

# ACORDA THERAPEUTICS INC

## FORM 10-K (Annual Report)

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**  
**FORM 10-K**

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

**For the fiscal year ended December 31, 2014**

**OR**

☐ **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**  
(State or other jurisdiction of incorporation  
or organization)  
**420 Saw Mill River Road, Ardsley, New York**  
(Address of principal executive offices)

**13-3831168**  
(I.R.S. Employer Identification No.)  
**10502**  
(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**  
Common Stock \$0.001 par value

**Name of each exchange on  
which registered**  
NASDAQ Global Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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 ☒ No ☐

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

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

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

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

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

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



## **DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a proxy statement for its 2015 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2014. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

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

Part III, Item 11, Executive Compensation.

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

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

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

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**ACORDA THERAPEUTICS, INC.**  
**2014 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 realize the benefits anticipated from the Civitas Therapeutics, Inc. transaction and to successfully integrate Civitas's operations into our operations; our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this Annual Report, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.*

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

## PART I

### Item 1. Business.

#### Company Overview

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

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

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

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

We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial of dalfampridine to evaluate the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. Also, we have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study in

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

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

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

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

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

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

## **Company Highlights**

### ***Ampyra***

Ampyra (dalfampridine) Extended Release Tablets, 10mg was approved by the FDA in January 2010 for the improvement of walking in people with MS. This was demonstrated by an increase in walking speed. To our knowledge, Ampyra is the first and only product indicated to improve walking in people with MS. Ampyra was made commercially available in the U.S. in March 2010, using our own specialty sales force, and had net revenue

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

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

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

Approximately 400,000 people in the U.S. suffer from MS, and each year approximately 10,000 people in the U.S. are newly diagnosed. In a poll of more than 2,000 people with MS, 87% said they experienced some limitation to their walking ability and limited activities that involved walking. Among MS patients diagnosed within the last 5 years, 58% report experiencing mobility issues at least twice a week. Even in early stages of the disease, walking can be a significant issue; approximately 1 out of every 4 MS patients experiences walking difficulty by the time of diagnosis, according to a 2011 Harris poll sponsored by Acorda. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

### *Ampyra/Fampyra Patents*

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

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

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

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

### ***Civitas Acquisition; CVT-301 and ARCUS Technology***

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

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

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

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

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

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

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

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

***Ampyra/Dalfampridine Development Programs.*** We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the

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

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

*Cimaglermin alfa (previously GGF2)/Neuregulins.* Cimaglermin alfa (which we previously referred to as GGF2) is our lead product candidate for our neuregulin program. We have completed a cimaglermin Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or to enter into a partnership, most likely with a cardiovascular-focused company.

*Remyelinating Antibodies.* rHlgM22 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 rHlgM22 to assess the safety and tolerability of rHlgM22 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 rHlgM22, found no dose-limiting toxicities at any of the five dose levels studied. Additional data from this trial will be presented at future medical meetings. Based on these data, we intend to advance clinical development of rHlgM22 for MS. We are currently developing the protocol for our next Phase 1 clinical trial of rHlgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse.

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

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

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

### ***Corporate Update***

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

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

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

### **Our Strategy**

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

- Continue to make disciplined investments in growing sales of Ampyra.
- Progress our Phase 3 clinical trial of CVT-301 for the treatment of OFF episodes in Parkinson's disease.
- Progress our Phase 3 clinical trial that is assessing the use of dalfampridine as a treatment for chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke, and continue efforts with external partners to develop a new QD formulation that could be included in future post-stroke studies.
- Complete our discussions and reach agreement with the FDA regarding the requirements for re-submission of the Plumiaz NDA, and begin the clinical work that will be necessary for re-submission.
- Complete our Phase 1 clinical trial of cimaglermin alfa (previously referred to as GGF2), our lead product candidate for our neuregulin program.
- Advance clinical development of rHlgM22 for MS by initiating a second Phase 1 trial.

- Initiate a Phase 1 clinical trial of CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes using our ARCUS pulmonary delivery technology.
- Expand our pipeline through potential in-licensing and/or acquisition of neurology and/or other specialty products and technologies, focusing on late stage/near commercial or commercial products. We will also consider earlier-stage programs based on compelling science and the potential to address significant unmet medical needs .

## Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Ampyra	MS	FDA-approved and marketed in the U.S.	Acorda (U.S.)
Fampyra	MS	Approved in a number of countries across Europe, Asia and the Americas	Biogen Idec (outside U.S.)
Zanaflex Capsules and an authorized generic version of the capsules	Spasticity	FDA-approved	Acorda (U.S.); authorized generic marketed by Actavis/Watson Pharma
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
Qutenza	Post Herpetic Neuralgia	FDA-approved	Acorda (U.S. Canada, Latin America and certain other countries )
Research and Development Programs	Proposed Therapeutic Area (s)	Stage of Development	Marketing Rights
CVT-301	OFF episodes of Parkinson's disease	Phase 3 clinical trial ongoing	Acorda/Worldwide
Dalfampridine	Chronic post-stroke deficits	Phase 3 clinical trial ongoing	Acorda/Worldwide (contract governs Biogen ex-U.S. option)
Plumiaz	Seizure Clusters/Acute Repetitive Seizures	NDA to be re-submitted to the FDA	Acorda/Worldwide (excluding certain Asian countries)
Neuregulin Program	Heart failure*	cimaglermin alfa (previously GGF2) Phase 1b clinical trial ongoing	Acorda/Worldwide
Remyelinating Antibodies Program	MS	Phase 1; protocol for next Phase 1 clinical trial of rHlgM22 under development	Acorda/Worldwide
CVT-427	Migraines	Pre-IND; Phase 1 clinical trial preparations underway	Acorda/Worldwide
Chondroitinase Program	Spinal cord injury	Research	Acorda/Worldwide
NP-1998	No current plans for development	Phase 3, but no current plans for development	Acorda (U.S. Canada, Latin America and certain other countries)

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

### Background on Neurological and Other Conditions

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

## *Multiple Sclerosis*

Multiple Sclerosis, or MS, is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. These nerve fibers consist of long, thin fibers, or axons, surrounded by a myelin sheath, which facilitates the transmission of electrical impulses, much as insulation facilitates conduction in an electrical wire. In MS, the myelin sheath is damaged by the body's own immune system, causing areas of myelin sheath loss, also known as demyelination. This damage, which can occur at multiple sites in the central nervous system, blocks or diminishes conduction of electrical impulses. Patients with MS may suffer impairments in a wide range of neurological functions. These impairments vary from individual to individual and over the course of time, depending on which parts of the brain and spinal cord are affected, and often include difficulty walking. Individuals vary in the severity of the impairments they suffer on a day-to-day basis, with impairments becoming better or worse depending on the activity of the disease on a given day.

Approximately 400,000 people in the U.S. suffer from MS, and each year approximately 10,000 people in the U.S. are newly diagnosed. In a poll of more than 2,000 people with MS, 87% said they experienced some limitation to their walking ability and limited activities that involved walking. Among MS patients diagnosed within the last 5 years, 58% report experiencing mobility issues at least twice a week. Even in early stages of the disease, walking can be a significant issue; approximately 1 out of every 4 MS patients experiences walking difficulty by the time of diagnosis, according to a 2011 Harris poll sponsored by Acorda. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

## *Stroke*

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

## *Parkinson's Disease*

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

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

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

### *Heart Failure*

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

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

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

### *Epilepsy*

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

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

### *Neuropathic Pain*

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

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

## *Spinal Cord Injury*

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

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

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

## *Spasticity*

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

## *Migraine*

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

## Ampyra

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

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

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

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

### Background

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

### Clinical Studies and Safety Profile

Our New Drug Application, or NDA, for Ampyra was based on data from a comprehensive development program assessing the safety and efficacy of Ampyra, including two Phase 3 trials that involved 540 people with MS. The primary measure of efficacy in our two Phase 3 MS trials was walking speed (in feet per second) as measured by the Timed 25-foot Walk (T25FW), using a responder analysis. A responder was defined as a patient who showed faster walking speed for at least three visits out of a possible four during the double-blind period than the maximum speed achieved in the five non-double-blind, no treatment visits (four before the double-blind period and one after). A significantly greater proportion of patients taking Ampyra 10 mg twice daily were

responders compared to patients taking placebo, as measured by the T25FW (Trial 1: 34.8% vs. 8.3%; Trial 2: 42.9% vs. 9.3%). The increased response rate in the Ampyra group was observed across all four major types of MS. During the double-blind treatment period, a significantly greater proportion of patients taking Ampyra 10 mg twice daily had increases in walking speed of at least 10%, 20%, or 30% from baseline, compared to placebo. In both trials, the consistent improvements in walking speed were shown to be associated with improvements on a patient self-assessment of ambulatory disability, the 12 item Multiple Sclerosis Walking Scale (MSWS-12), for both drug and placebo treated patients. However, a drug vs. placebo difference was not established for that outcome measure.

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

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

### ***Zanaflex Products***

Zanaflex Capsules and Zanaflex tablets contain tizanidine hydrochloride, one of the two leading active ingredients used for the management of spasticity. Tizanidine hydrochloride is approved by the FDA as a short-acting drug for the management of spasticity. We acquired from Alkermes plc (formerly Elan) all of its U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. There are currently a number of generic versions of tizanidine hydrochloride tablets on the market. Zanaflex Capsules were approved by the FDA in 2002, but were never marketed by Elan. We began marketing Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. In February 2012, we launched an authorized generic version of tizanidine hydrochloride capsules under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), following the launch by Apotex Inc. of its generic tizanidine hydrochloride capsules. In March 2013, Mylan Laboratories also launched generic tizanidine hydrochloride capsules.

Clinical trials conducted by Elan demonstrated that Zanaflex Capsules, when taken with food, produce average peak levels of tizanidine hydrochloride in a person's blood that are lower and rise more gradually compared to the peak levels following a similar dose of the tablet form. The FDA recognizes these pharmacokinetic differences and therefore has determined that Zanaflex tablets and generic tizanidine hydrochloride tablets are not therapeutically equivalent, that is, are not AB-rated to Zanaflex Capsules. As a result, under state pharmacy laws, prescriptions written for Zanaflex Capsules may not be filled by the pharmacist with Zanaflex tablets or generic tizanidine hydrochloride tablets, although some substitution does take place in practice. However, they may be filled with generic tizanidine hydrochloride capsules or our authorized generic capsules.

***Qutenza***

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

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

***Research and Development Programs***

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

*Civitas Acquisition; CVT-301 and ARCUS Technology*

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

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

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

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

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

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

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

#### *Ampyra/Dalfampridine Development Programs*

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

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

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

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

*Plumiaz; Neuronex Acquisition*

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

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

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

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

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

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

Neuronex, our wholly-owned subsidiary since the acquisition, licenses patent, patent application, other intellectual property and other rights relating to Diazepam Nasal Spray products from SK Biopharmaceuticals Co., Ltd., or SK. Pursuant to the SK license, which grants worldwide rights to Neuronex except certain specified Asian countries, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to Diazepam Nasal Spray products (including \$1 million that was paid in 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz), and up to \$3 million upon the

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

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

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

#### *Cimaglermin alfa (previously GGF2) / Neuregulins*

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

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

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

### *Remyelinating Antibodies Program*

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

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

### *Chondroitinase Program*

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

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

At least six independent laboratories have published animal studies showing that application of chondroitinase results in improved recovery of function following injuries to various areas of the brain or spinal cord. These functions have included walking, forelimb grasping, sensation, and visual and bladder function. We have successfully tested the ability of one of these molecules, Chondroitinase ABC-I, to improve function in an animal model of spinal cord injury, or SCI. These studies were published in the *Journal of Neurotrauma* in February 2005. In these studies, rats that sustained an SCI were treated with either chondroitinase or an ineffective enzyme control and evaluated over 10 weeks of recovery. Animals treated with chondroitinase showed significant improvements both in motor function of the limbs and in bladder function, compared to those treated with the control enzyme. We have also produced and successfully tested a recombinant version of naturally occurring Chondroitinase ABC-I in these same animal models.

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

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

### *NP-1998*

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

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

### *AC105*

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

## **Sales, Marketing and Managed Markets**

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

We have contracted with a third-party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource of support services that coordinates the prescription process among healthcare providers, people with MS and insurance carriers. Prescriptions for Ampyra are processed through the APSS center, where dedicated and experienced customer care agents are responsible for helping healthcare professionals process prescriptions; working with insurance carriers to facilitate coverage; and working with a limited network of specialty pharmacy providers that deliver the medication directly to a patient's home. In addition, APSS assists in directing patients to available copay and patient assistance programs, where permitted by law. The process begins when a prescription is submitted by a

physician to APSS through a Service Request Form, or SRF. If insurance coverage is confirmed, APSS will transmit the prescription information to the specialty pharmacy provider that has contracted with the patient's insurance carrier. The specialty pharmacy provider will then mail the prescription directly to the patient. In some cases, the specialty pharmacy provider will coordinate the insurance benefits investigation on behalf of the patient or will receive a prescription directly from a prescribing physician. Those people with MS who meet income and other requirements may receive Ampyra at no cost, where permitted by law, through Acorda's patient assistance program. We have also established a program to assist individuals who have private insurance in managing their copayment costs through a copay mitigation program, where permitted by law.

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

Ampyra is distributed in the United States exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. The distribution process through specialty pharmacy providers is well established within the MS community, and physicians and patients are familiar with this model. This distribution process is intended to provide the best possible patient experience, improve patient adherence to the required drug regimen, including dosage, and assist in educating patients regarding the risks associated with Ampyra.

Zanaflex Capsules are principally distributed through wholesale pharmaceutical distributors to retail pharmacies. Our authorized generic version of tizanidine hydrochloride capsules is marketed under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

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

## Scientific and Medical Network

We have an established advisory team and network of well-recognized scientists, clinicians and opinion leaders in relevant fields, including for example the fields of multiple sclerosis, spinal cord injury, Parkinson's disease, epilepsy, stroke, and heart failure. Depending on their expertise, these advisors provide assistance in trial design, conduct clinical trials, keep us apprised of the latest scientific advances and help us identify and evaluate business development opportunities.

## Material and Other Collaborations and License Agreements

### *Biogen Idec (Fampyra)*

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

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

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

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

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

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

The Collaboration Agreement will terminate upon the expiration of Biogen Idec's royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of expiration of the last-to-expire patent covering a licensed product, fifteen years following first commercial sale of such licensed product, the expiration of regulatory exclusivity and the existence of certain levels of sales by competing products. The Collaboration Agreement and the Supply Agreement will automatically terminate upon the termination of our license agreement with Alkermes in its entirety or with respect to all countries outside of the U.S. We cannot terminate our license agreement with Alkermes without Biogen Idec's prior written consent under certain circumstances. Biogen Idec may terminate the Collaboration Agreement in its entirety or on a country-by-country basis at any time upon 180 days' prior written notice, subject to our right to accelerate such termination. The Collaboration Agreement may also be terminated by either party if the other party fails to cure a material breach under the agreement, which termination will be limited to a particular country or region under certain circumstances. However, if Biogen Idec has the right to terminate the Collaboration Agreement due to our material uncured breach, Biogen Idec may instead elect to keep the agreement in effect, but decrease the royalty rates they pay us by a specified percentage. We may also terminate the Collaboration Agreement if Biogen Idec does not commercially launch a licensed product within a specified time period after receiving regulatory approval for such licensed product or otherwise fails to meet certain commercialization obligations. In addition, we may terminate the Collaboration Agreement under certain circumstances if (i) Biogen Idec, its affiliates or its sublicensees challenge certain of our patents or (ii) there is a change in control of Biogen Idec or its parent company or certain dispositions of assets by Biogen Idec, its parent or its affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen Idec's territory of more than a specified percentage within a certain period of time after such change in control or disposition. The Supply Agreement may be terminated by either party if the other party fails to cure a material breach under the Supply Agreement. In addition, the Supply Agreement will terminate automatically upon termination of the Collaboration Agreement, and the Collaboration Agreement will terminate automatically if the Supply Agreement is terminated for any reason other than for a material breach that we are responsible for. To the extent permitted by law, each party may terminate the Collaboration Agreement and the Supply Agreement if the other party is subject to bankruptcy proceedings.

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

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

In connection with the entry into the Collaboration Agreement, Biogen Idec and Alkermes entered into a Consent Agreement with us. Under the Consent Agreement, Alkermes consented to our sublicense of rights to Biogen Idec, and the three parties agreed to set up a committee to coordinate activities under our agreements with

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

***Alkermes, formerly Elan Corporation plc (Ampyra and Zanaflex)***

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

***Ampyra***

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

Alkermes (now the licensor under this agreement due to its 2011 acquisition of Elan's Drug Technologies business) is also obligated under this agreement to supply us with our commercial requirements for Ampyra in the U.S., as well as to supply Biogen Idec under the Supply Agreement and Consent Agreement with Fampyra for Biogen Idec's clinical trials and for Biogen Idec's commercial requirements.

Alkermes may terminate our license in countries in which we have a license, if we fail to file for regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for the related NDA equivalent. We could also lose our rights under the license agreement if we fail to launch a product in such countries within 180 days of NDA or equivalent approval and receipt of other needed regulatory approvals, or if we fail to fulfill our payment obligations under the license agreement. If Alkermes terminates our license in any applicable country, Alkermes is entitled to license from us our patent rights and know-how relating to the product and to market the product in the applicable country, subject to royalty payments to us.

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

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

*Zanaflex*

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

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

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

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

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

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

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

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

We agreed to pay Rush a license fee, milestone payments of up to \$850,000 and royalties based on net sales of the product for neurological indications. We have made or accrued an aggregate of \$850,000 in milestone payments and \$27.8 million in royalties under this agreement through December 31, 2014. In 2014, with our consent Rush sold its right to receive these royalties along with certain related rights to a third party, though this transfer did not materially change any of our obligations under the license. The FDA approval of Ampyra triggered the final milestone of \$750,000, which was paid in 2010. The Rush license may be terminated by either party following an uncured material breach by the other party and notice. The Rush license may also be terminated upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party. We also entered into an agreement with Elan relating to the allocation of payments between us and Elan of certain payments to Rush under the Rush license. Subject to the early termination provisions, the Rush license terminates upon expiration of the royalty obligations, which expire fifteen years from the date of the agreement (2018).

### ***Alkermes (ARCUS products)***

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

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

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

### ***SK Biopharmaceuticals Co., Ltd. (Plumiaz)***

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

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

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

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

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

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

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

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

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

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

- We have a mutual, exclusive cross license and coordination agreement with Astellas Pharma Europe Ltd., which we entered into in connection with our acquisition of Qutenza and NP-1998, pursuant to which the parties may share certain data and may collaborate and/or share costs of future clinical trials relating to these products.

- We have an exclusive, worldwide license from the Canadian Spinal Research Organization for specified patents and know-how relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.
- We have an exclusive, worldwide license from Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King's College London to specified patents and patent applications for products related to enzymatic methods, including chondroitinase, of treating CNS disorders. Under the same license, we also have non-exclusive rights to these patents and patent applications for products related to small molecule inhibitors for use in treating CNS disorders.
- We have an exclusive, worldwide license from the Mayo Foundation for Education and Research, or Mayo Clinic, to specified patents, patent applications, and other intellectual property on certain antibodies relating to our research on the therapeutic use of these antibodies, specifically myelination and remyelination in MS and SCI.
- We have an exclusive, worldwide sublicense from Paion AG (formerly CeNeS Pharmaceuticals plc) to certain patents, patent applications and know-how relating to cimaglermin alfa, which we previously referred to as GGF2, or fragments thereof and non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sub-license these patents were granted to Paion by the Ludwig Institute for Cancer Research. We also have an exclusive, worldwide sublicense from Paion to certain Paion patents, patent applications, and know-how relating to the neuregulin growth factor gene NRG-2.
- We have a license from Brigham and Women's Hospital, Inc., or Brigham, acting on its own behalf and on behalf of Beth Israel Deaconess Medical Center, or Beth Israel, to patent rights relating to the use of cimaglermin in the treatment of congestive heart failure. Our rights in the U.S. are co-exclusive, with Brigham and Beth Israel having retained rights for internal research, clinical, and education purposes, and our rights outside the U.S are exclusive.

## Manufacturing and Supply

### *Ampyra*

We are party to a September 2003 agreement with Elan (now Alkermes, following Alkermes's 2011 acquisition of Elan's Drug Technologies business) for our clinical and commercial supply of Ampyra. Under that agreement, we are required to purchase at least 75% of our annual commercial requirements of Ampyra from Alkermes unless Alkermes is unable or unwilling to meet our requirements. In addition, the agreement also obligates us to make compensatory payments if we do not purchase 100% of our requirements from Alkermes.

