of dalfampridine (described below), will establish the next steps for the program.

We have been exploring a once-daily (QD) formulation of dalfampridine for use in the 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 currently have three prototypes from three different partners based on in vitro testing, which do not have the alcohol dose dumping issue we identified with the initial QD formulation. All three prototypes are currently in Phase 1 pharmacokinetic studies, and we expect to provide an update on these studies by the end of the first quarter of 2016.

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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 included 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. In April 2015, we presented additional safety data from this trial at the 67th American Academy of Neurology Annual Meeting. The additional data showed that rHIgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. This data was presented at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. We are advancing clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1 trial using one of two doses of rHIgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the first half of 2017.

Cimaglermin alfa/Neuregulins

Cimaglermin alfa is our lead product candidate for our neuregulin program. We 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, which resolved within several days. In March 2015, we presented new analyses of data from this trial at the American College of Cardiology (ACC) 64th Annual Scientific Session and Expo. These analyses found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In 2013, we commenced 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. In June 2015, we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within several days, as was the case with the one Hy's Law case reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

Corporate Update

We currently lease approximately 163,000 square feet of office and laboratory space in Ardsley, NY. This space includes 25,405 square feet of expansion space that we occupied in the first quarter of 2015 pursuant to expansion options in our lease for this facility.

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In January 2016, we engaged Burkhard Blank, M.D., to assume the responsibilities of Chief Medical Officer on an interim basis. Dr. Blank has more than 25 years of industry experience, holding senior leadership positions with responsibility for managing international clinical trial programs, as well as heading regulatory affairs, statistics, drug safety and related departments. Dr. Blank was engaged upon the departure of Enrique Carrazana, M.D., our former Chief Medical Officer. Dr. Carrazana is expected to serve as a consultant to the company for at least six (6) months following his departure.

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 neurology as strategic points of access to additional nervous system markets, including stroke, Parkinson's disease, and epilepsy. In 2016, we are focused on the following priorities:

- Progressing development of our late stage programs, including: CVT-301, an inhaled formulation of levodopa, or L-dopa, using our proprietary ARCUS technology in Phase 3 development for the treatment of OFF periods in Parkinson's disease; Plumiaz, a proprietary nasal spray formulation of diazepam, in Phase 3 development for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures; and our program evaluating the use of twice-daily (BID) dalfampridine to improve waking in people who are suffering from chronic post-stroke walking deficits (PSWD), and exploring a once daily (QD) formulation of dalfampridine for use in this program.

- Advancing our other clinical development programs, including: rHIgM22, a remyelinating antibody that is in Phase 1 development as a treatment for MS; and CVT-427, an inhaled triptan in Phase 1 development as an acute treatment for migraine using our ARCUS pulmonary delivery.

- Making disciplined investments in growing sales of Ampyra, and defending our intellectual property relating to Ampyra.

- Completing our pending acquisition of Biotie Therapeutics, and continuing to seek opportunities to 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 that leverage our competencies in neurology. We will also consider earlier-stage programs based on compelling science and the potential to address significant unmet medical needs.

Pending Biotie Therapies Acquisition

On January 19, 2016, we entered into a combination agreement to acquire Biotie Therapies Corp. for a cash purchase price of approximately $363 million. Pursuant to the combination agreement, which is further described below, we will make a public all cash tender offer in the U.S. and Finland for all of Biotie's outstanding capital stock. If we close the tender offer pursuant to the combination agreement, we expect to complete the acquisition of the balance of any Biotie capital stock not acquired through the tender offer in the third quarter of 2016. We believe this pending acquisition is an important step in our strategic plan described above.

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Biotie is a biopharmaceutical company primarily focused on developing therapeutics for central nervous system disorders. Biotie's currently active pipeline includes:

- Tozadenant, an oral product candidate, and selective inhibitor of the adenosine A2a receptor that Biotie is developing as an adjunct to levodopa, or L-dopa, for the treatment of Parkinson's disease to reduce OFF time;

- SYN120, an oral product candidate to treat both cognitive deficits and psychosis, which frequently coincide in neurodegenerative diseases such as Parkinson's disease and Alzheimer's disease; and

- BTT1023, a product candidate for the orphan disease Primary Sclerosing Cholangitis (PSC), a chronic and progressive fibrotic liver disease for which there is no FDA-approved treatment.

Also, Biotie receives double digit royalties from sales of Selincro, a European Medicines Agency (EMA)-approved orally administered therapy for alcohol dependence therapy. Selincro has been introduced across Europe in 29 countries by Biotie's partner, H. Lundbeck A/S, a Danish pharmaceutical company specializing in central nervous system products. Selincro is not approved for use in the U.S. and is not under development for use in the U.S.

Combination Agreement

Pursuant to the terms of the combination agreement, we will offer to acquire all of the outstanding shares, American Depositary Shares ("ADS"), options, restricted unit awards and warrants (collectively, the "Equity Interests") in Biotie through a public tender offer (the "Tender Offer"), and, if necessary, through subsequent compulsory redemption proceedings in accordance with the Finnish Companies Act (together with the Tender Offer, the "Transaction").

Pursuant to the terms and conditions of the combination agreement, the consideration offered by us for all issued and outstanding shares, ADSs, options, restricted unit awards and warrants of Biotie in the Transaction is (i) EUR 0.2946 in cash per share, (ii) EUR 23.5680 in cash per ADS, (iii) various prices for the options and restricted unit awards depending on their exercise price and (iv) EUR 0.1664 in cash per warrant.

The consummation of the Transaction is subject to certain customary conditions, including, among others, (i) the valid tender to (or other acquisition by) us of at least 90 percent of the issued and outstanding shares and voting rights of Biotie on a fully diluted basis, and (ii) the combination agreement not having been terminated. The waiting period for the Transaction under the Hart-Scott-Rodino Antitrust Improvement Act expired on February 16, 2016.

Consummation of the Transaction is not conditioned on our receipt of any financing. The consummation of the Tender Offer is expected to occur in the second quarter of 2016 and the consummation of the Transaction is expected to occur in the third quarter of 2016.

We and Biotie have each made customary representations and warranties in the combination agreement.

The combination agreement includes certain customary termination provisions. In particular, the combination agreement may be terminated with immediate effect at any time prior to closing (i) by Biotie if its board of directors has cancelled or changed its recommendation concerning the Transaction in compliance with the provisions of the combination agreement, (ii) by us if Biotie's board of directors has cancelled or changed its recommendation concerning the Transaction in a manner detrimental to us or (iii) by either party if the closing of the Tender Offer has not occurred by June 19, 2016 (except where the failure to close by such date resulted from such party's breach of the combination agreement). The combination agreement also provides for Biotie to pay us a termination fee of USD 4,500,000 as compensation for our reasonable costs if the combination agreement is, as a result of a competing offer or competing proposal, terminated by Biotie or us in connection

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with a cancellation or change of the recommendation of Biotie's board of directors concerning the Transaction.

The combination agreement is governed by and construed in accordance with the laws of Finland.

Certain Biotie shareholders and ADS holders representing more than a majority of the outstanding shares and votes (on a fully diluted basis) in Biotie have, subject to certain customary conditions, irrevocably undertaken to accept the Tender Offer. This includes all the holders of Biotie warrants and members of the management team of Biotie, who have subject to certain customary conditions irrevocably undertaken to tender their equity instruments into the Tender Offer. Each of the undertakings will terminate upon certain customary termination events, including in the event the combination agreement is terminated.

2015 Financing Transactions

Concurrently with our entering into the Biotie combination agreement described above, we announced two separate financing transactions. The first was the issuance of 2,250,900 shares of our common stock to an initial purchaser in a private placement transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"). The shares were issued to the initial purchaser in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act. The aggregate offering price for the shares the initial purchaser was $74,999,988. In connection with the private placement, we paid $2,250,900 in aggregate discounts and commissions. The settlement of the shares with the initial purchaser occurred on January 26, 2016. We intend to use the net proceeds from the issuance of the shares to fund, in part, the acquisition of Biotie described above. If the acquisition of Biotie is not consummated for any reason, we will use all of the net proceeds from the issuance of the shares for general corporate purposes. The shares will not be registered under the Securities Act or any state securities laws and may not be offered or sold in the U.S. absent an effective registration statement or an applicable exemption from registration requirements or a transaction not subject to the registration requirements of the Securities Act or any state securities laws.

Also, we received a commitment from JPMorgan Chase Bank N.A. for a $60 million asset based revolving credit facility which will be secured by our assets and the assets of our domestic subsidiaries. Availability under the facility will be based on our and our domestic subsidiaries' accounts receivable, inventory and certain machinery and equipment, and the closing of the facility is subject to customary conditions, including the negotiation and execution of definitive documentation. The closing of this transaction is expected to occur in the first quarter of 2016.

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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 (outside U.S.)
Zanaflex Capsules and an authorized generic version of the capsules	Spasticity	FDA-approved	Acorda (U.S.); authorized generic marketed by Actavis (an Allergan plc subsidiary/ formerly 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 periods of Parkinson’s disease	Phase 3 clinical trials ongoing	Acorda/Worldwide
Plumiaz	Seizure Clusters/Acute Repetitive Seizures	Phase 3 clinical trials ongoing	Acorda/Worldwide (excluding certain Asian countries)
Dalfampridine	Chronic post-stroke deficits	Phase 3 clinical trial ongoing	Acorda/Worldwide (contract governs Biogen ex-U.S. option)
CVT-427	Migraines	Phase 1 clinical trial completed	Acorda/Worldwide
Remyelinating Antibodies Program	MS	Second Phase 1 clinical trial of rHIgM22 ongoing	Acorda/Worldwide
Neuregulin Program	Heart failure	cimaglermin alfa Phase 1b clinical trial on hold	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)

Background on Neurological and Other Conditions

We are a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore 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.

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

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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. 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.

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 U. S. 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 periods. OFF periods, which are characterized by a re-emergence of Parkinson's disease symptoms, increase in frequency and severity during the course of the disease. About half of people with Parkinson's disease treated with L-dopa therapy experience OFF periods. For the approximately 350,000 people in the U.S. who experience them, OFF periods are inadequately addressed by available therapies and are considered one of the greatest unmet medical needs facing people with Parkinson's disease.

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 tests for epilepsy.

The Centers for Disease Control and Prevention, or 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 seizure clusters or acute repetitive seizures, or ARS, which are

characterized by bouts of increased seizure activity.

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Ischemic Stroke

An ischemic 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. Approximately 87% of all strokes are classified as ischemic strokes. Current treatments for post-stroke deficits include physical and occupational therapy, but there are no pharmacologic therapies indicated specifically to improve function. Approximately half of those living with post-stroke deficits - 3.5 million people - have ongoing mobility issues. Total direct annual stroke-related medical costs for 2012 were estimated to be approximately $72 billion.

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 U. S., 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 for acute treatment of migraine. Oral triptans, which account for the majority 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. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in a nasally-delivered formulation. However, based on available data, we believe that nasally-delivered triptans generally have an onset of action similar to orally administered triptans.

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

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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.

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.

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.

Neuropathic Pain

There are several underserved neuropathic pain conditions that, together, represent approximately 4 million cases in the U. S. 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.

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,

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progressive relapsing and primary progressive). Ampyra can be used alone or with concurrent medications, including immunomodulatory drugs. The majority of patients in our two Phase 3 clinical trials for Ampyra (63%) were taking immunomodulatory drugs (interferons, glatiramer acetate, or natalizumab). Ampyra is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), which was previously referred to as fampridine.

We have 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. Also, Ampyra has Orphan Drug designation from the FDA for dalfampridine in MS, which will provide Ampyra with seven years of market exclusivity for this use, until January 2017. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights.

Ampyra is marketed as Fampyra outside the U.S. by Biogen under a 2009 license and collaboration agreement. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra available in additional markets in 2016.

Background

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

Clinical Studies and Safety Profile

Our New Drug Application, or NDA, for Ampyra was based on data from a comprehensive development program assessing the safety and efficacy of Ampyra, including two Phase 3 trials that involved 540 people with MS. The primary measure of efficacy in our two Phase 3 MS trials was walking speed (in feet per second) as measured by the Timed 25-foot Walk (T25FW), using a responder analysis. A responder was defined as a patient who showed faster walking speed for at least three visits out of a possible four during the double-blind period than the maximum speed achieved in the five non-double-blind, no treatment visits (four before the double-blind period and one after). A significantly greater proportion of patients taking Ampyra 10 mg twice daily were responders compared to patients taking placebo, as measured by the T25FW (Trial 1: 34.8% vs. 8.3%; Trial 2: 42.9% vs. 9.3%). The increased response rate in the Ampyra group was observed across all four major types of MS. During the double-blind treatment period, a significantly greater proportion of patients taking Ampyra 10 mg twice daily had increases in walking speed of at least 10%, 20%, or 30% from baseline, compared to placebo. In both trials, the consistent improvements in walking speed were shown to be associated with improvements on a patient self-assessment of ambulatory disability, the 12 item Multiple Sclerosis Walking Scale (MSWS-12), for both drug and placebo treated patients. However, a drug vs. placebo difference was not established for that outcome measure.

In October 2015, we presented 5-year post-marketing safety data for dalfampridine extended release tablets in MS at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. The data presented continue to be consistent with those reported in double-blind clinical trials, with incidence of reported seizure remaining stable over time.

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

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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 an Allergan plc subsidiary (originally Watson Pharma, Inc., now part of the Actavis business owned by Allergan), 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.

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 U.S., 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 U.S. 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.

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Research and Development Programs

We have an industry leading pipeline of novel neurological therapies addressing a range of disorders, including MS, Parkinson's disease, chronic post-stroke walking deficits (PSWD), epilepsy and migraine. As further described below, our pipeline includes three late stage programs for which we are expecting important clinical milestones in 2016.

CVT-301, CVT 427 and ARCUS Technology

On October 22, 2014, we completed the acquisition of Civitas Therapeutics, Inc. ("Civitas"), a privately-held pharmaceutical company with global rights to CVT-301, a Phase 3 treatment candidate for OFF periods of Parkinson's disease, or PD. 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 an inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods 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 for the treatment of Parkinson's disease is oral levodopa (L-dopa), but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remains one of the most challenging aspects of the disease.

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 periods 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 the fourth quarter of 2016, and pending timely recruitment for clinical trials, our goal is to file a new drug application, or NDA, in the U.S. by the first quarter of 2017. 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 long term safety study will also be required. We are projecting that, if approved, annual peak net revenue of CVT-301 in the U.S. alone could exceed $500 million.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF period, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured.

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.

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For example, we are currently developing CVT-427, an inhaled triptan intended for acute treatment of migraine by using the ARCUS delivery system. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority 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. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in a nasally-delivered formulation. However, based on available data, we believe that nasally-delivered triptans generally have an onset of action similar to orally administered triptans.
We have selected zolmitriptan as the active ingredient for CVT-427. In December 2015, we initiated and completed a Phase 1 clinical trial of CVT-427 for acute treatment of migraine. We expect to provide an update on this program by the end of the first quarter of 2016.

In July 2015, the Bill & Melinda Gates Foundation awarded us a $1.4 million grant to support the development of a formulation and delivery system for a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome, or RDS. The formulation will be based on our proprietary ARCUS technology, and will be produced in collaboration with the Massachusetts Institute of Technology. RDS is a condition affecting newborns in which fluid collects in the lungs' air sacs; it most commonly affects infants born prematurely. It can be fatal, or lead to severe, chronic health issues caused by a lack of oxygen getting to the baby’s brain and other organs. The syndrome is caused by the infants’ inability to produce enough surfactant, a liquid lining the inside of the lungs. Delivering liquid surfactant to the lungs via intubation is the standard of care. This grant will support the development of a portable and easily administered inhaled form of surfactant, which may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. This program is not aimed at developing a commercial product, but our work on this program could potentially generate information that is useful for adapting the ARCUS technology to commercial pediatric uses.

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 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 trial data in the third quarter of 2016. This analysis, combined with the results from our development efforts on a once-daily formulation of dalfampridine (discussed below) will establish the next steps for the program.

We have been exploring a once daily (QD) formulation of dalfampridine for use in the 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 currently have three prototypes from three different partners based on in vitro testing, which do not have the alcohol dose dumping issue we identified with the initial QD

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formulation. All three prototypes are currently in Phase 1 pharmacokinetic studies, and we expect to provide an update on these studies by the end of the first quarter of 2016.

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

Plumiaz

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy on stable regimens of antiepileptic drugs, or AEDs, who experience 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 2013, 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. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA.

In May 2015, we announced that we completed discussions with the FDA, and are advancing the development of Plumiaz. Based on these discussions, we are conducting three clinical trials for Plumiaz:

- The first trial is a long-term open-label study assessing safety and tolerability of Plumiaz over 52 weeks. This trial will enroll approximately 100 participants ages 12-65.

- The second trial is assessing the bioavailability, safety and tolerability of Plumiaz compared to diazepam rectal gel (Diastat®). This open-label, randomized, crossover trial will enroll approximately 120 people with refractory epilepsy ages 12-65 who experience seizure clusters.

- The third trial is a pharmacokinetic dose proportionality study in healthy adults.

All three trials have been initiated and are currently enrolling. We are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months.

In December 2015, we presented analyses from a study showing the effect of rescue medication for seizure clusters on both clinical outcomes and healthcare resource utilization. The study found there were more adverse outcomes and greater use of healthcare resources among those who did not always use a rescue medication to treat seizure clusters, compared to those who always used a rescue medication. Seizure clusters are defined as multiple, distinct seizures that occur over a 24-hour period. These analyses were presented at the 69th Annual Meeting of the American Epilepsy Society.

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 license two patent families relating to the clinical formulation of diazepam nasal spray, including a granted U.S. patent that is set to expire in 2029. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval. If approved, we project peak U.S. annual net revenue of more than $200 million.

We acquired the Plumiaz program in December 2012, in connection with our acquisition of Neuronex, Inc., a privately-held development stage pharmaceutical company. We completed the acquisition pursuant to a merger agreement with Neuronex and Moise A. Khayrallah, acting as the Stockholders' Representative on behalf of the former Neuronex equity holders. In July 2015, we entered into an amendment to the merger agreement

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with Mr. Khayrallah, as Stockholders' Representative. Pursuant to the amendment, the Stockholders' Representative, acting on behalf of the former Neuronex equity holders, agreed to certain modifications to our future contingent payment obligations regarding the development and potential commercialization of Plumiaz, described below. In consideration of those modifications, pursuant to the amendment we paid the former Neuronex equity holders $8.75 million in the three-month period ended September 30, 2015.

Under the merger agreement, the former equity holders of Neuronex will be entitled to receive payments from us, in addition to payments we have already made under the merger agreement, upon the achievement of specified regulatory, manufacturing-related, and sales milestones with respect to Plumiaz. Pursuant to the merger agreement as amended by the amendment, we are obligated to pay (i) up to $3 million in specified regulatory and manufacturing-related milestone payments, a reduction from up to $18 million in such payments that were originally specified in the merger agreement, and (ii) up to $100 million upon the achievement of specified sales milestones, a reduction from up to $105 million in such payments that were originally specified in the merger agreement. Under the merger agreement, the former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments on worldwide net revenue of Plumiaz, if any. The rates for these payments pursuant to the merger agreement originally ranged from the upper single digits to lower double digits, but were modified pursuant to the amendment and now range from the mid-single digits to mid-double digits. These payments are payable on a country-by-country basis until the earlier to occur of ten years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the merger agreement.

The patent and other intellectual property and other rights relating to Plumiaz are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, our subsidiary Neuronex is obligated to pay SK up to $8 million upon the achievement of specified development milestones with respect to Plumiaz (including a $1 million payment that was triggered in 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 the diazepam nasal spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net revenue of Plumiaz.

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/Neuregulins

Cimaglermin alfa 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

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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. 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, which resolved within several days. In March 2015, we presented new analyses of data from this trial at the American College of Cardiology (ACC) 64th Annual Scientific Session and Expo. These analyses found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

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 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. In June 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within several days, as was the case with the one Hy's Law case reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

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.

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.

rHIgM22 is the lead antibody in our remyelinating antibody program. We are developing rHIgM22 as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore

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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 included 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. In April 2015, we presented additional safety data from this trial at the 67th American Academy of Neurology Annual Meeting. The additional data showed that rHIgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. This data was presented at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis annual meeting. We are advancing clinical development of rHIgM22 for MS.

We are currently enrolling a Phase 1 trial using one of two doses of rHIgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the first half of 2017.

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. These studies were published in the Journal of Neurotrauma in February 2005. In these studies, rats that sustained a spinal cord injury were treated with either chondroitinase or an ineffective enzyme control and evaluated over 10 weeks of recovery. Animals treated with chondroitinase showed significant improvements both in motor function of the limbs and in bladder function, compared to those treated with the control enzyme. We have also produced and successfully tested a recombinant version of naturally occurring Chondroitinase ABC-I in these same animal models.

We are conducting a research program to develop second generation approaches to overcoming the proteoglycan matrix. Our research is currently focused on spinal cord injury but we are also looking at other neurotraumatic indications. The approaches we are developing include novel enzyme molecules and alternative approaches to blocking matrix formation. In 2003, we obtained an exclusive worldwide license to certain patents, patent applications, and technology from Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King’s College London related to our chondroitinase program. We are also building our intellectual property position with respect to this technology with patent applications around uses of the known compound and new chemical structures.

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NP-1998

NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were 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 U.S., 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, we have no current plans to invest in further development of NP-1998 for neuropathic pain.

Sales, Marketing and Managed Markets

Ampyra

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 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.

Our First Step program which provides eligible patients with two months of Ampyra at no cost. During 2015, on average more than 70% of new Ampyra patients enrolled in First Step. The program is in its fifth 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 therapy with the First Step free trial program convert to paid prescriptions.

We have contracted with a third-party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource of support services that coordinates the prescription process among healthcare providers, people with MS and insurance carriers. Prescriptions for Ampyra are processed through the APSS center, where dedicated and experienced customer care agents are responsible for helping healthcare professionals process prescriptions; working with insurance carriers to facilitate coverage; and working with a limited network of specialty pharmacy providers that deliver the medication directly to a patient's home. In addition, APSS assists in directing patients to available copay and patient assistance programs, where permitted by law. The process begins when a prescription is submitted by a physician to APSS through a Service Request Form, or SRF. Processing of most incoming requests for prescriptions by APSS begins within 24 hours of receipt. Patients will experience a range of time to receive their first shipment based on the processing times for insurance requirements. As with any prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription. 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

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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 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 U.S. 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. All of these customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar days.

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial 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.

Zanaflex

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 an Allergan plc subsidiary (originally Watson Pharma, Inc., now part of the Actavis business owned by Allergan).

Qutenza

Qutenza is distributed in the U.S. 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, Inc.) 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, Inc., and then ships the medication directly to the physician’s office, rather than dispensing Qutenza to the patient.

CVT-301

We anticipate an incremental expansion of our sales force if CVT-301 is approved.

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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.

Material and Other Collaborations and License Agreements

Biogen (Fampyra)

In 2009, we entered into a Collaboration Agreement with Biogen, pursuant to which we and Biogen 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 with its requirements for the licensed products through our existing supply agreement with Alkermes. Biogen Inc., the parent of Biogen, has guaranteed the performance of Biogen's obligations under the Collaboration Agreement and the Supply Agreement.

Under the Collaboration Agreement, Biogen, 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 chronic 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 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 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. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra available in additional markets in 2016.

In consideration for the rights granted to Biogen 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 would be $15 million, due when ex-U.S. net

sales exceed $100 million over four consecutive quarters.

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Under the Collaboration Agreement, we are also entitled to receive double-digit tiered royalties on sales of licensed products by Biogen, 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 may offset against the royalties payable to us a portion of certain royalties that it may need to pay to third parties.