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

Under a Consent Agreement among Elan (now Alkermes, following Alkermes's acquisition of Elan's Drug Technologies business), Biogen Idec and us, Alkermes consented to our sublicense of our rights under our agreements with Alkermes to Biogen Idec. The three parties agreed to set up a committee to coordinate activities under these agreements with respect to the development, supply and commercialization of the licensed products for Biogen Idec's territory. The Consent Agreement also amended our agreements with Alkermes by, among other things, permitting us to allow Biogen Idec to grant sublicenses to certain unaffiliated distributors, permitting us to allow Biogen Idec to package the licensed products and to work directly with Alkermes with respect to certain

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

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

### ***Zanaflex***

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

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

### ***Qutenza and NP-1998***

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

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

## ***Post-Stroke/Dalfampridine***

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

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

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

## ***CVT-301 and ARCUS Technology***

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

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

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

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

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

**Plumiaz**

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

***Cimaglermin alfa (previously GGF2)***

We have completed a Phase 1 clinical trial of cimaglermin alfa, which we previously referred to as GGF2, in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or to enter into a partnership, most likely with a cardiovascular-focused company.

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

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

***rHIgM22***

We have a remyelinating antibodies program that we acquired under license from the Foundation for Medical Education and Research, or Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate repair of the myelin sheath in three different animal models of MS. Some antibodies within this portfolio also stimulate the growth of neurons and may have applications beyond demyelinating disorders. First identified in mice, similar remyelinating antibodies were subsequently identified in human blood samples by Mayo Clinic. Our lead recombinant human remyelinating antibody, designated rHIgM22, has been produced under GMPs, tested for safety in non-clinical studies and advanced to human trials in patients with MS.

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

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

### ***Other Products in Development***

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

### **Intellectual Property**

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

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

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

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

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

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

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

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

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

### ***CVT-301 and ARCUS Technology***

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

### ***Plumiaz/Diazepam Nasal Spray***

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

### ***Cimaglermin alfa (previously GGF2)/Neuregulins***

We are the exclusive licensee under a license agreement with Paion AG (formerly CeNeS Pharmaceuticals, plc), of its worldwide portfolio of patents, patent applications and IP rights related to products of neuregulin genes, including cimaglermin alfa (which we previously referred to as GGF2). Collectively, these

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

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

### ***Remyelinating Antibodies/Antibodies Related to Nervous System Disorders***

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

### ***Chondroitinase***

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

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

### ***Zanaflex***

As part of our purchase from Elan of the Zanaflex assets, we acquired one issued U.S. patent and two pending U.S. patent applications. Our issued patent is generally directed to certain methods of reducing somnolence and reducing peak plasma concentrations in patients receiving tizanidine therapy. This issued patent expires in 2021. Our two pending U.S. patent applications are directed to multiparticulate formulations of tizanidine and certain other methods of using tizanidine. We also purchased the Zanaflex trademarks in the U.S. from Elan.

In addition, we entered into a Supply Agreement with Elan as part of the acquisition. This agreement is now with Alkermes due to Alkermes's 2011 acquisition of Elan's Drug Technologies business. Under this agreement, Zanaflex Capsules are manufactured for us by Alkermes using Alkermes's proprietary SODAS<sup>®</sup> 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 U.S. Patent No. 6,239,180. This patent is set to expire in 2016, absent any Hatch-Waxman extension for regulatory delays. Qutenza has Orphan Drug designation which gives it marketing exclusivity in the U.S. until 2016.

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

### ***Trademarks***

In addition to patents, our intellectual property portfolio includes registered trademarks, along with pending trademark applications. We own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks “Acorda Therapeutics,” our stylized Acorda Therapeutics logo, “Ampyra,” “Zanaflex,” “Zanaflex Capsules,” “Qutenza” and “ARCUS.” We also have trademark registrations for “Fampyra” and “Kampyra” and pending trademark applications therefore, in numerous foreign jurisdictions. In addition, our trademark portfolio includes several trademark registrations and pending trademark applications for potential product names and for disease awareness activities.

### ***Competition***

The market for developing and marketing pharmaceutical products is highly competitive. We are aware of many biotechnology and pharmaceutical companies that are engaged in development and/or marketing of therapeutics for a broad range of CNS conditions, including multiple sclerosis, or MS, stroke, Parkinson’s disease, or PD, epilepsy, heart failure, and spinal cord injury. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Furthermore, many of these companies have significantly more experience than we do in preclinical testing, human clinical trials, regulatory approval procedures and sales and marketing.

### ***Ampyra/MS***

Current disease management approaches to MS are classified either as relapse management, disease course management, or symptom management approaches. For relapse management, the majority of neurologists treat sudden and severe relapses with a four-day course of intravenous high-dose corticosteroids. Many of these corticosteroids are available generically. For disease course management, there are a number of FDA-approved MS therapies that seek to modify the immune system. These treatments attempt to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS, though their precise mechanisms of action are not known. These products include Avonex from Biogen Idec, Betaseron from Schering AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Merck Serono, Tysabri from Biogen Idec and Elan, and Gilenya and Extavia from Novartis AG.

To our knowledge, Ampyra is the first and only product that is approved as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed. Several biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS. Other companies also have products in clinical development, including products approved for other indications in MS, to address improvement of walking ability in people

with MS. BioMarin Pharmaceutical Inc. or BioMarin, acquired the rights formerly owned by EUSA Pharma to amifampridine phosphate, a 3,4-diaminopyridine compound, which in January 2010 received marketing authorization in the EU for use in Lambert Eaton Myasthenic Syndrome, or LEMS. In 2012, BioMarin outlicensed the North American rights to Catalyst Pharmaceuticals. In the EU, and the U.S., if this product is successfully developed and approved, physicians might prescribe it instead of Ampyra, even if it were not approved for MS.

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

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

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

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

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

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

### ***Zanaflex/Spasticity***

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

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

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

### ***CVT-301/Parkinson's disease***

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

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

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

### ***Plumiaz/Seizure Clusters or Acute Repetitive Seizures***

Plumiaz (Diazepam Nasal Spray) is a proprietary nasal spray formulation of diazepam that we are developing as a treatment for the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience intermittent bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment for people

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

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

### ***Qutenza/Post-Herpetic Neuralgia***

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

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

## **Government Regulation**

### ***FDA Regulation of Drugs and Drug Product Approval***

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

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

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

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

The research, development and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely or commercially viable basis, if at all.

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its safety and potential efficacy. The results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature must be submitted to the FDA as part of an IND application. The IND sponsor may initiate clinical trials 30 days after filing the IND application, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Further, an independent Institutional Review Board, or IRB, charged with protecting the welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial before it commences at that center. The IRB(s) must continue to monitor the trial until its completion. Many studies also employ a data safety monitoring board, or DSMB, with experts who are otherwise independent of the conduct of the study and are given access to the unblinded study data periodically during the study to determine whether the study should be halted. For example, a DSMB might halt a study if an unacceptable safety issue emerges, or if the data showing the effectiveness of the study drug would make it unethical to continue giving patients placebo. Study subjects must provide informed consent before their participation in the research study.

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

- *Phase 1.* The drug is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- *Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3.* When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken to confirm the clinical efficacy from Phase 2 and to further test for safety in an expanded population at geographically dispersed clinical trial sites.

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

Before proceeding with a Phase 3 trial, sponsors may seek a written agreement from the FDA regarding the design and size of clinical trials intended to form the primary basis of an effectiveness claim. This is known as a Special Protocol Assessment, or SPA. SPAs help establish up front agreement with the FDA about the adequacy of the design of a clinical trial, but the agreement is not binding if the sponsor and the FDA agree in writing or if a substantial scientific issue essential to determining the safety or effectiveness of the drug is identified after the testing has begun. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other burdensome post-approval requirements or limitations.

Federal and state law requires the submission of registry and results information for most clinical trials to a publicly available database at [www.clinicaltrials.gov](http://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.

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, labeling, distribution, GMPs, and import/export. The FDA's rules for advertising and promotion require, among other things, that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. On its own initiative, the FDA may require changes to the labeling of an approved drug, require post-approval studies or clinical trials, or impose a REMS post-approval if it becomes aware of new safety information that the agency believes impacts the drug's safety profile. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Foreign drug manufacturers must comply with similar local requirements and may be subject to inspections by FDA or local regulatory agencies. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMPs and other regulatory requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or FDA Form 483. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

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

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

## ***Orphan Drugs***

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

U.S. Requests for orphan drug designation must be submitted before the submission of an NDA, BLA, or supplemental NDA or BLA for the orphan use. We received an orphan drug designation for Ampyra for the treatment of both MS and incomplete SCI. The number of people affected by MS now exceeds 200,000. However, this does not affect Ampyra's orphan drug designation in the United States, as it was granted prior to the increase in prevalence above 200,000.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, and reduced filing fees for marketing applications. If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity for that use. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. FDA may approve a subsequent application from another sponsor if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior or demonstrates a major contribution to patient care, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves another sponsor's application for a drug that is the same as a drug with orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its approved use, including for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses.

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

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

Generic drugs are approved through an abbreviated regulatory process, which differs in important ways from the process followed for innovative products. For generic versions of drugs subject to an NDA, an abbreviated new drug application, or ANDA, is filed with the FDA. The ANDA must seek approval of a product candidate that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as a so-called "reference listed drug" approved pursuant to a full NDA. Only limited exceptions exist to this ANDA sameness requirement, including certain limited variations approved by the FDA through a special suitability petition process. ANDA applicants are not required to submit clinical data to demonstrate safety and efficacy. Instead, FDA relies on its findings of safety and effectiveness of the reference listed drug to approve the ANDA. As a result, the law requires the ANDA applicant submit only limited clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at a rate and extent consistent with that of the reference listed drug. This is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the reference listed drug.

Under the Federal Food, Drug, and Cosmetic Act, drugs that are new chemical 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:

- If the FDA does not classify the reference listed drug as an NCE, then the automatic stay is for 30 months from the date that the manufacturer of the reference listed drug receives the patent certification described above.
- If the reference listed drug is classified by the FDA as an NCE, then the timing of the automatic stay depends on when the ANDA is filed, as well as when the manufacturer of the reference listed drug receives the patent certification described above. No company can file an ANDA on a reference listed drug that FDA has designated as an NCE until five years after the reference listed drug's FDA approval, except that an ANDA may be submitted four years after the reference listed drug's FDA approval if the ANDA contains the patent certification described above. If the ANDA is filed five or more years after FDA approval of the NCE, then the 30 month stay is applicable. However, if an ANDA is filed in between the fourth and fifth years after FDA approval of the NCE, the automatic 30 month stay is extended by a number of months equal to the number of months remaining in the fifth year after approval of the reference listed drug, providing a total of up to a 42 month stay.

If the stay is either lifted or expires and the ANDA applicant is able otherwise meet the FDA's requirements for the approval of ANDAs, the generic manufacturer may begin selling its product even if patent litigation is pending. However, if the generic manufacturer launches before patent litigation is resolved, the launch is at the risk of the generic manufacturer being later held liable for patent infringement damages

Many states require or permit pharmacists to substitute generic equivalents for brand-name prescriptions unless the physician has prohibited substitution. Managed care organizations often urge physicians to prescribe drugs with generic equivalents, and to authorize substitution, as a means of controlling costs of prescriptions. They also may require lower copayments as an incentive to patients to ask for and accept generics.

While the question of substitutability is one of state law, most states look to the FDA to determine whether a generic is substitutable. The FDA lists therapeutic equivalence ratings in a publication often referred to as the "Orange Book." In general, a generic drug that is listed in the Orange Book as therapeutically equivalent to the branded product will be substitutable under state law and, conversely, a generic drug that is not so listed will not be substitutable. Solid oral dosage form drug products that are considered therapeutically equivalent are generally rated "AB" in the Orange Book.

To be considered therapeutically equivalent, a generic drug must first be a pharmaceutical equivalent of the branded drug. This means that the generic has the same active ingredient, dosage form, strength or concentration and route of administration as the brand-name drug. Tablets and capsules are currently considered different dosage forms that are pharmaceutical alternatives and therefore are not substitutable pharmaceutical equivalents. In addition to being pharmaceutical equivalents, therapeutic equivalents must be bioequivalent to their branded counterparts. Bioequivalence for this purpose is defined in the same manner as for ANDA

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

### ***Requirements Applicable to Medical Devices in the United States***

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

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

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

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

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

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

## ***Biosimilars***

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

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

## ***Foreign Regulation and Product Approval***

Outside the U.S., our ability or the ability of our collaboration partner Biogen Idec to market a product candidate is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Foreign marketing authorizations can be applied for at a national level, although within the European Union, or EU, registration procedures are available to companies wishing to market a product in the entire European Economic Area, or EEA (through the “centralized procedure,” which is mandatory for certain products, including biotechnology and advanced therapy medicinal products, orphan medicines and new active substances for the treatment of acquired immune deficiency syndrome (AIDS), cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions and viral diseases), or in more than one individual EU member state (through the “mutual recognition procedure” or “decentralized procedure”). The foreign regulatory approval process involves all of the risks associated with FDA approval discussed above.

## ***Other Regulations***

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation and oversight by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, and are affected by the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services on behalf of the states and must regularly submit certain pricing information to CMS. For products to be made available to authorized users of the Federal Supply Schedule administered by the Department of Veterans Affairs, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Administration and the Department of Defense, or DOD, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. In

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

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

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

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

### ***Reimbursement and Pricing Controls***

In many of the markets where we or Biogen Idec, our collaboration partner for Ampyra, would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls, by law, and to drug reimbursement programs with varying price control mechanisms.

In the U.S., there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the U.S., federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public healthcare programs such as Medicaid. Various states have adopted further mechanisms under Medicaid and other programs that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products.

Under the reimbursement methodology set forth in the Medicare Modernization Act, or MMA, physicians are reimbursed for drugs they administer to Medicare beneficiaries based on a product's "average sales price," or ASP. This ASP-based reimbursement methodology has generally led to lower reimbursement levels. The MMA also established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The ACA requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is

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

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

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

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

Public and private healthcare payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private healthcare payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA and/or appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, some governments influence the price of pharmaceutical products through reference pricing approaches to pharmaceutical reimbursement for national healthcare systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Health and Care Excellence, or NICE, in the United Kingdom which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

## **EMPLOYEES**

As of February 19, 2015, we had 489 employees. Of the 489 employees, 114 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 375 work in sales, marketing, managed markets, business development, manufacturing, technical

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

## CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 420 Saw Mill River Road, Ardsley, New York 10502. Our telephone number is (914) 347-4300. Our website is [www.acorda.com](http://www.acorda.com). The information contained on our website is not incorporated by reference into this report and should not be considered to be a part of this report. References to our website address in this report have been included as, and are intended to be, inactive textual references only that do not hyperlink to our website.

## ADDITIONAL INFORMATION AND WHERE TO FIND IT

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website (<http://www.acorda.com> under the “Investors” and then “SEC Filings” captions) as soon as reasonably practicable after we electronically file such material with, or furnish them to, the Securities and Exchange Commission (SEC). Also, the SEC allows us to “incorporate by reference” some information from our proxy statement for our 2015 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2015 Proxy Statement within 120 days after the end of our 2014 fiscal year, in accordance with SEC rules and regulations, and we recommend that you refer to the information that we indicate will be contained in our 2015 Proxy Statement.

### Item 1A. Risk Factors.

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

#### Risks related to our business

***We have a history of operating losses and, although we were profitable in 2013 and 2014, we may not be able to sustain profitability; and we expect to be substantially dependent on revenues from the sale of Ampyra for the foreseeable future.***

We will be highly dependent on the commercial success of Ampyra in the U.S. for the foreseeable future. We currently derive substantially all of our revenue from the sale of Ampyra, and we believe that sales of Ampyra will continue to constitute a significant and growing portion of our total revenue for the foreseeable future. We may be unable to meet our expectations with respect to Ampyra sales and/or sustain profitability and positive cash flow from operations.

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

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

- increasing our sales levels for Ampyra in the U.S. and supporting Biogen Idec's efforts to successfully obtain and maintain regulatory approval for Fampyra (as Fampridine Prolonged Release tablets) in the EU and other markets outside the U.S.;
- expanding the dalfampridine franchise, such as through our program evaluating the use of dalfampridine (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke ;
- successfully advancing our late-stage clinical development programs for new product candidates, including in particular our program to develop CVT-301 for the treatment of OFF episodes in Parkinson's disease , acquired with our purchase of Civitas in 2014, and our program to develop Plumiaz as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience seizure clusters or acute repetitive seizures ;
- continuing to advance our other clinical development programs, including our rHlgM22 and cimagermin alfa (previously GGF2) programs ;
- continuing to develop our preclinical product candidates and advance them into clinical trials; and
- evaluating and potentially expanding our product development pipeline through the potential in-licensing and/or acquisition of additional products and technologies.

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

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

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

- the effectiveness of our sales, managed markets and marketing efforts;
- the acceptance of Ampyra and our other products in the medical community, particularly with respect to whether physicians and patients view Ampyra and our other products as safe and effective for its labeled indication, and whether it has an acceptable benefit-to-risk profile, and the rate of adoption by healthcare providers and the target population of patients;
- the availability of adequate reimbursement by third-party payers;
- the continued use of compounded 4-AP instead of Ampyra, available through pharmacies in the U.S. and elsewhere that engage in compounding;
- the occurrence of any side effects, adverse reactions or misuse (or any unfavorable publicity relating thereto) stemming from the use of Ampyra or our other products;
- the development of products that compete with or are an alternative to Ampyra or our other products as therapies for the treatment of underlying medical conditions or their symptoms, the timing of market entry for those competing or alternative products, the perceived advantages of competing or alternative therapies over our products, and the pricing of our products as compared to the pricing of those competing or alternative products; and

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

Market acceptance of our products and product candidates depends on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness and our ability to demonstrate these benefits to physicians and patients. Market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payers, as well as on the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Ampyra or our other products are meaningful for patients. As described below in these risk factors, FDA-approved product labeling for Ampyra is limited and may harm its market acceptance. Also, if Ampyra is not listed on the preferred drug lists of third-party payers, or Ampyra is on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies, our sales may suffer.

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

The failure of any of our products or product candidates, once approved, to achieve market acceptance would limit our ability to generate revenue and would harm our results of operations. If market acceptance of our products in the U.S., EU, or other countries does not meet expectations, our revenues or royalties from product sales would suffer and this could cause our stock price to decline or could otherwise adversely affect our stock price.

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

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

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

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

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

***We operate in the highly-regulated pharmaceutical industry.***

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

In order to conduct clinical trials to obtain FDA approval to commercialize any product candidate, an investigational new drug, or IND, application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, if the product candidate is regulated as a drug, a new drug application, or NDA, must be submitted to the FDA and approved before commercial marketing may begin. The NDA must include the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. If the product candidate, such as an antibody, is regulated as a biologic, a biologic license application, or BLA, must be submitted and approved before commercial marketing may begin. Extensive submissions of preclinical and clinical trial data are required to demonstrate the safety, efficacy, potency and purity for each intended use. The FDA may refuse to accept our regulatory submissions for filing if they are incomplete. Of the large number of drugs in development, only a small percentage result in the submission of an NDA or BLA to the FDA, and even fewer are approved for commercialization.

The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Any regulatory approvals may be for fewer or narrower indications than we request, may include distribution restrictions, or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow a special risk evaluation and mitigation strategy, or REMS, to monitor and manage potential safety issues, all of which may eliminate or reduce the drug's market potential. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use.

Any product for which we currently have or may in the future obtain marketing approval is subject to continual post-approval requirements including, among other things, record-keeping and reporting requirements, packaging and labeling requirements, requirements for reporting adverse drug experiences, import/export controls, restrictions on advertising and promotion, and cGMP requirements. All of our products and operations are subject to periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, any approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

We may fail to comply with existing legal or regulatory requirements or be slow to adapt, or be unable to adapt, to new legal or regulatory requirements. We may encounter problems with our manufacturing processes, and we may discover previously unknown problems with our products. These circumstances could result in:

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

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and we may be subject to other local, state, federal and foreign regulations. We cannot predict the impact of those regulations on us, although they could impose significant restrictions on our business and we may have to incur additional expenses to comply with them.

***We have no manufacturing capabilities for our products or product candidates other than our Chelsea, Massachusetts facility used to manufacture CVT-301 and other ARCUS inhaled therapy product candidates, and we are dependent upon Alkermes and other third-parties to supply the materials for, and to manufacture, Ampyra and our other commercial products and products in development.***

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

We cannot be certain that we can reach agreement with (or renew existing agreements with) needed third party manufacturers or suppliers on reasonable terms, if at all. Manufacturers or suppliers may choose not to conduct business with us at all, for example if they determine that our particular business requirements would be unprofitable or otherwise not appropriate for their business. Even if we have agreements with third parties, they may not perform their obligations to us and/or they may be unable or unwilling to establish or increase production

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

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

The manufacturing facilities used to produce our products, including those of our third-party 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, or the loss of operating licenses. Based on the severity of the regulatory action, our clinical or commercial supplies could be interrupted or limited, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

In addition, our promotion of Ampyra must reflect only the specific approved indication as well as other limitations on use, and disclose the safety risks associated with the use of Ampyra as set out in the approved product labeling. We must submit all promotional materials to the FDA at the time of their first use. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and provide corrective information to healthcare practitioners, and we may face other adverse enforcement action, including civil and criminal penalties. For example, in June 2012, we received an untitled letter from the FDA stating that one of our Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of and minimized important safety information associated with Ampyra. In compliance with the untitled FDA letter, we discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional materials. In July 2013, we received a warning letter from the FDA stating that one of our consumer print advertisements for a local speaker program to educate consumers about Ampyra was false or misleading because it omitted risk information associated with the use of Ampyra. The warning letter cited the prior June 2012 untitled letter and stated that this was a serious and repeat violation. The FDA instructed us to immediately discontinue using the print advertisement and submit a written response to their letter, including a plan of action to disseminate corrective messages. The print advertisement was no longer in use, and in compliance with the FDA request, we timely submitted a written response to the warning letter, committing to take appropriate corrective action, with which the FDA agreed.

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

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

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

Also, our advertising and promotion are subject to stringent FDA rules and oversight. In particular, the claims in our promotional materials and activities must be consistent with the FDA approvals for our products, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of

the products. Any free samples we distribute to physicians must be carefully monitored and controlled, and must otherwise comply with the requirements of the Prescription Drug Marketing Act, as amended, and FDA regulations.

***The identification of new Ampyra side effects, or Ampyra side effects that are more frequent or severe than in the past, would harm our business and could lead to a significant decrease in sales of Ampyra or to the FDA's withdrawal of marketing approval.***

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

If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for Ampyra or any products perceived to be similar to Ampyra, then in any of these circumstances:

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

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

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

Under FDA regulations, we are required to monitor the safety of Ampyra and inform healthcare professionals about the risks of drug-associated seizures with Ampyra. We are required to document and investigate reports of adverse events, and to report them to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in withdrawing of marketing authorization or other regulatory action, civil actions against us, or criminal penalties, any of which could harm our business. Since 2010, we have submitted some late reports, including instances where specialty pharmacies that dispense Ampyra or a marketing partner have failed to timely report to us some of the reports of adverse events that they received. We reported these adverse events to the FDA immediately upon receipt. However, because these adverse events were not reported to us in a timely

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 fail timely to report adverse events and product complaints to us, or if we do not meet the requirements for safety reporting, our business may be harmed.

***We are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to other regulatory requirements that apply to drugs manufactured or distributed by us.***

If we receive a notice of inspectional observations or deficiencies from the FDA, we may be required to undertake corrective and preventive actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses. Failure to adequately address the FDA's concerns could expose us to enforcement and administrative actions.

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

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

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

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

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

Also, effective January 2015, the Federal Food, Drug & Cosmetic Act requires that trading partners such as our manufacturers, repackagers, wholesale distributors, and dispensers, take certain actions upon determining that a product in their possession or control is suspected to be: counterfeit, diverted, stolen; intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health 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 Idec to commercialize Ampyra outside of the U.S. (known as Fampyra outside the U.S.)***

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

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

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

***Our collaboration partner, Biogen Idec, will need to obtain and maintain regulatory approval in foreign jurisdictions where they seek to market or are currently marketing Fampyra.***

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

In July 2011, Biogen Idec received conditional approval from the European Commission for Fampyra (10 mg prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). The European Commission may grant a conditional marketing authorization if, at the time of the application, the marketing authorization applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective, verifiable reasons based on grounds specified in EU law.

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

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

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

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

fail to be safe and effective in preclinical tests or clinical trials, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. In addition, because we have limited resources, we are focusing on product candidates that we believe are the most promising. As a result, we may delay or discontinue particular development programs, and we may instead pursue other product candidates. From time to time, we may establish and announce certain development goals for our product candidates and programs, including, for example, development goals for our product candidates and programs set forth in this report. However, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. If we are unsuccessful in advancing our research and development programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

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

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

- negative or ambiguous results regarding the efficacy of the product candidate;
- undesirable side effects that delay or extend the trials, or other unforeseen or undesirable safety issues that make the product candidate not medically or commercially viable;
- inability to locate, recruit and qualify a sufficient number of patients for our trials;
- difficulty in determining meaningful end points or other measurements of success in our clinical trials;
- regulatory delays or other regulatory actions, including changes in regulatory requirements;
- difficulties in obtaining sufficient quantities of our product candidates manufactured under current good manufacturing practices;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board, or a data safety monitoring board, or clinical holds placed upon the trials by the FDA;
- FDA approval of new drugs that are more effective than our product candidates;
- change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and
- change in our financial position.

A delay in or termination of any of our clinical development programs could harm our business.

Clinical trials are subject to oversight by institutional review boards, data safety monitoring boards, and the FDA to ensure compliance with the FDA's good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices

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

***If third-party contract research organizations do not perform in an acceptable and timely manner, our preclinical testing or clinical trials could be delayed or unsuccessful.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract research organizations and consultants to perform some or all of the functions associated with preclinical testing and clinical trials. The failure of any of these vendors to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or preclinical testing or clinical trial protocols, could cause a delay or other adverse effect on our preclinical testing or clinical trials and ultimately on the timely advancement of our development programs.

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

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

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

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

regardless of the payer.

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

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

Pharmaceutical companies have been prosecuted under federal and state false claims laws for manipulating information submitted to the Medicaid Rebate Program or for knowingly submitting or using allegedly inaccurate pricing information in connection with federal pricing and discount programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

plan sponsors, some members of Congress support legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the Affordable Care Act contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. The Affordable Care Act requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.” Legislative or regulatory revisions to the Medicare Part D outpatient prescription drug benefit, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and harm our results of operations.

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

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

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

***If our competitors develop and market products that are more effective, safer or more convenient than our approved products, or obtain marketing approval before we obtain approval of future products, our commercial opportunity will be reduced or eliminated.***

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological conditions, including multiple sclerosis, or MS, stroke, Parkinson’s disease, or PD, epilepsy, heart failure, and spinal cord injury, or SCI.

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

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

*Ampyra.* We are aware that Catalyst Pharmaceuticals is developing a 3,4-diaminopyridine product, licensed from Biomarin, that may compete with Ampyra. Also, in certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available. Several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates.

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

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

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

*Plumiaz.* Plumiaz is a proprietary nasal spray formulation of diazepam, which is currently available as an FDA approved rectal gel and in other formulations, such as intramuscular and intravenous formulations used in certain indications. Our current understanding is that many patients would prefer a therapeutic product delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Plumiaz in preference over the other available formulations of diazepam or other products. Also, if we obtain FDA approval for and launch Plumiaz for the treatment of patients who require intermittent use of diazepam to control bouts of increased seizure activity, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Meridian Medical Technologies (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Upsher Smith is developing a nasal delivery form of midazolam, and Alexza is developing an inhaled version of alprazolam for use by patients who experience ARS, each of which could have a labeled indication similar to Plumiaz. Plumiaz could be subject to substantial competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors. Additionally, in May 2013, the diazepam auto-injector from Meridian Medical Technologies received

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

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

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

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

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

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed products or product candidates, for example by overestimating approvability by the FDA or the market potential of acquired or in-licensed products or product candidates. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. Any acquisition might distract resources from and otherwise harm sales of Ampyra or our other marketed products. We cannot assure you that we would be able to make the combination of our business with that of acquired businesses or companies or in-licensed products or product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product or product candidate may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our stock, which could dilute our current shareholders' ownership interest, or securities convertible into our stock, which could dilute current shareholders' ownership interest upon conversion. Also, although we may from time to time announce that we have entered into agreements to acquire other companies or assets, we cannot assure you that these acquisitions will be completed in a timely manner or at all. These transactions are subject to an inherent risk that they may not be completed, for example because required closing conditions cannot be met at all or within specified time periods, termination rights may be exercised such as due to a breach by one of the parties, or other contingencies may arise that affect the transaction.

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

If the use or misuse of Ampyra, Zanaflex Capsules, Zanaflex tablets, Qutenza, or any other FDA-approved products we may sell in the future harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payers or others. The use of our product candidates in clinical trials could also expose us to product liability claims. We currently maintain a product liability insurance policy that includes coverage for our marketed products as well as for our clinical trials. The total insurance limit is \$50 million per claim, and the aggregate amount of claims under the policy is also capped at \$50 million. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates and, therefore, the amount of insurance coverage we currently have may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with our scientific and medical network and the network of centers in the U.S. and Canada that conducts our clinical trials. We are highly dependent on the services of Dr. Ron Cohen, our President and Chief Executive Officer, as well as the other principal members of our management and scientific staff. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. We do not maintain "key man" life insurance policies on the lives of our officers, directors or employees. The loss of one or more of our key employees, or our inability to attract additional qualified

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

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

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

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

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

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

### **Risks related to our intellectual property**

***If we cannot protect, maintain and, if necessary, enforce our intellectual property, our ability to develop and commercialize our products will be severely limited.***

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent and trademark protection for the technologies, compounds and products, if any, resulting from our licenses and research and development programs. Without protection for the intellectual property we use or intend to use, other companies could offer substantially identical products for sale without incurring the sizable discovery, research, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have patent portfolios relating to Ampyra/aminopyridines, CVT-301 and our ARCUS inhaled therapeutic technology, cimaglermin alfa (previously GGF2)/neuregulins, remyelinating antibodies/antibodies relating to nervous system disorders, chondroitinase, Plumiaz/diazepam nasal spray, Qutenza and NP-1998/topical capsaicin formulations, comprised of both our own and in-licensed patents and patent applications. For some of our proprietary technologies, for example our ARCUS technology, we rely on a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property rights. Our intellectual property also includes copyrights and a portfolio of trademarks.

The process of obtaining patents and trademarks can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent or trademark may not issue, it may not issue in a timely manner, or it may not have sufficient scope or strength to protect the technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not allowed or issued for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or trademarks or the patents or trademarks of our licensors. For example, eight generic drug manufacturers have already filed Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra with the FDA. In filing these ANDAs for Ampyra, the generic drug manufacturers have challenged all of the Orange Book-listed patents that protect the Ampyra franchise. As such, to protect our intellectual property rights we have initiated legal proceedings asserting the challenged Orange Book-listed patents against these generic drug manufacturers. Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invent's Act, specifically *inter partes* review and/or post grant review before the U.S. Patent and Trademark Office. For example, in February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate *inter partes* review (IPR) petitions with the U.S. Patent and Trademark Office, challenging two of the five Ampyra Orange Book-listed patents. Patent litigation, IPR, and other legal proceedings involve complex legal and factual questions. We may need to devote significant resources to such legal proceedings, and if we are not successful our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such lawsuits and legal 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 consuming, and may distract management from other important tasks.

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

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

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

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

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

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

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

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

We are dependent on licenses for intellectual property related to Ampyra, Qutenza, and all of our research and development programs such as our program evaluating the use of dalfampridine as a treatment for chronic post-stroke deficits and our CVT-301 and Plumiaz development programs. Our failure to meet any of our obligations under these license agreements could result in the loss of our rights to this intellectual property. If we lose our rights under any of these license agreements, we may be unable to commercialize, or continue commercializing, a product that uses licensed intellectual property.

We could lose our rights to dalfampridine under our license agreement with Alkermes in countries in which we have a license, if we fail to file for regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for the NDA-equivalent. We could also lose our rights under our license agreement with Alkermes in markets outside the U.S. if we fail to launch a product within 180 days of NDA-equivalent approvals and receipt of other needed regulatory approvals in those countries. Alkermes could also terminate our license agreement if we fail to make payments due under the license agreement. If we lose our rights to dalfampridine, our prospects for generating revenue would be materially harmed as we currently derive substantially all of our revenue from Ampyra.

### **Risks relating to our common stock**

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

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

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

- sales of substantial amounts of our stock;
- delay or failure in initiating, completing or analyzing pre-clinical trials or unsatisfactory design or result of these trials;
- variations in product revenue and profitability;
- variations in our anticipated or actual operating results; and
- changes in healthcare reimbursement policies.

Many of these factors are beyond our control, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

In addition, the stock markets in general, and the Nasdaq Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations in recent years. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

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

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater stockholders or other stockholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of February 17, 2015, we had outstanding 42,575,393 shares of voting common stock. Also, options to acquire 7,679,975 shares of common stock were outstanding as of February 17, 2015, exercisable at an average exercise price of \$29.27 per share, and additional shares of common stock are authorized for issuance pursuant to options and other awards under our 2006 Employee Incentive Plan. To the extent that option holders exercise outstanding options, there may be further dilution and the sales of shares issued upon such exercises could cause our stock price to drop further.

***If our officers, directors and largest stockholders choose to act together, they may be able to control the outcome of stockholder vote.***

As of December 31, 2014, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 53% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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

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

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

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

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

Not applicable.

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

##### ***Ardsley, New York***

In June 2011, we entered into a 15 year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. In July 2012, we relocated our corporate headquarters, and all employees based at our prior Hawthorne, NY location, to the Ardsley facility. We have grown substantially over the last several years, and the new facility provides state-of-the art office and laboratory space that accommodates our current needs and allows for future growth. We have options to extend the term of the lease for three additional five-year periods, and we have an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, we have rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. Our extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease. In 2014, we exercised our option to expand into an additional 25,405 square feet of office space, which we occupied in January 2015.

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

### ***Chelsea, Massachusetts***

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

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

### ***Apotex***

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

### ***Ampyra Patents***

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis FL, Inc., Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe

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

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

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

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

Not applicable.

## 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
<b>Fiscal Year Ended December 31, 2014</b>		
Fourth Quarter	\$ 41.65	\$ 30.22
Third Quarter	\$ 37.85	\$ 28.26
Second Quarter	\$ 39.48	\$ 29.32
First Quarter	\$ 39.95	\$ 27.51

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

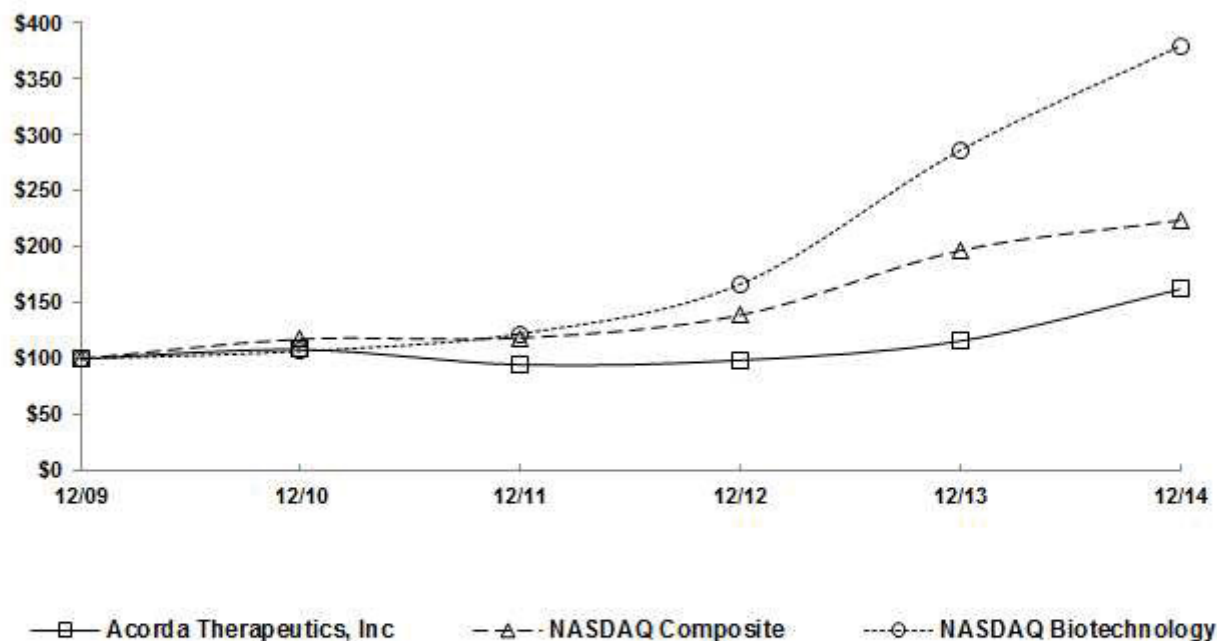
Computershare is the transfer agent and registrar for our common stock. As of February 17, 2015, we had approximately 20 registered holders of record of our common stock.

**Stock Price Performance Graph**

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

## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

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



\*\$100 invested on 12/31/09 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

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

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

### Dividend Policy

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

### Issuer Purchases of Equity Securities

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

**Item 6. Selected Financial Data.**

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

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

	As of December 31,				
	2014	2013	2012	2011	2010
			(in thousands)		
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents and investments	\$307,618	\$367,227	\$333,188	\$295,907	\$240,030
Working capital	294,754	270,690	234,192	273,599	217,274
Total assets	1,080,679	607,127	565,332	379,488	342,101
Long-term liabilities	426,040	70,131	80,540	86,936	96,944
Accumulated deficit	(220,410)	(238,082)	(254,523)	(409,481)	(440,086)
Long term debt	289,883	3,228	4,244	5,230	6,186
Total stockholders' equity	540,255	440,353	385,921	205,209	151,261

## 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 neurological 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. In October 2014, we acquired Civitas Therapeutics, Inc., a biopharmaceutical company which is developing CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease.

### Ampyra

#### General

Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. To our knowledge, Ampyra is the first and only product approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the United States in March 2010. Net revenue for Ampyra was \$366.2 million for the year ended December 31, 2014 and \$302.6 million for the year ended December 31, 2013.

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

higher compliance and persistency rates over time compared to non-First Step patients. Approximately 50% of patients who initiate Ampyra therapy with the First Step free trial program convert to paid prescriptions.

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, Managed Markets Account Directors who provide information and assistance to payers and physicians on Ampyra, National Trade Account Managers who work with wholesalers and our limited network of specialty pharmacies, and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Ampyra is distributed in the United States exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which 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 between 10 to 30 days.

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

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

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

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen Idec anticipates making Fampyra commercially available in additional markets in 2015. Under our agreement with Biogen Idec, 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 Idec in 2011, which was triggered by Biogen Idec's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

#### *Ampyra Patent Update*

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

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

- The second is U.S. Patent No. 5,540,938 (“the ‘938 patent”), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In April 2013, the ‘938 patent received a five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the ‘938 patent will expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan’s Drug Technologies business).
- The third, which issued in January 2013, is U.S. Patent No. 8,354,437, which includes claims relating to methods to improve walking, increase walking speed, and treat walking disability in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2026.
- The fourth, which issued in May 2013, is U.S. Patent No. 8,440,703, which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025.
- The fifth, which issued in March of 2014, is U.S. Patent No. 8,663,685 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Absent patent term adjustment, the patent is set to expire in 2025.

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

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis FL, Inc., Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. This litigation is further described above in Part I, Item 3 of this report. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notice Letters. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

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

In 2011, the European Patent Office, or EPO, granted EP 1732548, the counterpart European patent to U.S. Patent No. 8,354,437 with claims relating to, among other things, use of a sustained release aminopyridine

composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC ehf filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines.

### ***Civitas Acquisition; CVT-301 and ARCUS Technology***

On October 22, 2014, we completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation. As a result of the acquisition, we acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease, which is further described below. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Approximately 45 Civitas employees based at the Chelsea facility have joined the Acorda workforce in connection with the acquisition.

The Civitas acquisition was completed under an Agreement and Plan of Merger, dated as of September 24, 2014, by and among Acorda, Five A Acquisition Corporation, a Delaware corporation and our wholly-owned subsidiary, Civitas and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the securityholders' representative. Pursuant to the terms of the merger agreement, Five A Acquisition Corporation 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, all outstanding shares of Civitas common stock and Civitas preferred stock, options to purchase shares of Civitas common stock and warrants to purchase shares of Civitas preferred stock, other than shares of Civitas common stock and Civitas preferred stock held by Civitas (which were cancelled as a result of the merger) were converted into the right to receive \$525.0 million in cash in the aggregate, without interest, less (i) \$5.3 million due and payable under Civitas' existing secured loan facility, consisting of \$5.0 million in principal and \$0.3 million in prepayment fees, (ii) \$30.0 million due and payable to Alkermes, Inc. in connection with the exercise by Civitas of its option to purchase manufacturing facility equipment from Alkermes and (iii) a portion of Civitas' transaction expenses. Also pursuant to the merger agreement, upon consummation of the merger, \$39.375 million of the aggregate consideration was deposited into escrow to secure the indemnification obligations of Civitas and Civitas's securityholders, and an additional \$0.5 million of the aggregate consideration was deposited with SRS for reimbursements payable to SRS under the terms of the merger agreement. We financed the transaction with cash on hand.

### ***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 \$1.5 million for the year ended December 31, 2014 and \$4.1 million for the year ended December 31, 2013. 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 Watson Pharma (a subsidiary of Actavis). 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 2015 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 United States, Canada, Latin America and certain other territories. Qutenza was approved by the FDA in 2010 and launched in April 2010 but NeurogesX discontinued active promotion of the product in March 2012. In January 2014, we re-launched Qutenza in the United States using our existing commercial organization, including our specialty neurology sales force as well as our medical and safety reporting infrastructure. Net revenue for Qutenza was \$947,000 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, and includes the CVT-301 program that we recently acquired with Civitas, described above. We have evaluated and reprioritized our research and development pipeline based on our recent acquisition of Civitas. As further described below, we terminated our AC105 program in 2014, and have no current plans to invest in further development of NP-1998 for neuropathic pain.