Biogen exclusively purchases all of Biogen's, its affiliates' and its sublicensees' requirements of the licensed products from us. The purchase price paid by Biogen 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 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'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's prior written consent under certain circumstances. Biogen 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 has the right to terminate the Collaboration Agreement due to our material uncured breach, Biogen 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 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, its affiliates or its sublicensees challenge certain of our patents or (ii) there is a change in control of Biogen or its parent company or certain dispositions of assets by Biogen, its parent or its affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen'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 for an uncured material breach, we will waive our right for Alkermes to exclusively supply the licensed products to us solely to permit Biogen to negotiate terms with Alkermes for the supply of licensed products to Biogen. If the Supply Agreement is otherwise terminated, Biogen will not have any future obligations to purchase licensed products from us and we will not have any future obligations to supply Biogen with licensed products. If the Collaboration Agreement is terminated, Biogen 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'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 for a material uncured breach that we are responsible for, in which case the parties will negotiate a payment to Biogen to reflect the net value of such assigned and licensed rights.

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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 and Alkermes entered into a Consent Agreement with us. Under the Consent Agreement, Alkermes consented to our sublicense of rights to Biogen, and the three parties agreed to set up a committee to coordinate activities under our agreements with Alkermes with respect to the development, supply and commercialization of the licensed products for Biogen's territory. The Consent Agreement also amended our agreements with Alkermes by, among other things, permitting us to allow Biogen to grant sublicenses to certain unaffiliated distributors; permitting us to allow Biogen 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 (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, 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 under the Supply Agreement and Consent Agreement with Fampyra for Biogen’s clinical trials and for Biogen’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

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on the last to occur of fifteen years from the date of the agreement (2018), the expiration of the last to expire Alkermes patent or the existence of competition in that country.

Zanaflex

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

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

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

Alkermes manufactures Zanaflex Capsules for us (and the authorized generic version of Zanaflex capsules being marketed by an Allergan plc subsidiary as part of its Actavis business, originally Watson Pharma, Inc.) 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,

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we entered into an agreement with Rush and Elan terminating the Rush license to Elan and providing for mutual releases. We also entered into a license agreement with Rush in 2003 in which Rush granted us an exclusive worldwide license to its know-how relating to dalfampridine for the treatment of MS. Rush has also assigned to us its Orphan Drug Designation for dalfampridine for the relief of symptoms of MS.

We agreed to pay Rush a license fee, milestone payments of up to $850,000 and royalties based on net sales of the product for neurological indications. We have made or accrued an aggregate of $850,000 in milestone payments and $37.4 million in royalties under this agreement through December 31, 2015. 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.

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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 of antiepileptic drugs, or AEDs, who experience 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:

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- 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.

- 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 central nervous system 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 central nervous system 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 spinal cord injury.

- 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 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

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

Regis Technologies, Inc. is the sole supplier of 4-aminopyridine, the active pharmaceutical ingredient in Ampyra. If Regis experiences any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until 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 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 an Allergan plc subsidiary as part of its Actavis business (originally Watson Pharma, Inc.). Patheon is our sole manufacturer of Zanaflex tablets. Farmak a.s. is the sole supplier of tizanidine hydrochloride, the active pharmaceutical ingredient, or API, in Zanaflex Capsules and Zanaflex tablets.

The Zanaflex supply agreement with Alkermes has two year terms that automatically renew unless the agreement is terminated. Either party may terminate the agreement by notifying the other party at least 12 months prior to the expiration of a 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.

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

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.

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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 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 currently have three prototypes from three different partners based on in vitro testing, which do not have the alcohol dose dumping issue we identified with the initial QD formulation. All three prototypes are currently in Phase 1 pharmacokinetic studies, and we expect to provide an update on these studies by the end of the first quarter of 2016.

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 may owe royalties on sales of the product to the development company under our agreements with them. In such event, we would also owe royalties to Alkermes on sales of the product under our existing agreements with Alkermes.

CVT-301, CVT-427 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 to 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 Parkinson's disease. 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 current good manufacturing practices, or cGMP-quality human doses of CVT-301 for Phase 1 and Phase 2 clinical trials and is now producing cGMP-quality CVT-301 powder for our ongoing Phase 3 clinical trials. As we are already at commercial scale, we believe that this will support rapid commercialization should we receive marketing approval from the FDA. However, if we obtain approval from the FDA, we anticipate the need to expand our manufacturing operations at the Chelsea facility after product launch to meet demand depending on the timing and extent of sales growth. 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. As described above, we have manufactured drug product at research and development 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 cGMP 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.

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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 trials and anticipated commercial launch have been implemented, and the molds have been produced.

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

We have completed a Phase 1 clinical trial of cimaglermin alfa 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. In June 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within several days, as was the case with the one Hy's Law case reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

We contracted with CMC ICOS Biologics, Inc. in 2008 to produce and purify cimaglermin bulk material under cGMPs. Acorda and CMC 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, now Ajinomoto Althea, Inc., 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

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samples by Mayo Clinic. Our lead recombinant human remyelinating antibody, designated rHIgM22, has been produced under cGMPs, tested for safety in non-clinical studies and advanced to human trials in patients with MS.

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, CVT-427 and the ARCUS technology; cimaglermin alfa/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, 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 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 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, this 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 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.

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the USPTO. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in Part I, Item 3 of this report.

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In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), 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. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

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, CVT-427 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. The CVT-427 program, which also utilizes the ARCUS technology, has a pending application directed to formulations, which, if granted would expire in 2036 absent any patent term adjustment.

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

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

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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 central nervous system (CNS) diseases, spinal cord injury (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 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

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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 central nervous system 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, Betaseron from Schering AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Merck Serono, Tysabri from Biogen and Elan, Gilenya and Extavia from Novartis AG, Aubagio from Genzyme Corporation (a Sanofi company), Glatopa from Sandoz International GmbH (a Novartis AG company), Lemtrada from Genzyme Corporation (a Sanofi company), Plegridy from Biogen, and Tecfidera from Biogen.

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 with MS. BioMarin Pharmaceutical Inc. or BioMarin, acquired the rights formerly owned by EUSA Pharma (UK) Ltd. 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, Inc.. 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.

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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. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights. We will need to devote significant resources to these 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 these 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.

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 an Allergan plc subsidiary (originally Watson Pharma, Inc., now part of the Actavis business owned by Allergan) 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 2016 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 periods and other therapies for the on-demand treatment of OFF periods. 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

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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 periods 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 Laboratories 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. 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 periods, CVT-301 would compete against on-demand therapies that aim to specifically address OFF periods. At this time, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF periods. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Cynapsus Therapeutics, Inc. is developing a sublingual, or under the tongue, formulation of apomorphine. This program is in Phase 3 clinical development and could potentially be commercially launched ahead of CVT-301.

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 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 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, Inc. (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Upsher-Smith is developing a nasal delivery form of midazolam, Neurelis, Inc. is developing a nasal delivery form of diazepam, and Alexza Pharmaceuticals, Inc. 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, Meridian Medical Technologies, Inc. received orphan drug designation for a diazepam (autoinjector) used in 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. In December 2015, Neurelis, Inc. received

orphan drug designation for NRL-1 (intranasal diazepam) for the treatment of acute repetitive seizures. If either of these products receives FDA approval before Plumiaz, Plumiaz will be excluded from the market for seven (7) years unless we are able to

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prove to the FDA that the Plumiaz nasal spray is clinically superior to, or offers a major contribution to, patient care relative to these alternative diazepam products 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 post-herpetic neuralgia 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.

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, drug/medical device combinations and as biological products. Drugs and biologics primarily are regulated under 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.

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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.

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.

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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 does not guarantee FDA approval even if the SPA is followed. For example a substantial scientific issue essential to determining the safety or effectiveness of the drug could be 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 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.

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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.

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, distribution, current good manufacturing practices, or cGMPs, and import/export, as well as any other requirements imposed by the applicants NDA or BLA. 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 the FDA or local regulatory agencies. We cannot be

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certain that we or our present or future suppliers will be able to comply with the current good manufacturing practices, or 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 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. The 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

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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 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:

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- 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 otherwise meets the FDA's requirements for the approval of ANDAs, the generic manufacturer may decide to 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 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;

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- 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 post market 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.

Biosimilars

The Affordable Care Act amended the Public Health Service Act to authorize the FDA to approve "biosimilars" (follow-on versions of products approved pursuant to a BLA) 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, the 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.

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Foreign Regulation and Product Approval

Outside the U.S., our ability or the ability of our collaborator Biogen 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, as well as medical devices, 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, the Drug Enforcement Administration (DEA), and state and local governments. For example, controlled substances that are scheduled by the DEA are subject to additional regulatory requirements including, among other things, special security and handling requirements, and potential restrictions on distribution, sales, marketing, scientific/educational grant programs, and other Acorda interactions with healthcare professionals, must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, and may be 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/or 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 health care programs including Medicare and Medicaid. In addition, under legislative changes made in 2009, discounted prices must also be offered for certain DOD purchases for its TRICARE 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,

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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, our collaborator 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 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

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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 22, 2016, we had 535 employees. Of the 535 employees, 127 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 408 work in sales, marketing, managed markets, business development, manufacturing, technical operations, medical affairs, communications, and general and administrative.

CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 420 Saw Mill River Road, Ardsley, New York 10502. Our telephone number is (914) 347-4300. Our website is www.acorda.com. 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

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Securities and Exchange Commission ("SEC"). Also, the SEC allows us to "incorporate by reference" some information from our proxy statement for our 2016 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2016 Proxy Statement within 120 days after the end of our 2015 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 2016 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 have been profitable in recent years, 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, 2015, we had an accumulated deficit of approximately $209.4 million. We had net income of $11.1 million for the year ended December 31, 2015, $17.7 million for the year ended December 31, 2014, and $16.4 million for the year ended December 31, 2013. 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.

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'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 periods 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;

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continuing to advance our other clinical development programs, including our rHIgM22, CVT-427 and cimaglermin alfa programs (though we note that the cimaglermin program is subject to a clinical hold, as further described in this report);

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- 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 2016 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, customer complaints or misuse (or any unfavorable publicity relating thereto) stemming from the use of Ampyra or our other products or identified in ongoing or future studies of dalfampridine;

- 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

- 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.

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Ampyra is marketed as Fampyra outside the U.S. by Biogen pursuant to a conditional approval obtained from the European Commission in 2011. The conditional approval must be reassessed and renewed annually, and pursuant to the requirements of the conditional approval Biogen is carrying out additional studies on the long-term effectiveness and safety of Fampyra, including Biogen's ENHANCE clinical trial assessing the long term efficacy and safety of Fampyra. Adverse results from the ENHANCE study could jeopardize Biogen's ability to maintain the European Commission approval for Fampyra. Also, regardless of the status of the European Commission approval for Fampyra, market acceptance of Ampyra in the U.S. could be harmed if the ENHANCE trial results fail to show efficacy or are inconclusive on efficacy of Fampyra, even though the ENHANCE trial is evaluating a primary efficacy endpoint that is different from the primary endpoint we used in our clinical trials that formed the basis for our FDA approval of Ampyra. Also, market acceptance of Ampyra in the U.S. could be harmed if the ENHANCE trial results demonstrate safety concerns that are inconsistent with our clinical trial results and post-marketing experience in the U.S. Such adverse safety results from the ENHANCE clinical trial could also potentially affect FDA approval of Ampyra. If the ENHANCE study produces safety findings that are inconsistent with the trial results we previously submitted to the FDA, we would be obligated to report those findings to the FDA. We are expecting the announcement of results from this trial in the second half of 2016.

Also, 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, 2015, we had approximately $194 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 U.S. 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 U.S. 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 drug or biological 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, 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, cGMP requirements as well as any other requirements imposed by the applicants NDA or BLA. 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, controlled substances 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 where relevant any medical devices that are part of our commercial products. We similarly rely and expect to continue to rely on third parties 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 our commercial and investigational products, or components of those products. This dependence on others 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, and the manufacture of medical devices, are 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 manufacturers 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, product seizures, loss of operating licenses, and other civil and criminal penalties. 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. In some cases, these third-party manufacturers may also be subject to GMP inspections by foreign regulatory authorities. Failure to pass such inspections by foreign regulatory authorities could impede our ability to manufacture product needed for clinical trials or impede our ability to secure product approvals.

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

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months for Ampyra following the submission of our written 18-month forecast, we are obligated to purchase the quantity specified in the forecast, even if our actual requirements are greater or less. Alkermes is not obligated to supply us with quantities in excess of our forecasted amounts, although it has agreed to use commercially reasonable efforts to do so. If our forecasts of our supply requirements are inaccurate, we may have an excess or insufficient supply of Ampyra.

We similarly rely on Alkermes and other third parties for the manufacture of our Zanaflex and authorized tizanidine hydrochloride generic products and the supply of tizanidine hydrochloride, 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, Phase 2 clinical trials, of CVT-301 in our own manufacturing facility, and we are in the process of manufacturing the capsules for our ongoing 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. These companies will be subject to FDA approval and we cannot be certain that the FDA would provide such approval. These third party manufacturers would also be required to comply with the Controlled Substances Act and applicable regulations. Lastly, in some cases we are relying on single source providers, and our ability to commercialize our Plumiaz product would be harmed if we fail to reach agreement with the single source provider or if the single source provider cannot pass an FDA inspection our Plumiaz product.

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 Chelsea, Massachusetts manufacturing facility that we occupy under a lease that expires in December 2025, 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 current good manufacturing practices, or cGMP, requirements, the FDA may not grant marketing approval for our product. If we obtain approval from the FDA for CVT-301, we anticipate the need to expand our manufacturing operations at the Chelsea facility after product launch to meet demand depending on the

timing and extent of sales growth.

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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.

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. Our other commercially marketed products have similar approved labeling, which similarly limit our ability to promote those products.

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

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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 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 risk evaluation and mitigation strategy, or 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.

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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. We face similar risks with respect to our other marketed products.

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 manner, they were considered late reports to the FDA. Also, FDA inspections have identified issues with our adverse event reporting which have led 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 or collaborators 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 or foreign regulatory authorities, 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, or foreign regulatory agency’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 Ampyra 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

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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. In February 2016, the FDA conducted what it classified as a biennial routine inspection. The inspection focused on pharmacovigilance reporting and product complaint handling. This inspection resulted in one FDA Form 483 observation related to Ampyra "lack of effect" complaint trends analysis. We will have 15 days to respond to the Form 483. 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.

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. 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. In some cases, our third-party suppliers' drug manufacturing sites may also be subject to inspection by foreign regulatory authorities. We face similar risks to our business if those third-party manufacturers are unable to comply with foreign regulatory requirements. 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.

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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 consequences 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;
- 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 to commercialize Ampyra outside of the U.S. (known as Fampyra outside the U.S.)

Pursuant to our Collaboration Agreement with Biogen, entered into in June 2009, we granted Biogen 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 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;

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- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;

- the collaborations may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates; and

- collaborators may experience financial difficulties.

While we have negotiated some terms in the Collaboration Agreement with Biogen 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 collaborator, Biogen, 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 non-clinical testing as well as additional regulatory agency inspections. The time required to obtain approval may differ from that required to obtain FDA approval. We and our collaborator 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 collaborator 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 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 will be able to satisfy the requirements for maintaining the approval. As part of its conditional approval,

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Biogen is carrying out additional studies on the long-term effectiveness and safety of Fampyra, including Biogen's ENHANCE clinical trial, and the results of these studies could affect renewal of the conditional approval or granting of full approval. We are expecting the announcement of results from this trial in the second half of 2016. The requirements to conduct supplemental trials add to the cost and risks of development and approval, and in particular adverse results from the ENHANCE trial, could jeopardize Biogen's ability to maintain the European Commission authorization for Fampyra. These 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. Adverse safety results from the ENHANCE trial could potentially affect FDA approval of Ampyra.

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 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;

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- 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 both by the FDA and similar foreign regulatory authorities;
- difficulties in obtaining sufficient quantities of our product candidates, or where applicable comparator product or other ancillary materials needed, manufactured under cGMP;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board (or ethics committee), or a data safety monitoring board, or clinical holds placed upon the trials by the FDA or similar foreign regulatory authorities;
- Approval by FDA and/or foreign regulatory authorities 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 (or similar ethics committees), data safety monitoring boards, the FDA, and similar foreign regulatory authorities to ensure compliance with good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any of those standards are not complied with in a clinical trial, the resulting data from the clinical trial may not be usable or we, an institutional review board, the FDA, or a similar foreign regulatory authority may suspend or terminate a trial, which would severely delay our development and possibly end the development of the product candidate.

We rely on third-party contract research organizations, medical centers and others to perform our preclinical and non-clinical testing and clinical trials, our research and development programs could be harmed if they do not perform in an acceptable and legally compliant manner.

We do not have the ability to conduct all aspects of our preclinical or non-clinical 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 and non-clinical testing and clinical trials. Additionally, we have historically conducted clinical trials in the U.S. and Canada, and recently we have expanded our clinical trial activities into other jurisdictions, particularly Europe. Because we have limited experience conducting clinical trials outside the U.S. and Canada, we place even greater reliance on third-party contract research organizations to manage, monitor and carry out clinical trials in these other jurisdictions. The failure of any of these parties to perform in an acceptable and timely manner in the future, including in accordance with any applicable U.S. or foreign 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 or non-clinical testing or clinical trials and ultimately on the timely advancement of our research and development programs. Similarly, we rely on medical centers to conduct our clinical trials, and if they fail to comply with applicable regulatory requirements or clinical trial protocols, our research and development programs could be harmed.

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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. Industry relationships with specialty pharmacies have also recently been scrutinized under these provisions. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce or facilitate prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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

Sanctions under these federal and state laws may include requirements to make payments to government-funded health plans to correct for insufficient rebates 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

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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 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.

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

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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. 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 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.

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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 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, primarily depends 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

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collaborators, such as Biogen, 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 collaborators, such as Biogen, 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 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's sales of Fampyra and therefore the amount of the royalty we receive from Biogen. Furthermore, the adverse financial impact of these measures in any particular country, in addition to related reimbursement or regulatory constraints, could prevent the commercial launch or continued commercialization 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 cause the products to be priced lower.

Ampyra. We are aware that Catalyst Pharmaceuticals, Inc. is developing a 3,4-diaminopyridine product, licensed from Biomarin, that may compete with Ampyra. Also, 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. In addition, 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

CVT-301. We believe that the main competitors for CVT-301 are therapies that can limit the occurrence of OFF periods and other therapies for the on-demand treatment of OFF periods. 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 periods 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

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DOPA decarboxylase (an enzyme found throughout the body) referred to as carbidopa, such as extended-release formulations 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 or Duodopa, is approved in the U.S. and EU, and AbbVie may gain approval in 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 periods, CVT-301 would compete against on-demand therapies that aim to specifically address OFF periods. At this time, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF periods. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Cynapsus Therapeutics, Inc. is developing a sublingual, or under the tongue, formulation of apomorphine. This program is in Phase 3 clinical development and could potentially be commercially launched ahead of CVT-301.

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, Inc. (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Upsher-Smith is developing a nasal delivery form of midazolam, Neurelis, Inc. is developing a nasal delivery form of diazepam, and Alexza Pharmaceuticals, Inc. 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, Meridian Medical Technologies, Inc. received orphan drug designation for a diazepam (autoinjector) used in 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. In December 2015, Neurelis, Inc. received orphan drug designation for NRL-1 (intranasal diazepam) for the treatment of acute repetitive seizures. If either of these products receive 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 Plumiaz nasal spray is clinically superior to, or offers a major contribution to, patient care relative to these alternative diazepam products 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.

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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 or assumption of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- regulatory compliance issues, such as with the FDA, associated with the acquired or in-licensed company, business or product candidate, which may be difficult or impossible to identify at the time of acquisition or licensing;
- difficulties in assimilating the personnel and/or operations of the acquired companies;
- diversion of our management's attention away from other business concerns;
- commencement of business in markets where 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, 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 non-clinical and clinical studies. In January 2013, we submitted a request in writing to the FDA 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, which the FDA again denied in March 2015. Subsequently in March 2015, we received a notice of non-compliance with PREA. In April 2015, we responded in writing to this notice and also submitted a request for waiver from the pediatric commitments, and we await a further response from the FDA. 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). This post-marketing commitment has been fulfilled. 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 manufacture and/or distribute prescription drugs, although the scope of these laws varies, particularly where out-of-state distributors are concerned. We have obtained licenses in all of the jurisdictions in which we believe we are required to be licensed. 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, 2015, we had approximately $353.3 million in cash, cash equivalents and short-term investments. We have several product candidates in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We may need to seek additional equity or debt financing or strategic collaborations to complete our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote fewer resources to marketing Ampyra or our other commercial products.

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

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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. 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 personnel, could

substantially impair our ability to implement our business plan.

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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.

We have patent portfolios relating to Ampyra/aminopyridines, CVT-301, CVT-427 and our ARCUS inhaled therapeutic technology, cimaglermin alfa/neuregulins, remyelinating antibodies/antibodies relating to nervous system

disorders, chondroitinase, Plumiaz/diazepam nasal spray, Qutenza and NP-1998/topical capsaicin

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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, several generic drug manufacturers have 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. As further described under Legal Proceedings in Part I, Item 3 of this report, there is currently a statutory stay which 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. If the stay is either lifted or expires, as described, and the generic drug manufacturers otherwise meet the FDA’s requirements for the approval of ANDAs, the generic manufacturers may decide to begin selling a generic version of Ampyra even if our lawsuits against these manufacturers are still pending and despite the fact that if we later win these lawsuits the generic manufacturers could be held liable for patent infringement damages. 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. Although the U.S. Patent and Trademark Office Patent Trials and Appeals Board chose not to institute inter partes review of these patents, the hedge fund has filed motions for reconsideration requesting that the denial to institute these two IPRs be reversed. In addition, in September 2015 the same hedge fund filed four additional IPR petitions challenging four of the five listed Orange Book patents, including two of the same patents that were the subject of the February 2015 IPR petitions. Patent litigation, IPR, and other legal proceedings involve complex legal and factual questions. We need to devote significant resources to the existing ANDA and IPR legal proceedings, and we may need to devote significant resources to other legal proceedings that arise in the future. If we are not successful, we could lose some or all of our Orange Book listed patents and our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such lawsuits and legal proceedings.

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

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consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in areas that are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which could have an adverse effect on us, even if we are successful in defending such claims.

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

Our business could be harmed by requirements to publicly disclose our clinical trial data.

There is an increasing trend across multiple jurisdictions, including the United States and the EU, towards requiring greater transparency, particularly in the area of clinical trial results. In many jurisdictions, including the U.S. and the EU, we are required to register most of our clinical trials as well as disclose summaries of the results of those clinical trials. Further requirements for transparency could result in the disclosure of data down to the individual patient level. In the EU, for example, the European Medicines Agency, or EMA, has instituted a new policy on transparency of clinical trial data submitted to the agency in applications for marketing authorization. These data traditionally have been regarded as confidential commercial information not subject to disclosure. Although the precise implementation of the EMA’s new policy remains in flux and subject to legal challenge, it ultimately could result in the EMA’s public disclose of sponsor clinical study reports and/or patient level data in some circumstances. This could negatively impact our business in a variety of ways, including for example through disclosure of our trade secret methodologies for clinical development of our products, and/or by potentially enabling competitors to use our clinical data to gain approvals for their own products in the same or other jurisdictions. Regardless of how the EMA institutes its new policy, the trend across governments is for increased transparency, which could diminish our ability to protect our confidential commercial information.

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;

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

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

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

We are dependent on our license agreements and if we fail to meet our obligations under these license agreements, or our agreements are terminated for any reason, we may lose our rights to our in-licensed patents and technologies.

We are dependent on licenses for intellectual property related to Ampyra, 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.

Our stock price could fluctuate significantly due to a number of factors, including:

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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

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development by us, our collaborators, or our competitors;

- announcements of new acquisitions, collaborations, financings or other transactions, or of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents; including litigation and other legal proceedings;
- regulatory developments in the U.S. and foreign countries;
- changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;
- sales of substantial amounts of our stock or short selling activity by certain investors;
- variations in our anticipated or actual operating results;
- conditions or trends in the pharmaceutical or biotechnology industries;
- changes in healthcare reimbursement policies; and
- economic or other crises or other external factors.