#### ***CVT-301 and ARCUS Technology***

We acquired CVT-301 in October 2014 with our acquisition of Civitas, described above. CVT-301 is a Phase 3-ready inhaled formulation of levodopa, or L-dopa, for the treatment of OFF episodes in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease is characterized by symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care is oral L-dopa, but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects. The unpredictable re-emergence of symptoms is referred to as an OFF episode, and current strategies for treating these OFF episodes are widely regarded as inadequate.

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

In December 2014, we announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from the efficacy trial in 2016, and plan to file a new drug application, or NDA, in the U.S. by the end of 2016. We expect that the NDA will be filed under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from the branded L-dopa product Sinemet®. Based on Civitas's interactions with the FDA, we believe a single Phase 3 efficacy study will be needed for filing an NDA, supported by existing Phase 2b data. A separate safety study will also be required, and we believe this can be completed following submission of an NDA. However, the FDA will determine the

ultimate filing requirements for the NDA. We are projecting that, if approved, annual peak sales of CVT-301 in the U.S. alone could exceed \$500 million.

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

#### *Ampyra/Dalfampridine Development Programs*

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

#### *Plumiaz*

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We are continuing to work with the FDA to define the additional clinical work necessary for the re-submission of the NDA and approval of Plumiaz, and we are encouraged by the progress of our discussions.

We 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. We believe this product has the potential to generate peak annual sales significantly higher than \$100 million.

#### *Cimaglermin alfa (previously GGF2) /Neuregulins*

Cimaglermin alfa, which we previously referred to as GGF2, is our lead product candidate for our neuregulin program. We have completed a cimaglermin Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with

heart failure is assessing tolerability of three dose levels of cimaglermin , which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or to enter into a partnership, most likely with a cardiovascular-focused company.

### *Remyelinating Antibodies*

rHlgM22 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 rHlgM22 to assess the safety and tolerability of rHlgM22 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 rHlgM22, found no dose-limiting toxicities at any of the five dose levels studied. Additional data from this trial will be presented at future medical meetings. Based on these data, we intend to advance clinical development of rHlgM22 for MS. We are currently developing the protocol for our next Phase 1 clinical trial of rHlgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse.

### *Chondroitinase Program*

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 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.

### *AC105*

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

## ***Convertible Senior Notes***

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

## ***Corporate Update***

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

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

## ***Outlook for 2015***

### ***Financial Guidance for 2015***

We are providing the following guidance with respect to our 2015 financial performance:

- We expect 2015 net revenue from the sale of Ampyra to range from \$405 million to \$420 million.
- We expect Zanaflex (tizanidine hydrochloride) and ex-U.S. Fampyra (prolonged-release fampridine tablets) 2015 revenue to be approximately \$25 million, which includes net sales of branded Zanaflex products, and royalties from ex-U.S. Fampyra and authorized generic tizanidine hydrochloride capsule sales.
- Research and development expenses in 2015 are expected to range from \$150 million to \$160 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 2015 is primarily related to Phase 3 studies of dalfampridine and CVT-301. Additional expenses include continued development of Plumiaz, clinical trials for cimaglermin alfa (previously GGF2) and rHlgM22 and CVT-427, as well ongoing preclinical studies.
- Selling, general and administrative expenses in 2015 are expected to range from \$180 million to \$190 million, excluding share-based compensation charges. We are setting a high priority on managing selling, general and administrative expenses in 2015.

The range of SG&A and R&D expenditures for 2015 are non-GAAP financial measures because they exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe that non-GAAP financial measures that exclude share-based compensation charges 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 2015 are as follows:

- Continue progressing our Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from this efficacy trial in 2016, and plan to file a new drug application, or NDA, in the U.S. by the end of 2016.
- Continue progressing our Phase 3 clinical trial assessing the use of a once-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, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We are working with different external partners to develop a once-daily (QD) formulation that could be included in future post-stroke studies.
- We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We are continuing to work with the FDA to define the additional clinical work necessary for the re-submission of the NDA and approval of Plumiaz, and we are encouraged by the progress of our discussions.
- Complete our second clinical trial of cimaglermin alfa (previously GGF2), a Phase 1b single-infusion trial in people with heart failure assessing the tolerability of three dose levels of cimaglermin, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In October 2013, we announced that the first patient had been enrolled in this clinical trial. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015.
- Our Phase 1 clinical trial of rHlgM22 found no dose-limiting toxicities at any of the five dose levels studied. Based on these data, we intend to advance clinical development of rHlgM22 for MS. We are currently developing the protocol for our next Phase 1 clinical trial of rHlgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse.
- Initiate a Phase 1 clinical trial of CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes.

## Results of Operations

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

#### Net Revenue

##### *Ampyra*

We recognize product sales of Ampyra following shipment of product to 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 and Step Together programs. 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. We expect a similar trend in 2015. Effective January 1, 2015, 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*

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets 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 Actavis 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 increase 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 shipment of product to our specialty distributors. We recognized net revenue from the sale of Qutenza of \$947,000 and \$407,000 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 revenues.

*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 Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

*Royalty Revenue*

We recognized \$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 Idec. In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product's comparative efficacy. Biogen Idec launched Fampyra in Germany in August 2011. During the three-month period ended June 30, 2012, the government agency completed its comparative efficacy assessment of Fampyra indicating a range of pricing below Biogen Idec's initial launch price, which was unregulated for the first 12 months after launch consistent with German law. The Company recognized royalty revenue during a portion of 2012 based on the lowest point of the initially indicated German pricing authority range. The Company 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 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 \$411,000 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 \$355,000 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 \$634,000 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 Idec 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 \$587,000 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 \$888,000 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, and an increase of \$815,000 in franchise tax expenses. 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.

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 \$6.9 million, or 458%. The increase was due to an increase in interest expense of \$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 \$232,000, 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. We will report interest expense in future quarters of between \$3.6 million and \$4.3 million related to the Notes.

*(Provision for)/benefit from 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 this year 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.

***Year Ended December 31, 2013 Compared to Year Ended December 31, 2012****Net Revenue**Ampyra*

We recognize product sales of Ampyra following shipment of product to 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 \$302.6 million and \$266.1 million for the years ended December 31, 2013 and 2012, respectively. This net revenue reflected a 10.75% increase in our sale price for Ampyra effective January 2, 2013. The net revenue increase was comprised of net volume increases of \$10.5 million and price increases and discount and allowance adjustments of \$26.0 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2013 compared to the year ended December 31, 2012 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 Q4 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. Effective January 1, 2014, we increased our sale price to our customers by 10.75%.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, discounts, and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser 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*

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$4.1 million for the year ended December 31, 2013, as compared to \$13.2 million for the year ended December 31, 2012. Net product revenues also include \$3.2 million, which represents the sale of our Zanaflex Capsules authorized generic product to Actavis for the year ended December 31, 2013 as compared to \$3.1 million for the year ended December 31, 2012. Generic competition has caused a significant decline in net revenue of Zanaflex Capsules and is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2014 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 shipment of product to our specialty distributors. We recognized net revenue from the sale of Qutenza to these customers of \$407,000 for the year ended December 31, 2013. 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, 2013 and 2012, respectively, related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

### Royalty Revenue

We recognized \$9.3 million and \$7.1 million in royalty revenue for the years ended December 31, 2013 and 2012, respectively, related to ex-U.S. sales of Fampyra by Biogen Idec. In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product’s comparative efficacy. Biogen Idec launched Fampyra in Germany in August 2011. During the three-month period ended June 30, 2012, the government agency completed its comparative efficacy assessment of Fampyra indicating a range of pricing below Biogen Idec’s initial launch price, which was unregulated for the first 12 months after launch consistent with German law. The Company recognized royalty revenue during a portion of 2012 based on the lowest point of the initially indicated German pricing authority range. The Company 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 \$7.8 million in royalty revenue for the year ended December 31, 2013 as compared to \$7.2 million for the year ended December 31, 2012, related to the authorized generic sale of Zanaflex Capsules which started in February 2012.

### Cost of Sales

We recorded cost of sales of \$66.0 million for the year ended December 31, 2013 as compared to \$57.0 million for the year ended December 31, 2012. 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 \$355,000 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 sales for the year ended December 31, 2012 consisted primarily of \$46.1 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2012 also consisted of \$7.0 million in royalty fees based on net product shipments, \$0.6 million in amortization of intangible assets, and \$261,000 in period costs related to freight, stability testing, and packaging. Cost of sales also included \$3.1 million which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2012.

### Cost of License Revenue

We recorded cost of license revenue of \$634,000 for the years ended December 31, 2013 and 2012, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

### Research and Development

Research and development expenses for the year ended December 31, 2013 were flat at \$53.9 million as compared to \$53.9 million for the year ended December 31, 2012. There was a decrease of \$7.6 million related to our life cycle management program for Ampyra due to higher costs in 2012 for our post-approval commitment study examining the use of a 5 mg dose of dalfampridine to improve walking in people with MS and higher costs in 2012 related to our post stroke program. There was also a decrease of \$560,000 in our cimaglermin alfa (previously referred to as GGF2) program, a decrease of \$480,000 in our AC105 program, and a decrease of \$380,000 in our chondroitinase program.

These decreases in research and development expenses were offset by increases in overall research and development staff, compensation, and related expenses of \$6.3 million to support our various pipeline initiatives. Additionally, there was an increase in our remyelinating antibodies program (rHlgM22) of \$2.1 million and an overall increase in expenses relating to work on our Plumiaz program of \$393,000. It should be noted that for the year ended December 31, 2012, total expenses for the Plumiaz program included \$6.6 million net charges for Neuronex acquisition expenses. This included a \$2.0 million upfront payment, payments of \$1.5 million for research funding per the terms of the agreement with Neuronex, payments of \$6.8 million representing closing consideration for purchasing Neuronex during the fourth quarter of 2012 less net assets acquired of \$3.7 million which were primarily the taxable amount of the Neuronex net operating loss carryforwards. For the year ended December 31, 2013, total research and development expenses for the Plumiaz program were \$6.9 million, including a \$1.0 million milestone upon our submission of an NDA to the FDA.

### *Selling, General and Administrative*

Sales and marketing expenses for the year ended December 31, 2013 were \$109.2 million compared to \$105.3 million for the year ended December 31, 2012, an increase of approximately \$3.9 million, or 4%. The increase was attributable to an increase in overall compensation, benefits, and other selling expenses of \$5.2 million and an increase of \$3.6 million for pre-launch activities associated with the possible commercialization of Plumiaz, if approved. The increase in sales and marketing expenses was partially offset by a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of \$5.4 million.

General and administrative expenses for the year ended December 31, 2013 were \$76.3 million compared to \$63.4 million for the year ended December 31, 2012, an increase of approximately \$12.9 million, or 20%. This increase was the result of an increase of \$11.4 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 post product approval work on Ampyra and Zanaflex of \$2.2 million as well as an increase in business development expenses of \$940,000 relating to the acquisition of two neuropathic pain management assets from NeurogesX, Inc. The increases in general and administrative expenses for the year ended December 31, 2013 were partially offset by a decrease in medical affairs expenses including educational programs of \$1.4 million.

### *Other Expense*

Other expense was \$1.5 million for the year ended December 31, 2013 compared to \$1.3 million for the year ended December 31, 2012, an increase of approximately \$200,000, or 15%. The increase was due to an increase in interest expense of approximately \$300,000 primarily related to the revenue interest agreement partially offset by an increase in interest income of \$100,000.

### *(Provision for)/benefit from Income Taxes*

We recorded a \$12.4 million provision for income taxes for the year ended December 31, 2013 as compared to a \$130.7 million benefit for income taxes for the year ended December 31, 2012, resulting in an effective tax rate of 43% and (539)%, respectively. 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 state income taxes, nondeductible stock-based compensation and various tax credits/settlements.

The large fluctuation in the effective tax rate from prior year was driven by the benefit of the Company's release of the valuation allowance against net deferred tax assets in the year ended December 31, 2012. 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 and Zanaflex Capsules, and, to a lesser extent, from loans, government grants and our revenue interest financing arrangement.

We were cash flow positive in 2014 and 2013. We expect to remain cash flow positive in 2015. At December 31, 2014, we had \$307.6 million of cash, cash equivalents and short-term and long-term investments, compared to \$367.2 million at December 31, 2013. There were no investments classified as long-term at December 31, 2014. We believe that we have sufficient cash, cash equivalents and short-term investments on hand, in addition to cash expected to be generated from operations, to fund our operations, including our currently anticipated development pipeline activities as currently planned.

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, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of December 31, 2014, \$3.3 million of these promissory notes was outstanding, which amount includes accrued interest. The fifth of seven annual payments on this note was due and paid on to the five year anniversary of Ampyra approval in January 2015 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 PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006. An additional \$5.0 million was due to us if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. Under the terms of the amendment, we repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met. In November 2014, PRF sold its Zanaflex revenue interest to Valeant Pharmaceuticals International, Inc.

Under the revenue interests assignment agreement and the amendment, 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 agreement that are at least 2.1 times the aggregate amount PRF paid us under the agreement, Valeant will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we have a liability as of December 31, 2014, referred to as the revenue interest liability, of \$900,000. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid

in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 5.8%. 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.

Upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, representations or warranties we make under the agreement, Valeant may (i) require us to repurchase the rights we sold them at the “put/call price” in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets that secure our obligations to Valeant. Except in the case of certain bankruptcy events, if Valeant exercises its right, which we refer to as Valeant’s put option, to cause us to repurchase the rights we assigned to it, Valeant may not foreclose unless we fail to pay the put/call price as required. If we experience a change of control we have the right, which we refer to as our call option, to repurchase the rights we sold under the revenue interests assignment agreement at the “put/call price” in effect on the date such right is exercised. The put/call price on a given date is the greater of (i) all payments made by PRF/Valeant to us as of such date, less all payments received by PRF/Valeant from us 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 to us as of such date, taking into account the amount and timing of all payments received by PRF/Valeant from us as of such date. We have determined that Valeant’s put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. As of December 31, 2014 we have no liability recorded related to the put/call option to reflect its current estimated fair value. This liability is revalued on an as needed basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

On August 3, 2012, we received a letter from PRF alleging that we breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also included an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it did not specify or quantify those injuries. If the put option were validly exercised, we estimate that the incremental cost to the Company in excess of amounts already accrued at December 31, 2014 would be no more than approximately \$0.6 million. In connection with our consenting to the PRF/Valeant transaction described above, PRF released us from these asserted claims.

#### *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 Securities and Exchange Commission (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 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 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, 2014 consisted of the following:

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

### *Investment Activities*

At December 31, 2014, cash, cash equivalents and short-term investments were approximately \$307.6 million, as compared to \$367.2 million at December 31, 2013. 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, 2014, our cash and cash equivalents were \$182.2 million, as compared to \$48.0 million as of December 31, 2013. 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 \$125.4 million as of December 31, 2014, as compared to \$225.9 million as of December 31, 2013. There were no investments classified as long-term at December 31, 2014. Our long-term investments as of December 31, 2013 consisted of US Treasury bonds with original maturities greater than one year. The balance of these investments was \$93.3 million as of December 31, 2013.

### *Net Cash Provided by Operations*

Net cash provided by operations was \$75.0 million and \$39.3 million for year ended December 31, 2014 and 2013, respectively. 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.

Cash provided by operations for the year ended December 31, 2013 was primarily attributable to net income of \$16.4 million principally resulting from an increase in net product and royalty revenues, a non-cash share-based compensation expense of \$25.1 million, a deferred tax provision of \$9.5 million, depreciation and amortization of \$7.0 million, and amortization of net premiums and discounts on short-term investments of \$2.5 million. Cash provided by operations was partially offset by a net decrease of \$12.8 million due to changes

in working capital items due to a decrease in deferred license revenue of \$9.1 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009, an increase of inventory held by the Company and others of \$5.1 million, an increase of \$4.5 million in accounts receivable, a decrease of \$5.8 million in accounts payable, accrued expenses, and other current liabilities resulting from payment timing, an increase in deferred product revenue related to Zanaflex of \$2.8 million, and an increase in prepaid expenses and other current assets of \$377,000.

### *Net Cash Used in Investing*

Net cash used in investing activities for the year ended December 31, 2014 was \$293.8 million, due to \$580.4 million in purchases of short-term and long-term investments, \$476.2 million paid for the acquisition of Civitas, net of cash received, purchases of property and equipment of \$5.1 million, and purchases of intangible assets of \$2.7 million, partially offset by \$770.5 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, 2014 was \$352.9 million, due to \$337.5 million in net proceeds from the issuance of the convertible senior notes as well as \$16.0 million in net proceeds from the exercise of stock options partially offset by \$562,000 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, 2014 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)	\$383,604	\$6,038	\$12,075	\$12,075
Convertible note payable (3)	3,432	1,144	2,288	—
Operating leases (4)	22,863	4,787	8,815	9,261
Inventory purchase commitments (5)	44,307	44,307	—	—
<b>Total</b>	<b>\$454,206</b>	<b>\$56,276</b>	<b>\$23,178</b>	<b>\$21,336</b>

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- (1) Excludes revenue interest liability principal and interest payments, due to uncertainty as to the amount and timing of such payments. Also excluded from the above table is a liability for uncertain tax positions totaling \$3.3 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 3 annual payments of principal and interest to be made on the convertible note payable to Saints Capital.

- (4) Represents payments for the operating lease of our Ardsley, NY headquarters. The payments for our Chelsea manufacturing facility sublease are included in the “less than 1 year column” through December 31, 2015, the date the current lease term expires. The Company is unable to determine the fair-market value of the payments for the 5-year lease renewal option for the Chelsea sublease at this time, therefore, no value is included for the Chelsea sublease in the “1-3 year” and “4-5 year” columns.
- (5) Represents Zanaflex, Ampyra, 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.

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 \$204 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, 2014, 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 shipment of product to these customers. Our customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

Our net revenues represent total revenues less allowances for customer credits, including estimated 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 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 revised our returns good policy in December 2012 and no longer accept returns of Ampyra except for product damaged in shipping. Historically, it has been rare for us to have product damaged in shipping. We will exchange product from inventory for product damaged in shipping.

### Zanaflex

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

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

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

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

We accept returns of Zanaflex Capsules and Zanaflex tablets for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. We do not exchange product from inventory for the returned product. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize. In addition, we record a charge to cost of goods sold for the cost basis of the estimated product returns we believe may ultimately be realized at the time of product shipment to wholesalers. We recognize this charge at the date of shipment since it is probable that we will receive a level of returned products; upon the return of such product we will be unable to resell the product considering its expiration dating; and, we can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns. The charge to cost of goods sold amounted to \$274,000 and \$347,000 for the years ended December 31, 2014 and 2013, respectively. A 10% change in this expense estimate would have had an approximate \$27,400 and \$34,700 effect on the Company's cost of sales for the years ended December 31, 2014 and 2013, respectively.

### 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 chargebacks and rebate percentages on a regular basis to reflect the most recent chargebacks and rebate experience. Our government chargebacks and rebates accruals were \$5.0 million and \$3.8 million at December 31, 2014 and December 31, 2013, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate \$2.5 million and \$2.0 million effect on our net revenue for the years ended December 31, 2014 and December 31, 2013, respectively.

*Managed Care Contract Rebates*: We contract with various managed care organizations including health insurance companies and pharmacy benefit managers in order to provide improved access to Ampyra for patients that are members of such organizations. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided Ampyra is 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 began to enter into these contracts during the three months ended December 31, 2010. We continue to monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. Our managed care contract rebate accruals were \$1.2 million and \$821,000 at December 31, 2014 and December 31, 2013, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$580,000 and \$338,000 effect on our net revenue for the years ended December 31, 2014 and December 31, 2013, 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 \$743,000 and \$578,000 at December 31, 2014 and December 31, 2013, respectively. A 10% change in our copay

mitigation rebate allowances would have had an approximate \$678,000 and \$548,000 effect on our net revenue for the years ended December 31, 2014 and December 31, 2013, respectively.

*Cash Discounts*: We sell Ampyra directly to our network of specialty pharmacies, Kaiser and the specialty distributor to the U.S. Department of Veterans Affairs (VA). 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 its customers. Discounts are accrued based on historical usage rates at the time of product shipment. We adjust accruals based on actual activity as necessary. Cash discounts are typically settled with our customers within 30 days after the end of each calendar month. Our cash discounts accruals were \$392,000 and \$318,000 at December 31, 2014 and December 31, 2013, respectively. A 10% change in our cash discounts allowances would have had an approximate \$408,000 and \$344,000 effect on our net revenue for the years ended December 31, 2014 and December 31, 2013, respectively.

*Product Returns*: Prior to December 1, 2012, our specialty pharmacies had the right to return any unopened Ampyra product during the eight-month period beginning two months prior to the labeled expiration date and ending six months after the labeled expiration date. Once product had been dispensed, it was no longer eligible for return. If specialty pharmacies returned product, they were to be given a credit against amounts owed to us. We did not replace returned product with new product unless it had been damaged in shipping. As of December 1, 2012, we changed our returned goods policy with respect to Ampyra and no longer accept returned product with the exception of that damaged in shipping. Therefore, we reversed the majority of the returns accrual for Ampyra during the three-month period ended December 31, 2012. Our returns accrual for Ampyra was \$10,000 at December 31, 2014 and December 31, 2013.

We record Zanaflex Capsule and tablet revenue based on a deferred revenue model and recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. Therefore, there is no returns reserve for Zanaflex.

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 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 accrual for Qutenza was \$5,000 and \$20,000 at December 31, 2014 and December 31, 2013, respectively. A 10% change in our returns would have had an approximate \$2,000 and \$6,000 dollar effect on our net revenue for the years ended December 31, 2014 and December 31, 2013, 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 (APSS), which in turn provides data to us. We pay a data fee to the specialty pharmacies for each line of data provided and the Company provides an allowance for these data fees. A line of data is defined as data pertaining to a single prescription. We 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 and \$875,000 at December 31, 2014 and December 31, 2013, respectively. A 10% change in our data fee and fee for service

allowances would have had an approximate \$356,000 and \$334,000 effect on our net revenue for the years ended December 31, 2014 and 2013, respectively.

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

The following table provides a summary of activity with respect to the Company's sales discounts and allowances during 2014, 2013, and 2012:

(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
<b>Balance at December 31, 2011</b>	\$3,099	\$273	\$135	\$303	\$480	\$998	-	\$5,288
Allowances for sales 2012	14,609	3,126	5,073	3,265	-	3,481	-	29,554
Allowances for prior year sales	72	(10)	(86)	(71)	(452)	(17)	-	(564)
Actual credits for sales during 2012	(11,651)	(2,386)	(4,851)	(2,967)	(18)	(2,688)	-	(24,561)
Actual credits for prior year sales	(3,280)	(263)	(49)	(237)	-	(982)	-	(4,811)
<b>Balance at December 31, 2012</b>	\$2,849	\$740	\$222	\$293	\$10	\$792	\$-	\$4,906
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)
<b>Balance at December 31, 2013</b>	\$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)
Actual credits for prior year sales	(3,099)	(726)	(259)	(288)	-	(724)	-	(5,096)
<b>Balance at December 31, 2014</b>	\$5,000	\$1,203	\$743	\$392	\$15	\$1,121	\$1,347	\$9,821

### Collaborations

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

### *Milestones and royalties*

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

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

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

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

### *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 (CROs) in conjunction with preclinical studies;
- fees paid to organizations in conjunction with contract manufacturing;
- costs of materials used in research and development;
- upfront and milestone payments under contractual agreements;
- consulting, license and sponsored research fees paid to third parties; and
- depreciation of capital resources used to develop our products.

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



upfront, milestone and monthly expenses as well as reimbursement for pass through costs. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations. All research and development costs are expensed as incurred except when we are accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. In these cases, these payments are capitalized at the time of payment and expensed ratably over the period the research and development activity is performed.

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

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

(in thousands)	Year Ended December 31,		
	2014	2013	2012
<b>Preclinical and clinical development:</b>			
Contract expenses—Ampyra LCM	\$8,990	\$5,206	\$12,840
Contract expenses—Diazepam Nasal Spray/Plumiaz	7,805	6,890	843
Contract expenses—cimaglermin alfa (previously GGF2)	6,157	5,592	6,151
Contract expenses—rHlgM22	5,019	3,359	1,220
Contract expenses—CVT-301	3,625	-	-
Contract expenses—NP-1998	2,015	185	-
Contract expenses—AC105	1,296	1,200	1,197
Contract expenses—Chondroitinase	121	118	498
Contract expenses—other	38	-	-
<b>Research and development operating expenses:</b>	<b>38,329</b>	<b>30,252</b>	<b>23,929</b>
<b>Acquisitions, licenses and milestones:</b>			
Diazepam Nasal Spray/Plumiaz	-	1,000	6,653
AC105	20	20	500
rHlgM22	25	25	20
cimaglermin alfa (previously GGF2)	10	10	10
Other	20	20	20
<b>Total research and development</b>	<b>\$73,470</b>	<b>\$53,877</b>	<b>\$53,881</b>

With respect to previously established clinical study accruals in prior periods and for the twelve-month period ended December 31, 2014 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.

### *Asset Impairment*

Asset impairment pertains to impairment charges for non-financial assets such as property, plant and equipment 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 contingent liability.

### *Other Income (Expense)*

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

### *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.

We have based our current assumptions on the following:

<u>Assumption</u>	<u>Method of estimating</u>
<ul style="list-style-type: none"> <li>• Estimated expected term of options</li> <li>• Expected volatility</li> <li>• Risk-free interest rate</li> </ul>	<ul style="list-style-type: none"> <li>• Historical term of our options based on exercise data</li> <li>• Historic volatility of our common stock</li> <li>• Yields of U.S. Treasury securities corresponding with the expected life of option grants</li> </ul>
<ul style="list-style-type: none"> <li>• Forfeiture rates</li> </ul>	<ul style="list-style-type: none"> <li>• Historical forfeiture data</li> </ul>

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

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

Our financial instruments consist of cash and cash equivalents, short-term and long-term investments, grants receivable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2014.

We have cash equivalents and short-term investments at December 31, 2014, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and US Treasury bonds, the carrying values of our cash equivalents and short-term investments approximate their fair values at December 31, 2014. There were no investments classified as long-term at December 31, 2014. At December 31, 2014, we held \$307.6 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.

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

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

As required by Rule 13a-15 under the Securities Exchange Act of 1934, or 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 2014 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, 2014, 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, 2014 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 2014 (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, 2014, 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.

On October 22, 2014, the Company completed its acquisition of Civitas Therapeutics, Inc., which is included in the Company's 2014 consolidated financial statements and constituted \$10.8 million and \$3.8 million of total and net assets, respectively, as of December 31, 2014 and \$0 and \$11 million of revenues and net loss, respectively, for the year then ended. As the acquisition occurred during 2014, management excluded the Civitas business from its assessment of internal control over financial reporting.

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, 2014. This attestation report appears below.

## Report of Independent Registered Public Accounting Firm

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

We have audited Acorda Therapeutics, Inc. internal control over financial reporting as of December 31, 2014, 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.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

As indicated in the accompanying management's report on internal control over financial reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Civitas Therapeutics, Inc., which is included in the 2014 consolidated financial statements of Acorda Therapeutics, Inc. and constituted \$10.8 million and \$3.8 million of total and net assets, respectively, as of December 31, 2014 and \$0 and \$11 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Acorda Therapeutics and subsidiaries also did not include an evaluation of the internal control over financial reporting of Civitas Therapeutics, Inc.

In our opinion, Acorda Therapeutics, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2014 consolidated financial statements of Acorda Therapeutics, Inc. and subsidiaries and our report dated February 27, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 27, 2015

**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 2015 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](http://www.acorda.com) .

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

**Item 11. Executive Compensation.**

The information required by this item will be contained in our 2015 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 2015 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 2015 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 2015 Proxy Statement under the caption for the proposal relating to the “Ratification of Independent Auditors” and is incorporated herein by this reference.

## PART IV

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

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

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

Financial Statements of Acorda Therapeutics, Inc. and Subsidiaries:

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

Consolidated Balance Sheets as of December 31, 2014 and 2013

Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Comprehensive Income for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012

Notes to Financial Statements

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 27, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 27, 2015

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2014	2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 182,170	\$ 48,037
Restricted cash	1,205	277
Short-term investments	125,448	225,891
Trade accounts receivable, net of allowances of \$771 and \$698, as of December 31, 2014 and 2013, respectively	32,211	30,784
Prepaid expenses	15,523	8,398
Finished goods inventory held by the Company	26,256	25,535
Finished goods inventory held by others	581	637
Deferred tax asset	18,420	19,314
Other current assets	7,324	8,460
Total current assets	409,138	367,333
Long-term investments	—	93,299
Property and equipment, net of accumulated depreciation	46,090	16,525
Goodwill	182,952	—
Deferred tax asset	—	107,985
Intangible assets, net of accumulated amortization	432,822	17,459
Non-current portion of deferred cost of license revenue	3,540	4,174
Other assets	6,137	352
Total assets	<u>\$ 1,080,679</u>	<u>\$ 607,127</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 17,751	\$ 15,922
Accrued expenses and other current liabilities	56,118	37,569
Deferred product revenue—Zanaflex	29,420	32,090
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interests liability	893	861
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	114,383	96,643
Convertible senior notes (due 2021)	287,699	—
Acquired contingent consideration	52,600	—
Non-current portion of deferred license revenue	50,570	59,628
Non-current portion of convertible notes payable	2,184	3,228
Deferred tax liability	23,885	—
Other non-current liabilities	9,103	7,275
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2014 and 2013; issued and outstanding 41,883,843 and 40,896,355 shares, including those held in treasury, as of December 31, 2014 and 2013, respectively	42	41
Treasury stock at cost (12,420 shares at December 31, 2014 and December 31, 2013)	(329)	(329)
Additional paid-in capital	761,026	678,686
Accumulated deficit	(220,410)	(238,082)
Accumulated other comprehensive income	(74)	37
Total stockholders' equity	540,255	440,353
Total liabilities and stockholders' equity	<u>\$ 1,080,679</u>	<u>\$ 607,127</u>

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(In thousands, except per share data)

	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Revenues:			
Net product revenues	\$ 373,292	\$ 310,317	\$ 282,381
Royalty revenues	19,131	17,056	14,376
License revenue	9,057	9,057	9,057
Total net revenues	401,480	336,430	305,814
Costs and expenses:			
Cost of sales	79,981	66,009	57,007
Cost of milestone and license revenue	634	634	634
Research and development	73,470	53,877	53,881
Selling, general and administrative	201,813	185,545	168,690
Asset impairment	6,991	—	—
Changes in fair value of acquired contingent consideration	2,200	—	—
Total operating expenses	365,089	306,065	280,212
Operating income	36,391	30,365	25,602
Other expense (net):			
Interest and amortization of debt discount expense	(9,288)	(2,170)	(1,880)
Interest income	674	668	552
Other income (expense)	232	—	(6)
Total other expense (net)	(8,382)	(1,502)	(1,334)
Income before taxes	28,009	28,863	24,268
(Provision for) / benefit from income taxes	(10,337)	(12,422)	130,690
Net income	\$ 17,672	\$ 16,441	\$ 154,958
Net income per share—basic	\$ 0.43	\$ 0.41	\$ 3.93
Net income per share—diluted	\$ 0.42	\$ 0.39	\$ 3.84
Weighted average common shares outstanding used in computing net income per share— basic	41,150	40,208	39,459
Weighted average common shares outstanding used in computing net income per share— diluted	42,544	41,682	40,332

See accompanying Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Comprehensive Income**

(In thousands)

	<u>Year ended December 31,</u> <u>2014</u>	<u>Year ended December 31,</u> <u>2013</u>	<u>Year ended December 31,</u> <u>2012</u>
Net income	\$ 17,672	\$ 16,441	\$ 154,958
Other comprehensive loss:			
Unrealized losses on available-for-sale securities, net of tax	(111)	(25)	(4)
Other comprehensive loss, net of tax	(111)	(25)	(4)
Comprehensive income	<u>\$ 17,561</u>	<u>\$ 16,416</u>	<u>\$ 154,954</u>

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common stock						Accumulated other comprehensive income (loss)	Total stockholders' equity
	Number of shares	Par value	Treasury stock	Additional paid-in capital	Accumulated deficit			
Balance at December 31, 2011	39,328	\$ 39	\$ (329)	\$ 614,914	\$ (409,481)		\$ 66	\$ 205,209
Compensation expense for issuance of stock options to employees	—	—	—	15,206	—		—	15,206
Compensation expense for issuance of restricted stock to employees	224	—	—	6,212	—		—	6,212
Exercise of stock options	252	1	—	4,339	—		—	4,340
Other comprehensive loss	—	—	—	—	—		(4)	(4)
Net income	—	—	—	—	154,958		—	154,958
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	—	—	—	38,166	—		—	38,166
Debt issuance costs	—	—	—	(1,277)	—		—	(1,277)
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

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Cash flows from operating activities:			
Net income	\$ 17,672	\$ 16,441	\$ 154,958
Adjustments to reconcile net loss to net cash provided by/(used in) operating activities:			
Share-based compensation expense	29,437	25,139	21,418
Amortization of net premiums and discounts on investments	3,571	2,526	4,382
Amortization of debt discount and debt issuance costs	4,291	—	—
Amortization of revenue interest issuance cost	27	50	67
Depreciation and amortization expense	8,473	6,999	4,663
Intangible asset impairment	6,991	—	664
Change in contingent consideration obligation	2,200	—	—
Gain on put/call liability	(147)	(182)	(701)
Deferred tax provision (benefit)	6,681	9,520	(133,042)
Excess tax benefit from share-based compensation arrangements	—	(91)	—
Changes in assets and liabilities:			
Increase in accounts receivable	(1,427)	(4,457)	(3,499)
Increase in prepaid expenses and other current assets	(4,083)	(377)	(2,961)
(Increase) decrease in inventory held by the Company	(721)	(5,269)	7,082
Decrease in inventory held by others	56	145	345
Decrease in non-current portion of deferred cost of license revenue	634	634	634
Decrease (increase) in other assets	34	34	(3,753)
Increase (decrease) in accounts payable, accrued expenses, other current liabilities	13,180	(5,785)	11,743
Increase in revenue interest liability interest payable	108	18	600
Decrease in non-current portion of deferred license revenue	(9,057)	(9,057)	(9,057)
(Decrease) increase in other non-current liabilities	(301)	78	(22)
(Decrease) increase in deferred product revenue—Zanaflex	(2,670)	2,816	(1,325)
Decrease (increase) in restricted cash	71	103	(77)
Net cash provided by operating activities	75,020	39,285	52,119
Cash flows from investing activities:			
Purchases of property and equipment	(5,084)	(4,043)	(10,384)
Purchases of intangible assets	(2,699)	(3,121)	(3,194)
Acquisitions, net of cash received	(476,151)	(7,499)	—
Purchases of investments	(580,381)	(221,429)	(322,455)
Proceeds from maturities of investments	770,490	191,000	264,750
Net cash used in investing activities	(293,825)	(45,092)	(71,283)
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	16,015	12,786	4,339
Excess tax benefit from share-based compensation arrangements	—	91	—
Repayments of revenue interest liability	(562)	(909)	(1,253)
Net cash provided by financing activities	352,937	11,968	3,086
Net increase (decrease) in cash and cash equivalents	134,133	6,161	(16,078)
Cash and cash equivalents at beginning of period	48,037	41,876	57,954
Cash and cash equivalents at end of period	\$ 182,170	\$ 48,037	\$ 41,876
Supplemental disclosure:			
Cash paid for interest	\$ 4,522	\$ 2,022	\$ 1,122
Cash paid for taxes	4,392	2,630	2,706

See accompanying Notes to Consolidated Financial Statements.

## **ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

### **Notes to Consolidated Financial Statements**

#### **(1) Organization and Business Activities**

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies to 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.

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

##### ***Principles of Consolidation***

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

##### ***Use of Estimates***

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

##### ***Cash and Cash Equivalents***

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

##### ***Restricted Cash***

Restricted cash represents a 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.

##### ***Investments***

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

longer than one year. The Company classifies its short-term and long-term investments as available-for-sale. Available-for-sale securities are recorded at 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 income.

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

### ***Accumulated Other Comprehensive Income***

The Company's accumulated other comprehensive income is comprised of 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 adjusts its inventory value based on an estimate of inventory that may be returned or not sold based on sales projections and establishes reserves as necessary for obsolescence and excess inventory.

### ***Ampyra***

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

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

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed on 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 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 records 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.

### ***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 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.

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 between 10 to 30 days.

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

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

*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.

*Milestones and royalties*

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

If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

*Collaborations*

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

*Concentration of Risk*

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

evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

The Company does not own or operate, and currently does not plan to own or operate, facilities for production and packaging of Ampyra or its other commercial products, Zanaflex Capsules, 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 now subleases a manufacturing facility in Chelsea, Massachusetts which produces CVT-301 for clinical trials and 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, 2014 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. Four customers individually accounted for more than 10% of the Company's revenue in 2014 through 2012. Four customers individually accounted for more than 10% of the Company's accounts receivable as of December 31, 2014 and three customers individually accounted for more than 10% of the Company's accounts receivable as of December 31, 2013. The Company's net product revenues are generated in the United States.

#### ***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 \$4.1 million and \$3.4 million for the years ended December 31, 2014 and 2013, respectively. The Company's accruals for cash discount allowances were \$392,000 and \$319,000 as of December 31, 2014 and 2013, respectively.

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

A portion of the Company's accounts receivable may not be collected due principally to customer disputes and sales returns. The Company provides reserves for these situations based on the evaluation of the aging of its trade receivable portfolio and an analysis of high-risk customers. The Company has not historically experienced material losses related to credit risk. The Company has recognized an allowance related to one customer of approximately \$379,000 as of December 31, 2014 and December 31, 2013. For the year ended December 31, 2014, the Company recorded no provision and did not record any write-offs. For the year ended December 31, 2013, the Company recorded a provision of \$119,000 and did not record any write-offs.

#### ***Contingencies***

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

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

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

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

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

### ***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 United States.

## ***Comprehensive Income***

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

## ***Recent Accounting Pronouncements***

In July 2013, the FASB issued Accounting Standards Update "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss (NOL) carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when (1) the uncertain tax position would reduce the NOL or other carryforward under the tax law of the applicable jurisdiction and (2) the entity intends to use the deferred tax asset for that purpose. ASU 2013-11 is effective prospectively for fiscal years and interim periods within those years, beginning after December 15, 2013 for public entities. The adoption of ASU 2013-11 did not have a significant impact on the Company's consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09), which requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. The Company is currently evaluating the impact of the new standard.

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 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.

## ***Subsequent Events***

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

**(3) 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 episodes of Parkinson's disease. 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 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 have been expensed as selling, general and administrative expenses in the year ended December 31, 2014.

The fair value of consideration transferred 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	<u>\$ 529,526</u>

In accordance with the acquisition method of accounting, the Company allocated the preliminary 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 acquired 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, a phase 3 candidate for the treatment of OFF episodes of Parkinson's Disease and CVT-427, a pre-clinical development stage product intended to provide relief from acute migraine episodes. Refer to Note 10 for further discussion about the Alkermes ARCUS agreement.

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.

The following table presents the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

(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	(102,633)
Other non-current liabilities	(1,065)
Fair value of acquired assets and liabilities	346,574
Goodwill	182,952
Aggregate purchase price	529,526
Amount paid to extinguish long-term debt	(5,325)
Cash Paid	\$ 524,201

The Company may update its preliminary acquisition accounting for provisional amounts for which the accounting is incomplete during the reporting period in which the acquisition occurred, and may continue to update the provisional amounts until the amounts are no longer provisional, but for no longer than one year from the date of the acquisition. Any updates to the fair value of consideration given or fair value assigned to assets acquired and liabilities assumed during the measurement period would be adjusted through goodwill.

### ***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 have been expensed in selling, general and administrative expenses.

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 United States 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 \$100,000,000 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 – *Fair Value Measurements* for more information on the contingent consideration liability.

Total purchase price is summarized as follows:

(In thousands)	
Cash paid to NeurogesX shareholders and its creditors	\$ 7,499
Fair value of contingent liabilities	205
Total preliminary estimated purchase price	<u>\$ 7,704</u>

The allocation of the purchase price to the fair value of assets acquired reflects 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 will classify the fair value of 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 purchase price to assets acquired:

(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	<u>7,704</u>
Aggregate purchase price	<u>7,704</u>
Goodwill	<u>\$ —</u>

Refer to Note 13 for 2014 impairment discussion.

### ***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.

(In thousands)	Year ended December 31, 2014		Year ended December 31, 2013	
	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, 2014				
US Treasury bonds	\$ 125,443	\$ 14	\$ (9)	\$ 125,448
December 31, 2013				
US Treasury bonds	319,123	69	(2)	319,190

The Company's short-term and long-term investments consist of US Treasury bonds. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment would be charged to earnings for the difference between the investment's cost and fair value at such date and a new cost basis for the security established. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment; and, issues that raise concerns about the issuer's ability to continue as a going concern. The Company has determined that there were no other-than-temporary declines in the fair values of its short term investments as of December 31, 2014.

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 \$149.8 million and \$28.3 million as of December 31, 2014 and 2013, 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, 2014. The Company's long-term investments as of December 31, 2013 consisted of US Treasury bonds with original maturities greater than one year. The balance of these investments was \$93.3 million as of December 31, 2013.

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 income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding gain on available-for-sale investments during the years ended December 31, 2014 and 2013 were as follows (in thousands):

	Net Unrealized Gains (Losses) on Marketable Securities
(In thousands)	
Balance at December 31, 2012	\$ 62
Other comprehensive loss before reclassifications:	(25)
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive loss	(25)
Balance at December 31, 2013	37
Other comprehensive loss before reclassifications:	(111)
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive loss	(111)
Balance at December 31, 2014	\$ (74)

## (5) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2014	December 31, 2013	Estimated useful lives used
Machinery and equipment	\$ 21,026	\$ 173	2-7 years
Leasehold improvements	15,763	10,260	Lesser of useful life or remaining lease term
Computer equipment	12,118	9,586	1-3 years
Laboratory equipment	5,247	3,555	2-5 years
Furniture and fixtures	1,163	1,067	4-7 years
Capital in progress	4,501	439	2-3 years
	59,818	25,080	
Less accumulated depreciation	(13,728)	(8,555)	
	<u>\$ 46,090</u>	<u>\$ 16,525</u>	

Depreciation and amortization expense on property and equipment was \$5.1 million and \$4.6 million for the years ended December 31, 2014 and 2013, respectively.