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, 2016, we had outstanding 45,749,265 shares of voting common stock. Also, options to acquire 8,198,874 shares of common stock were outstanding as of February 17, 2016, exercisable at an average exercise price of $31.14 per share, issued under our 2006 Employee Incentive Plan or our 2015 Omnibus Incentive Compensation Plan, and additional shares of common stock are authorized for issuance pursuant to options and other awards under our 2015 Omnibus Incentive Compensation 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, 2015, our officers, directors and holders of 5% or more of our outstanding common

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stock beneficially owned approximately 56% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

- Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors.

- Our board of directors may issue, without stockholder approval, shares of preferred stock with rights, preferences and privileges determined by the board of directors. The ability to authorize and issue preferred stock with voting or other rights or preferences makes it possible for our board of directors to issue preferred stock with super voting, special approval, dividend or other rights or preferences on a discriminatory basis that could impede the success of any attempt to acquire us.

- Our board of directors is divided into three classes, each with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of stockholders, and each of the two other classes of directors will continue to serve for the remainder of their respective three-year terms, limiting the ability of stockholders to reconstitute the board of directors.

- The vote of the holders of 75% of the outstanding shares of our common stock is required in order to take certain actions, including amendment of our bylaws, removal of directors for cause and certain amendments to our certificate of incorporation.

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

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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.

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 $4.4 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 included a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas, now our wholly-owned subsidiary, previously subleased the Chelsea, Massachusetts facility from Alkermes, Inc., which leased the facility from the owner, H&N Associates, LLC. The Civitas sublease and Alkermes head lease were scheduled to expire on December 31, 2015, but in the first quarter of 2015 Civitas and Alkermes exercised options that extended the terms of the sublease and head lease for five additional years, until December 31, 2020. In the fourth quarter of 2015, Civitas entered into an assignment and amendment of the head lease with Alkermes and H&N Associates pursuant to which, among other things, Civitas became the direct lessee of the Chelsea facility from H&N Associates under the terms and conditions of the Alkermes head lease, as modified by the assignment and amendment. Pursuant to the assignment and amendment, the term of the head lease has been extended an additional five years, to December 31, 2025, and Civitas has two additional extension options of five years each. The assignment and amendment also specifies the rent during the current extended term, as well as during the additional extension periods should Civitas exercise its options for those extension periods. The base annual rent under the head lease is currently $1.0 million per year.

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

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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. Apotex has appealed both the motion to dismiss and summary judgment decisions to the Second Circuit Court of Appeals. The briefing period and oral argument have been completed and we are now awaiting a decision from the Second Circuit Court of Appeals. The Company will defend itself vigorously throughout the appeal process.

Ampyra ANDA Litigation

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd. ("Aurobindo"), 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 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. These lawsuits with the eight ANDA filers have been consolidated into a single case. The U.S. District Court for the District of Delaware has scheduled a Markman hearing on March 7, 2016, and has set a five day bench trial starting on September 19, 2016. The Markman hearing will be conducted to determine the scope and limitations of certain patent claims that are asserted in the litigation. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. 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.

In October and December 2015, we entered into settlement agreements with Actavis and Aurobindo to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreements, Actavis and Aurobindo will be permitted to market generic versions of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The Court entered an order dismissing the case against Actavis without prejudice on October 21, 2015. As a result of the settlement agreement with Aurobindo, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Aurobindo on December 22, 2015. The parties have submitted the agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with Actavis and Aurobindo do not resolve pending patent litigation that we brought against the other ANDA filers, as described in this report.

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. The parties presented oral arguments on the appeal in January 2016, and we are waiting for a decision on the appeal from the Court. The Company will defend itself vigorously throughout

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the appeal process. 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 our 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 along with the cases against the other eight ANDA filers (see below) at the present time.

In May 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. ("Sun") advising that they had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and also asserted that generic versions of their products may not infringe certain claims of these patents. In response to the filing of the ANDA, in May 2015 we filed a lawsuit against Sun in the U. S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685, which was within the 45 days from the date of receipt of Sun's Paragraph IV Certification Notice which instituted the 30 month statutory stay of approval period to the Sun ANDA under the Hatch-Waxman Act. In October 2015, we entered into a settlement agreement with Sun to resolve this patent litigation. As a result of the settlement agreement, Sun will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. As a result of the settlement agreement, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Sun on October 29, 2015. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Sun does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

In September 2015, we received a Paragraph IV Certification Notice from Par Pharmaceutical, Inc. ("Par") advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Par challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they have also asserted that generic versions of its products may not infringe certain claims of these patents. In response to the filing of the ANDA, in September 2015 we filed a lawsuit against Par in the U. S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. In January 2016, we entered into a settlement agreement with Par to resolve this patent litigation. As a result of the settlement agreement, Par will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. As a result of the settlement agreement, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Par on January 21, 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Par does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

Ampyra IPR Proceedings

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, or PTO, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. In August 2015, the U.S. Patent and Trademark Office Patent Trials and Appeals Board ruled that it would not institute inter partes review of either of these patents. On September 23, 2015, however, the hedge fund filed two motions for reconsideration to the U.S. Patent and Trademark Office Patent Trials and Appeals Board, requesting that the denial to institute these two IPRs be reversed.

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On September 2 and 3, 2015, the same hedge fund filed four separate IPR petitions with the PTO. These new IPR petitions challenge the same two patents that were the subject of the February 2015 IPR petitions and also U.S. Patent Nos. 8,354,437 and 8,440,703. The challenged patents are four of the five Ampyra Orange-Book listed patents. We have opposed the requests to institute these IPRs, and if one or more is allowed to proceed, we will oppose the full proceedings and defend our patents. We are expecting a decision from the PTO's Patent Trials and Appeals Board in March 2016 on whether or not it will allow these IPR petitions to proceed. 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 will vigorously defend our intellectual property rights.

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, 2015		
Fourth Quarter	$ 43.63	$ 26.06
Third Quarter	$ 36.28	$ 25.50
Second Quarter	$ 35.70	$ 28.52
First Quarter	$ 45.45	$ 32.39

	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

Computershare is the transfer agent and registrar for our common stock. As of February 17, 2016, we had approximately 26 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, 2010 and its relative performance is tracked through December 31, 2015.

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	12/10	12/11	12/12	12/13	12/14	12/15
Acorda Therapeutics, Inc.	100.00	87.45	91.20	107.12	149.93	156.93
NASDAQ Composite	100.00	100.53	116.92	166.19	188.78	199.95
NASDAQ Biotechnology	100.00	113.92	153.97	263.29	348.49	369.06

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.

Sales of Unregistered Securities

On January 19, 2016, we agreed to issue 2,250,900 shares of our common stock to JP Morgan Securities LLC, as initial purchaser, in a private placement transaction exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”). The settlement of the shares with the initial purchaser occurred on January 26, 2016. The shares were issued to the initial purchaser in reliance on the exemption afforded by

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Section 4(a)(2) under the Securities Act. The aggregate offering price for the sale of the shares to the initial purchaser was $74,999,988. In connection with the private placement, we paid $2,250,900 in aggregate discounts and commissions. We intend to use the net proceeds from the issuance of the shares to fund, in part, the acquisition of Biotie described above in this report. If the acquisition of Biotie is not consummated for any reason, we will use all of the net proceeds from the issuance of the shares for general corporate purposes. The shares will not be registered under the Securities Act or any state securities laws and may not be offered or sold in the U.S. absent an effective registration statement or an applicable exemption from registration requirements or a transaction not subject to the registration requirements of the Securities Act or any state securities laws.

Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fiscal year ended December 31, 2015. 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, 2015 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,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Statement of Operations Data:					
Total net revenues	$ 492,660	$ 401,480	$ 336,430	$ 305,814	$ 292,237
Costs and expenses:					
Cost of sales	92,297	79,981	66,009	57,007	64,183
Cost of milestone and license revenue	634	634	634	634	2,384
Research and development	149,209	73,470	53,877	53,881	42,108
Selling, general and administrative	205,630	201,813	185,545	168,690	148,508
Asset impairment	—	6,991	—	—	—
Changes in fair value of acquired contingent consideration	10,900	2,200	—	—	—
Total operating expenses	458,670	365,089	306,065	280,212	257,183
Operating income	33,990	36,391	30,365	25,602	35,054
Other expense:					
Interest and amortization of debt discount expense	(15,472)	(9,288)	(2,170)	(1,880)	(3,570)
Interest income	440	674	668	552	552
Other income (expense)	411	232	—	(6)	(18)
Total other expense	(14,621)	(8,382)	(1,502)	(1,334)	(3,036)
Income before income taxes	19,369	28,009	28,863	24,268	32,018
(Provision) benefit for income taxes	(8,311)	(10,337)	(12,422)	130,690	(1,413)
Net income	$ 11,058	$ 17,672	$ 16,441	$ 154,958	$ 30,605
Net income per share —basic	$ 0.26	$ 0.43	$ 0.41	$ 3.93	$ 0.78
Net income per share —diluted	$ 0.25	$ 0.42	$ 0.39	$ 3.84	$ 0.76
	42,230	41,150	40,208	39,459	39,000

Weighted average shares of common stock outstanding used in computing net income per share —basic					
Weighted average shares of common stock outstanding used in computing net income per share —diluted	43,621	42,544	41,682	40,332	40,064

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	As of December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and investments	$ 353,305	$ 307,618	$ 367,227	$ 333,188	$ 295,907
Working capital	360,725	276,335	251,376	199,101	273,599
Total assets	1,116,343	1,065,065	607,127	565,332	379,488
Long-term liabilities	422,726	410,427	70,131	80,540	86,936
Accumulated deficit	(209,352)	(220,410)	(238,082)	(254,523)	(409,481)
Long term debt	296,576	289,883	3,228	4,244	5,230
Total stockholders' equity	603,025	540,255	440,353	385,921	205,209

On December 31, 2015, the Company early adopted the provisions of Accounting Standards updated 2015-17, "Income Taxes" (Topic 740): Balance Sheet Classification of Deferred Taxes (ASU 2015-17), which simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in the balance sheet. The Company adopted the new guidance retrospectively and updated the classification of the deferred tax liabilities and assets to noncurrent in the balance sheet for the current year and all prior periods presented.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes included in this Annual Report on Form 10-K.

Background

We are a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore function and improve the lives of people with neurological disorders. We market three FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. 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.

Ampyra

General

Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. To our knowledge, Ampyra is the first and only drug approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the United States in March 2010. Net revenue for Ampyra was $436.9 million for the year ended December 31, 2015 and $366.2 million for the year ended December 31, 2014.

Since the March 2010 launch of Ampyra, more than 110,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. As of December 31, 2015, approximately 70% of all people with MS who were

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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. Our First Step program provides eligible patients with two months of Ampyra at no cost. During 2015, on average more than 70% of new Ampyra patients were enrolled in First Step. The program is in its fifth 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.

Ampyra is marketed in the U.S. through our own specialty sales force and commercial infrastructure. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information and assistance to payers and physicians on Ampyra; National Trade Account Managers who work with 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 the Company's strategic initiatives.

Ampyra is distributed in the U.S. 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. All of these customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar days.

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

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial 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.

In October 2015, we presented 5-year post-marketing safety data for dalfampridine extended release tablets in MS at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. The data presented continue to be consistent with those reported in double-blind clinical trials, with incidence of reported seizure remaining stable over time.

License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen, 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 anticipates making Fampyra available in additional markets in 2016. Under our agreement with Biogen, we are entitled to receive double-digit

tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a $25 million milestone payment from Biogen in 2011, which was triggered by Biogen's receipt of conditional approval from the European

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Commission for Fampyra. The next expected milestone payment would be $15 million, due when ex-U.S. net sales exceed $100 million over four consecutive quarters.

Ampyra Patent Update

We have five issued patents listed in the Orange Book for Ampyra, 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 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, this 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, this 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 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.

Ampyra also has Orphan Drug designation, which gives it marketing exclusivity in the U.S. until January 2017.

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in Part I, Item 3 of this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), 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. On February 24, 2016, the EPO Opposition Division

rendered a decision that revoked the EP 2377536 patent. We

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believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

Zanaflex

Zanaflex Capsules and Zanaflex tablets are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many central nervous system disorders, including MS and spinal cord injury. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. We launched Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. Combined net revenue of Zanaflex Capsules and Zanaflex tablets was $24.4 million for the year ended December 31, 2015 and $1.5 million for the year ended December 31, 2014. Net revenue includes the impact of a one-time increase in net revenue of $22.2 million in the quarter ended September 30, 2015, representing the cumulative impact of our conversion from the sell-through to the sell-in method of revenue recognition. Under the sell-in method of revenue recognition, revenue is recognized when the product is shipped to the distributor, whereas under the sell-through method, revenue is recognized when the product is prescribed to the patient. Going forward, Zanaflex revenue will be recognized under the sell-in method of revenue recognition.

In 2012, Apotex commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by an Allergan subsidiary as part of its Actavis business (originally Watson Pharma, Inc.). In March 2013, Mylan Pharmaceuticals commercially launched their own generic version of Zanaflex Capsules. The commercial launch of generic tizanidine hydrochloride capsules has caused a significant decline in net revenue from the sale of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2016 and beyond.

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 U.S., 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 U.S. using our existing commercial organization, including our specialty neurology sales force as well as our medical and safety reporting infrastructure. Net revenue for Qutenza was $1.0 million for the year ended December 31, 2015 and $0.9 million for the year ended December 31, 2014.

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 & 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.

CVT-301, CVT-427 and ARCUS Technology

We acquired CVT-301 in October 2014 with our acquisition of Civitas. CVT-301 is a Phase 3-ready inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in Parkinson's disease. Parkinson's

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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 for the treatment of Parkinson's disease is oral levodopa (L-dopa), but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease.

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 periods in Parkinson's disease. We expect results from the efficacy trial in the fourth quarter of 2016, and pending timely recruitment for clinical trials, our goal to file a new drug application, or NDA, in the U.S. in the first quarter of 2017. 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 long-term safety study will also be required. We are projecting that, if approved, annual peak net revenue of CVT-301 in the U.S. alone could exceed $500 million.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF period, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured.

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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS delivery system. Triptans are the class of drug most commonly prescribed for the acute treatment of migraine. Oral triptans, which account for the majority 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. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in a nasally-delivered formulation. However, based on available data, we believe that nasally-delivered triptans generally have an onset of action similar to orally administered triptans. In December 2015, we initiated and completed a Phase 1 clinical trial of CVT-427 for acute treatment of migraine. We expect to provide an update on this program by the end of the first quarter of 2016.

Pursuant to the merger agreement under which we acquired Civitas, upon consummation of the acquisition $39.375 million of the aggregate cash consideration was deposited into escrow to secure the indemnification obligations of Civitas and Civitas's securityholder. The escrow fund was released to the former Civitas securityholders in accordance with the merger agreement in the fourth quarter of 2015.

Plumiaz

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures. In 2013, we submitted a

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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. In May 2015, we announced that we completed discussions with the FDA, and are advancing development of Plumiaz. Based on these discussions, we are conducting three clinical trials for Plumiaz:

- The first trial is a long-term open-label study assessing safety and tolerability of Plumiaz over 52 weeks. This trial will enroll approximately 100 participants ages 12-65.

- The second trial is assessing the bioavailability, safety and tolerability of Plumiaz compared to diazepam rectal gel (Diastat®). This open-label, randomized, crossover trial will enroll approximately 120 people with refractory epilepsy ages 12-65 who experience seizure clusters.

- The third trial is a pharmacokinetic dose proportionality study in healthy adults.

All three trials have been initiated and are currently enrolling. We are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months. 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 licensed two patent families relating to the clinical formulation for diazepam nasal spray, including a granted U.S. patent that is set to expire in 2029. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval. If approved, we project peak annual U.S. net revenue of more than $200 million.

We acquired the Plumiaz program in December 2012 in connection with our acquisition of Neuronex, Inc., a privately-held development stage pharmaceutical company. We completed the acquisition pursuant to a merger agreement with Neuronex and Moise A. Khayrallah, acting as the Stockholders' Representative on behalf of the former Neuronex equity holders. In July 2015, we entered into an amendment to the merger agreement with Mr. Khayrallah, as Stockholders' Representative. Pursuant to the amendment, the Stockholders' Representative, acting on behalf of the former Neuronex equity holders, agreed to certain modifications to our future contingent payment obligations regarding the development and potential commercialization of Plumiaz, described below. In consideration of those modifications, pursuant to the amendment we paid the former Neuronex equity holders $8.75 million in the three-month period ended September 30, 2015.

Under the merger agreement, the former equity holders of Neuronex will be entitled to receive payments from us, in addition to payments we have already made under the merger agreement, upon the achievement of specified regulatory, manufacturing-related, and sales milestones with respect to Plumiaz. Pursuant to the merger agreement as amended by the amendment, we are obligated to pay (i) up to $3 million in specified regulatory and manufacturing-related milestone payments, a reduction from up to $18 million in such payments that were originally specified in the merger agreement, and (ii) up to $100 million upon the achievement of specified sales milestones, a reduction from up to $105 million in such payments that were originally specified in the merger agreement. Under the merger agreement, the former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments on worldwide net sales of Plumiaz, if any. The rates for these payments pursuant to the merger agreement originally ranged from the upper single digits to lower double digits, but were modified pursuant to the amendment and now range from the mid-single digits to mid double digits. These payments are payable on a country-by-country basis until the earlier to occur of ten years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the Agreement.

The patent and other intellectual property and other rights relating to Plumiaz are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, the Company's subsidiary Neuronex is obligated to pay SK up to $8 million upon the

achievement of specified development milestones with respect to Plumiaz (including a $1 million payment that was triggered in 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz),

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and up to $3 million upon the achievement of specified sales milestones with respect to the diazepam nasal spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Plumiaz.

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 trial data in the third quarter of 2016. This analysis, combined with the results from our development efforts on a once-daily formulation of dalfampridine (described below), will establish the next steps for the program.

We have been exploring a once-daily (QD) formulation of dalfampridine for use in the 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 currently have three prototypes from three different partners based on in vitro testing, which do not have the alcohol dose dumping issue we identified with the initial QD formulation. All three prototypes are currently in Phase 1 pharmacokinetic studies, and we expect to provide an update on these studies by the end of the first quarter of 2016.

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. In April 2015, we presented additional safety data from this trial at the 67th American Academy of Neurology Annual Meeting. The additional data showed that rHIgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. This data was presented at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. We are advancing clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1 trial using one of two doses of rHIgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the first half of 2017.

Cimaglermin alfa /Neuregulins

Cimaglermin alfa 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, which resolved within several days. In March 2015, we presented new analyses of data from this trial at the American College of Cardiology (ACC) 64th Annual Scientific Session and Expo. These analyses found that cimaglermin

produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In October 2013, we commenced 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

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efficacy. In June 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within several days, as was the case with the one Hy's Law case reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

Chondroitinase Program

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

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 no current plans to invest in further development of NP-1998 for neuropathic pain.

Outlook for 2016

Financial Guidance for 2016

We are providing the following guidance with respect to our 2016 financial performance:

- We expect 2016 net revenue from the sale of Ampyra to range from $475 million to $485 million.

- Research and development (R&D) expenses in 2016 are expected to range from $165 million to $175 million, excluding share-based compensation charges and expenditures related to the potential acquisition of new products or other business development activities. The increase in research and development expenses in 2016 is primarily related to Phase 3 studies of CVT-301, Plumiaz and dalfampridine and continuing development costs for rHIgM22 and CVT-427, as well ongoing preclinical studies.

- Selling, general and administrative (SG&A) expenses in 2016 are expected to range from $195 million to $205 million, excluding share-based compensation charges. We are setting a high priority on managing selling, general and administrative expenses in 2016.

The range of SG&A and R&D expenditures for 2016 excludes potential expenses related to the acquisition of Biotie as we are unable to make a determination about the potential expenses for Biotie until the acquisition is completed.

The range of SG&A and R&D expenditures for 2016 are non-GAAP financial measures because they exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition. Non-

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GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe that non-GAAP financial measures that exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses non-GAAP financial measures that exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition to establish budgets and operational goals, and to manage our business and to evaluate its performance.

Development Pipeline Goals

Our planned goals and key initiatives with respect to our pipeline during 2016 and beyond are as follows:

- Continue progressing our Phase 3 efficacy and safety studies of CVT-301 for the treatment of OFF periods in Parkinson's disease. We expect results from the efficacy trial in the fourth quarter of 2016, and pending timely recruitment for clinical trials, our goal is to file a new drug application, or NDA, in the U.S. by the first quarter of 2017.

- Continue progressing our Phase 3 clinical trial assessing the use of a twice-daily (BID) formulation of dalfampridine as a treatment for 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 trial data in the third quarter of 2016. This analysis, combined with the results from our development efforts on a once-daily (QD) formulation of dalfampridine, will establish the next steps for the program. We are working with different external partners to develop a once-daily (QD) formulation that could be included in future post-stroke studies. We currently have three prototypes from three different partners based on in vitro testing, which do not have the alcohol dose dumping issue we identified with the initial QD formulation. All three prototypes are currently in Phase 1 pharmacokinetic studies, and we expect to provide an update on these studies by the end of the first quarter of 2016.

- We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters or 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. In May 2015, we announced that we completed discussions with the FDA, and are advancing the development of Plumiaz. Based on these discussions, we are conducting three clinical trials for Plumiaz, which have been initiated and are currently enrolling. We are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months.

- In June 2015 we announced that we had stopped enrollment in our second clinical trial of cimaglermin based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to the clinical hold. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

- Our Phase 1 clinical trial of rHIgM22 found no dose-limiting toxicities at any of, and was well tolerated in each of, the five dose levels studied. In October 2015, we presented pharmacokinetics from the trial in

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patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. We are advancing clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1 trial using one of two doses of rHIgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the first half of 2017.

- In December 2015, we initiated and completed a Phase 1 clinical trial of CVT-427 for acute treatment of migraine. We expect to provide an update on this program by the end of the first quarter of 2016.

Results of Operations

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Net Revenue

Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of $436.9 million and $366.2 million for the years ended December 31, 2015 and 2014, respectively. This net revenue reflected a 10.95% increase in our sale price for Ampyra effective January 1, 2015. The net revenue increase was comprised of net volume increases of $30.1 million and price increases and discount and allowance adjustments of $40.6 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2015 compared to the year ended December 31, 2014 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our First Step program. As with a number of specialty pharmaceuticals, first quarter sales for Ampyra typically have been lower than the preceding fourth quarter sales due to inventory build in the fourth quarter, and the temporary effects of people changing insurance plans and entering the Medicare donut hole at the beginning of the year. We expect a similar trend in 2016. Effective January 1, 2016, we increased our sale price to our customers by 10.95%.

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

Zanaflex

Prior to the third quarter of 2015, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company’s revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The

Company’s sales and revenue recognition reflected the Company’s estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. We also recognize product sales on the

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transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex products of $24.4 million for the year ended December 31, 2015, as compared to $1.5 million for the year ended December 31, 2014. The Company recognized a one-time increase in net revenue of $22.2 million for the year ended December 31, 2015, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns. Net product revenues also include $3.8 million which represents the sale of our Zanaflex Capsules authorized generic product to an Allergan plc subsidiary (originally Watson Pharma, Inc.), or Allergan, for the year ended December 31, 2015 as compared to $4.6 million for the year ended December 31, 2014.

Generic competition has caused a significant decline in net revenue of Zanaflex products and is expected to cause the Company's net revenue from Zanaflex products to decline further in 2016 and beyond.

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

Qutenza

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of $1.0 million and $0.9 million for the years ended December 31, 2015 and 2014, respectively. For the foreseeable future we do not expect that sales of this product will materially contribute to our revenues.