## (6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2014	December 31, 2013
Accrued inventory	\$ 12,453	\$ 8,632
Bonus payable	10,696	7,899
Product discount and allowances accruals	10,165	6,007
Research and development expense accruals	6,918	1,841
Sales force commissions and incentive payments payable	3,039	1,583
Royalties payable	2,540	2,063
Vacation accrual	2,038	1,629
Commercial and marketing expense accruals	2,091	3,435
Other accrued expenses	6,178	4,480
Total	<u>\$ 56,118</u>	<u>\$ 37,569</u>

## (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, 2014, the Company had granted an aggregate of 2,385,883 shares as restricted stock or subject to issuance upon exercise of stock options under the 1999 Plan, of which 4,659 shares remained 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). This 2006 Plan serves as the successor to the Company's 1999 Plan, as amended, and no further option grants or stock issuances shall be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. All employees of the Company are eligible to participate in the 2006 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 2006 Plan also covers the issuance of restricted stock. The 2006 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and restricted stock, determines the time or times at which options and restricted stock shall be granted under the 2006 Plan, determines the number of shares to be granted subject to any option or restricted stock under the 2006 Plan and the duration of each option and restricted stock, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Since inception, the number of shares of common stock authorized for issuance under the 2006 Plan as of December 31, 2014 is 13,216,463 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, shall automatically increase on January 1 of each year during the term of this plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board approved the automatic increases of 4% for 2014, 2013, and 2012. Upon the exercise of options in the future, the Company intends to issue new shares. As of December 31, 2014, the Company had granted an aggregate of 12,075,770 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 7,781,630 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,		
	2014	2013	2012
Employees and directors:			
Estimated volatility	51.26%	55.91%	60.67%
Expected life in years	5.84	5.82	5.64
Risk free interest rate	1.79%	1.16%	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 5.84 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, 2014, 2013 and 2012 amounted to approximately \$17.61, \$15.95, and \$13.67, respectively. No options were granted to non-employees for the years ended December 31, 2014, 2013 and 2012.

During the year ended December 31, 2014, the Company granted 2,739,118 stock options and restricted stock awards to employees and directors under the 2006 Plan. The stock options were issued with a weighted average exercise price of \$36.54 per share. As a result of these grants the total compensation charge to be recognized over the service period is \$51.1 million, of which \$9.7 million was recognized during the year ended December 31, 2014.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$29.4 million, \$25.1 million, and \$21.4 million, for the years ended December 31, 2014, 2013 and 2012, respectively. There were no compensation costs capitalized in inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, sales and marketing and general and administrative expense based on employee job function. The following table summarizes share-based compensation expense included within the Company's consolidated statements of operations:

(In thousands)	Year ended December 31,		
	2014	2013	2012
Research and development	\$ 5,939	\$ 5,805	\$ 5,122
Selling, general and administrative	23,498	19,334	16,296
Total	<u>\$ 29,437</u>	<u>\$ 25,139</u>	<u>\$ 21,418</u>

A summary of share-based compensation activity for the year ended December 31, 2014 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, 2011	4,793	\$ 21.31		
Granted	1,292	25.69		
Forfeited and expired	(166)	27.98		
Exercised	(252)	17.24		
Balance at December 31, 2012	5,667	22.30		
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	6.9	\$92,053
Vested and expected to vest at December 31, 2014	7,695	\$ 28.98	6.9	\$91,513
Vested and exercisable at December 31, 2014	4,464	\$ 25.67	5.5	\$67,834

	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2014 (In thousands)	Weighted- average remaining contractual life	Weighted- average exercise price	Exercisable as of December 31, 2014 (In thousands)	Weighted- average exercise price
<b><u>Range of exercise price</u></b>					
\$2.45 - \$16.88	381	1.5	\$ 9.60	381	\$ 9.60
\$17.52 - \$21.97	755	4.0	20.20	730	20.17
\$22.00 - \$24.93	1,035	5.2	22.35	942	22.31
\$25.05 - \$29.92	1,245	7.0	26.88	804	26.73
\$30.12 - \$41.07	4,370	8.3	34.48	1,607	33.43
	<u>7,786</u>	<u>6.9</u>	<u>\$ 29.05</u>	<u>4,464</u>	<u>\$ 25.67</u>

### ***Restricted Stock Activity***

<b><u>Restricted Stock</u></b>	<b><u>Number of Shares (In thousands)</u></b>
Nonvested at December 31, 2011	377
Granted	320
Vested	(224)
Forfeited	(15)
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	<u>519</u>

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2014 totaled \$93.4 million and is expected to be recognized over a weighted average period of approximately 2.7 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, 2014, 2013 and 2012:

(In thousands, except per share data)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
<b>Basic and diluted</b>			
Net income	\$ 17,672	\$ 16,441	\$ 154,958
Weighted average common shares outstanding used in computing net income per share— basic	41,150	40,208	39,459
Plus: net effect of dilutive stock options and unvested restricted common shares	1,394	1,474	873
Weighted average common shares outstanding used in computing net income per share— diluted	42,544	41,682	40,332
Net income per share—basic	\$ 0.43	\$ 0.41	\$ 3.93
Net income per share—diluted	\$ 0.42	\$ 0.39	\$ 3.84

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

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

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

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
<b>Denominator</b>			
Stock options and restricted common shares	4,078	2,419	3,573
Convertible note	29	39	48

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)/benefit from income taxes is based on income before income taxes as follows:

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Income before taxes	\$ 28,009	\$ 28,863	\$ 24,268

The (provision for)/benefit from income taxes in 2014, 2013 and 2012 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Current:			
Federal	\$ (1,105)	\$ (665)	\$ (640)
State	(1,819)	(2,050)	(1,138)
Foreign	(732)	(154)	(574)
	<u>(3,656)</u>	<u>(2,869)</u>	<u>(2,352)</u>
Deferred:			
Federal	(6,085)	(6,815)	119,247
State	(596)	(2,738)	13,795
Foreign	<u>—</u>	<u>—</u>	<u>—</u>
	<u>(6,681)</u>	<u>(9,553)</u>	<u>133,042</u>
Total (provision for)/benefit from income taxes	<u>\$ (10,337)</u>	<u>\$ (12,422)</u>	<u>\$ 130,690</u>

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

Due to the amount of net operating loss (NOL) and tax credit carryforwards, the Company does not currently pay substantial U.S. federal income taxes. The Company expects to pay cash taxes in various US states and Puerto Rico where it has operations and NOL carryforwards are not available or limited. The Company was subject to the alternative minimum tax during 2014 and 2013 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 \$215.2 million and \$173.8 million and state NOL carryforwards of approximately \$14.7 million and \$22.8 million as of December 31, 2014 and 2013, respectively, which are available to offset future taxable income. The net operating loss carryforwards include approximately \$31.9 million of deductions related to the exercise of stock options. This amount represents an excess tax benefit of \$11.2 million and has not been included in the gross deferred tax asset reflected. The tax benefit 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 2004 is subject to review. In 2013 the Company completed an IRS exam for tax years 2009 through 2011 with no material findings. The Company also has research and development credit carry-forwards of \$11.9 million and \$6.4 million as of December 31, 2014 and 2013, respectively that are subject to expiration starting in 2017. The Company also has Alternative Minimum Tax credit carry-forwards of \$3.3 million and \$2.2 million as of December 31, 2014 and 2013, 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 current limitation was triggered in the current period for 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, 2014	Year ended December 31, 2013	Year ended December 31, 2012
U.S. federal statutory tax rate	35.0%	35.0%	35.0%
State and local income taxes	3.7%	10.7%	2.4%
Foreign income tax	1.8%	0.1%	1.5%
Stock option compensation	0.5%	2.0%	1.9%
Stock option shortfall	—	0.3%	5.6%
Neuronex acquisition	—	—	9.4%
Research and development credit	(13.2%)	(7.6%)	—
Other nondeductible and permanent differences	6.9%	2.5%	3.3%
Provision (benefit) attributable to valuation allowance	2.2%	—	(597.6%)
Effective income tax rate	36.9%	43.0%	(538.5%)

The effective tax rate related to state taxes reflects 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.

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, 2014	December 31, 2013
Deferred tax assets:		
Net operating loss and other carryforwards	\$ 69,149	\$ 52,017
Tax credits	13,199	6,871
Deferred revenue	29,144	33,557
Stock based compensation	22,776	19,030
Amortization	—	7,912
Other	11,359	7,912
Total deferred tax assets	145,627	127,299
Valuation allowance	(5,497)	—
Total deferred tax assets net of valuation allowance	140,130	127,299
Deferred tax liabilities:		
Intangible assets	(123,593)	—
Convertible debt	(22,002)	—
Total deferred tax liabilities	(145,595)	—
Net deferred tax asset (liability)	\$ (5,465)	\$ 127,299

(In thousands)	December 31, 2014	December 31, 2013
<b>Current deferred tax assets, net:</b>		
Current deferred tax assets, net of deferred tax liabilities	\$ 19,143	\$ 19,314
Valuation allowance	(723)	—
Current deferred tax assets, net	18,420	19,314
<b>Non-current deferred tax assets, net:</b>		
Non-current deferred tax assets, net of deferred tax liabilities	(19,111)	107,985
Valuation allowance	(4,774)	—
Non-current deferred tax assets (liabilities), net	(23,885)	107,985
<b>Net deferred tax asset (liability)</b>	<b>\$ (5,465)</b>	<b>\$ 127,299</b>

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

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

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Beginning of period balance	\$ 2,244	\$ 1,936	\$ —
Increases for tax positions taken during a prior period	451	589	1,936
Decreases for tax positions taken during a prior period	(200)	(511)	—
Increases for tax positions taken during the current period	800	230	—
Reduction as a result of a lapse of statute of limitations	—	—	—
	<b>\$ 3,295</b>	<b>\$ 2,244</b>	<b>\$ 1,936</b>

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.

On September 13, 2013, the Internal Revenue Service issued final Tangible Property Regulations (TPR) under Internal Revenue Code (IRC) Section 162 and IRC Section 263(a), which prescribe the capitalization treatment of certain repair costs, asset betterments and other costs which could affect temporary deferred taxes. Although the regulations are not effective until tax years beginning on or after January 1, 2014, certain portions may require an accounting method change on a retroactive basis, thus requiring an IRC Section 481(a) adjustment related to fixed and real asset deferred taxes. Pursuant to U.S. GAAP, as of the date of the issuance, the release of the regulations is treated as a change in tax law. Therefore, the Company is required to determine whether there will be an impact on its financial statements. The Company is currently analyzing the expected impact of the new

regulations and does not believe the impact will be material to its financial position or results of operations. The Company will continue to monitor any future changes in the TPR prospectively.

## **(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 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, 2014 the unpaid principal was convertible into 28,918 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 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.

As of December 31, 2014, the Company made or accrued royalty payments totaling \$27.8 million.

### *Biogen Idec*

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

Under the Collaboration Agreement, the Company was entitled to an upfront payment of \$110.0 million as of June 30, 2009, which was received in July 2009, and a \$25 million milestone payment upon approval of the product in the European Union, which was received in August 2011. The Company is also entitled to receive additional payments of up to \$10 million based on the successful achievement of future regulatory milestones and up to \$365 million based on the successful achievement of future sales milestones. Due to the uncertainty

surrounding the achievement of the future regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned. The Company is not able to reasonably predict if and when the milestones will be achieved. Under the Collaboration Agreement, Biogen Idec will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen Idec will pay for licensed products under the Supply Agreement will reflect the price owed to the Company's suppliers under its supply arrangements with Alkermes or other suppliers for ex-U.S. sales. The Company and Biogen Idec may also carry out future joint development activities regarding licensed product under a cost-sharing arrangement. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen Idec, will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Ampyra independently in the United States.

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

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

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen Idec as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized \$9.1 million in amortized license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$634,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during each of the twelve-month periods ended December 31, 2014, 2013 and 2012.

On January 21, 2011 Biogen Idec announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of Fampyra to improve walking ability in adult patients with multiple sclerosis. Biogen Idec, working closely with the Company, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). The Company changed the amortization period on a prospective basis during the three-month period ended March 31, 2011 by five months and currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

As part of its ex-U.S. license agreement, Biogen Idec owes Acorda royalties based on ex-U.S. net sales,

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

Cost of milestone and license revenue includes \$634,000 in cost of license revenue for the twelve-month periods ended December 31, 2014, 2013 and 2012, which represents the amortized portion of the \$7.7 million paid to Alkermes in 2009.

### *Actavis/Watson*

The Company has an agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, which was launched in February 2012. In accordance with the agreement, the Company receives a royalty based on Watson's gross margin, as defined by the agreement, of the authorized generic product. During the twelve-month periods ended December 31, 2014 and 2013, the Company recognized royalty revenue of \$9.1 million and \$7.8 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the twelve-month periods ended December 31, 2014 and 2013, the Company also recognized revenue and a corresponding cost of sales of \$4.6 million and \$3.2 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Actavis, 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 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 (its trade name for Diazepam Nasal Spray). Plumiaz is a proprietary nasal spray formulation of diazepam that it is 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 intermittent bouts of increased seizure activity also known as seizure clusters or acute repetitive seizures, or ARS.

Under the terms of the agreement, the Company made an upfront payment of \$2.0 million in February 2012. The Company also paid \$1.5 million during the twelve month period ended December 31, 2012 pursuant to a commitment under the agreement to fund research to prepare for the 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 \$300,000 holdback provision. After adjustment for Neuronex's working capital upon closing of the acquisition, approximately \$120,000 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.

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

The patent and other intellectual property and other rights relating to 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 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 the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

The Company evaluated the transaction based upon the guidance of ASC 805, *Business Combinations*, and concluded that it will only acquire inputs and did not acquire any processes. The Company 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 twelve-month period 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 \$1.9 million, \$1.5 million and \$1.3 million for the years ended December 31, 2014, 2013, and 2012, 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 being 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 \$4.1 million per year, which reflects an annual 2.5% escalation factor as well as the recent expansion, described above.

#### ***Chelsea, Massachusetts***

The Company's 2014 acquisition of Civitas Therapeutics, Inc. 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 subleases the Chelsea, Massachusetts facility from Alkermes, Inc. The sublease is an operating lease that expires December 31, 2015, which Civitas may extend for two five-year terms. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and Civitas will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period. Alkermes leases the building from H&N Associates, LLC pursuant to an overlease dated December 6, 2000, as amended. Civitas assumed all of Alkermes's rights and obligations under the overlease. The base rent is currently \$722,000 per year.

Future minimum commitments under all non-cancelable operating leases subsequent to December 31, 2014 are as follows:

(In thousands)	
2015	\$ 4,787
2016	4,353
2017	4,462
2018	4,573
2019	4,688
Later years	16,780
	<u>\$ 39,643</u>

Rent expense under these operating leases during the years ended December 31, 2014, 2013 and 2012 was approximately \$6.2 million, \$3.4 million, and \$2.3 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 \$204 million over the life of the contracts. The FDA approval of Ampyra triggered a milestone of \$2.5 million to Alkermes that was paid during the quarter ended June 30, 2010. An additional milestone payment to Alkermes was paid during the quarter ended March 31, 2012 with an additional \$2.5 million recorded as an intangible asset. Further milestone amounts are payable in connection with additional indications.

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

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

Under the Company's supply agreement with Alkermes, it provides Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for its supply requirements of Ampyra and two-year forecasts for its supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra following the submission of 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.

### ***Employment Agreements***

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

year annual bonus and (y) target annual bonus for the year of termination. The Chief Executive Officer is also entitled to COBRA premium payments for the 24 month severance period.

The Company also has employment agreements with some of its other executive officers, including the Company's Chief Scientific Officer, President, International and General Counsel, Chief Financial Officer, and Chief of Business Operations that govern the terms and conditions of their employment. These agreements were amended during 2011 with the exception of the agreement with the Chief Financial Officer which was executed in 2014. Under these agreements as amended, if the Company terminates the employment of any of the executive officers for reasons other than cause, or if any of the executive officers terminates his or her employment for good reason, the Company must (i) make severance payments equal to the base salary the executive would have received during the twelve month period immediately following the date of termination, plus (ii) a bonus equal to the executive officer's target cash bonus for the year of termination, prorated based on the number of days in the calendar year elapsed as of the termination date. If the termination occurs within 18 months after a change in control, then the severance payment is 24 months of base salary and is paid in a lump sum, and the bonus is an amount equal to two (2) times the executive officer's target cash bonus for the year of termination. The executive officers are also entitled to COBRA premium payments for the relevant severance period.

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

### ***Other***

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, 2014. Litigation expenses are expensed as incurred.

The Company is currently party to the other legal proceedings described in Part I, Item 3 of this annual report on Form 10-K, 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 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 the matters described in Part I, Item 3, Legal Proceedings, of this annual report on Form 10-K, 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.

## **(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 episodes 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 episodes 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.

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

In April 2011 the Company announced the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/010,828 entitled "Sustained Release Aminopyridine Composition." The claims of the patent application relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issued from this application was accorded an initial patent term adjustment by the USPTO of 298 days, initially extending its term to early October 2025. In August 2011 the USPTO issued the Company's Patent Application No. 11/010,828 as U.S. Patent No. 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.

### 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, 2014, 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, 2014	December 31, 2013	Estimated remaining useful lives as of December 31, 2014
In-process research & development – CVT-301/ARCUS	\$ 423,000	\$ —	Indefinite-lived
In-process research & development – NP-1998	—	6,991	n/a
Ampyra milestones	5,750	5,750	12 years
Ampyra CSRO royalty buyout	3,000	3,000	5 years
Qutenza developed technology	—	450	n/a
Website development costs	11,319	8,435	1-3 years
Website development costs – in process	306	492	3 years
	443,375	25,118	
Less accumulated amortization	10,553	7,659	
	<u>\$ 432,822</u>	<u>\$ 17,459</u>	

The Company recorded \$3.3 million and \$2.4 million in amortization expense related to these intangible assets in the years ended December 31, 2014 and 2013, 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 three-month period ended December 31, 2014.

Estimated future amortization expense for intangible assets subsequent to December 31, 2014 is as follows:

(In thousands)	
2015	\$ 3,014
2016	2,099
2017	1,331
2018	588
2019	588
Thereafter	2,202
	<u>\$ 9,822</u>

### Goodwill

At December 31, 2014, the Company recorded goodwill associated with the acquisition of Civitas

Therapeutics. The carrying value of goodwill at December 31, 2014 was approximately \$183.0 million.

The change in the carrying value of goodwill is as follows:

Balance at December 31, 2013	\$	—
Acquisition of Civitas Therapeutics		182,952
Balance at December 31, 2014	\$	<u>182,952</u>

## **(14) Debt**

### ***Convertible Senior Notes***

On June 17, 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 (File No. 333-196803) (the Registration Statement) and a related preliminary and final prospectus supplement, filed with the Securities and Exchange Commission (the Offering). The principal amount of Notes includes \$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 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, beginning on December 15, 2014. The first payment was made on December 9, 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 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.

The outstanding note balances as of December 31, 2014 consisted of the following:

(In thousands)	December 31, 2014
Liability component:	
Principal	\$ 345,000
Less: debt discount, net	(57,301)
Net carrying amount	\$ 287,699
Equity component	\$ 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 carrying amount of the Company's borrowings of \$287.7 million approximated fair value at December 31, 2014.

As of December 31, 2014, the remaining contractual life of the Notes is approximately 6.5 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through December 31, 2014. The following table sets forth total interest expense recognized related to the Notes for the year ended December 31, 2014:

	<b>Year ended December 31, 2014</b>
(In thousands)	
Contractual interest expense	\$ 3,153
Amortization of debt issuance costs	397
Amortization of debt discount	3,894
Total interest expense	<u>\$ 7,444</u>

### ***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 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 \$1.7 million, \$2.0 million and \$1.7 million in interest expense related to this agreement in 2014, 2013 and 2012, respectively. Through December 31, 2014, \$50.8 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 Company does not currently intend to exercise its call option if it becomes exercisable as a result of such a transaction but may reevaluate whether it would exercise the option during the 180-day period. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF as of such date, less all payments received by PRF/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, 2014 the Company has 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.

## **(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.

### ***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, 2014 and December 31, 2013, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(In thousands)	Level 1	Level 2	Level 3
<b>2014</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 149,754	\$ —	\$ —
Short-term investments	—	125,448	—
Long-term investments	—	—	—
<b>Liabilities Carried at Fair Value:</b>			
Acquired contingent consideration	—	—	52,600
Put/call liability	—	—	—
Contingent purchase price	—	—	—
<b>2013</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 28,308	\$ —	\$ —
Short-term investments	—	225,891	—
Long-term investments	—	93,299	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability	—	—	147
Contingent purchase price	—	—	236

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, 2014	Year ended December 31, 2013
<b>Acquired contingent consideration:</b>		
Balance, beginning of period	\$ —	\$ —
Fair value of acquired contingent consideration as of October 22, 2014	50,400	—
Total (gains) losses included in the statement of operations	2,200	—
Balance, end of period	<u>\$ 52,600</u>	<u>\$ —</u>

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach. 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. 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 the estimated CVT-301 and CVT-427 revenue forecasts and the probability factors, the estimated fair value could be significantly higher or lower than the fair value determined. The Company may be required to record losses in future periods, which may be significant.

### *Put/call liability*

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013
<b>Put/call liability:</b>		
Balance, beginning of period	\$ 147	\$ 329
Total (gains) losses included in selling, general and administrative expenses	(147)	(182)
Balance, end of period	<u>\$ —</u>	<u>\$ 147</u>

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

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

### *Contingent purchase price*

(In thousands)	Year ended December 31, 2014	Year ended December 31, 2013
<b>Contingent purchase price:</b>		
Balance, beginning of period	\$ 236	\$ —
Fair value of contingent purchase price acquired as of July 8, 2013	—	205
Total (gains) losses included in selling, general and administrative expenses:	(236)	31
Balance, end of period	<u>\$ —</u>	<u>\$ 236</u>

The Company measured the fair value of the contingent purchase price using a Monte Carlo simulation. Using this approach, the present value of each of the milestone payments is calculated using the probability of milestone achievement under various different scenarios. Some of the more significant assumptions used in the valuation included (i) the probability of FDA approval for NP-1998 and (ii) the variability in net sales for NP-1998 if FDA approval is achieved. The milestone achievement probabilities ranged from 0% to 10%, and the milestone payment outcomes range from \$0 to \$5.0 million. The valuation was performed periodically when the significant assumptions changed. Fair value adjustments are included in selling, general and administrative

expenses. Refer to Note 3 for more information on the milestones associated with the contingent consideration liability.

The contingent purchase price was classified as a Level 3 liability as its valuation requires significant 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 probability of FDA approval for NP-1998 and the likelihood of trigger events, the estimated fair value could have been significantly higher or lower than the fair value determined.

### ***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 2013.

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

The Company has evaluated and reprioritized its research and development pipeline based on the recent 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.

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

(In thousands, except per share amounts)

	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 (1)	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

	2013			
	March 31	June 30	September 30	December 31
Total net revenues	\$ 71,865	\$ 87,053	\$ 84,919	\$ 92,593
Gross profit	58,223	69,960	67,548	74,057
Net income (loss)—basic and diluted	(1,139)	3,910	7,477	6,193
Net income (loss) per share—basic	\$ (0.03)	\$ 0.10	\$ 0.19	\$ 0.15
Net income (loss) per share—diluted	(0.03)	0.09	0.18	0.15

(1) 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.

**(b) Exhibits.**

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

<b>Exhibit No.</b>	<b>Description</b>
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	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.
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.
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.

Exhibit No.	Description
10.4**	Acorda Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.5**	Acorda Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2006. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.
10.6**	Forms of Equity Award Documents. Incorporated herein by reference to Exhibit 10.58 to Registrant's Annual Report on Form 10-K filed on March 1, 2011.
10.7**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.8**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.9**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.10**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.11**	Amendment to August 11, 2002 Employment Agreement dated June 21, 2011, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.12**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.13**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.14**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.67 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.15**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.16**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.17**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.68 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.18**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Exhibit No.	Description
10.19**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.20**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.69 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.21**	Employment offer letter, dated 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.
10.22**	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.
10.23**	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.
10.24**	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.
10.25**	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.
10.26**	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.
10.27**	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.
10.28**	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.
10.29**	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.
10.30**	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.
10.31**	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.
10.32**	Restricted Stock Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman.
10.33**	Letter agreement dated September 4, 2012, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 8, 2012.

Exhibit No.	Description
10.34	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.
10.35	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.
10.36	Lease Agreement, dated as of December 6, 2000, by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.37	First Amendment, dated August 22, 2002, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.38	Second Amendment, dated December 4, 2006, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.39	Sublease Agreement, dated December 27, 2010, by and between Alkermes, Inc. and Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.).
10.40	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.
10.41	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.
10.42	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.
10.43	First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.l. and Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.
10.44	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.
10.45*	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.
10.46	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.
10.47*	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.

Exhibit No.	Description
10.48*	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.
10.49	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.
10.50*	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.
10.51	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.
10.52*	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.
10.53*	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.
10.54	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.
10.55	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.
10.56	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.
10.57	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.
10.58*	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.
10.59*	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.
10.60*	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.
10.61*	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.

Exhibit No.	Description
10.62*	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.
10.63	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.
10.64*	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.
10.65*	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.
10.66	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.
10.67	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.
10.68	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.
10.69	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.
10.70	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.
10.71	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.
10.72*	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.
10.73*	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.
10.74*	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.
10.75*	Asset Purchase and License Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.) and Alkermes, Inc.

<b>Exhibit No.</b>	<b>Description</b>
10.76*	Amendment to Asset Purchase and License Agreement, dated as of December 9, 2011, by and between Civitas Therapeutics, Inc. and Alkermes, Inc.
10.77*	Second Amendment to Asset Purchase and License Agreement, dated as of December 19, 2014, by and between 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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\* 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 27th day of February, 2015.

### ACORDA THERAPEUTICS, INC.

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RON COHEN, M.D.</u> Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2015
<u>/s/ MICHAEL ROGERS</u> Michael Rogers	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2015
<u>/s/ BARRY GREENE</u> Barry Greene	Director	February 27, 2015
<u>/s/ PEDER K. JENSEN, M.D.</u> Peder K. Jensen, M.D.	Director	February 27, 2015
<u>/s/ JOHN P. KELLEY</u> John P. Kelley	Director	February 27, 2015
<u>/s/ SANDRA PANEM, PH.D.</u> Sandra Panem, Ph.D.	Director	February 27, 2015
<u>/s/ LORIN J. RANDALL</u> Lorin J. Randall	Director	February 27, 2015
<u>/s/ STEVEN M. RAUSCHER, M.B.A.</u> Steven M. Rauscher, M.B.A.	Director	February 27, 2015
<u>/s/ IAN SMITH</u> Ian Smith	Director	February 27, 2015

## EXHIBIT INDEX

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
10.31**	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.
10.32**	Restricted Stock Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman.
10.36	Lease Agreement, dated as of December 6, 2000, by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.37	First Amendment, dated August 22, 2002, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.38	Second Amendment, dated December 4, 2006, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc.
10.39	Sublease Agreement, dated December 27, 2010, by and between Alkermes, Inc. and Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.).
10.75*	Asset Purchase and License Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.) and Alkermes, Inc.
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  - \*\* 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.”

Option Number: NQ4060

27,768 Shares

**ACORDA THERAPEUTICS, INC.****2006 Employee Stock Option Plan  
Non-Statutory Stock Option Certificate**

Acorda Therapeutics, Inc. (the "Company"), a Delaware corporation, hereby grants to the person named below an option to purchase shares of Common Stock, par value \$0.001 per share, of the Company (the "Option") under and subject to the Company's 2006 Employee Stock Option Plan (the "Plan") exercisable on the following terms and conditions and those set forth on the reverse side of this certificate:

Name of Optionee: Andrew Hindman  
 Address: 550 West 45th Street  
 #2903  
 New York, NY 10036  
 Social Security No: 559-51-5385  
 Number of Shares: 27,768  
 Option Price: \$30.35  
 Date of Grant: May 13, 2014  
 Vesting Start Date: May 13, 2014

The Option is not an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). **Please refer to the table below for the details of the Exercisability Schedule as well as your E-Trade account under the Stock Plan tab. Total vesting shall not exceed 27,768.**

**Exercisability Schedule**

Annual Shares	Vest Schedule Ending On Annual Vest Date	In Full
27,768	On Vest Date	May 13, 2017

Expiration Date: May 13, 2024

By acceptance of this Option, the Optionee agrees to the terms and conditions hereof.

**ACORDA THERAPEUTICS, INC.**

Date: \_\_\_\_\_

By: /s/ Ron Cohen  
 Name: Ron Cohen  
 Title: President & CEO

**ACCEPTED:**

/s/ Andrew Hindman  
 Andrew Hindman

Date: 11/13/14

## ACORDA THERAPEUTICS, INC. 2006 EMPLOYEE STOCK OPTION PLAN

### Non-Statutory Stock Option Terms and Conditions

1. Plan Incorporated by Reference. This Option is issued pursuant to the terms of the Plan and may be amended as provided in the Plan. Capitalized terms used and not otherwise defined in this certificate have the meanings given to them in the Plan. This certificate does not set forth all of the terms and conditions of the Plan, which are incorporated herein by reference. The Committee administers the Plan and its determinations regarding the operation of the Plan are final and binding. Copies of the Plan may be obtained upon written request without charge from the President of the Company. In the event of a conflict between the Plan and this certificate, the terms of the Plan shall control unless otherwise expressly provided for herein.
2. Option Price. The price to be paid for each share of Common Stock issued upon exercise of the whole or any part of this Option is the Option Price set forth on the face of this certificate.
3. Exercisability Schedule. Subject to Section 12 below, this Option may be exercised at any time and from time to time for the number of shares and in accordance with the exercisability schedule set forth on the face of this certificate, but only for the purchase of whole shares. This Option may not be exercised as to any shares after the Expiration Date.
4. Method of Exercise. To exercise this Option, the Optionee shall deliver written notice of exercise to the President of the Company specifying the number of shares with respect to which the Option is being exercised accompanied by payment of the Option Price for such shares in cash, by certified check or in such other form, including shares of Common Stock of the Company valued at their Fair Market Value on the date of delivery, as the Committee may at the time of exercise approve. Promptly following such notice, the Company will deliver to the Optionee a certificate representing the number of shares with respect to which the Option is being exercised.
5. Non-Statutory Stock Option. The Option is a Non-Statutory Stock Option.
6. Rights as a Stockholder or Employee. The Optionee shall not have any rights in respect of shares as to which the Option shall not have been exercised and payment made as provided above. The Optionee shall not have any rights to continued employment by the Company or any Subsidiary by virtue of the grant of this Option.
7. Tender Offer; Change in Control. Subject to Section 12 below, as provided in the Plan, in the event of certain corporate transactions affecting the Company's outstanding Common Stock, if this Option is not assumed or substituted as described in the Plan, the Option may be adjusted or terminated as set forth in the Plan.
8. Option Not Transferable. This Option is not transferable by the Optionee otherwise than by will or the laws of descent and distribution, and is exercisable, during the Optionee's lifetime, only by Optionee. Any attempted assignment, transfer, pledge, hypothecation or other disposition other than in accordance with the terms set forth herein and in the Plan shall be void and of no effect.
9. Compliance with Securities Laws. It shall be a condition to the Optionee's right to purchase shares of Common Stock hereunder that the Company may, in its discretion, require (a) that the shares of Common Stock reserved for issue upon the exercise of this Option shall have been duly listed, upon official notice of issuance, upon any national securities exchange or automated quotation system on which the Company's Common Stock may then be listed or quoted, (b) that either (i) a registration statement under the Securities Act of 1933 with respect to the shares shall be in effect, or (ii) in the opinion of counsel for the Company, the proposed purchase shall be exempt from registration under that Act and the Optionee shall have made such undertakings and agreements with the Company as the Company may reasonably require, and (c) that such other steps, if any, as counsel for the Company shall consider necessary to comply with any law applicable to the issue of such shares by the Company shall have been taken by the Company or the Optionee, or both. The certificates representing the shares purchased under this Option may contain such legends as counsel for the Company shall consider necessary to comply with any applicable law.
10. Payment of Taxes. The Optionee shall pay to the Company, or make provision satisfactory to the Company for payment of, any taxes required by law to be withheld with respect to the exercise of this Option. The Committee may, in its discretion, require any other Federal or state taxes imposed on the sale of the shares to be paid by the Optionee. In the Committee's discretion, such tax obligations may be paid in whole or in part in shares of Common Stock, including shares retained from the exercise of this Option, valued at their Fair Market Value on the date of delivery. The Company and its Subsidiaries may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to the Optionee.
11. Vesting Upon Death. In the event of the Optionee's death while this Option is outstanding, this Option shall become fully vested, notwithstanding the vesting schedule in the Non-Statutory Stock Option Certificate, provided that:
  - i) the Optionee had at least one full year of service with the Company and had not been on probation during the 24-month period preceding death;
  - ii) the Optionee had not been on disability for longer than two consecutive years at the time of death; and
  - iii) the Optionee's death was not due to suicide or did not result from any illness, injury, or disease that resulted from illegal drug use; was not incurred while the Optionee was engaged in criminal conduct; or was not intentionally self-inflicted.
12. Change in Control. Notwithstanding Section 11(b) of the Plan, if a Reorganization Event occurs while this Option is outstanding (other than a Reorganization Event constituting a Change in Control, as defined below, within three (3) years after the Date of Grant specified herein) and a successor corporation does not assume this Option or an equivalent Award is not substituted as provided under Section 11(a) of the Plan, then the Committee shall, upon written or electronic notice to the Optionee, provide that one of the following will occur with respect to this Option:

i) this Option will become exercisable in full (or free from restrictions, as applicable) as of a specified time prior to the Reorganization Event and will terminate immediately prior to the consummation of such Reorganization Event, except to the extent exercised or sold by the Optionee prior to the consummation of the Reorganization Event; or

ii) this Option will terminate upon consummation of such Reorganization Event and the Optionee will receive, in exchange therefore, a cash payment equal to the amount (if any) by which (x) the amount payable in the Reorganization Event with respect to shares of Stock multiplied by the number of shares of Stock subject to this Option exceeds (y) the aggregate exercise price (if any) of this Option.

Notwithstanding anything to the contrary contained elsewhere in the Non-Statutory Stock Option Certificate or in Section 11 of the Plan, upon the occurrence of a Change in Control within three (3) years after the Date of Grant specified herein, this Option shall thereupon immediately be forfeited and terminate.

For purposes of this Section 12, a Change in Control refers to any of the following events: a consolidation or merger of the Company if, after such consolidation or merger, shareholders of the Company immediately prior to such merger or consolidation hold, directly or indirectly, less than 50% of the voting stock of the surviving entity; a sale or transfer of all or substantially all of the assets of the Company in one or a series of transactions or a complete liquidation or dissolution of the Company; or any individual or entity or group acting in concert and affiliates thereof, acquires, directly or indirectly, more than 50% of the outstanding shares of voting stock of the Company.

13. Entire Understanding. This certificate and the Plan constitute the entire understanding between the Optionee and the Company regarding the Option. Any prior agreements, commitments, or negotiations concerning the Option are superseded.

Restricted Stock Number: R-4062

## RESTRICTED STOCK AGREEMENT

This Agreement is entered into as of the May 13, 2014 by and between ACORDA THERAPEUTICS, INC., a Delaware corporation (“Company”), and Andrew Hindman (“Employee”) at 1020 Vallejo Street, Apt 6, San Francisco, CA 94133.

WITNESSETH:

NOW, THEREFORE, in consideration of the mutual covenants herein contained and other good and valuable consideration, in accordance with the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan, as amended and restated (the “Plan”) the parties hereto hereby agree as follows:

1. Grant. Simultaneously herewith, the Company has made a restricted stock award to Employee and has issued 9,256 shares of the Company’s common stock, \$.001 par value per share (such common stock hereinafter being referred to as the “Common Stock” and such shares hereinafter being referred to as the “Restricted Stock”), registered in the name of Employee, subject to the terms of the Plan and the restrictions and provisions of this Agreement.

2. Treatment During Restricted Period.

a. *Certificates*. Each certificate representing shares of Restricted Stock shall be registered in the name of the Employee and held, together with a stock power endorsed in blank, by the Company, subject to the provisions hereof. Each certificate of Restricted Stock shall bear a legend reflecting the limitation of transferability, the risk of forfeiture and other restrictions under this Agreement and applicable securities law restrictions.

b. *Restrictions Applicable Prior to Vesting*. Shares of Restricted Stock shall be subject to the following restrictions until they vest:

i) *Nontransferability*. Except as otherwise required by law, Restricted Stock which has not vested may not be sold, assigned, exchanged, transferred, pledged, hypothecated or otherwise disposed of, except to the Company as provided herein.

ii) *Voting*. Employee hereby appoints the Company’s General Counsel or any successor appointed by the Company (the “Trustee”) to act as Employee’s proxy, and grants the Trustee the power to vote the unvested shares of Restricted Stock at any annual or special meeting of stockholders of the Company, or any adjournment or adjournments thereof at which the shares would be entitled to vote. The Trustee will vote such shares in connection with any matter on a pro rata basis in accordance with all other shares voted with respect to such matter. This proxy is coupled with an interest and is irrevocable.

iii) *Dividends and Distributions*. Any cash dividends or other distributions in respect of the shares of Restricted Stock, including, but not limited to, shares received as a result of a stock dividend, stock split, combination of shares or otherwise, shall be retained by the Company and either delivered together with the applicable shares in accordance with Section 2(e) hereof or forfeited together with the applicable shares in accordance with Section 2(c) hereof. In no event shall any dividend or distribution be paid later than 2-1/2 months after the calendar year in which such dividend or distribution is no longer subject to a substantial risk of forfeiture.

iv) *Other Restrictions*. The Board may impose such other restrictions on the Restricted Stock as it may deem advisable, including, without limitation, stop-transfer orders and other restrictions set forth in the terms of this Agreement or as the Board may reasonably deem advisable.

c. *Forfeiture*. If Employee’s employment terminates before all of the shares of Restricted Stock are vested in accordance in Section 2 (d), any of the shares of Restricted Stock that are unvested or otherwise subject to restrictions shall be forfeited to the Company on the effective date of the termination of Employee’s employment.

d. *Vesting; Termination of the Restricted Period.* The shares of Restricted Stock shall no longer be subject to the forfeiture provisions of Section 2(c) ( *i.e.* , the shares shall vest) in accordance with the following schedule. To the extent that Employee remains continuously employed by the Company:

9,256 shares will vest in full on May 13, 2017. The restricted shares under this special grant will not be subject to 100% vesting in the event of a Change in Control.

e. *Vesting Upon Death.* In the event of the Employee's death while the restricted stock award is outstanding, such award shall immediately become fully vested, notwithstanding the vesting schedule in this Agreement, provided that:

- (i) the Employee had at least one full year of service with the Company and had not been on probation during the 24-month period preceding death;
- (ii) the Employee had not been on disability for longer than two consecutive years at the time of death; and
- (iii) the Employee's death was not due to suicide or did not result from any illness, injury, or disease that resulted from illegal drug use; was not incurred while the Employee was engaged in criminal conduct; or was not intentionally self-inflicted.

f. *Delivery following Vesting .* Promptly after they become vested, the Company shall deliver to Employee (or Employee's legal representative) the shares of vested Restricted Stock in the form of a transferable certificate, with a legend reflecting any applicable securities law restrictions; provided, however, that the Company need not deliver such shares to Employee until Employee has paid or caused to be paid all taxes required to be withheld pursuant to Section 3 hereof.

3. Withholding. The Company may withhold any taxes resulting from this Agreement that the Company determines it is required to withhold under the laws and regulations of any governmental authority, whether federal, state or local and whether domestic or foreign. Subject to applicable legal requirements, Employee may elect to satisfy such withholding requirements either by (i) delivery to the Company of a certified check prior to the delivery of shares of Restricted Stock which are vested pursuant to Section 2, (ii) if agreed to at the time by the Company, instructing the Company to retain a sufficient number of shares of Restricted Stock to cover the withholding requirements, (iii) instructing the Company to satisfy the withholding requirements from Employee's salary; or (iv) any other method acceptable to the Company.

4. Notice. All notices, requests, demands, waivers and communications required or permitted to be given hereunder shall be in writing and shall be delivered in person or mailed, certified or registered mail with postage prepaid, or sent by facsimile, as follows:

If to the Company, to:

Acorda Therapeutics, Inc.  
420 Saw Mill River Road  
Ardsley, New York 10502  
Facsimile: (914) 347-4560  
Attention: Chief Financial Officer

If to Employee, to his last known mailing address specified in the Company's employee records.

or to such other address as either party hereto shall specify by notice in writing to the other party in accordance with this Section. All such notices, requests, demands, waivers and communications shall be deemed to have been received on the date when given unless mailed, in which case on the third business day after the mailing.

5. No Employment Rights. Nothing contained in this Agreement shall restrict in any way the right of the Company to terminate Employee's employment at any time, with or without cause. As used throughout this Agreement, the term "employment" includes employment with the Company, a subsidiary of the Company or an affiliate of the Company.

6. Award Subject to Plan. Employee acknowledges receipt of a copy of the Plan. The Restricted Stock grant has been made pursuant to the Plan and is in all respects subject to the terms and conditions thereof. In the event of any conflict between this Agreement and the Plan, the terms of the Plan shall control.

7. Board Determinations. In the event that any question or controversy shall arise with respect to the nature, scope or extent of any one or more rights conferred by this Agreement, the determination by the Board (or the Committee established by the Board to administer the Plan) of the rights of the Employee shall be conclusive, final and binding upon Employee and upon any other person who shall assert any right pursuant to this Agreement.