License Revenue

We recognized $9.1 million in amortized license revenue for the years ended December 31, 2015 and 2014, respectively, related to the $110.0 million received from Biogen in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

Royalty Revenue

We recognized $10.5 million and $10.0 million in royalty revenue for the years ended December 31, 2015 and 2014, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized $7.0 million in royalty revenue for the year ended December 31, 2015 as compared to $9.1 million for the year ended December 31, 2014, related to the authorized generic sale of Zanaflex Capsules.

Cost of Sales

We recorded cost of sales of $92.3 million for the year ended December 31, 2015 as compared to $80.0 million for the year ended December 31, 2014. Cost of sales for the year ended December 31, 2015 consisted primarily of $77.5 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2015 also consisted of $10.0 million in royalty fees based on net product shipments, $0.6 million in amortization of intangible assets, and $0.4 million in period costs related to freight, stability testing, and packaging. Cost of sales also included $3.8 million which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2015.

Cost of sales for the year ended December 31, 2014 consisted primarily of $65.4 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2014 also consisted of $8.6 million in royalty fees based on net product shipments, $1.0 million in amortization of intangible assets, and $0.4 million in period costs

related to freight, stability testing, and packaging. Cost of sales also included $4.6 million which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2014.

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Cost of License Revenue

We recorded cost of license revenue of $0.6 million for the years ended December 31, 2015 and 2014, respectively. Cost of license revenue represents the recognition of a portion of the deferred $7.7 million paid to Alkermes in 2009 in connection with the $110.0 million received from Biogen as a result of our collaboration agreement.

Research and Development

Research and development expenses for the year ended December 31, 2015 were $149.2 million as compared to $73.5 million for the year ended December 31, 2014, an increase of $75.7 million, or 103.0%. The increase was primarily due to $49.3 million in research and development expenses related to CVT-301. The increase was also due to increases in expenses for various other research and development programs, including $6.3 million related to our life cycle management program for Ampyra, $10.8 million in expenses relating to work on Plumiaz, and $1.9 million in expenses related to cimaglermin alfa (previously referred to as GGF2). The increase was also due to an increase in overall research and development staff, compensation, and related expenses of $9.0 million to support our various research and development initiatives. The increases in research and development expenses were partially offset by decreases of $0.9 million related to AC105 and $0.5 million related to rHIgM22. R&D expenses are expected to be significantly higher in 2016 based on continuation of Phase 3 clinical trials and advancement of other pipeline products.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2015 were $102.7 million compared to $108.7 million for the year ended December 31, 2014, a decrease of approximately $6.0 million, or 5.5%. There was a decrease in overall marketing, selling, distribution, and market research expenses of $6.3 million partially offset by an increase in other selling expenses of $0.3 million.

General and administrative expenses for the year ended December 31, 2015 were $102.9 million compared to $93.1 million for the year ended December 31, 2014, an increase of approximately $9.8 million, or 10.5%. This increase was the result of an increase of $8.4 million for staff and compensation expenses and other expenses related to supporting the growth of the organization. The increase in general and administrative expenses was also attributable to an increase in legal and human resource expenses of $5.6 million and $0.7 million, respectively. The increases in general and administrative expenses for the year ended December 31, 2015 were partially offset by a decrease in business development expenses of $3.8 million and post approval FDA commitment expenses for Zanaflex of $1.4 million.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded expenses pertaining to changes in the fair-value of our acquired contingent consideration of $10.9 million for the year ended December 31, 2015 compared to $2.2 million for the year ended December 31, 2014, an increase of $8.7 million or 395%. The increase was due primarily to changes in fair value being measured over a full 12 month period in 2015 compared to changes in fair value being measured over approximately a 2 month period in 2014. The changes in the fair-value of the acquired contingent consideration were due to the re-calculation of discounted cash flows for the passage of time and updates to certain other estimated assumptions.

Other Expense

Other expense was $14.6 million for the year ended December 31, 2015 compared to $8.4 million for the year ended December 31, 2014, an increase of $6.2 million, or 73.8%. The increase was due to an increase in

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interest expense of $6.2 million, principally related to the cash and non-cash portions of interest expense for the convertible senior notes issued in June 2014 (the Notes). Interest expense related to the Notes was $14.6 million for the year ended December 31, 2015, of which the non-cash portion was $8.6 million.

Provision for Income Taxes

We recorded an $8.3 million provision for income taxes for the year ended December 31, 2015 as compared to a $10.3 million provision for income taxes for the year ended December 31, 2014. The provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the year ended December 31, 2015 and 2014 were 43% and 37%, respectively. The variances in the effective tax rates for the year ended December 31, 2015 and 2014 were due primarily to the non-deductible $8.8 million payment in July 2015 to the former equity holders of Neuronex and an increased benefit from the research and development tax credit. The Company's effective tax rate for this year differed from the U.S. federal statutory rate of 35% primarily due to the impact of the research and development tax credit, the orphan drug tax credit, and state income taxes.

We continue to evaluate the realizability of the Company's deferred tax assets and consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance will be required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods. The Company maintains a valuation allowance on acquired state tax attributes expected to expire prior to their utilization.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Net Revenue

Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of $366.2 million and $302.6 million for the years ended December 31, 2014 and 2013, respectively. This net revenue reflected a 10.75% increase in our sale price for Ampyra effective January 2, 2014. The net revenue increase was comprised of net volume increases of $31.7 million and price increases and discount and allowance adjustments of $31.9 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2014 compared to the year ended December 31, 2013 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our First Step program. As with a number of specialty pharmaceuticals, first quarter sales for Ampyra typically have been lower than the preceding fourth quarter sales due to inventory build in fourth quarter, and the temporary effects of people changing insurance plans and entering the Medicare donut hole at the beginning of the year.

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

Zanaflex

During 2013 and 2014, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize

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revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. We recognized net revenue from the sale of Zanaflex products of $1.5 million for the year ended December 31, 2014, as compared to $4.1 million for the year ended December 31, 2013. Net product revenues also include $4.6 million, which represents the sale of our Zanaflex Capsules authorized generic product to an Allergan plc subsidiary (originally Watson Pharma, Inc.), or Allergan, for the year ended December 31, 2014 as compared to $3.2 million for the year ended December 31, 2013. Generic competition has caused a significant decline in net revenue of Zanaflex Capsules and is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2015 and beyond. The decrease in net revenues was also the result of a disproportionate decrease in discounts and allowances due to the mix of customers continuing to purchase our product. These customers receive higher levels of rebates and allowances.

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

Qutenza

We started selling Qutenza in July 2013 as a result of the NeurogesX transaction. We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of $0.9 million and $0.4 million for the years ended December 31, 2014 and 2013, respectively. For the foreseeable future we do not expect that sales of this product will materially contribute to our revenue.

License Revenue

We recognized $9.1 million in amortized license revenue for the years ended December 31, 2014 and 2013, respectively, related to the $110.0 million received from Biogen in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

Royalty Revenue

We recognized $10.0 million and $9.3 million in royalty revenue for the years ended December 31, 2014 and 2013, respectively, related to ex-U.S. sales of Fampyra by Biogen. In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product's comparative efficacy. Biogen Idec launched Fampyra in Germany in August 2011. During the three-month period ended June 30, 2012, the government agency completed its comparative efficacy assessment of Fampyra indicating a range of pricing below Biogen Idec's initial launch price, which was unregulated for the first 12 months after launch consistent with German law. The Company recognized royalty revenue during a portion of 2012 based on the lowest point of the initially indicated German pricing authority range. The Company began recognizing royalty revenue at the negotiated fixed price effective upon the signing of Biogen Idec's pricing agreement in the first quarter of 2013.

We recognized $9.1 million in royalty revenue for the year ended December 31, 2014 as compared to $7.8 million for the year ended December 31, 2013, related to the authorized generic sale of Zanaflex Capsules.

Cost of Sales

We recorded cost of sales of $80.0 million for the year ended December 31, 2014 as compared to $66.0 million for the year ended December 31, 2013. Cost of sales for the year ended December 31, 2014 consisted

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primarily of $65.4 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2014 also consisted of $8.6 million in royalty fees based on net product shipments, $1.0 million in amortization of intangible assets, and $0.4 million in period costs related to freight, stability testing, and packaging. Cost of sales also included $4.6 million which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2014.

Cost of sales for the year ended December 31, 2013 consisted primarily of $54.2 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2013 also consisted of $7.6 million in royalty fees based on net product shipments, $0.7 million in amortization of intangible assets, and $0.4 million in period costs related to freight, stability testing, and packaging. Cost of sales also included $3.2 million which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2013.

Cost of License Revenue

We recorded cost of license revenue of $0.6 million for the years ended December 31, 2014 and 2013, respectively. Cost of license revenue represents the recognition of a portion of the deferred $7.7 million paid to Alkermes in 2009 in connection with the $110.0 million received from Biogen as a result of our collaboration agreement.

Research and Development

Research and development expenses for the year ended December 31, 2014 were $73.5 million as compared to $53.9 million for the year ended December 31, 2013, an increase of $19.6 million, or 36%. The increase was primarily due to $8.1 million in CVT-301 expenses incurred after the acquisition of Civitas in October 2014. The increase was also due to increases in expenses for various other research and development programs, including $3.8 million related to our life cycle management program for Ampyra, $1.8 million in expenses relating to work on our NP-1998 program, $1.7 million in preclinical expenses for the remyelinating antibodies program (rHIgM22), and $0.6 million related to the cimaglermin alfa (previously referred to as GGF2) development program. The increase was also due to an increase in overall research and development staff, compensation, and related expenses of $4.6 million to support the various research and development initiatives. These increases in research and development expenses were offset by a decrease of $1.1 million in regulatory expenses across various research and development programs. R&D expenses are expected to be significantly higher in 2015 based on initiation of Phase 3 clinical trials and advancement of other pipeline products.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2014 were $108.7 million compared to $109.3 million for the year ended December 31, 2013, a decrease of approximately $0.6 million, or 0.5%. There was a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of $7.9 million partially offset by an increase in overall compensation, benefits, and other selling expenses of $5.8 million and an increase of $0.9 million for pre-launch activities associated with the possible commercialization of Plumiaz (diazepam) nasal spray.

General and administrative expenses for the year ended December 31, 2014 were $93.1 million compared to $76.3 million for the year ended December 31, 2013, an increase of approximately $16.8 million, or 22%. This increase was the result of an increase of $7.9 million for staff and compensation expenses and other expenses related to supporting the growth of the organization. The increase in general and administrative expenses was also attributable to an increase in business development and legal expenses of $5.3 million and $4.5 million, respectively, primarily relating to the acquisition of Civitas. The increases in general and administrative expenses for the year ended December 31, 2014 were partially offset by a decrease in drug safety and surveillance expenses of $3.0 million.

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Impairment of Acquired IPR&D Intangible Assets

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. The acquired assets related to the development of NP-1998 were determined to be an indefinite lived intangible asset, specifically In-Process R&D (IPR&D), and were assigned an acquisition date fair value of $7.0 million. We have evaluated and reprioritized our 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. The IPR&D asset was determined to be fully impaired and a charge of $7.0 million was taken in the fourth quarter of 2014 to write the value of the asset down to $0.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda has acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty will be assessed quarterly. We recorded a $2.2 million expense pertaining to changes in the fair-value of our acquired contingent consideration as of December 31, 2014.

Other Expense

Other expense was $8.4 million for the year ended December 31, 2014 compared to $1.5 million for the year ended December 31, 2013, an increase of approximately $6.9 million, or 458%. The increase was due to an increase in interest expense of approximately $7.1 million, principally related to the cash and non-cash portions of interest expense for the convertible senior notes issued in June 2014 (the Notes). The increase was partially offset by an increase in other income of $0.2 million, principally related to realized gains on available-for-sale securities. Interest expense related to the Notes was $7.4 million for the year ended December 31, 2014, of which the non-cash portion was $4.3 million.

Provision for Income Taxes

We recorded a $10.3 million provision for income taxes for the year ended December 31, 2014 as compared to a $12.4 million provision for income taxes for the year ended December 31, 2013, resulting in an effective tax rate of 37% and 43%, respectively. The Company’s effective tax rate for 2014 and 2013 differed from the U.S. federal statutory rate of 35% primarily due to the impact of state income taxes, nondeductible stock-based compensation and various tax credits/settlements. We continue to evaluate our ability to realize our deferred tax assets and consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance will be required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods.

Liquidity and Capital Resources

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

At December 31, 2015, we had $353.3 million of cash, cash equivalents and short-term investments, compared to $307.6 million at December 31, 2014. There were no investments classified as long-term at December 31, 2015. Following the closing of the Biotie transaction, we expect that our existing cash, combined with the net

proceeds from the private placement of common stock, the cash balance of Biotie, any cash flows from operations, and the expected availability under the asset-based credit facility, will be sufficient to fund our ongoing operations.

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Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Ampyra, the continued progress of our research and development activities, the amount and timing of milestone or other payments payable under collaboration, license and acquisition agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, and capital required or used for future acquisitions or to in-license new products and compounds including the development costs relating to those products or compounds. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund our operations. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all.

Financing Arrangements

Saints Capital Notes

In January 1997, Elan International Services, Ltd. ("EIS") loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. As of December 31, 2015, $2.3 million of these promissory notes remained outstanding, which amount includes accrued interest. The sixth of seven annual payments on this note was due and paid on the six year anniversary of Ampyra's approval in January 2016 and will continue to be paid annually until paid in full.

Zanaflex Revenue Interests Assignment

On December 23, 2005, we entered into a revenue interests assignment agreement with Paul Royalty Fund ("PRF"), a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covered all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015.

Convertible Senior Notes

In June 2014, the Company entered into an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC (the "Underwriter") relating to the issuance by the Company of $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the "Notes") in an underwritten public offering pursuant to the Company's Registration Statement on Form S-3 (the "Registration Statement") and a related preliminary and final prospectus supplement, filed with the SEC (the "Offering"). The principal amount of Notes included $45 million aggregate principal amount of Notes that was purchased by the Underwriter pursuant to an option granted to the Underwriter in the Underwriting Agreement, which option was exercised in full. The net proceeds from the offering, after deducting the Underwriter's discount and the offering expenses paid by the Company, were approximately $337.5 million.

The Notes are governed by the terms of an indenture, dated as of June 23, 2014 (the "Base Indenture") and the first supplemental indenture, dated as of June 23, 2014 (the "Supplemental Indenture", and together with the Base Indenture, the "Indenture"), each between the Company and Wilmington Trust, National Association, as trustee (the "Trustee"). The Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per $1,000 principal amount of Notes (which represents an initial conversion price of approximately $42.56 per share), only in the following circumstances and to the following extent: (1) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000

principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (2) during any calendar quarter commencing after the calendar quarter ending on September 30, 2014 (and only during such calendar quarter), if the last

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reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (3) if the Company calls any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; (4) upon the occurrence of specified events described in the Indenture; and (5) at any time on or after December 15, 2020 through the second scheduled trading day immediately preceding the maturity date.

The Company may not redeem the Notes prior to June 20, 2017. The Company may redeem for cash all or part of the Notes, at the Company's option, on or after June 20, 2017 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending within five trading days prior to the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The Company will pay 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year. The first payment was made in December 2014 in the amount of $2.9 million. The Notes will mature on June 15, 2021.

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their Notes in principal amounts of $1,000 or an integral multiple thereof. The fundamental change repurchase price will be equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the Notes.

The Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the

conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the

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seven-year term of the Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

Our outstanding note balances as of December 31, 2015 consisted of the following:

(In thousands)

	December 31, 2015
Liability component:	
Principal	$ 345,000
Less: debt discount, net	(49,531)
Net carrying amount	$ 295,469
Equity component	$ 61,195

Investment Activities

At December 31, 2015, cash, cash equivalents and short-term investments were approximately $353.3 million, as compared to $307.6 million at December 31, 2014. Our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in a Treasury money market fund and US Treasury bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of December 31, 2015, our cash and cash equivalents were $153.2 million, as compared to $182.2 million as of December 31, 2014. Our short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. The balance of these investments was $200.1 million as of December 31, 2015, as compared to $125.4 million as of December 31, 2014. There were no investments classified as long-term at December 31, 2015 and 2014.

Net Cash Provided by Operations

Net cash provided by operations was $38.5 million and $74.6 million for the years ended December 31, 2015 and 2014, respectively. Cash provided by operations for the year ended December 31, 2015 was primarily attributable to non-cash share-based compensation expense of $33.5 million, net income of $11.1 million principally resulting from an increase in net product and royalty revenues, depreciation and amortization of $15.0 million, amortization of debt discount and debt issuance costs of $8.6 million, a deferred tax provision of $4.0 million, and non-cash charges for the change in contingent consideration obligation of $10.9 million. Cash provided by operations was partially offset by the one time recognition of deferred product revenue for Zanaflex of $22.2 million due to the change in revenue recognition policy from the deferred or sell through method of revenue recognition to the traditional or sell-in method of revenue recognition, an increase in inventory held by the Company of $10.2 million, a decrease in deferred license revenue of $9.1 million due to the amortization of the upfront collaboration payment received in 2009, and an increase in restricted cash of $4.8 million.

Cash provided by operations for the year ended December 31, 2014 was primarily attributable to a non-cash share-based compensation expense of $29.4 million, net income of $17.7 million principally resulting from an increase in net product and royalty revenues, depreciation and amortization of $8.5 million, amortization of net premiums and discounts on investments, debt discount and debt issuance costs of $7.8 million, a deferred tax provision of $6.7 million, and non-cash charges for intangible asset impairment on NP-1998 IPR&D and the change in contingent consideration obligation of $7.0 million and $2.2 million, respectively. Cash provided by operations was

also positively impacted by a net increase in working capital items due to an increase of $13.2 million in accounts payable, accrued expenses and other current liabilities resulting from payment timing, partially offset by a decrease in Zanaflex deferred product revenue of $2.7 million, an increase in prepaid expenses and other current assets of $4.1 million, an increase of $1.4 million in accounts receivable, and an increase in inventory held by the Company and others of $0.7 million. Cash provided by operations was also partially offset by a decrease in deferred license revenue of $9.1 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009.

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Net Cash Used in Investing

Net cash used in investing activities for the year ended December 31, 2015 was $85.2 million, due to $434.7 million in purchases of short-term investments, purchases of property and equipment of $5.9 million, and purchases of intangible assets of $1.1 million, partially offset by $356.5 million in proceeds from maturities and sales of short-term investments.

Net Cash Provided by Financing

Net cash provided by financing activities for the year ended December 31, 2015 was $17.8 million, due to $18.1 million in net proceeds from the exercise of stock options and $0.2 million pertaining to excess tax benefits from share-based compensation arrangements partially offset by $0.5 million in repayments of the revenue interest liability.

Contractual Obligations and Commitments

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Under certain supply agreements and other agreements with manufacturers and suppliers, we are required to make payments for the manufacture and supply of our clinical and approved products. Our major outstanding contractual obligations are for payments related to our convertible notes, our facility leases and our commitments to purchase inventory. The following table summarizes our minimum significant contractual obligations at December 31, 2015 and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

(In thousands)	Payments due by period (1)			
	Total	Less than 1 year	1-3 years	4-5 years
Convertible Senior Notes (2)	$ 377,594	$ 6,038	$ 12,075	$ 12,075
Convertible note payable (3)	2,288	1,144	1,144	—
Operating leases (4)	28,363	5,396	11,200	11,767
Inventory purchase commitments (5)	34,566	34,566	—	—
Total	$ 442,811	$ 47,144	$ 24,419	$ 23,842

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(1) Excludes a liability for uncertain tax positions totaling $4.8 million. This liability has been excluded because we cannot currently make a reliable estimate of the period in which the liability will be payable, if ever.

(2) Represents the future payments of principal and interest to be made on the Convertible Senior Notes issued in June 2014 and due in 2021.

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

(4) Represents payments for the operating leases of our Ardsley, NY headquarters and our manufacturing facility in Chelsea, MA.

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

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

Under certain agreements, we are also required to pay license fees and milestones for the use of technologies and products in our R&D activities and in the commercialization of products. We have committed to make potential future milestone payments to third parties of up to approximately $157 million as part of our various agreements, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2015, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

Effects of Inflation

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, primarily employee compensation and contract services, which could increase our level of expenses.

Critical Accounting Policies and Estimates

The following discussion of critical accounting policies identifies the accounting policies that require application of management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies, which are more fully described in Note 2 of the notes to the consolidated financial statements included in this document. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management’s judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result.

Revenue Recognition

Ampyra

Ampyra is available in the U.S. through a network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. We recognize product sales of Ampyra following receipt of product by these customers. Our customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 days.

Our net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to our customers, an adjustment is recorded for estimated discounts, rebates, and chargebacks. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in

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the factors that impact such reserves. In determining the amounts of certain allowances and accruals, we must make significant judgments and estimates. Allowances for discounts, rebates, and chargebacks are established based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

Based on the data that we receive from our customers, and returns experience of other specialty products with similar selling models, we have been able to make a reasonable estimate for product returns. We do not accept returns of Ampyra except for product damaged in shipping. Historically, it has been rare for us to have product damaged in shipping. We will exchange product from inventory for product damaged in shipping.

Zanaflex

We apply the revenue recognition guidance in Accounting Standards Codification ("ASC") 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex tablet and capsule (Zanaflex products) shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. As of the third quarter of 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes it now has sufficient history to reasonably estimate expected returns. For the three-month period ended September 30, 2015, the Company recognized a one-time increase in net revenue of $22.2 million, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns.

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

We accept returns of Zanaflex products for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. We do not exchange product from inventory for returned product. Prior to the three months ended September 30, 2015, product returns were charged directly against deferred revenue, reducing the amount of deferred revenue that we would recognize. In addition, we recorded a charge to cost of goods sold for the cost basis of the estimated product returns we believed would ultimately be realized at the time of product shipment to wholesalers. We recognized this charge at the date of shipment since it was probable that we would receive a level of returned product; upon the return of such product we would be unable to resell the product considering its expiration dating; and, we could reasonably estimate a range of returns. This charge represented the cost basis for the low end of

the range of the Company's estimated returns. As a result of

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the change in revenue recognition policy, the Company recorded a charge to cost of goods sold of approximately $0.6 million for the year ended December 31, 2015.

Qutenza

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.

The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. This means that, for Qutenza, the Company recognizes product sales following shipment of product to its specialty distributors.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates, chargebacks, and returns. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped, an adjustment is recorded for estimated rebates, chargebacks, and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates, chargebacks, and returns are established based on the contractual terms with customers, historical trends, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

Discounts and Allowances

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

Government Chargebacks and Rebates: We contract for Medicaid and other government programs such as the Federal Supply Schedule which commits us to providing favorable pricing for Ampyra, Zanaflex and Qutenza. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. We also contract with the Centers for Medicare and Medicaid Services to participate in the Coverage Gap Discount Program (the program given rise by the Affordable Care Act which closes the Medicare Part D "donut hole"). Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for chargebacks and rebates. We monitor the sales trends and adjust the chargeback and rebate percentages on a regular basis to reflect the most recent chargebacks and rebate experience. Our government chargeback and rebate accruals were $7.1 million and $5.0 million at December 31, 2015 and December 31, 2014, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate $3.3 million and $2.5 million effect on our net revenue for the years ended December 31, 2015 and December 31, 2014, respectively.

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Managed Care Contract Rebates: We contract with various managed care organizations including health insurance companies and pharmacy benefit managers in order to provide improved access to Ampyra for patients that are members of such organizations. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided Ampyra is placed on a specific tier on the organization's drug formulary. Based upon our contracts and the most recent experience with respect to sales through managed care channels, we provide an allowance for managed care contract rebates. We continue to monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. Our managed care contract rebate accruals were $1.6 million and $1.2 million at December 31, 2015 and December 31, 2014, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate $0.6 million effect on our net revenue for the years ended December 31, 2015 and December 31, 2014, respectively.

Copay Mitigation Rebates: We offer copay mitigation to commercially insured patients who have coverage for Ampyra (in accordance with applicable law) and are responsible for a cost share regardless of financial need (income status). The copay mitigation program is intended to reduce the patient's financial responsibility for Ampyra to a specified dollar amount. Based upon our contracts and the most recent experience with respect to actual copay assistance provided, we provide an allowance for copay mitigation rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience. Our copay mitigation rebate accruals were $0.1 million and $0.7 million at December 31, 2015 and December 31, 2014, respectively. A 10% change in our copay mitigation rebate allowances would have had an approximate $0.7 million and $0.7 million effect on our net revenue for the years ended December 31, 2015 and December 31, 2014, respectively.

Cash Discounts: We sell Ampyra directly to our network of specialty pharmacies, Kaiser and the specialty distributor to the U.S. Department of Veterans Affairs. We sell Zanaflex directly to wholesalers and Qutenza to specialty distributors. We generally provide invoice discounts for prompt payment for Ampyra and Zanaflex. We estimate our cash discounts based on the terms offered to our customers. Discounts are accrued based on historical usage rates at the time of product shipment. We adjust accruals based on actual activity as necessary. Cash discounts are typically settled with our customers within 30 days after the end of each calendar month. Our cash discounts accruals were $0.5 million and $0.4 million at December 31, 2015 and December 31, 2014, respectively. A 10% change in our cash discount allowances would have had an approximate $0.5 million and $0.4 million effect on our net revenue for the years ended December 31, 2015 and December 31, 2014, respectively.

Product Returns: We do not accept returns of Ampyra except for product damaged in shipping. Our returns accrual for Ampyra was $10,000 at December 31, 2015 and December 31, 2014.

We accept returns of Zanaflex products for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. Prior to the three month period ended September 30, 2015, we recorded Zanaflex product revenue based on a deferred revenue model and recognized revenue when prescriptions were filled to an end-user because once a prescription was filled the product could not be returned. Therefore, there was no returns reserve established for Zanaflex products prior to the three month period ended September 30, 2015. As of the three month period ended September 30, 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes it now has sufficient history to reasonably estimate expected returns. At December 31, 2015, our returns reserve for Zanaflex products was $4.3 million. A 10% change in our returns would have had an approximate $0.7 million effect on our net revenue for the year ended December 31, 2015.

Our specialty distributors for Qutenza have the right to return any unopened Qutenza product during the nine-month period beginning three months prior to the labeled expiration date and ending six months after the labeled expiration date. Once product has been opened or its expiration date does not fall within our

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return goods policy for Qutenza, it is no longer eligible for return. If product is returned, credit is given to the specialty distributors against amounts owed to us. We do not replace returned product with new product unless it has been damaged in shipping. Our returns accruals for Qutenza were immaterial for the years ended December 31, 2015 and December 31, 2014, respectively.

Data Fees and Fees for Service Payable to Wholesalers: We have contracted with the Ampyra specialty pharmacies (not including ASD Specialty Healthcare, Inc.) to obtain transactional data related to Ampyra in order to ascertain a better understanding of our selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. These contracts stipulate that the specialty pharmacies provide data directly to us, as well as indirectly through Ampyra Patient Support Services, which in turn provides data to us. We pay a data fee to the specialty pharmacies for each line of data provided and the Company provides an allowance for these data fees. A line of data is defined as data pertaining to a single prescription. We also pay a fee for service to certain wholesalers on contractually determined rates for distribution, inventory management and data reporting services. We estimate our fee for service accruals and allowances based on sales to each wholesaler and the applicable contracted rate. Our fee for service expenses are accrued at the time of product shipment and are typically settled with the wholesalers within 60 days after the end of each respective quarter. Our data fee and fee for service accruals were $1.1 million at December 31, 2015 and December 31, 2014, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate $335,000 and $356,000 effect on our net revenue for the years ended December 31, 2015 and 2014, respectively.

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

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The following table provides a summary of activity with respect to the Company's sales discounts and allowances during 2015, 2014, and 2013:

(in thousands)	Government chargebacks and rebates	Managed care contract rebates	Copay mitigation rebates	Cash discounts	Product returns	Data fees and fees for services payable to wholesalers	Other vendor allowances	Total
Balance at December 31, 2012	$2,849	$740	$222	$293	$10	$792	$-	$4,906
Allowances for sales 2013	19,935	3,421	5,481	3,452	64	3,408	-	35,761
Allowances for prior year sales	48	(43)	-	(14)	-	(73)	-	(82)
Actual credits for sales during 2013	(16,265)	(2,600)	(4,903)	(3,131)	(43)	(2,533)	-	(29,475)
Actual credits for prior year sales	(2,777)	(697)	(222)	(282)	-	(719)	-	(4,697)
Balance at December 31, 2013	$3,790	$821	$578	$318	$31	$875	$-	$6,413
Allowances for sales 2014	25,630	5,849	6,776	4,099	24	3,705	1,347	47,430
Allowances for prior year sales	(141)	(53)	-	(14)	-	(140)	-	(348)
Actual credits for sales during 2014	(21,180)	(4,688)	(6,352)	(3,723)	(40)	(2,595)	-	(38,578)
	(3,099)	(726)	(259)	(288)	-	(724)	-	(5,096)

Actual credits for prior year sales								
Balance at December 31, 2014	$5,000	$1,203	$743	$392	$15	$1,121	$ 1,347	$9,821
Allowances for sales 2015	34,188	6,510	7,529	5,083	914	3,480	329	58,033
Allowances for prior year sales	(276)	(263)	(481)	2	6,246	(129)	-	5,099
Actual credits for sales during 2015	(27,179)	(5,163)	(7,479)	(4,568)	-	(2,475)	-	(46,864)
Actual credits for prior year sales	(4,588)	(664)	(184)	(395)	(2,864)	(859)	-	(9,554)
Balance at December 31, 2015	$7,146	$1,623	$127	$514	$4,311	$1,137	$ 1,676	$16,535

Collaborations

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

Milestones and royalties

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

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

License Revenue and Cost of License Revenue

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

Inventory

The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development.

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

Cost of Sales

Ampyra

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

Zanaflex

Cost of sales consists of cost of inventory, expense due to inventory reserves when necessary, royalty expense, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and milestone obligations are set forth in the agreements entered into in connection with our Zanaflex acquisition. Any payments we made in connection with the revenue interests assignment transaction entered into

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in December 2005 did not constitute royalty expense or otherwise affect our cost of sales. See "—Liquidity and Capital Resources—Financing Arrangements."

Qutenza

Cost of sales consists of cost of inventory, expense due to inventory reserves when necessary, royalty expense, amortization of the intangible asset associated with the Qutenza acquisition, packaging costs, freight and required inventory stability testing costs.

Research and Development

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

Research and development expense consists primarily of:

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

For those studies that we administer ourselves, we account for our clinical study costs by estimating the patient cost per visit in each clinical trial and recognizing this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. For those studies for which we use a CRO, we account for our clinical study costs according to the terms of the CRO contract. These costs include upfront, milestone and monthly expenses

as well as reimbursement for pass through costs. All research and development costs are expensed as incurred except when we are accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. In these cases, these payments are capitalized at the time of payment and expensed ratable over the period the research and development activity is

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performed. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations.

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

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

(in thousands)	Year Ended December 31,		
	2015	2014	2013
Preclinical and clinical development:			
Contract expenses—CVT-301 / CVT-427	$ 35,897	$ 3,625	$ -
Contract expenses—Ampyra LCM	15,311	8,990	5,206
Contract expenses—Diazepam Nasal Spray/Plumiaz	9,825	7,805	6,890
Contract expenses—cimaglermin alfa (previously GGF2)	8,017	6,157	5,592
Contract expenses—rHIgM22	4,554	5,019	3,359
Contract expenses—NP-1998	908	2,015	185
Contract expenses—Chondroitinase	753	121	118
Contract expenses—AC105	384	1,296	1,200
Contract expenses—other	-	38	-
Research and development operating expenses:	64,750	38,329	30,252
Acquisitions, licenses and milestones:			
Diazepam Nasal Spray/Plumiaz	8,750	-	1,000
AC105	-	20	20
rHIgM22	30	25	25
cimaglermin alfa (previously GGF2)	10	10	10
Other	20	20	20
Total research and development	$ 149,209	$ 73,470	$ 53,877

With respect to previously established clinical study accruals in prior periods and for the twelve-month period ended December 31, 2015 we did not make any significant adjustments to our clinical study costs.

Sales and Marketing Expenses

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

General and Administrative Expenses

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

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Asset Impairment

Asset impairment pertains to impairment charges for non-financial assets such as property, plant and equipment, goodwill and intangible assets including IPR&D, developed technology, website development costs, and other assets that are determined to be impaired.

Changes in Fair Value of Acquired Contingent Consideration

Changes in fair value of acquired contingent consideration represents changes in the estimated fair value of the Company's acquired contingent liability.

Other Income (Expense)

Interest income consists of income earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest expense related to our revenue interest liability, accrued interest on our convertible notes, and cash and non-cash interest expense for the convertible senior notes issued in June 2014.

Income Taxes

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

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

We will continue to evaluate the realizability of our deferred tax assets and liabilities on a periodic basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities and the progress of ongoing tax audits, if any. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods.

Share-Based Compensation

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

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We have based our current assumptions on the following:

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

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

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

Our financial instruments consist of cash and cash equivalents, short-term investments, grants receivable, convertible notes payable, senior notes and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2015, except for the fair value of the Company's convertible senior notes, which was approximately $398.0 million as of December 31, 2015.

We have cash equivalents and short-term investments at December 31, 2015, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and U.S. Treasury bonds, the carrying values of our cash equivalents and short-term investments approximate their fair values at December 31, 2015. There were no investments classified as long-term at December 31, 2015. At December 31, 2015, we held $353.3 million in cash and cash equivalents and short-term investments, which had an average interest rate of approximately 0.1%.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

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Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act"), we carried out an evaluation of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of our 2015 fiscal year (the period covered by this report). This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on that evaluation, these officers have concluded that, as of December 31, 2015, our disclosure controls and procedures were effective to achieve their stated purpose.

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

Change in internal control over financial reporting

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our Chief Executive Officer and Chief Financial Officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

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

Management's Report on Internal Control Over Financial Reporting

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

Under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting as of the end of 2015 (the period covered by this report) based on the framework and criteria established in Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, our management has concluded that, as of December 31, 2015, our internal control over financial reporting was effective. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions.

Ernst & Young LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2015. This attestation report appears below.

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Report of Independent Registered Public Accounting Firm

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

We have audited Acorda Therapeutics, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Acorda Therapeutics, Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Acorda Therapeutics, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2015 consolidated financial statements of Acorda Therapeutics, Inc. and Subsidiaries and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut
February 29, 2016

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Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2016 Proxy Statement under the caption for the proposal relating to the "Election of Directors," as well as the captions "Information Concerning Executive Officers," "Executive Compensation," and "Additional Information," and such information is incorporated herein by this reference.

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

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

Item 11. Executive Compensation.

The information required by this item will be contained in our 2016 Proxy Statement under the caption for the proposal relating to the "Election of Directors," as well as the captions "Information Concerning Executive Officers," "Compensation Committee Report," "Compensation Discussion and Analysis," "Executive Compensation," and "Additional Information," and such information is incorporated herein by this reference.

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

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management," "Information Concerning Executive Officers" and "Additional Information" and is incorporated herein by this reference.

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

The information required by this item will be contained in our 2016 Proxy Statement under the caption for the proposal relating to the "Election of Directors," as well as the caption "Certain Relationships and Related Transactions," and such information is incorporated herein by this reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in our 2016 Proxy Statement under the caption for the proposal relating to the "Ratification of Independent Auditors" and is incorporated herein by this reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

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

Financial Statements of Acorda Therapeutics, Inc. and Subsidiaries:

(2) Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto listed in (a)(1) above.

(3) Exhibits
Exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately following the signature page of this Report and incorporated herein by reference.

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INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and Subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Acorda Therapeutics, Inc. and Subsidiaries at December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut
February 29, 2016

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$153,204	$182,170
Restricted cash	6,032	1,205
Short-term investments	200,101	125,448
Trade accounts receivable, net of allowances of $884 and $771, as of December 31, 2015 and 2014, respectively	31,466	32,211
Prepaid expenses	16,079	15,523
Finished goods inventory held by the Company	36,476	26,256
Finished goods inventory held by others	—	581
Other current assets	7,959	7,324
Total current assets	451,317	390,718
Property and equipment, net of accumulated depreciation	40,204	46,090
Goodwill	183,636	182,952
Deferred tax asset	2,128	2,806
Intangible assets, net of accumulated amortization	430,856	432,822
Non-current portion of deferred cost of license revenue	2,906	3,540
Other assets	5,296	6,137
Total assets	$1,116,343	$1,065,065
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$14,233	$17,751
Accrued expenses and other current liabilities	66,133	56,118
Deferred product revenue—Zanaflex	—	29,420
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interests liability	25	893
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	90,592	114,383
Convertible senior notes (due 2021)	295,469	287,699
Acquired contingent consideration	63,500	52,600
Non-current portion of deferred license revenue	41,513	50,570
Non-current portion of convertible notes payable	1,107	2,184
Deferred tax liability	12,146	8,271
Other non-current liabilities	8,991	9,103

Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value. Authorized 80,000,000 shares at December 31, 2015 and 2014; issued and outstanding 42,999,377 and 41,883,843 shares, including those held in treasury, as of December 31, 2015 and 2014, respectively	43	42
Treasury stock at cost (12,420 shares at December 31, 2015 and December 31, 2014)	(329)	(329)
Additional paid-in capital	812,782	761,026
Accumulated deficit	(209,352)	(220,410)
Accumulated other comprehensive loss	(119)	(74)
Total stockholders' equity	603,025	540,255
Total liabilities and stockholders' equity	$1,116,343	$1,065,065

See accompanying Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(In thousands, except per share data)

	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Revenues:			
Net product revenues	$ 466,111	$ 373,292	$ 310,317
Royalty revenues	17,492	19,131	17,056
License revenue	9,057	9,057	9,057
Total net revenues	492,660	401,480	336,430
Costs and expenses:			
Cost of sales	92,297	79,981	66,009
Cost of milestone and license revenue	634	634	634
Research and development	149,209	73,470	53,877
Selling, general and administrative	205,630	201,813	185,545
Asset impairment	—	6,991	—
Changes in fair value of acquired contingent consideration	10,900	2,200	—
Total operating expenses	458,670	365,089	306,065
Operating income	33,990	36,391	30,365
Other expense (net):			
Interest and amortization of debt discount expense	(15,472)	(9,288)	(2,170)
Interest income	440	674	668
Other income	411	232	—
Total other expense (net)	(14,621)	(8,382)	(1,502)
Income before taxes	19,369	28,009	28,863
Provision for income taxes	(8,311)	(10,337)	(12,422)
Net income	$ 11,058	$ 17,672	$ 16,441
Net income per share—basic	$ 0.26	$ 0.43	$ 0.41
Net income per share—diluted	$ 0.25	$ 0.42	$ 0.39
Weighted average common shares outstanding used in computing net income per share—basic	42,230	41,150	40,208
Weighted average common shares outstanding used in computing net income per share—diluted	43,621	42,544	41,682

See accompanying Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income

(In thousands)

	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Net income	$ 11,058	$ 17,672	$ 16,441
Other comprehensive loss:			
Unrealized losses on available-for-sale securities, net of tax	(45)	(111)	(25)
Other comprehensive loss, net of tax	(45)	(111)	(25)
Comprehensive income	$ 11,013	$ 17,561	$ 16,416

See accompanying Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common stock						
	Number of shares	Par value	Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance at December 31, 2012	39,804	$40	$(329)	$640,671	$(254,523)	$62	$385,921
Compensation expense for issuance of stock options to employees	—	—	—	18,036	—	—	18,036
Compensation expense for issuance of restricted stock to employees	264	—	—	7,103	—	—	7,103
Exercise of stock options	828	1	—	12,785	—	—	12,786
Excess tax benefit from share-based compensation arrangements	—	—	—	91	—	—	91
Other comprehensive loss, net of tax	—	—	—	—	—	(25)	(25)
Net income	—	—	—	—	16,441	—	16,441
Balance at December 31, 2013	40,896	$41	$(329)	$678,686	$(238,082)	$37	$440,353
Compensation expense for issuance of stock options to employees	—	—	—	21,910	—	—	21,910

Compensation expense for issuance of restricted stock to employees	242	—	—	7,527	—	—	7,527
Exercise of stock options	746	1	—	16,014	—	—	16,015
Equity component of the convertible notes, issuance, net	—	—	—	37,795	—	—	37,795
Debt issuance costs	—	—	—	(1,277)	—	—	(1,277)
Excess tax benefit from share-based compensation arrangements	—	—	—	371	—	—	371
Other comprehensive loss, net of tax	—	—	—	—	—	(111)	(111)
Net income	—	—	—	—	17,672	—	17,672
Balance at December 31, 2014	41,884	$42	$(329)	$761,026	$(220,410)	$(74)	$540,255
Compensation expense for issuance of stock options to employees		—	—	25,026	—	—	25,026
Compensation expense for issuance of restricted stock to employees	244	—	—	8,441	—	—	8,441
Exercise of stock options	871	1	—	18,095	—	—	18,096
Excess tax benefit from share-based compensation arrangements	—	—	—	194	—	—	194
Other comprehensive loss, net of tax	—	—	—	—	—	(45)	(45)
Net income	—	—	—	—	11,058	—	11,058
	42,999	$43	$(329)	$812,782	$(209,352)	$(119)	$603,025

Balance at December 31, 2015	

See accompanying Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Cash flows from operating activities:			
Net income	$ 11,058	$ 17,672	$ 16,441
Adjustments to reconcile net income to net cash provided by operating activities:			
Recognition of deferred product revenue - Zanaflex	(22,186)	—	—
Share-based compensation expense	33,467	29,437	25,139
Amortization of net premiums and discounts on investments	3,366	3,571	2,526
Amortization of debt discount and debt issuance costs	8,562	4,291	—
Amortization of revenue interest issuance cost	15	27	50
Depreciation and amortization expense	15,012	8,473	6,999
Intangible asset impairment	—	6,991	—
Change in contingent consideration obligation	10,900	2,200	—
Gain on put/call liability	—	(147)	(182)
Deferred tax provision	3,975	6,681	9,520
Excess tax benefit from share-based compensation arrangements	(194)	(371)	(91)
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	744	(1,427)	(4,457)
Increase in prepaid expenses and other current assets	(998)	(4,083)	(377)
Increase in inventory held by the Company	(10,220)	(721)	(5,269)
Decrease in inventory held by others	581	56	145
Decrease in non-current portion of deferred cost of license revenue	634	634	634
Decrease in other assets	34	34	34
(Decrease) increase in accounts payable, accrued expenses and other current liabilities	(825)	13,180	(5,785)
	(374)	108	18

(Decrease) increase in revenue interest liability interest payable			
Decrease in non-current portion of deferred license revenue	(9,057)	(9,057)	(9,057)
(Decrease) increase in other non-current liabilities	(198)	(301)	78
(Decrease) increase in deferred product revenue—Zanaflex	(989)	(2,670)	2,816
(Increase) decrease in restricted cash	(4,826)	71	103
Net cash provided by operating activities	38,481	74,649	39,285
Cash flows from investing activities:			
Purchases of property and equipment	(5,921)	(5,084)	(4,043)
Purchases of intangible assets	(1,145)	(2,699)	(3,121)
Acquisitions, net of cash received	—	(476,151)	(7,499)
Purchases of investments	(434,670)	(580,381)	(221,429)
Proceeds from maturities of investments	356,500	770,490	191,000
Net cash used in investing activities	(85,236)	(293,825)	(45,092)
Cash flows from financing activities:			
Proceeds from issuance of convertible senior notes	—	345,000	—
Debt issuance costs	—	(7,516)	—
Proceeds from issuance of common stock and option exercises	18,096	16,015	12,786
Excess tax benefit from share-based compensation arrangements	194	371	91
Repayments of revenue interest liability	(501)	(562)	(909)
Net cash provided by financing activities	17,789	353,308	11,968
Net (decrease) increase in cash and cash equivalents	(28,966)	134,133	6,161
Cash and cash equivalents at beginning of period	182,170	48,037	41,876
Cash and cash equivalents at end of period	$ 153,204	$ 182,170	$ 48,037
Supplemental disclosure:			
Cash paid for interest	$ 7,218	$ 4,522	$ 2,022
Cash paid for taxes	4,697	4,392	2,630

See accompanying Notes to Consolidated Financial Statements.

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

(1) Organization and Business Activities

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies to restore function and improve the lives of people with neurological disorders.

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

(2) Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of the consolidated financial statements requires management to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include share-based compensation accounting, which are largely dependent on the fair value of the Company’s equity securities. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

Restricted Cash

Restricted cash represents a bank account with funds to cover the Company’s self-funded employee health insurance and cash deposits held in connection with obligations under facility leases. At December 31, 2015, restricted cash of $5.8 million is related to cash collateralized standby letters of credit (see Note 14).

Investments

Short-term investments consist of U.S. Treasury bonds. The Company classifies marketable securities available to fund current operations as short-term investments in current assets on its consolidated balance sheets. Marketable securities are classified as long-term investments in long-term assets on the consolidated balance sheets if the Company has the ability and intent to hold them and such holding period is longer than one year. The

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Company classifies its short-term investments as available-for-sale. Available-for-sale securities are recorded at the fair value of the investments based on quoted market prices.

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

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

Other Comprehensive (Loss) Income

The Company’s other comprehensive (loss) income is comprised of unrealized gains and losses on available-for-sale securities and is recorded and presented net of income tax.

Inventory

Inventory is stated at the lower of cost or market value and includes amounts for Ampyra, Zanaflex tablet, Zanaflex Capsule and Qutenza inventories and is recorded at its net realizable value. The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Cost is determined using the first-in, first-out method (FIFO) for all inventories. The Company establishes reserves as necessary for obsolescence and excess inventory.

Ampyra

The cost of Ampyra inventory manufactured by Alkermes plc (Alkermes) is based on agreed upon pricing with Alkermes. In the event Alkermes does not manufacture the products, Alkermes is entitled to a compensating payment for the quantities of product provided by Patheon, the Company’s alternative manufacturer. This compensating payment is included in the Company’s inventory balances.

Property and Equipment

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

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company’s business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. See Note 13 for discussion on goodwill.

Intangible Assets

The Company has finite lived intangible assets related to milestones for Ampyra, and for certain website development costs. These intangible assets are amortized on a straight line basis over the period in which the Company expects to receive economic benefit and are reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. The determination of the expected life will be

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dependent upon the use and underlying characteristics of the intangible asset. In the Company's evaluation of the intangible assets, it considers the term of the underlying asset life and the expected life of the related product line. If the carrying value is not recoverable, impairment is measured as the amount by which the carrying value exceeds its estimated fair value. Fair value is generally estimated based on either appraised value or other valuation techniques. The Company also has indefinite lived intangible assets for the value of acquired in-process research and development related to CVT-301. The Company reviews the carrying value of indefinite lived intangible assets annually and whenever indicators of impairment are present. See also "In-Process Research and Development" and Note 13 for discussion on intangible assets.

Contingent Consideration

The Company may record contingent consideration as part of the cost of business acquisitions. Contingent consideration is recognized at fair value as of the date of acquisition and recorded as a liability on the consolidated balance sheet. The contingent consideration is re-valued on a quarterly basis using a probability weighted discounted cash-flow approach until fulfillment or expiration of the contingency. Changes in the fair value of the contingent consideration are recognized in the statement of operations. See Note 10 for discussion on the Alkermes ARCUS agreement.

Impairment of Long-Lived Assets

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

Patent Costs

Patent application and maintenance costs are expensed as incurred.

Research and Development

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

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In-Process Research and Development

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects will be further developed or have an alternative future use; otherwise they are expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method”, and uses estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense is recognized in the statement of operations. These assets are tested at least annually or sooner when a triggering event occurs that could indicate a potential impairment.

Accounting for Income Taxes

The Company provides for income taxes in accordance with ASC Topic 740 (ASC 740). Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance for the amounts of any tax benefits which, more likely than not, will not be realized. On December 31, 2015, the Company early adopted the provisions of Accounting Standards updated 2015-17, “Income Taxes” (Topic 740): Balance Sheet Classification of Deferred Taxes (ASU 2015-17), which simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in the balance sheet. The Company adopted the new guidance retrospectively and updated the classification of the deferred tax liabilities and assets to noncurrent in the balance sheet for the current year and all prior periods presented.

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

Revenue Recognition

Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail; Kaiser Permanente, 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. Ampyra is not available in retail pharmacies. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. The Company recognizes

product sales of Ampyra following shipment of product to a network of specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. The specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 days.

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The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies, Kaiser Permanente and ASD Specialty Healthcare, Inc., an adjustment is recorded for estimated discounts, rebates, and chargebacks. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for discounts, rebates, and chargebacks are established based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.The Company does not accept returns of Ampyra with the exception of product damages that occur during shipping.

Zanaflex

The Company applies the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex tablet and capsule (Zanaflex products) shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company is recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. For the three-month period ended September 30, 2015, the Company recognized a one-time increase in net revenue of $22.2 million, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks and returns.

Qutenza

Qutenza is distributed in the U.S. 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. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. This means that, for Qutenza, the Company recognizes product sales following shipment of product to its specialty distributors.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates, chargebacks, and returns.

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Milestones and royalties

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

Collaborations

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

Concentration of Risk

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

The Company does not own or operate, and currently does not plan to own or operate, facilities for production and packaging of Ampyra or its other commercial products, Zanaflex Capsules, Zanaflex tablets or Qutenza. It relies and expects to continue to rely on third parties for the production and packaging of its commercial products and clinical trial materials for all of its products except CVT-301. As part of the Civitas acquisition in 2014, the Company leases a manufacturing facility in Chelsea, Massachusetts which produces CVT-301 for clinical trials and eventually will produce commercial supply, if approved.

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

The Company's principal direct customers as of December 31, 2015 were a network of specialty pharmacies, Kaiser Permanente, and ASD Specialty Healthcare, Inc. for Ampyra, wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets, and two specialty distributors for Qutenza. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. Three customers individually accounted for more than 10% of the Company's revenue in 2015 and

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four customers individually accounted for more than 10% of the Company's revenue in 2014 and 2013. Three customers individually accounted for more than 10% of the Company's accounts receivable as of December 31, 2015 and four customers individually accounted for more than 10% of the Company's accounts receivable as of December 31, 2014. The Company's net product revenues are generated in the U.S.

Allowance for Cash Discounts

An allowance for cash discounts is accrued based on historical usage rates at the time of product shipment. The Company adjusts accruals based on actual activity as necessary. Cash discounts are typically settled with customers within 30 days after the end of each calendar month. The Company had cash discount allowances of $5.1 million and $4.1 million for the years ended December 31, 2015 and 2014, respectively. The Company's accruals for cash discount allowances were $0.5 million and $0.4 million as of December 31, 2015 and 2014, respectively.

Allowance for Doubtful Accounts

A portion of the Company's accounts receivable may not be collected due principally to customer disputes. The Company provides reserves for these situations based on the evaluation of the aging of its trade receivable portfolio and an analysis of high-risk customers. The Company has not historically experienced material losses related to credit risk. The Company has recognized an allowance related to one customer of approximately $0.4 million as of December 31, 2015 and December 31, 2014. For the year ended December 31, 2015 and 2014, the Company recorded no provision and did not record any write-offs.

Contingencies

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

Fair Value of Financial Instruments

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

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

(a) Cash equivalents, grants receivable, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these instruments;

(b) Available-for-sale securities are recorded based primarily on quoted market prices;

(c) Put/call liability's fair value is based on revenue projections and business, general economic and market conditions that could be reasonably evaluated as of the valuation date;

(d) Contingent purchase price related to the NeurogesX acquisition was measured at fair value using a Monte Carlo simulation;

(e)

Acquired contingent consideration related to the Civitas acquisition is measured at fair value using a probability weighted, discounted cash flow approach; and

(f) Convertible Senior Notes were measured at fair value based on market quoted prices of debt securities with similar terms and maturities using other observable inputs.

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Earnings per Share

Basic net income per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the vesting of restricted stock and the potential dilutive effects of the conversion option on the Company's convertible debt. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options. See Note 8 for discussion on earnings per share.

Share-based Compensation

The Company has various share-based employee and non-employee compensation plans, which are described more fully in Note 7.

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

Segment and Geographic Information

The Company is managed and operated as one business which is focused on the identification, development and commercialization of novel therapies to improve the lives of people with neurological disorders. The entire business is managed by a single management team that reports to the Chief Executive Officer. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare discrete financial information with respect to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment. Net product revenues reported to date are derived from the sales of Ampyra, Zanaflex and Qutenza in the U.S.

Accumulated Other Comprehensive (Loss) Income

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers" (Topic 606) (ASU 2014-09). This new standard will replace all current U.S. GAAP guidance on this topic and eliminate all industry-specific guidance. In July 2015, the FASB decided to defer the effective date of the new revenue standard for interim and annual periods beginning after December 15, 2017 (previously December 15, 2016). The change will allow public entities to adopt the new standard as early as the original public entity effective date (i.e. annual reporting periods beginning after December 15, 2016 and interim periods therein). Early adoption prior to that date will not be permitted. ASU 2014-09 allows for either full

retrospective or modified retrospective adoption. The Company is evaluating the transition method that will be elected and the potential effects of adopting the provisions of ASU No. 2014-09.

In August 2014, the FASB issued Accounting Standards Update 2014-15, “Presentation of Financial Statements-Going Concern” (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (ASU 2014-15), which defines management’s responsibility to assess an entity’s ability to

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continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update 2015-03, "Interest – Imputation of Interest" (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. ASU-2014-15 is effective for fiscal years and interim periods therein beginning after December 15, 2015, with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements or related disclosures.

On June 12, 2015, the FASB issued Accounting Standards Update 2015-10, "Technical Corrections and Improvements". With regard to fair value measurement disclosures, ASU 2015-10 clarified that, for nonrecurring measurements estimated at a date during the reporting period other than the end of the reporting period, an entity should clearly indicate that the fair value information presented is not as of the period's end as well as the date or period that the measurement was taken. This change was effective immediately upon issuance of ASU 2015-10. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements or related disclosures.

In July 2015, the FASB issued Accounting Standards Update 2015-11, "Inventory" (Topic 330): Simplifying the Measurement of Inventory (ASU 2015-11), which requires the measurement of inventory at the lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods therein with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements, results of operations or related disclosures.

In September 2015, the FASB issued Accounting Standards update 2015-16, "Business Combinations" (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (ASU 2015-16), which requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the period in which the adjustment amount is determined. The acquirer is required to also record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. In addition the acquirer is required to present separately on the face of the income statement or disclose in the notes to the financial statements the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. This guidance is effective for fiscal years and interim periods therein beginning after December 15, 2015, and requires prospective application. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements, results of operations or related disclosures.

In November 2015, the FASB issued Accounting Standards updated 2015-17, "Income Taxes" (Topic 740): Balance Sheet Classification of Deferred Taxes (ASU 2015-17), which simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets and associated valuation allowances be classified as noncurrent on the balance sheet instead of distinguishing between current and noncurrent. This guidance is effective for fiscal years and interim periods therein beginning after December 15, 2016, and may be applied prospectively or retrospectively with early adoption permitted. The Company early adopted this guidance effective with its fiscal year ending December 31, 2015 and elected to apply this guidance retrospectively. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements or related disclosures. The impact of the adoption of this guidance on the Company's Consolidated Balance Sheet as of December 31, 2014 was a reclassification of $18.4 million of current deferred tax assets and $23.8 million of noncurrent deferred tax liabilities to $2.8 million

of noncurrent deferred tax assets and $8.2 million of non current deferred tax liabilities.

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In January 2016, the FASB issued Accounting Standards Update 2016-01, “Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities.” The main objective of this update is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. The new guidance addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. This ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the new guidance to determine the impact it may have on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-02, “Leases” (Topic 842). The main objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the new guidance to determine the impact it may have on its consolidated financial statements.

Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined the following subsequent event required disclosure in our financial statements.

On January 19, 2016, we entered into a Combination Agreement to acquire Biotie Therapies Corp. for a cash purchase price of approximately $363 million. Biotie Therapies is a biopharmaceutical company primarily focused on developing therapeutics for central nervous system disorders. Biotie’s currently active pipeline includes:

- Tozadenant, an oral product candidate, and selective inhibitor of the adenosine A2a receptor that Biotie Therapies is developing as an adjunct to levodopa for the treatment of Parkinson’s disease in patients experiencing end-of-dose wearing-off;

- SYN120, an oral product candidate to treat both cognitive deficits and psychosis, which frequently coincide in neurodegenerative diseases such as Parkinson’s disease and Alzheimer’s disease; and

- BTT1023, a product candidate for the orphan disease Primary Sclerosing Cholangitis (PSC), a chronic and progressive fibrotic liver disease for which there is no FDA-approved treatment.

Also, Biotie Therapies receives double digit royalties from sales of Selincro, a European Medicines Agency (EMA)-approved orally administered therapy for alcohol dependence therapy. Selincro is not approved for use in the U.S. and is not under development for use in the U.S.

Concurrently with the announcement of the Biotie Therapies transaction, we announced two separate financing transactions. The first was a private placement of 2,250,900 shares of our common stock for an aggregate purchase price of approximately $75 million. We paid discounts and commissions of $2.3 million in connection with the private placement, which settled on January 26, 2016. We intend to use the net proceeds from the private placement to fund, in part, the acquisition of Biotie Therapies described above. If the acquisition is not consummated for any reason, we will use all of the net proceeds from the private placement for general corporate purposes. We also announced a commitment from JPMorgan Chase, N.A. for an asset-based credit facility for up to $60 million. The closing of this credit facility transaction is expected to occur in the first quarter of 2016.

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(3) Acquisitions

Civitas Therapeutics, Inc. Acquisition

On October 22, 2014, the Company completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation (Civitas). As a result of the acquisition, the Company acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF periods of Parkinson's disease and CVT-427 which at the time of acquisition was a pre-clinical developmental stage candidate. The acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which management believes has 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 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 (the Merger Agreement), by and among Acorda, Five A Acquisition Corporation, a Delaware corporation and its wholly-owned subsidiary (Merger Sub), Civitas and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the securityholders' representative (SRS). Pursuant to the terms of the Merger Agreement, Merger Sub has 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, aggregate merger consideration was $525 million plus $4.5 million in Civitas transaction costs paid by the Company. Additionally and pursuant to the Merger Agreement, upon consummation of the merger, $39.375 million of the aggregate merger consideration was deposited into escrow to secure representation and warranty indemnification obligations of Civitas and Civitas' securityholders. The escrow amount was released in the fourth quarter of 2015 in accordance with the Merger Agreement. The transaction was financed with cash on hand. The Company incurred approximately $7.2 million of its own transactions costs related to legal, valuation and other professional and consulting fees associated with the acquisition. These transaction costs were expensed as selling, general and administrative expenses in the year ended December 31, 2014.

The fair value of consideration transferred as of the acquisition date of October 22, 2014 totaled approximately $529.5 million summarized as follows:

(In thousands)	
Cash paid	$524,201
Extinguishment of long-term debt	5,325
Fair value of consideration transferred	$529,526

In accordance with the acquisition method of accounting, the Company allocated the purchase price to the estimated fair values of the identifiable assets acquired and liabilities assumed, with any excess allocated to goodwill. The fair value of the IPR&D will be classified as an indefinite lived intangible asset until the successful completion or abandonment of the associated research and development efforts. The Company accounted for the transaction as a business combination. The results of Civitas' operations have been included in the consolidated statements of operations from the date of acquisition.

Acquired contingent consideration represents the estimated fair value of certain royalty payments due under a prior acquisition agreement between Alkermes and Civitas pertaining to sales of licensed products using the ARCUS technology. The estimated fair value of the acquired contingent consideration was determined by applying a probability adjusted, discounted cash flow approach based on estimated future sales expected from CVT-301 and CVT-427. CVT-427 is an inhaled triptan intended to provide acute treatment of migraine by using the ARCUS

delivery system. Refer to Note 10 for further discussion about the Alkermes ARCUS agreement.

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Goodwill represents the amount of the purchase price paid in excess of the estimated fair value of the assets acquired and liabilities assumed. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax deduction. None of the goodwill is deductible for tax purposes.

The following table presents the final allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date of October 22, 2014:

(In thousands)	
Current assets	$54,911
Property and equipment	27,913
Identifiable intangible assets:	
In-process research and development	423,000
Other non-current assets	1,002
Current liabilities	(6,154)
Contingent consideration	(50,400)
Deferred taxes	(103,317)
Other non-current liabilities	(1,065)
Fair value of acquired assets and liabilities	345,890
Goodwill	183,636
Aggregate purchase price	529,526
Amount paid to extinguish long-term debt	(5,325)
Cash Paid	$524,201

The Company completed its purchase price allocation for the Civitas acquisition in the third quarter of 2015 which resulted in an increase of approximately $0.7 million to the provisional amount recorded for deferred tax liabilities, resulting in an increase to goodwill.

The following table presents the changes to the goodwill balance associated with the completion of the accounting for the Civitas acquisition:

(In thousands)	
Goodwill – balance at October 22, 2014	$182,952
Increase to goodwill for final purchase price allocation	684
Goodwill – balance at December 31, 2015	$183,636

NeurogesX Acquisition

On July 8, 2013, Acorda acquired certain assets from NeurogesX, Inc. (NeurogesX), including two neuropathic pain management assets: Qutenza and NP-1998. Qutenza is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia. NP-1998 is a Phase 3 ready prescription strength capsaicin topical solution being assessed for the treatment of neuropathic pain. NP-1998 was previously referred to as NGX-1998. Prior to the acquisition, NeurogesX was a specialty pharmaceutical company focused on developing and commercializing a portfolio of novel non-opioid pain management therapies headquartered in San Mateo, CA. Acquisition-related costs during the year ended December 31, 2013 of approximately $1.0 million for advisory, legal, regulatory and valuation costs incurred in connection with the NeurogesX acquisition were expensed as selling, general and administrative expenses.

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Astellas Pharma Europe Ltd. (Astellas) has exclusive commercialization rights for Qutenza in the European Economic Area 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. Astellas also has an option to develop NP-1998 in those same territories.

In consideration for the acquisition of assets pursuant to the Asset Purchase Agreement, Acorda paid NeurogesX $7.5 million in cash and may pay up to an additional $5.0 million of post-closing milestone payments (Milestone Payments), as follows:

- $2.0 million upon the approval for sale of an NP-1998 liquid formulation product in the U.S. for the cutaneous treatment of PDN in humans, if FDA approval is obtained prior to December 31, 2016; and

- $3.0 million if net sales of an NP-1998 approved product in Acorda's territory reaches $100 million during the first 12 months that such product is sold in Acorda's territory, commencing with the first date that such product is commercially available for purchase anywhere in Acorda's territory. Acorda's territory consists of all territories worldwide other than those jurisdictions covered by the Astellas Agreement, which generally comprise countries in Europe, Africa and the Middle East.

There is no assurance that any of the conditions for the Milestone Payments will be met. Refer to Note 15 for information regarding the contingent consideration liability.

Total purchase price as of the acquisition date of July 8, 2013 is summarized as follows:

(In thousands)	
Cash paid to NeurogesX shareholders and its creditors	$7,499
Fair value of contingent liabilities	205
Total purchase price	$7,704

The allocation of the purchase price to the fair value of the assets acquired reflected the estimated fair values of NeurogesX's assets as of the acquisition date. In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the NeurogesX transaction to the underlying assets acquired by the Company, based upon the estimated fair values of those assets at the date of acquisition and classified the fair value of the acquired IPR&D as an indefinite-lived intangible asset until the successful completion or abandonment of the associated research and development efforts. The Company accounted for the transaction as a business combination.

The following table presents the allocation of the purchase price to the assets acquired as of the acquisition date of July 8, 2013:

(In thousands)	
Inventory	$90
Equipment	173
Identifiable intangible assets:	
Developed technology – Qutenza	450
In-process research and development – NP-1998	6,991
Fair value of acquired assets	7,704
Aggregate purchase price	7,704
Goodwill	$—

Refer to Note 13 for information regarding the full impairment of IPR&D in 2014.

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Pro-Forma Financial Information Associated with Acquisitions (Unaudited)

The following table summarizes certain supplemental pro forma financial information for the years ended December 31, 2014 and 2013 as if the acquisitions of Civitas and NeurogesX had occurred as of January 1, 2013 and January 1, 2012, respectively. The unaudited pro forma financial information for the year ended December 31, 2014 reflects (i) the impact to operations resulting from the elimination of transaction costs related to the Civitas acquisition; (ii) the impact to depreciation expense based on fair value adjustments to the property, plant and equipment acquired from Civitas; (iii) the elimination of interest costs associated with Civitas' debt retired during the acquisition that were included in the results of operations for the year ended December 31, 2014; and the related tax effects of those adjustments. The unaudited pro forma financial information for December 31, 2013 reflects (i) the impact to depreciation expense based on fair value adjustments to the property, plant and equipment acquired from Civitas, (ii) the impact to operations resulting from the elimination of transaction costs related to the NeurogesX transaction; and the related tax effects of those adjustments. The unaudited pro forma financial information was prepared for comparative purposes only and is not necessarily indicative of what would have occurred had the acquisitions been made at those times or of results which may occur in the future.

	Year ended December 31, 2014		Year ended December 31, 2013	
(In thousands)	Reported	Pro Forma	Reported	Pro Forma
Net revenues	$401,480	$401,480	$336,430	$337,130
Net income/(loss)	17,672	(14,084)	16,441	(5,976)

(4) Investments

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

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
December 31, 2015				
US Treasury bonds	$ 200,244	$ —	$ (143)	$ 200,101
December 31, 2014				
US Treasury bonds	$ 125,443	$ 14	$ (9)	$ 125,448

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

term investments as of December 31, 2015.

Short-term investments with maturity of three months or less from date of purchase have been classified as cash and cash equivalents, and amounted to $83.5 million and $149.8 million as of December 31, 2015 and 2014, respectively. Short-term investments have original maturities of greater than 3 months but less than 1 year and long-term investments are greater than 1 year. There were no investments classified as long-term at December 31, 2015 and 2014.

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The Company holds available-for-sale investment securities which are reported at fair value on the Company's balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive (loss) income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the net unrealized holding losses on available-for-sale investments during the years ended December 31, 2015 and 2014 were as follows (in thousands):

(In thousands)	Net Unrealized Gains (Losses) on Marketable Securities
Balance at December 31, 2013	$ 37
Other comprehensive loss before reclassifications:	(356)
Amounts reclassified from accumulated other comprehensive loss	245
Net current period other comprehensive loss	(111)
Balance at December 31, 2014	(74)
Other comprehensive loss before reclassifications:	(45)
Amounts reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive loss	(45)
Balance at December 31, 2015	$ (119)

(5) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2015	December 31, 2014	Estimated useful lives used
Machinery and equipment	$ 21,026	$ 21,026	2-7 years
Leasehold improvements	19,135	15,763	Lesser of useful life or remaining lease term
Computer equipment	15,776	12,118	1-3 years
Laboratory equipment	6,514	5,247	2-5 years
Furniture and fixtures	2,064	1,163	4-7 years
Capital in progress	1,318	4,501	
	65,833	59,818	
Less accumulated depreciation	(25,629)	(13,728)	
	$ 40,204	$ 46,090	

Depreciation and amortization expense on property and equipment was $11.9 million and $5.1 million for the years ended December 31, 2015 and 2014, respectively.

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(6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2015	December 31, 2014
Product allowance accruals	$ 18,325	$ 10,165
Bonus payable	12,324	10,696
Research and development expense accruals	10,447	6,918
Accrued inventory	6,497	12,453
Commercial and marketing expense accruals	3,054	2,091
Royalties payable	2,838	2,540
Vacation accrual	2,270	2,038
Sales force commissions and incentive payments payable	1,978	3,039
Medical affairs expenses	1,498	223
Administrative expenses	1,133	1,025
Other accrued expenses	5,769	4,930
Total	$ 66,133	$ 56,118

(7) Common Stock Options and Restricted Stock

On June 18, 1999, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the 1999 Plan). All employees of the Company were eligible to participate in the 1999 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The number of shares authorized for issuance under the 1999 Plan was 2,481,334. As of December 31, 2015, the Company had granted an aggregate of 2,384,345 shares as restricted stock of stock options under the 1999 Plan, of which there were no remaining shares subject to outstanding options.

On January 12, 2006, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan (the 2006 Plan). The 2006 Plan served as the successor to the Company's 1999 Plan, as amended, and no further option grants or stock issuances were to be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. All employees of the Company were eligible to participate in the 2006 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 2006 Plan also covered the issuance of restricted stock.

The 2006 Plan was administered by the Compensation Committee of the Board of Directors, which selected the individuals to be granted options and restricted stock, determined the time or times at which options and restricted stock were to be granted, determined the number of shares to be granted subject to any option or restricted stock and the duration of each option and restricted stock, and made any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. The number of shares of common stock authorized for issuance under the 2006 Plan as of December 31, 2015 was 14,912,048 shares. The total number of shares of common stock available for issuance under the 2006 Plan, including shares of common stock subject to the then outstanding awards, automatically increased on January 1 of each year during the term of the 2006 Plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board approved the automatic increases of 4% for 2015, 2014,

and 2013. As of December 31, 2015, the Company had granted an aggregate of 13,221,911 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 7,899,235 shares remained subject to outstanding options.

On June 9, 2015, the Company's stockholders approved the adoption of the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan (the 2015 Plan). The 2015 Plan serves as the successor to the Company's 2006 Plan, as amended, and no further option grants or stock issuances will be made under the 2006 Plan after the effective date, as determined under Section 1 of the 2015 Plan. All employees of the Company are eligible to participate in the 2015 Plan, including executive officers, as well as directors, consultants, advisors and

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other service providers of the Company or any of its subsidiaries. The 2015 Plan also covers the issuance of restricted stock.

The 2015 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and restricted stock, determines the time or times at which options and restricted stock are to be granted, determines the number of shares to be granted subject to any option or restricted stock and the duration of each option and restricted stock, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2015 Plan. Under the 2015 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Since inception, the number of shares of common stock authorized for issuance under the 2015 Plan as of December 31, 2015 is 3,000,000 shares. Upon the exercise of options in the future, the Company intends to issue new shares. As of December 31, 2015, the Company had granted an aggregate of 332,904 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 324,250 shares remained subject to outstanding options.

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

	Year ended December 31,		
	2015	2014	2013
Employees and directors:			
Estimated volatility	46.68%	51.26%	55.91%
Expected life in years	5.88	5.84	5.82
Risk free interest rate	1.74%	1.79%	1.16%
Dividend yield	—	—	—

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using the historic volatility of the Company's stock price. The expected life used to estimate the fair value of employee options is 5.88 years which is based on the historical life of the Company's options based on exercise data.

The weighted average fair value per share of options granted to employees and directors for the years ended December 31, 2015, 2014 and 2013 amounted to approximately $15.85, $17.61, and $15.95, respectively. No options were granted to non-employees for the years ended December 31, 2015, 2014 and 2013.

During the year ended December 31, 2015, the Company granted 1,872,592 stock options and restricted stock awards to employees and directors under the 2015 Omnibus Plan. The stock options were issued with a weighted average exercise price of $35.45 per share. As a result of these grants the total compensation charge to be recognized over the service period is $30.2 million, of which $7.5 million was recognized during the year ended December 31, 2015.

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Compensation costs for options and restricted stock granted to employees and directors amounted to $33.5 million, $29.4 million, and $25.1 million, for the years ended December 31, 2015, 2014 and 2013, respectively. There were no compensation costs capitalized in inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, and selling, general and administrative expense based on employee job function. The following table summarizes share-based compensation expense included within the Company's consolidated statements of operations:

	Year ended December 31,		
(In thousands)	2015	2014	2013
Research and development	$8,474	$5,939	$5,805
Selling, general and administrative	24,992	23,498	19,334
Total	$33,466	$29,437	$25,139

A summary of share-based compensation activity for the year ended December 31, 2015 is presented below:

Stock Option Activity

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at December 31, 2012	5,667	22.30		
Granted	1,835	31.50		
Forfeited and expired	(188)	27.90		
Exercised	(828)	15.45		
Balance at December 31, 2013	6,486	25.61		
Granted	2,352	36.56		
Forfeited and expired	(306)	32.40		
Exercised	(746)	21.46		
Balance at December 31, 2014	7,786	$ 29.05		
Granted	1,651	35.45		
Forfeited and expired	(343)	34.85		
Exercised	(871)	20.77		
Balance at December 31, 2015	8,223	$ 30.97	6.7	$97,163
Vested and expected to vest at December 31, 2015	8,141	$ 30.92	6.7	$96,569
Vested and exercisable at December 31, 2015	5,110	$ 28.50	5.6	$72,974

	Options Outstanding			Options Exercisable	
Range of exercise price	Outstanding as of December 31, 2015 (In thousands)	Weighted-average remaining contractual life	Weighted-average exercise price	Exercisable as of December 31, 2015 (In thousands)	Weighted-average exercise price
$2.45 - $25.33	1,682	3.5	$ 20.94	1,658	$ 20.90
$25.39 - $30.46	2,067	6.6	28.70	1,500	28.29
$30.49 - $35.01	1,646	7.0	32.87	1,080	32.95
$35.09 - $39.38	2,648	8.5	37.19	852	37.72
$39.67 - $44.50	181	9.1	41.72	20	41.05
	8,223	6.7	$ 30.97	5,110	$ 28.50

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Restricted Stock Activity

Restricted Stock	Number of Shares (In thousands)
Nonvested at December 31, 2012	458
Granted	258
Vested	(264)
Forfeited	(31)
Nonvested at December 31, 2013	421
Granted	387
Vested	(241)
Forfeited	(48)
Nonvested at December 31, 2014	519
Granted	205
Vested	(244)
Forfeited	(39)
Nonvested at December 31, 2015	441

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2015 totaled $57.5 million and is expected to be recognized over a weighted average period of approximately 2.4 years.

(8) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2015, 2014 and 2013:

(In thousands, except per share data)	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Basic and diluted			
Net income	$ 11,058	$ 17,672	$ 16,441
Weighted average common shares outstanding used in computing net income per share—basic	42,230	41,150	40,208
Plus: net effect of dilutive stock options and unvested restricted common shares	1,391	1,394	1,474
	43,621	42,544	41,682

Weighted average common shares outstanding used in computing net income per share—diluted			
Net income per share—basic	$ 0.26	$ 0.43	$ 0.41
Net income per share—diluted	$ 0.25	$ 0.42	$ 0.39

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

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

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

(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Denominator			
Stock options and restricted common shares	4,179	4,078	2,419
Convertible note	19	29	39

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net income per diluted share.

(9) Income Taxes

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

(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Income before taxes	$ 19,369	$ 28,009	$ 28,863

The (provision for) income taxes in 2015, 2014 and 2013 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Current:			
Federal	$ (603)	$ (1,105)	$ (665)
State	(2,773)	(1,819)	(2,050)
Foreign	(960)	(732)	(154)
	(4,336)	(3,656)	(2,869)
Deferred:			
Federal	(2,960)	(6,085)	(6,815)
State	(1,015)	(596)	(2,738)
Foreign	—	—	—
	(3,975)	(6,681)	(9,553)
Total (provision for) income taxes	$ (8,311)	$ (10,337)	$ (12,422)

Due to the amount of net operating loss (NOL) and tax credit carryforwards, the Company does not currently pay substantial U.S. federal income taxes. The Company expects to pay cash taxes in various US states and Puerto Rico where it has operations and NOL carryforwards are not available or limited. The Company was subject to the alternative minimum tax during 2015 and 2014 and expects it will continue to be subject to such tax in the near term.

The payment of alternative minimum tax generates a credit that may be carried forward indefinitely and can be used to offset its future regular income tax liability.

The Company had available federal NOL carryforwards of approximately $195.0 million and $215.2 million and state NOL carryforwards of approximately $11.8 million and $14.7 million as of December 31, 2015 and 2014, respectively, which are available to offset future taxable income. The net operating loss carryforwards include approximately $34.6 million of deductions related to the exercise of stock options.

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This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected above. The tax benefit of $12 million associated with the exercise of these stock options will be recorded in additional paid-in capital when the associated net operating loss is recognized. The federal losses are expected to begin to expire in 2025, while the state losses are expected to expire during similar periods, although not all states conform to the federal carryforward period and occasionally limit the use of net operating losses for a period of time. The Company is no longer subject to federal income tax audits for tax years prior to 2012 however, such net operating losses utilized by the Company in years subsequent to 2002 is subject to review. In 2013 the Company completed an IRS exam for tax years 2009 through 2011. In 2015, the IRS began an audit of the Company for the tax year 2013.

The Company also has research and development credit carry-forwards of $20.3 million and $11.9 million as of December 31, 2015 and 2014, respectively and begin to expire in 2017. The Company also has Alternative Minimum Tax credit carry-forwards of $3.8 million and $3.3 million as of December 31, 2015 and 2014, respectively. Such credits can be carried forward indefinitely and have no expiration date.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. The Company has determined that these limiting provisions were triggered during a prior year for both Acorda Therapeutics and Neuronex, its wholly owned subsidiary and a limitation was triggered in the year of acquisition of Civitas, another wholly owned subsidiary of Acorda Therapeutics. However, it believes that such limitation is not expected to result in the expiration or loss of any of its federal NOL’s and income tax credit carryforwards. Future ownership changes may limit the use of these carryforwards.

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

	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
U.S. federal statutory tax rate	35.0%	35.0%	35.0%
State and local income taxes	13.3%	3.7%	10.7%
Non-deductible payment to prior shareholders	15.8%	—	—
Foreign income tax	3.2%	1.8%	0.1%
Stock option compensation	10.4%	4.8%	3.5%
Stock option shortfall	—	—	0.3%
Research and development and orphan drug credits	(42.9%)	(15.5%)	(9.1%)
Increase to Uncertain Tax Positions	7.1%	2.3%	1.5%

Other nondeductible and permanent differences	1.9%	2.6%	1.0%
Provision (benefit) attributable to valuation allowance	(0.9%)	2.2%	—
Effective income tax rate	42.9%	36.9%	43.0%

The effective tax rate related to state taxes is primarily driven by Acorda's state tax return filings as a stand-alone entity, without the benefit of Civitas losses. The state taxes reflect amended tax return filings and the deferred impact of customary state tax law and apportionment changes that occurred during the year; the state effective tax rate is not necessarily indicative of the company's expected state tax rate for the foreseeable future.

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

(In thousands)	December 31, 2015	December 31, 2014
Deferred tax assets:		
Net operating loss and other carryforwards	$ 60,889	$ 69,149
Tax credits	20,778	13,199
Deferred revenue	13,949	29,144
Stock based compensation	27,142	22,776
Contingent consideration	23,298	19,142
Other	13,723	11,359
Total deferred tax assets	$ 159,779	$ 164,769
Valuation allowance	$ (5,277)	$ (5,497)
Total deferred tax assets net of valuation allowance	$ 154,502	$ 159,272
Deferred tax liabilities:		
Intangible assets	(145,433)	(142,735)
Convertible debt	(19,087)	(22,002)
Total deferred tax liabilities	$ (164,520)	$ (164,737)
Net deferred tax asset (liability)	$ (10,018)	$ (5,465)

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Income Taxes, which provides presentation requirements to classify all deferred tax assets and liabilities as noncurrent in a classified statement of financial position. The standard is effective for fiscal years ending after December 15, 2016. Early adoption is permitted for any interim and annual financial statements that had not been issued as of the date of the pronouncement.

The Company has elected to early adopt ASU 2015-17 effectively December 31, 2015, retrospectively. The effects of the accounting change on December 31, 2014 were as follows:

(In thousands)	December 31, 2014	
	Revised	As Reported
Current deferred tax asset	$—	$ 18,420
Non-current deferred tax asset	2,806	—
Current deferred tax liability	—	—
Non-current deferred tax liability	(8,271)	(23,885)
Net deferred tax (liabilities)/assets	$(5,465)	$ (5,465)

The Company follows authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax

position taken or expected to be taken in a tax return.

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

(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Beginning of period balance	$ 3,295	$ 2,244	$ 1,936
Increases for tax positions taken during a prior period	308	451	589
Decreases for tax positions taken during a prior period	—	(200)	(511)
Increases for tax positions taken during the current period	1,232	800	230
Reduction as a result of a lapse of statute of limitations	—	—	—
	$ 4,835	$ 3,295	$ 2,244

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

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

(10) License, Research and Collaboration Agreements

Alkermes plc, formerly Elan plc

The Company has entered into agreements with Elan Corporation plc, including those described immediately below and elsewhere in these financial statements. In September 2011, Alkermes plc acquired Elan's Drug Technologies business and Elan transferred the 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 the agreements.

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

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

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

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100% of the products, it is entitled to a compensating payment for the quantities of product provided by the alternative manufacturer.

Convertible Note

Under the Agreement, Alkermes also loaned to the Company an aggregate of $7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Alkermes transferred these promissory notes to funds affiliated with Saints Capital. One promissory note in the amount of $5.0 million bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note. The original unpaid principal was convertible into 67,476 shares of common stock. As of December 31, 2015 the unpaid principal is convertible into 19,279 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the products to be developed, subject to limitations related to gross margin on product sales. The $5.0 million promissory note restricts the Company's ability to incur indebtedness that is senior to the notes, subject to certain exceptions, including for the Company's revenue interests assignment arrangement (See Note 14).

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

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

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

Supply Agreement

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

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

Rush-Presbyterian St. Luke's Medical Center

In 1990, Alkermes licensed from Rush know-how relating to dalfampridine (4-aminopyridine, 4-AP, the formulation used in Ampyra), for the treatment of MS. The Company subsequently licensed this know-how from Alkermes. In September 2003, the Company entered into an agreement with Rush and Alkermes terminating the Rush license to Alkermes and providing for mutual releases. The Company also entered into a license agreement

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with Rush in 2003 in which Rush granted the Company an exclusive worldwide license to its know-how relating to dalfampridine for the treatment of MS. Rush has also assigned to the Company its Orphan Drug Designation for dalfampridine for the relief of symptoms of MS.

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

As of December 31, 2015, the Company made or accrued royalty payments totaling $37.4 million.

Biogen Inc.

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

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

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

The Company considered the following deliverables with respect to the revenue recognition of the $110.0 million upfront payment: (1) the license to use the Company's technology, (2) the Collaboration Agreement to develop and commercialize licensed product in all countries outside the U.S., and (3) the Supply Agreement. Due to the inherent uncertainty in obtaining regulatory approval, the applicability of the Supply Agreement is outside the control of the Company and Biogen. Accordingly, the Company has determined the Supply Agreement is a contingent deliverable at the onset of the agreement. As a result, the Company has determined the Supply Agreement does not meet the

definition of a deliverable that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant and incremental discount related to the supply agreement since Biogen will pay the same amount for inventory that the Company would pay and the

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Company effectively acts as a middle man in the arrangement for which it adds no significant value due to various factors such as the Company does not have any manufacturing capabilities or other know-how with respect to the manufacturing process.

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized $9.1 million in amortized license revenue, a portion of the $110.0 million received from Biogen, and $0.6 million in cost of license revenue, a portion of the $7.7 million paid to Alkermes, during each of the years ended December 31, 2015, 2014 and 2013.

As part of its ex-U.S. license agreement, Biogen owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval and new indications. These milestones included a $25.0 million payment for approval of the product in the European Union which was recorded and paid in the three-month period ended September 30, 2011. Based on Acorda's worldwide license and supply agreement with Alkermes, Alkermes received 7% of this milestone payment from Acorda during the same period. For revenue recognition purposes, the Company has determined this milestone to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen leveraged Acorda's U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was achieved based in part on Acorda's past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement. Therefore, the payment was recognized in its entirety as revenue and the cost of the milestone revenue was recognized in its entirety as an expense during the three-month period ended September 30, 2011.

Allergan/Watson

The Company has an agreement with an Allergan plc subsidiary (originally Watson Pharma, Inc.), or Allergan, to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, which was launched in February 2012. In accordance with the agreement, the Company receives a royalty based on Allergan's gross margin, as defined by the agreement, of the authorized generic product. During the years ended December 31, 2015 and 2014, the Company recognized royalty revenue of $7.0 million and $9.1 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the years ended December 31, 2015 and 2014, the Company also recognized revenue and a corresponding cost of sales of $3.8 million and $4.6 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Allergan, which is recorded in net product revenues and cost of sales.

Alkermes (ARCUS products)

In December 2010, Civitas, the Company's wholly-owned subsidiary, entered into the Alkermes Agreement, in which Civitas licensed or acquired from Alkermes certain pulmonary development programs and INDs, underlying intellectual property and laboratory equipment associated with the pulmonary business of Alkermes. The assets acquired includes (i) patents, patent applications and related know-how and documentation; (ii) a formulation of inhaled L-dopa; (iii) several other pulmonary development programs and INDs, which are part of the platform device

and formulation IP; (iv) instruments, laboratory equipment and apparatus; and (v) inhalers, inhaler molds, tools, and the associated assembled equipment. In addition, Civitas signed the sublease for the facility where the Alkermes operations were housed in Chelsea, Massachusetts.

Under the terms of the Alkermes Agreement, Civitas will also pay to Alkermes royalties for each licensed product as follows: (i) for all licensed products sold by Civitas, Civitas will pay Alkermes a mid-single digit

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percentage of net sales of such licensed products and (ii) for all licensed products sold by a collaboration partner, Civitas will pay Alkermes the lower of a mid-single digit percentage of net sales of such licensed products in a given calendar year or a percentage in the low-to-mid-double digits of all collaboration partner revenue received in such calendar year. 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 calendar year.

As consideration for the agreement with Alkermes, Civitas issued stock and also agreed to pay Alkermes royalties on future net product sales from products developed from licensed technology under the Alkermes Agreement. The fair value of the future royalties is classified as contingent consideration. The Company estimates the fair value of this contingent consideration based on future revenue projections and estimated probabilities of receiving regulatory approval and commercializing such products. Refer to Note 15 – Fair Value Measurements for more information on the contingent consideration liability.

Neuronex

In December 2012, the Company acquired Neuronex, Inc., a privately-held development stage pharmaceutical company (Neuronex) developing Plumiaz (our trade name for Diazepam Nasal Spray). Plumiaz is a proprietary nasal spray formulation of diazepam that we are developing under Section 505(b)(2) of the Food, Drug and Cosmetic Act as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience bouts of increased seizure activity also known as seizure clusters or acute repetitive seizures, or ARS.

The Company completed the acquisition pursuant to a merger agreement with Neuronex and Moise A. Khayrallah, acting as the Stockholders' Representative on behalf of the former Neuronex equity holders. In July 2015, the Company entered into an amendment to the merger agreement (Amendment) with Mr. Khayrallah, as Stockholders' Representative. Pursuant to the Amendment, the Stockholders' Representative, acting on behalf of the former Neuronex equity holders, agreed to certain modifications to the Company's future contingent payment obligations regarding the development and potential commercialization of Plumiaz, described below. In consideration of those modifications, pursuant to the Amendment the Company paid the former Neuronex equity holders $8.75 million in July 2015.

Under the terms of the agreement, the Company made an upfront payment of $2.0 million in February 2012. The Company also paid $1.5 million during the year ended December 31, 2012 pursuant to a commitment under the agreement to fund research to prepare for the Plumiaz pre-NDA meeting with the FDA. In December 2012, the Company completed the acquisition by paying $6.8 million to former Neuronex shareholders less a $0.3 million holdback provision. After adjustment for Neuronex's working capital upon closing of the acquisition, approximately $0.1 million of the holdback amount was remaining as of December 31, 2013. This balance was paid to the former equity holders of Neuronex pursuant to the merger agreement in February 2014.

Under the merger agreement, the former equity holders of Neuronex will be entitled to receive payments from the Company, in addition to payments the Company has already made under the merger agreement, upon the achievement of specified regulatory, manufacturing-related, and sales milestones with respect to Diazepam Nasal Spray products (Plumiaz). Pursuant to the merger agreement as amended by the Amendment, the Company is obligated to pay (i) up to $3 million in specified regulatory and manufacturing-related milestone payments, a reduction from up to $18 million in such payments that were originally specified in the merger agreement, and (ii) up to $100 million upon the achievement of specified sales milestones, a reduction from up to $105 million in such payments that were originally specified in the merger agreement. Under the merger agreement, the former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments on worldwide net sales of Diazepam Nasal Spray products (Plumiaz), if any. The rates for these payments pursuant to the merger agreement originally ranged from the upper single digits to lower double digits, but were modified pursuant to the Amendment and now range from the mid-single

digits to mid double digits. These payments are payable on a country-by-country basis until the earlier to occur of ten years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the Agreement.

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The patent and other intellectual property and other rights relating to Diazepam Nasal Spray products are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, the Company's subsidiary Neuronex is obligated to pay SK up to $8 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product (including a $1 million payment that was triggered during the three-month period ending September 30, 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz and paid during the three-month period ending December 31, 2013), and up to $3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

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

(11) Employee Benefit Plan

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The plan includes an employer match contribution to employee deferrals. For each dollar an employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was $2.4 million, $1.9 million and $1.5 million for the years ended December 31, 2015, 2014, and 2013, respectively.

(12) Commitments and Contingencies

Operating Leases

Ardsley, New York

In June 2011, the Company 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, the Company relocated its corporate headquarters, and all employees based at the prior Hawthorne, NY location, to the Ardsley facility. The Company has grown substantially over the last several years, and the new facility provides state-of-the art office and laboratory space that accommodates the Company's current needs and allows for future growth. The Company has options to extend the term of the lease for three additional five-year periods, and the Company has an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, the Company has rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. The Company's 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 the Company not be in default under the lease. In 2014, the Company exercised its option to expand into an additional 25,405 square feet of office space, which the Company occupied in January 2015.

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 funded by the facility owner prior to the Company's occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and

other facility fees and charges. The base rent is currently $4.4 million per year, which reflects an annual 2.5% escalation factor as well as the recent expansion, described above.

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Chelsea, Massachusetts

Our 2014 acquisition of Civitas included a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas, now our wholly-owned subsidiary, previously subleased the Chelsea, Massachusetts facility from Alkermes, Inc., which leased the facility from the owner, H&N Associates, LLC. The Civitas sublease and Alkermes head lease were scheduled to expire on December 31, 2015, but in the first quarter of 2015 Civitas and Alkermes exercised options that extended the terms of the sublease and head lease for five additional years, until December 31, 2020. In the fourth quarter of 2015, Civitas entered into an assignment and amendment of the head lease with Alkermes and H&N Associates pursuant to which, among other things, Civitas became the direct lessee of the Chelsea facility from H&N Associates under the terms and conditions of the Alkermes head lease, as modified by the assignment and amendment. Pursuant to the assignment and amendment, the term of the head lease has been extended an additional five years, to December 31, 2025, and Civitas has two additional extension options of five years each. The assignment and amendment also specifies the rent during the current extended term, as well as during the additional extension periods should Civitas exercise its options for those extension periods. The base annual rent under the head lease is currently $1.0 million per year.

Future minimum commitments under all non-cancelable operating leases subsequent to December 31, 2015 are as follows:

(In thousands)	
2016	$ 5,396
2017	5,531
2018	5,669
2019	5,811
2020	5,956
Later years	18,177
	$ 46,540

Rent expense under these operating leases during the years ended December 31, 2015, 2014 and 2013 was approximately $4.8 million, $3.5 million, and $3.4 million, respectively.

License Agreements

Under the Company’s Ampyra license agreement with Alkermes, the Company is obligated to make milestone payments to Alkermes of up to $15.0 million over the life of the contract and royalty payments as a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda. In addition, under the Company’s various other research, license and collaboration agreements with other parties, it is obligated to make milestone payments of up to an aggregate of approximately $157 million over the life of the contracts. The FDA approval of Ampyra triggered a milestone of $2.5 million to Alkermes that was paid during the quarter ended June 30, 2010. An additional milestone payment to Alkermes was paid during the quarter ended March 31, 2012 with an additional $2.5 million recorded as an intangible asset. Further milestone amounts are payable in connection with additional indications.

Under the Company’s Ampyra supply agreement with Alkermes, payments for product manufactured by Alkermes are calculated as a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda. Under this agreement, Acorda also has the option to purchase up to an agreed to quantity of product from a second source. However, if Acorda obtains supply from the second source, Acorda must make a compensating payment to

Alkermes for the quantities of product provided by the second source.

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

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Under the Company's supply agreement with Alkermes, it provides Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for its supply requirements of Ampyra and two-year forecasts for its supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra following the submission of its written 18-month forecast, the Company is obligated to purchase the quantity specified in the forecast, even if its actual requirements are greater or less. Inventory purchase commitments were $34.6 million as of December 31, 2015.

Employment Agreements

The Company has employment agreements with all of its executive officers which provide for, among other benefits, certain severance, bonus and other payments and COBRA premium coverage, as well as certain rights relating to their equity compensation awards, if their employment is terminated for reasons other than cause or if they terminate their employment for good reason (as those terms are defined in the agreements). The agreements also provide for certain increased rights if their employment terminates following a change in control (as defined in the agreements). Our contractual commitments table does not include these severance payment obligations.

Other

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. While losses, if any, are possible the Company is not able to estimate any ranges of losses as of December 31, 2015. Litigation expenses are expensed as incurred.

The Company is currently a party to various legal proceedings which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability or range of losses can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. While it is not possible to determine the outcome of these matters the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the Company's consolidated results of operations in any one accounting period. Litigation expenses are expensed as incurred.

(13) Intangible Assets and Goodwill

Intangible Assets

CVT-301 and ARCUS Technology IPR&D

In October 2014, the Company acquired through the acquisition of Civitas (Note 3), global rights to CVT-301, a Phase 3 treatment candidate for OFF periods of Parkinson's disease. The acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which the Company believes has potential applications in multiple disease areas. CVT-301 is an inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in Parkinson's disease.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the transaction to the underlying assets acquired and liabilities assumed by the Company, based upon the estimated fair values of those assets and liabilities at the date of acquisition and classified the fair value of the acquired IPR&D as an indefinite-lived intangible asset until the successful completion or abandonment of the associated research and development efforts. The value allocated to the indefinite lived intangible asset was $423 million.

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Ampyra

On January 22, 2010, the Company received marketing approval from the FDA for Ampyra triggering two milestone payments of $2.5 million to Alkermes and $0.8 million to Rush-Presbyterian St. Luke's Medical Center (Rush) and an additional $2.5 million payable to Alkermes two years from date of approval. The Company made milestone payments totaling $3.25 million which were recorded as intangible assets in the consolidated financial statements during the three-month period ended March 31, 2010. An additional milestone payment to Alkermes was paid during the three-month period ended March 31, 2012 with an additional $2.5 million recorded as an intangible asset.

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

In August 2003, the Company entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization (CSRO). Under this agreement, the Company was granted an exclusive and worldwide license under certain patent assets and know-how of CSRO relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject. The agreement required the Company to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Ampyra and on the sale of dalfampridine for any other indication. During the three-month period ended March 31, 2010, the Company purchased CSRO's rights to all royalty payments under the agreement with CSRO for $3.0 million. This payment was recorded as an intangible asset in the consolidated financial statements. The estimated remaining useful life of this asset is presented in the table below.

NP-1998 IPR&D and Qutenza Developed Technology

In July 2013, the Company acquired rights in the U.S., Canada, Latin America and certain other countries to two neuropathic pain management assets from NeurogesX, Inc., including: Qutenza®, which is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain; and NP-1998, a Phase 3 ready, prescription strength capsaicin topical solution, that was being assessed for the treatment of neuropathic pain. In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the NeurogesX transaction to the underlying assets acquired by the Company, based upon the estimated fair values of those assets at the date of acquisition and classified the fair value of the acquired IPR&D as an indefinite-lived asset classified under intangible assets until the successful completion or abandonment of the associated research and development efforts. The value allocated to this indefinite lived asset was approximately $7.0 million. The value allocated to the Qutenza developed technology was determined to be approximately $450,000 and was recorded as an intangible asset.

The Company evaluated and reprioritized its research and development pipeline based on the 2014 acquisition of Civitas, and as a result has no current plans to invest in further development of NP-1998 for neuropathic pain. Therefore, the Company believes that the intangible assets associated with NP-1998 and Qutenza were fully impaired based on the currently estimated fair value of the assets, and the Company recorded asset impairment charges of approximately $7.0 million and $0.3 million to fully write off the carrying value of the NP-1998 and Qutenza assets, respectively, during the three-month period ended December 31, 2014.

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Websites

Intangible assets also include certain website development costs which have been capitalized. The Company has developed several websites, each with its own purpose, including the general corporate website, product information websites and various other websites.

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its intangible assets may warrant revision or that the carrying value of these assets may be impaired. As of December 31, 2015, the Company does not believe that there are any facts or circumstances that would indicate a need for changing the estimated remaining useful life of the Company's other intangible assets.

Intangible assets consisted of the following:

(In thousands)	December 31, 2015	December 31, 2014	Estimated remaining useful lives as of December 31, 2015
In-process research & development – CVT-301/ARCUS	$ 423,000	$ 423,000	Indefinite-lived
Ampyra milestones	5,750	5,750	11 years
Ampyra CSRO royalty buyout	3,000	3,000	4 years
Website development costs	12,504	11,319	3 years
Website development costs – in process	266	306	
	444,520	443,375	
Less accumulated amortization	13,664	10,553	
	$ 430,856	$ 432,822	

The Company recorded $3.1 million and $3.3 million in amortization expense related to these intangible assets in the years ended December 31, 2015 and 2014, respectively. The Company recorded impairment charges of approximately $7.0 million and $0.3 million to write-off the carrying value of NP-1998 and Qutenza, respectively during the year ended December 31, 2014.

Estimated future amortization expense for intangible assets subsequent to December 31, 2015 is as follows:

(In thousands)	
2016	$ 2,558
2017	1,587
2018	918
2019	588
2020	316

Thereafter	1,889
	$ 7,856

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Goodwill

At December 31, 2014, the Company recorded goodwill associated with the acquisition of Civitas Therapeutics. The carrying value of the goodwill was $183.6 million and $183.0 million at December 31, 2015 and 2014, respectively.

(14) Debt

Convertible Senior Notes

On June 17, 2014, the Company issued $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the Notes) in an underwritten public offering. The net proceeds from the offering, after deducting the Underwriter's discount and the offering expenses paid by the Company, were approximately $337.5 million.

The Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per $1,000 principal amount of Notes (which represents an initial conversion price of approximately $42.56 per share), only in the following circumstances and to the following extent: (1) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (2) during any calendar quarter commencing after the calendar quarter ending on September 30, 2014 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (3) if the Company calls any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; (4) upon the occurrence of specified events, as described; and (5) at any time on or after December 15, 2020 through the second scheduled trading day immediately preceding the maturity date.

The Company may not redeem the Notes prior to June 20, 2017. The Company may redeem for cash all or part of the Notes, at the Company's option, on or after June 20, 2017 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending within five trading days prior to the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The Company will pay 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year, beginning on December 15, 2014. The Notes will mature on June 15, 2021.

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their Notes in principal amounts of $1,000 or an integral multiple thereof. The fundamental change repurchase price will be equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes

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by notice to the Company and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the Notes.

The Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The outstanding note balance as of December 31, 2015 and 2014 consisted of the following:

(In thousands)	December 31, 2015	December 31, 2014
Liability component:		
Principal	$ 345,000	$ 345,000
Less: debt discount, net	(49,531)	(57,301)
Net carrying amount	$ 295,469	$ 287,699
Equity component	$ 61,195	$ 61,195

In connection with the issuance of the Notes, the Company incurred approximately $7.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $7.5 million of debt issuance costs, $1.3 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $6.2 million were allocated to the liability component and recorded as deferred financing costs included in other assets on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the Notes using the effective interest method.

The Company determined the expected life of the debt was equal to the seven year term on the Notes. The fair value of the Company's convertible senior notes was approximately $398.0 million as of December 31, 2015.

As of December 31, 2015, the remaining contractual life of the Notes is approximately 5.5 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through December 31, 2015. The following table sets forth total interest expense recognized related to the Notes for the years ended December 31, 2015 and 2014:

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(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014
Contractual interest expense	$ 6,038	$ 3,153
Amortization of debt issuance costs	792	397
Amortization of debt discount	7,770	3,894
Total interest expense	$ 14,600	$ 7,444

Convertible Note

The Company is a party to an amended and restated license agreement and a supply agreement with Alkermes, which replaced two prior license and supply agreements for Ampyra. Under the license agreement, Alkermes also loaned to the Company an aggregate of $7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Alkermes transferred these promissory notes to funds affiliated with Saints Capital. One promissory note remains outstanding in the amount of $5.0 million and bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note (See Note 10).

Revenue Interests Assignment

On December 23, 2005, the Company entered into an agreement with an affiliate of Paul Royalty Fund (PRF), under which the Company received $15 million in cash. In exchange the Company has assigned PRF revenue interest in Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all Zanaflex net revenues (as defined in the agreement) generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, the Company entered into an amendment to the revenue interests assignment agreement with PRF. Under the terms of the amendment, PRF paid the Company $5.0 million in November 2006. An additional $5.0 million was due to the Company if net revenues during the fiscal year 2006 equaled or exceeded $25.0 million. This milestone was met and the receivable was reflected in the Company's December 31, 2006 financial statements. Under the terms of the amendment, the Company repaid PRF $5.0 million on December 1, 2009 and an additional $5.0 million on December 1, 2010 since the net revenues milestone was met. In November 2014 PRF sold its Zanaflex revenue interest to Valeant Pharmaceuticals International, Inc.

Under the revenue interests assignment agreement and the amendment to the agreement, PRF was entitled to, and now as PRF's successor Valeant is entitled to, the following portion of Zanaflex net revenues:

- with respect to Zanaflex net revenues up to and including $30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;

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

- with respect to Zanaflex net revenues in excess of $60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF and Valeant, as PRF's successor, have received and retained payments under the amended agreement that are at least 2.1 times the aggregate amount PRF paid the Company under the agreement, Valeant will only be entitled to 1% of Zanaflex net revenues.

In connection with the transaction, the Company recorded a liability, referred to as the revenue interest liability. The Company imputes interest expense associated with this liability using the effective interest rate method and records a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. The Company currently estimates that the imputed interest rate associated with this liability will

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be approximately 5.8%. Payments made to Valeant as a result of Zanaflex sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability. The Company recorded approximately $0.9 million, $1.7 million and $2.0 million in interest expense related to this agreement in 2015, 2014 and 2013, respectively. Through December 31, 2015, $52.5 million in payments have been made as a result of Zanaflex sales levels and milestones reached.

The agreement also contains put and call options whereby the Company may repurchase the revenue interest at its option or can be required by Valeant to repurchase the revenue interest, contingent upon certain events. If the Company experiences a change of control, undergoes certain bankruptcy events, transfers any of their interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfers all or substantially all of its assets, or breaches certain of the covenants, representations or warranties made under the agreement, Valeant has the right, which the Company refers to as Valeant's put option, to require the Company to repurchase the rights sold to under the revenue interests assignment agreement at the "put/call price" in effect on the date such right is exercised. If the Company experiences a change of control it has the right, which the Company refers to as the Company's call option, to repurchase the rights sold to PRF/Valeant at the "put/call price" in effect on the date such right is exercised. If the Company's call option becomes exercisable as a result of this trigger, the Company will have a period of 180 days during which to exercise the option. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF as of such date, less all payments received by PRF/Valeant as of such date, and (ii) an amount that would generate an internal rate of return to PRF/Valeant of 25% on all payments made by PRF/Valeant as of such date, taking into account the amount and timing of all payments received by PRF/Valeant as of such date. The Company has determined that Valeant's put option and the Company's call option meet the criteria to be considered an embedded derivative and should be accounted for as such. As of December 31, 2015 and 2014 the Company had no liability related to the put/call option to reflect its current estimated fair value. This liability is revalued as needed to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings. For the year ended December 31, 2014, a gain of $147,000 was recorded as a result of the change in the fair value of the net put/call liability balance from December 31, 2013.

Letters of Credit

As of December 31, 2015, the Company has $5.8 million of cash collateralized standby letters of credit outstanding (see Note 2).

(15) Fair Value Measurements

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

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

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market

data for substantially the full term of the assets or liabilities.

- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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Recurring

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and December 31, 2014, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(In thousands)	Level 1	Level 2	Level 3
2015			
Assets Carried at Fair Value:			
Cash equivalents	$70,504	$13,009	$—
Short-term investments	—	200,101	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	63,500
2014			
Assets Carried at Fair Value:			
Cash equivalents	$149,754	$—	$—
Short-term investments	—	125,448	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	52,600
Put/call liability	—	—	—

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

Acquired contingent consideration

(In thousands)	Year ended December 31, 2015	Year ended December 31, 2014
Acquired contingent consideration:		
Balance, beginning of period	$ 52,600	$ —
Fair value of acquired contingent consideration as of October 22, 2014	—	50,400
Total losses included in the statement of operations	10,900	2,200
Balance, end of period	$ 63,500	$ 52,600

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach based on estimated future sales expected from CVT-301, a phase 3 candidate for the treatment of OFF periods of Parkinson's disease and CVT-427, a Phase 1 candidate. CVT-427 is an inhaled triptan intended for acute treatment of migraine using the ARCUS delivery system. Using this approach, expected future cash flows are calculated over the expected life of the agreement, are discounted, and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the valuation include (i) the estimated CVT-301 and CVT 427 revenue forecasts, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of revenue milestones ranged from 28.5% to 70% with milestone payment outcomes ranging from $0 to $60 million in the aggregate for CVT-301 and CVT-427. The valuation is performed quarterly. Gains and losses are included in the statement of operations. For the year ended December 31, 2015, changes in the fair value of the acquired contingent consideration were due to the recalculation of cash flows for the passage of time and updates to

certain other estimated assumptions. Refer to Note 10 for more information on the Alkermes ARCUS agreement.

The acquired contingent consideration has been classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach including, but not limited to, assumptions involving probability adjusted sales estimates for CVT-301 and CVT-427 and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value determined.

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Put/call liability

(In thousands)	Year ended December 31, 2014
Put/call liability:	
Balance, beginning of period	$ 147
Total (gains) losses included in selling, general and administrative expenses	(147)
Balance, end of period	$ —

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

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

Contingent purchase price

(In thousands)	Year ended December 31, 2014
Contingent purchase price:	
Balance, beginning of period	$ 236
Total (gains) losses included in selling, general and administrative expenses:	(236)
Balance, end of period	$ —

The Company measured the fair value of the contingent purchase price and determined that the fair value was $0 at December 31, 2015 and 2014. Refer to the “Assets Measured and Recorded at Fair Value on a Nonrecurring Basis” section below for further information regarding the Company’s plans to no longer invest in further development of NP-1998.

Assets Measured and Recorded at Fair Value on a Nonrecurring Basis

The Company’s non-financial assets, such as intangible assets and property, plant and equipment are only recorded at fair value if an impairment charge is recognized. The table below presents non-financial assets that were measured and recorded at fair value on a nonrecurring basis and the total impairment losses recorded during 2014. There were no impairment losses recorded during 2015.

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(in thousands)	Net Carrying Value as of December 31, 2014	Fair Value Measured and Recorded Using Level 1	Level 2	Level 3	Impairment Losses (Level 3) December 31, 2014
In-process research & development – NP-1998		$—	$—	$—	$6,991
Qutenza developed technology		—	—	—	257
Total impairment losses					$7,248

The Company evaluated and reprioritized its research and development pipeline based on the 2014 acquisition of Civitas, and as a result has no current plans to invest in further development of NP-1998 for neuropathic pain. Therefore, the Company believes that the intangible assets associated with NP-1998 and Qutenza were fully impaired based on the currently estimated fair value of the assets and the Company recorded asset impairment charges of approximately $7.0 million and $0.3 million to fully write off the carrying value of the NP-1998 and Qutenza assets, respectively, during the three-month period ended December 31, 2014. The impairment charges of $7.0 million for the IPR&D and $0.3 million for Qutenza were recorded in asset impairment and cost of sales, respectively.

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(16) Quarterly Consolidated Financial Data (unaudited)

(In thousands, except per share amounts)

	2015			
	March 31	June 30	September 30	December 31
Total net revenues (1)	$99,851	$113,707	$ 148,199	$ 130,903
Gross profit	81,247	90,840	123,299	104,343
Net (loss) income—basic and diluted (2)	(3,085)	997	3,941	9,205
Net (loss) income per share—basic	$(0.07)	$0.02	$ 0.09	$ 0.22
Net (loss) income per share—diluted	(0.07)	0.02	0.09	0.21

	2014			
	March 31	June 30	September 30	December 31
Total net revenues	$80,518	$97,129	$ 105,961	$ 117,872
Gross profit	64,831	78,071	85,227	92,737
Net income—basic and diluted (3)	703	4,685	11,953	331
Net income per share—basic	$0.02	$0.11	$ 0.29	$ 0.01
Net income per share—diluted	0.02	0.11	0.28	0.01

(1) In the third quarter of 2015, the Company recognized a one-time increase in net revenue of $22.2 million, representing previously deferred product sales for Zanaflex products due to the Company's conversion from the deferred revenue recognition model (sell-through) to the traditional revenue recognition model (sell-in).

(2) In the third quarter of 2015, the Company made a payment of $8.75 million to the former shareholders of Neuronex in exchange for certain modifications to the Company's future contingent payment obligations pertaining to Plumiaz. This payment was reflected as R&D expense.

(3) In the fourth quarter of 2014 the Company realized a non-recurring impairment charge of $7.0 million to write-off the IPR&D related to the NP-1998 program.

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(b) Exhibits.

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

Exhibit No.	Description
1.1	Underwriting Agreement dated June 17, 2014, by and between the Registrant and J.P. Morgan Securities LLC. Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
2.1*	Agreement and Plan of Merger, dated as of February 15, 2012, among the Registrant, ATI Development Corp., Neuronex, Inc., and Moise A. Khayrallah, Ph.D., solely as the Stockholders' Representative as set forth therein. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2012.
2.2*	Amendment No. 1 to Agreement and Plan of Merger, effective as of July 27, 2015, by and among the Registrant, Neuronex, Inc., and Moise A. Khayrallah, solely in his capacity as the Stockholders' Representative. Incorporated herein by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
2.3	Agreement and Plan of Merger, dated as of September 24, 2014, by and among the Registrant, Five A Acquisition Corporation, Civitas Therapeutics, Inc., and Shareholder Representative Services LLC, as Representative. Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on September 26, 2014.
2.4	Combination Agreement, dated as of January 19, 2016, by and among the Registrant and Biotie Therapies Corp. Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 19, 2016.
3.1	Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006.
3.2	Bylaws of the Registrant, as amended on December 15, 2011. Incorporated herein by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
4.1	Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
4.2	Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2014.

4.3	First Supplemental Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
4.4	Form of 1.75% Convertible Senior Note due 2021 (included in exhibit 4.3). Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
10.1**	Acorda Therapeutics 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

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Exhibit No.	Description
10.2**	Amendment to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.3**	Amendment No. 2 to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.4**	Acorda Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.5**	Acorda Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2006. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.
10.6**	Forms of Equity Award Documents. Incorporated herein by reference to Exhibit 10.58 to Registrant's Annual Report on Form 10-K filed on March 1, 2011.
10.7**	Acorda Therapeutics 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Appendix A to the Registrant's 2015 Proxy Statement filed as Schedule 14A on April 30, 2015.
10.8**	Forms of equity award documents for awards under the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.9**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.10**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.11**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.12**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.13**	

	Amendment to August 11, 2002 Employment Agreement dated June 21, 2011, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.14**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.15**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.16**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.67 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.

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Exhibit No.	Description
10.17**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.18**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.19**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.68 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.20**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.21**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.22**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.69 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.23**	Employment offer letter, dated January 22, 2010, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.57 to Registrant's Quarterly Report on Form 10-Q filed on May 10, 2010.
10.24**	Letter agreement dated November 7, 2011, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.70 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.25**	Employment Agreement, dated as of June 8, 2015, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.26**	Employment offer letter, dated August 18, 2011, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.64 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.

10.27**	Letter agreement dated October 19, 2011, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.66 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.28**	Employment Agreement, dated as of June 8, 2015, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.29**	Letter agreement dated September 4, 2012, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2012.
10.30**	Letter agreement dated October 28, 2014, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2014.

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Exhibit No.	Description
10.31**	Letter agreement dated June 15, 2015, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.32**	Employment offer letter, dated September 20, 2013, by and between the Registrant and Michael Rogers. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2013.
10.33**	Employment Agreement, dated as of October 7, 2013, by and between the Registrant and Michael Rogers. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K filed on March 3, 2014.
10.34**	Restricted Stock Agreement, dated as of October 7, 2013, by and between the Registrant and Michael Rogers. Incorporated herein by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K filed on March 3, 2014.
10.35**	Employment offer letter, dated May 1, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2014.
10.36**	Non-Statutory Stock Option Certificate under the 2006 Employee Stock Option Plan, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.37**	Restricted Stock Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.38**	Employment Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2015.
10.39**	Executive Employment Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (formerly Corregidor Therapeutics, Inc.) and Rick Batycky. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.40**	First Amendment to Executive Employment Agreement, dated as of June 27, 2013, between Civitas Therapeutics, Inc. and Rick Batycky. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.41**	Second Amendment to Executive Employment Agreement, dated as of June 30, 2014, between Civitas Therapeutics, Inc. and Rick Batycky. Incorporated herein by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed on

	August 7, 2015.
10.42**	Employment offer letter, dated December 5, 2014, by and between the Registrant and Richard Batycky. Incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.43	Lease, dated as of June 23, 2011, by and between the Registrant and BMR-Ardsley Park LLC. Incorporated herein by reference to Exhibit 10.62 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.44	Letter Agreement dated September 11, 2014, between the Registrant and BMR-Ardsley Park LLC. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 7, 2014.

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Exhibit No.	Description
10.45	First Amendment to Lease, dated as of May 21, 2015, by and between BMR-Ardsley Park LLC and the Registrant. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.46	Lease Agreement, dated as of December 6, 2000, by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.47	First Amendment, dated August 22, 2002, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.48	Second Amendment, dated December 4, 2006, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.49	Sublease Agreement, dated December 27, 2010, by and between Alkermes, Inc. and Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.). Incorporated herein by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.50	Letter agreement dated March 25, 2015, between Civitas Therapeutics, Inc. and Alkermes, Inc. regarding extension of the Sublease dated December 27, 2010, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2015.
10.51	Assignment and Amendment of Lease dated November 30, 2015, among H&N Associates, LLC, Civitas Therapeutics, Inc., and Alkermes, Inc.
10.52	Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.53	Note Modification and Amendment, dated as of December 23, 2005, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.54	Revenue Interests Assignment Agreement, dated as of December 23, 2005, between the Registrant and King George Holdings Luxembourg IIA S.à.r.l., an affiliate of Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.41 to the

	Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.55	First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.1. and Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.
10.56	License Agreement, dated September 8, 2000, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.57*	Side Letter Agreement, dated June 1, 2005, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.58	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.22 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.59*	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014.

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Exhibit No.	Description
10.60*	Amendment #1 to the License Agreement, dated March 15, 2012, by and between the Registrant and Paion Holdings UK Ltd (formerly CeNeS Pharmaceuticals, plc). Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2012.
10.61	Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.62*	Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.63	Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.64*	Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.65*	Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.66	Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.67	Amendment No. 1 Agreement and Sublicense Consent Between Elan Corporation, plc and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.56 to Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.
10.68	Amendment No. 2 to Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated March 29, 2012. Incorporated herein by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K filed on February 28, 2013.
10.69	

	Amendment No. 3 to the Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated February 14, 2013. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013.
10.70*	Development and Supplemental Agreement between Elan Pharma International Limited and the Registrant dated January 14, 2011. Incorporated herein by reference to Exhibit 10.59 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.71*	Collaboration and License Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.54 to Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.
10.72*	Supply Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on August 7, 2014.

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Exhibit No.	Description
10.73*	Addendum Number 3 to Collaboration and License Agreement and to Supply Agreement between the Registrant and Biogen Idec International GmbH dated February 14, 2013. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013.
10.74*	Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization. Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.75	License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center. Incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.76*	Asset Purchase Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014.
10.77*	Zanaflex Supply Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.78	Patent Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.79	Trademark License Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.80	Agreement Relating to Additional Trademark, dated as of July 2005, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.81	Domain Name Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.82	

	Bill of Sale and Assignment and Assumption Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.83	License Agreement, dated as of December 19, 2003, by and among the Registrant, Cambridge University Technical Services Limited, and King's College London. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.84*	Amendment #1 to License Agreement among the Registrant, Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited), and Kings College London dated as of March 4, 2011. Incorporated herein by reference to Exhibit 10.60 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.85*	License Agreement, dated as of June 27, 2011, by and between the Registrant and Medtronic, Inc. and Warsaw Orthopedic, Inc. Incorporated herein by reference to Exhibit 10.63 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.86*	License Agreement dated as of July 6, 2010, between SK Biopharmaceuticals Co., Ltd. (formerly SK Holdings Co., Ltd.) and Neuronex, Inc. Incorporated herein by reference to Exhibit 10.65 to the Registrant's Annual Report on Form 10-K filed on February 28, 2013.

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Exhibit No.	Description
10.87*	Asset Purchase and License Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.) and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.75 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.88*	Amendment to Asset Purchase and License Agreement, dated as of December 9, 2011, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.76 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
10.89*	Second Amendment to Asset Purchase and License Agreement, dated as of December 19, 2014, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.77 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
21	List of Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

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Portions of this exhibit were redacted pursuant to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 406 under the Securities Act of 1933, as amended, or Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

** Indicates management contract or compensatory plan or arrangement.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 29 day of February, 2016.

Acorda Therapeutics, Inc.

By: /s/ Ron Cohen
Ron Cohen, M.D.
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Ron Cohen, M.D. Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2016
/s/ Michael Rogers Michael Rogers	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 29, 2016
/s/ Barry Greene Barry Greene	Director	February 29, 2016
/s/ Peder K. Jensen, M.D. Peder K. Jensen, M.D.	Director	February 29, 2016
/s/ John P. Kelley John P. Kelley	Director	February 29, 2016
/s/ Sandra Panem, Ph.D. Sandra Panem, Ph.D.	Director	February 29, 2016
/s/ Lorin J. Randall Lorin J. Randall	Director	February 29, 2016
/s/ Steven M. Rauscher, M.B.A. Steven M. Rauscher, M.B.A.	Director	February 29, 2016

/s/ Ian Smith Ian Smith	Director	February 29, 2016

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EXHIBIT INDEX

Exhibit No.	Description
10.51	Assignment and Amendment of Lease dated November 30, 2015, among H&N Associates, LLC, Civitas Therapeutics, Inc., and Alkermes, Inc.
21	List of Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

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