8. Change in Control. Notwithstanding Section 11(b) of the Plan, if a Reorganization Event occurs while the restricted stock award is outstanding and a successor corporation does not assume the restricted stock award or an equivalent award is not substituted as provided under Section 11(a) of the Plan, then the Committee shall, upon written or electronic notice to the Employee, provide that one of the following will occur with respect to the restricted stock award:

i) the restricted stock award will become vested in full and free from restrictions as of a specified time prior to the Reorganization Event and will terminate immediately prior to the consummation of such Reorganization Event, except to the extent sold by the Employee prior to the consummation of the Reorganization Event; or

ii) the restricted stock award will terminate upon consummation of such Reorganization Event and the Employee will receive, in exchange therefore, a cash payment equal to the amount payable in the Reorganization Event with respect to a share of Stock multiplied by the number of shares of Stock subject to the restricted stock award.

9. Definitions. All capitalized terms herein not otherwise defined shall have the meanings set forth in the Plan.

10. Assignment. The Company may assign its rights hereunder. Employee may not assign any of his rights hereunder. Neither party may assign any of their obligations hereunder.

By acceptance of this Award, the Awardee agrees to the terms and conditions hereof.

**ACORDA THERAPEUTICS, INC.**

Date: \_\_\_\_\_

By: /s/ Ron Cohen  
Name: Ron Cohen  
Title: President & CEO

**ACCEPTED:**

/s/ Andrew Hindman  
Andrew Hindman

Date: 11/13/14

LEASE

LANDLORD: H&N Associates, LLC, a Massachusetts Limited Liability Company

TENANT: Advanced Inhalation Research, Inc., a Delaware Corporation

PROPERTY: Brickyard Square  
190 Everett Avenue  
Chelsea, Massachusetts

DATED: December 6, 2000

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Lease dated as of the 6<sup>th</sup> day of December, 2000, by and between H&N Associates, LLC, a Massachusetts Limited Liability Company, as landlord ("Landlord"), and Advanced Inhalation Research, Inc., a Delaware Corporation, as tenant ("Tenant").

## ARTICLE I

### REFERENCE DATA

#### 1. (A)SUBJECTS REFERRED TO:

Each reference in this lease to any of the following subjects shall be construed to incorporate the data stated for that subject in this Section 1(A):

LANDLORD'S ADDRESS: c/o HCG & Associates, Inc.

637 Washington Street

Suite 200

Brookline, MA 02446

TENANT'S ADDRESS: 190 Everett Avenue, Chelsea, MA 02150

#### PROPERTY:

The land and improvements thereon and known as Brickyard Square, 190 Everett Avenue, Chelsea, Massachusetts

#### RENTABLE FLOOR AREA OF TENANTS SPACE:

All the rentable floor space in all the buildings on the property, including the buildings shown as buildings A, B, C, D and the garage on the site plan of the Property and containing approximately 90,675 square feet of floor area, but specifically excluding the square footage of the smoke stack

TOTAL RENTABLE FLOOR AREA OF ALL THE BUILDINGS ON THE PROPERTY:  
90,675 SQUARE FEET

COMMENCEMENT DATE: DECEMBER 15, 2000

ORIGINAL TERM: APPROXIMATELY FIFTEEN (15) YEARS FROM THE  
COMMENCEMENT DATE

OPTIONS: TWO (2) OPTIONS TO EXTEND THE TERM FOR FIVE (5) YEARS  
EACH

#### FIXED RENT:

DURING THE PERIOD FROM DECEMBER 15, 2000 THROUGH APRIL 30, 2002, THE FIXED RENT PAYABLE SHALL BE \$524,964.75 PAYABLE AT THE RATE OF \$31,816.05 PER MONTH;

DURING THE PERIOD FROM MAY 1, 2002 THROUGH DECEMBER 31, 2005, FIXED RENT SHALL BE PAYABLE AT THE ANNUAL RATE OF \$524,964.75/\$43,747.06 PER MONTH;



DURING THE PERIOD FROM JANUARY 1, 2006, THROUGH DECEMBER 31, 2010 FIXED RENT SHALL BE PAYABLE AT THE ANNUAL RATE OF \$632,401.75/\$52,700.15 PER MONTH; AND

DURING EACH YEAR OF THE BALANCE OF THE ORIGINAL TERM, FIXED RENT SHALL BE PAYABLE AT THE ANNUAL RATE OF \$722,105.25/\$60,175.44 PER MONTH

ADDITIONAL RENT FOR REAL ESTATE TAXES AND OPERATING COSTS:

TENANT PAYS ALL REAL ESTATE TAXES AND OPERATING COSTS OF THE PROPERTY FROM AND AFTER MAY 1, 2001

SECURITY DEPOSIT: N/A

GUARANTOR: ALKERMES, INC.

PERMITTED USE:

FOR PHARMACEUTICAL MANUFACTURING PURPOSES AND RELATED GENERAL OFFICE USE AND FOR ALL OTHER LEGAL PURPOSES PERMITTED BY THE APPLICABLE ZONING REGULATIONS

PUBLIC LIABILITY INSURANCE LIMITS:

BODILY INJURY: \$5,000,000

PROPERTY DAMAGE: \$2,000,000

## (B) EXHIBITS

The exhibits listed below in this Section are incorporated in this lease by reference and are to be construed as part of this lease:

EXHIBIT A	Plan Showing the Demised Premises
EXHIBIT B	Landlord's Required Work
EXHIBIT C	Tenant's Work
EXHIBIT D	Landlord's Services
EXHIBIT E	Intentionally Omitted
EXHIBIT F	Legal Description of Lot
GUARANTEE	

## ARTICLE II

### PREMISES

#### 2. PREMISES

Subject to and with the benefit of the provisions of this lease, Landlord hereby leases to Tenant, and Tenant leases from Landlord, the entire premises set forth on Exhibit A and described on Exhibit A including, but not limited to the buildings shown as building "A", building "B", building "C" and building "D", and including the smoke stack subject, however, to easements, reservations and restrictions of record. Tenant agrees that in the event Tenant subleases or otherwise permits any other entity to use space on the smoke stack for communications devices, Tenant shall first obtain the approval of Landlord therefor, and any revenues received by Tenant for such use shall be shared equally with Landlord after first deducting from such revenue all third party costs and expenses, brokerage commissions, legal fees and the like related to such use of the smoke stack. Tenant may place an antenna for Tenant's use on the smoke stack. Tenant's space is hereinafter referred to as "the demised premises". The parcel of land on which the buildings are located is sometimes hereafter referred to as "the Lot". The Lot is represented by the area outlined by a bold line upon

said Exhibit A. It is understood and agreed that said plan is intended only to show the approximate size of the Lot as presently constituted and the approximate size and location of the buildings and for no other purpose.

## ARTICLE III

### TERM AND CONSTRUCTION

#### 3. (A) ORIGINAL TERM

To have and to hold for a period of fifteen (15) and a fraction years (“the Term” or “the Original Term”) commencing on December 15, 2000 (being hereafter referred to as “the Commencement Date”) and, unless sooner terminated as provided herein, ending on December 31, 2015.

#### (B) LANDLORD’S REQUIRED WORK

Landlord agrees to use reasonable efforts to complete Landlord’s Required Work as described in Exhibit B, and within the time set forth therein.

Landlord shall permit Tenant access (at Tenant’s sole risk) for installing equipment and furnishings in the demised premises prior to the Commencement Date if it can be done without material interference with, or delay of, Landlord’s Required Work in the demised premises and/or in other portions of the buildings.

#### (C) TENANT’S WORK

Tenant agrees that Tenant’s Work shall be in accordance with the provisions of Exhibit C and Tenant shall diligently perform all work necessary and if required in order to cause the demised premises to not violate any applicable building, safety, fire and health codes or applicable zoning ordinance.

#### (D) GENERAL CONSTRUCTION PROVISIONS

All construction work required or permitted by this lease, whether by Landlord or by Tenant, shall be done in a good and workmanlike manner and in compliance with all applicable laws and all lawful ordinances, regulations and orders of governmental authorities and insurance rating or inspection bureaus having jurisdiction over the buildings. Either party may inspect the work of the other at reasonable times and shall promptly give notice of observed defects.

#### (E) CONSTRUCTION ALLOWANCE

As an inducement for Tenant to execute this lease and prepare the demised premises for Tenant’s occupancy, Landlord shall pay to Tenant the sum of 197,225.00 for Tenant’s work in the office space comprising part of the demised premises; \$30,000.00 for Tenant’s work on the warehouse bathrooms; \$80,000.00 for Tenant’s Work on the sprinkler system; and \$70,000.00 for Tenant’s Work on the warehouse heating system. In addition, Landlord shall pay to Tenant an additional \$5,000.00 in the event Tenant installs its own floor covering in the 600 square foot lobby. So long as Tenant shall not then be in default in the performance of its agreements contained in this lease, Landlord shall pay said sums to Tenant upon the last to occur of: (a) the thirtieth (30th) day after the Tenant’s architect certifies that Tenant’s Work has been substantially completed; and (b) the receipt by Landlord of waivers of liens from all contractors supplying labor and/or material for Tenant’s work. In the event Landlord fails to pay said allowance to Tenant within thirty (30) days after notice from Tenant that same is past due, Tenant may offset the amount of said allowance that remains unpaid, together with interest on the unpaid sum at the Default Rate (as defined below), from fifty percent (50%) of the monthly fixed rent thereafter payable by Tenant until paid in full. This shall be Tenant’s sole remedy for Landlord’s failure to pay said construction allowance.

## ARTICLE IV

### LANDLORD'S COVENANTS

#### 4. (A) LANDLORD'S COVENANTS DURING THE TERM:

Landlord covenants during the Term:

(1) To furnish, through Landlord's employees or independent contractors, the services listed in Exhibit D; and

(2) Except as otherwise provided in this lease, to repair the roof and make all structural repairs to the buildings and the parking lot and elevator as may be necessary to keep them in serviceable condition provided, however, that if any of said repairs due necessitated by Tenant's Work or Tenant's alterations or improvements, Tenant shall make all such repairs as may be necessary.

(3) Landlord warrants that the entrances and exits to the buildings shall be in compliance with the Americans with Disabilities Act upon the Commencement Date, and Landlord shall be responsible for maintaining said entrances and exits in compliance during the Term. Landlord represents that the Property is not in violation of applicable zoning regulations. Landlord has received no notice of any noncompliance of the Property with Massachusetts General Laws, Chapter 21E or the Department of Environmental Protection's Massachusetts Contingency Plan and, to the best of Landlord's knowledge, the buildings contain no asbestos or other hazardous materials.

(4) Landlord will keep the buildings and other structures (including all alterations, additions, and changes thereto to the extent made by Landlord) which are located within the Lot, insured under an all risks property insurance policy (not excluding from coverage perils normally included within the definitions of extended coverage, vandalism and malicious mischief, earthquake and flood), in the amount of one hundred percent (100%) of the replacement value of the base buildings (excluding Tenant's improvements), with endorsements for contingent liability from operation of building laws, increased costs of construction, and demolition costs which may be necessary to comply with building laws. The insurance required hereby shall be written by a company authorized to do business in the state of the location of the demised premises. Landlord will be responsible for determining the amount of property insurance to be maintained, but such coverage will be on an agreed value basis to eliminate the effects of co-insurance. Landlord will provide to Tenant a certificate from Landlord's insurer evidencing the coverage required under this lease, which certificate will include the waiver of subrogation.

Landlord shall also maintain from and after the date of this lease and throughout the lease Term, commercial general liability insurance on an occurrence basis against claims on account of bodily injury, death or property damage incurred upon any part of the demised premises. Such insurance policy will have combined single limits of not less than Two Million Dollars (\$2,000,000.00) per occurrence and provide contractual coverage of Landlord's liability to Tenant assumed under the indemnification provision under this lease. The insurance required hereby shall be written by a company authorized to do business in the state of the location of the demised premises. Landlord will provide to Tenant a certificate from Landlord's insurer evidencing the coverage required under this lease. Insurance against any or all of such risks may be maintained under a blanket policy covering the demised premises and other real estate of Landlord and/or its affiliated business organizations provided the demised premises is specifically scheduled. Said policies may contain sublimits on earthquake and flood insurance.

The proceeds of Landlord's property insurance in case of loss or damage will be applied on account of the obligation of Landlord to repair and/or rebuild the damaged or destroyed buildings (but excluding Tenant's improvements) in accordance with Article VIII of this lease provided, however, that Landlord may rebuild the buildings with a block structure, and not brick structure.

Tenant agrees to pay to Landlord, as additional rent and as part of Operating Expenses, the cost to Landlord of keeping the demised premises insured as hereinabove provided.

## (B) INTERRUPTIONS

Landlord shall not be liable to Tenant for any compensation or reduction of rent by reason of inconvenience or annoyance or for loss of business arising from (a) power losses or shortages, or (b) the necessity of Landlord's entering the demised premises for any of the purposes in this lease authorized, including without limitation, for repairing or altering the demised premises or any portion of the Building or for bringing materials into and/or through the demised premises in connection with the making of repairs or alterations.

In case Landlord is prevented or delayed from making any repairs, alterations or improvements or furnishing any service or performing any other covenant or duty to be performed on Landlord's part, by reason of any cause reasonably beyond Landlord's control, Landlord shall not be liable to Tenant therefor, nor, except as expressly otherwise provided in Article VIII, shall Tenant be entitled to any abatement or reduction of rent by reason thereof, nor shall the same give rise to a claim in Tenant's favor that such failure constitutes actual or constructive, total or partial, eviction from the demised premises. Landlord reserves the right to stop any service or utility system when necessary in Landlord's reasonable opinion by reason of accident or emergency or until necessary repairs have been completed. Except in case of emergency repairs, Landlord will give Tenant reasonable advance notice (but in any event not less than forty eight (48) hours) of any contemplated stoppage and, in any event, Landlord will use reasonable efforts to avoid unnecessary inconvenience to Tenant by reason thereof.

Notwithstanding anything in this Section (B) of Article IV to the contrary, in the event any such disruption to Tenant's operations and use of the demised premises is attributable to Landlord's negligence, or that of its agents, contractors, servants or employees, or is attributable to a breach by Landlord of its obligations under this lease, and if such disruption shall materially impair Tenant's use of the demised premises for a period in excess of five (5) business days in duration, then a just proportion of the Rent, according to the nature and extent of the impairment to Tenant's operation and use of the demised premises shall abate for any such period of time from the date of disruption which is in excess of said five (5) business days in duration.

## ARTICLE V

### RENT

#### 5. (A)FIXED RENT

Tenant agrees to pay, without any offset or reduction whatever (except as made in accordance with the express provisions of this lease), fixed monthly rent equal to 1/12th of the annual Fixed Rent, such rent to be paid in equal installments in advance on the first day of each calendar month included in the Term; and for any portion of a calendar month at the commencement or the end of the Term, a portion of such fixed monthly rent, prorated on a per diem basis. All payments of Fixed and additional rent shall be made in lawful money of the United States and shall be made to H&N Associates, LLC and sent to Landlord at the address set forth in Section (A) of Article I above, or to such other person and/or at such other address as Landlord may from time to time designate.

If any payment of rent or any other payment payable hereunder by Tenant to Landlord shall not be paid when due, the same shall bear interest from the date when the same was payable until the date paid at the lesser of (a) prime plus one percent (1%) with a floor of twelve percent (12%) per annum, or (b) the highest lawful rate of interest which Landlord may charge to Tenant without violating any applicable law ("the Default Rate"). Such interest shall constitute additional rent payable hereunder.

#### (B) ADDITIONAL RENT - TAXES

(1) For the purposes of this Section, "Tax Year" shall mean the twelve-month period in use in the City of Chelsea for the purpose of imposing ad valorem taxes upon real property. In the event that said City changes the period of its tax year, "Tax Year" shall mean a twelve-month period commencing on the first day of such new tax year, and each twelve-month period commencing on an anniversary of such date during the Term of this lease. For purposes of this Section "the Property" shall mean the Lot and all improvements thereon from time to time, including the buildings. For purposes of this Section the Real Estate Taxes imposed with respect to the Property shall mean the sum of: (i) the real estate taxes upon the buildings (determined in accordance with the real estate tax bill, the assessor's records or a certification from the assessor), plus (ii) the real estate taxes upon the Lot. Real Estate Taxes shall not include any of the following: (i) any franchise, gift, estate, inheritance, conveyance, transfer, capital investment or other tax assessed against Landlord or Landlord's heirs, successors or assigns; (ii) any income, excess profits or other tax, assessment, charge, or levy on the rent payable by Tenant under this lease; or (iii) any interest, fine, or penalty for late payment or nonpayment by Landlord of any Real Estate Taxes, provided Tenant has timely paid the Real Estate Taxes. Further, as regards any assessment which under the laws then in force may be paid in installments, there will be included within the meaning of the term "Real Estate Taxes" with respect to any fiscal year only the current annual installment.

(2) Tenant shall not be obligated to pay Real Estate Taxes assessed with respect to the Property for any period, prior to May 1, 2001. Commencing on May 1, 2001, and thereafter, during the Term. Tenant shall pay to Landlord, as additional rent, the Real Estate Taxes imposed with respect to the Property for each Tax Year, such amount to be apportioned on a per diem basis for any fraction of a Tax Year during which May 1, 2001, shall occur.

(3) If Landlord shall receive any tax refund or rebate or sum in lieu thereof with respect to any Tax Year after May 1, 2001, then out of any balance remaining thereof, after deducting Landlord's reasonable expenses incurred in obtaining such refund, rebate or other sum, Landlord shall pay to Tenant, provided that Tenant is not then in monetary default in the performance of any of its obligations hereunder, such refund or rebate, but in no event shall Landlord pay to Tenant out of such refund, rebate or other sum for any Tax Year more than the amount paid by Tenant to Landlord pursuant to this Section (B) for such Tax Year.

(4) Any betterment assessment, so-called "rent tax." or any other tax levied or imposed by any governmental authority, in lieu of or as a substitute for Real Estate Taxes shall nevertheless be deemed to be Real Estate Taxes for the purpose of this Section (B). Furthermore, to the extent that any equipment installed as part of the Property (e.g. heating or air conditioning equipment) shall be classified as personal property for purposes of taxation, and if such taxes are levied against Landlord or the Property, any personal property taxes thereon shall be deemed to be Real Estate Taxes for purposes of this Section (B).

(5) Landlord shall, within thirty (30) days of receiving notification thereof, send to Tenant notice of any increases in assessments for Real Estate Taxes. Provided Tenant at least thirty (30) days prior has requested Landlord to make such a contest and Landlord has not then previously filed or does not thereafter within said thirty (30) days file a contest of the amount or validity of specific Real Estate Taxes which are payable by Tenant, Tenant will have the right, at Tenant's expense, to contest the amount or validity of Real Estate Taxes by appropriate administrative and legal proceedings brought either in Tenant's name, Landlord's name or jointly with Landlord, as Tenant may deem appropriate, by counsel selected and engaged by Tenant. Landlord will execute and deliver to Tenant whatever documents may be necessary or proper to permit Tenant to contest Real Estate Taxes or which may be necessary to secure payment of any refund which may result from any such proceedings. Any refund resulting from a proceeding brought either by Tenant or Landlord or by them jointly will be applied first to reimburse the party or parties who brought the proceedings for the costs incurred with the proceedings, and then to reimburse Tenant for the difference between the amount Tenant paid for Real Estate Taxes for each fiscal year involved in the proceeding and the amount Tenant would have been required to pay if the Real Estate Taxes had been assessed in accordance with the decision rendered in the proceeding, together with interest in the amount of such difference at the annual rate allowed by the court on the overpayment of Real Estate Taxes. Any remaining balance will be paid to Landlord.

Landlord shall pay to the appropriate governmental authorities, on or before same are due, all taxes, assessments, levies or related charges due and payable to said authorities.

#### (C) ADDITIONAL RENT - OPERATING COSTS

(1) For the purposes of this Section, the following terms shall have the following respective meanings:

Operating Year: Each successive fiscal year (as adopted by Landlord) in which any part of the Term of this lease shall fall.

"Operating Expenses" shall mean all costs or expenses incurred for the operation, external cleaning, external maintenance, repair and upkeep of the Property (as such term is defined in subsection (B) above), including, without limitation, all costs of maintaining and repairing the elevator and the parking lot (including snow removal, landscaping and grounds maintenance, parking lot operation and maintenance and parking lot lighting and of all repairs and replacements (other than repairs or replacements for which Landlord has received reimbursement from contractors, or from others) necessary to keep the Property in good working order, repair, appearance and condition; all costs of any reasonable insurance carried by Landlord relating to the Property and as set forth in Subsection (4) of Section (A) of Article IV above, payments under all service contracts relating to the foregoing (provided the cost of same is reasonably competitive with other services offering a similar level of service); all compensation, fringe benefits, payroll taxes and workmen's compensation insurance premiums related thereto with respect to any employees of Landlord or its affiliates engaged in security and maintenance of the Property to the extent of time spent on the Property; and internal bookkeeping professional fees and expenses; and a management fee of three percent (3%) of the Fixed Rent. Notwithstanding the foregoing, Operating Expenses shall not include the following: (i) Real Estate Taxes; (ii) cost of capital improvements or capital repairs other than repair and repaving of the parking lot and the repair and replacement of the parking lot lighting, (iii) cost of roof repairs, unless caused by Tenant; (iv) cost of repairing design or construction defects; (v) cost of improvements, repairs, or replacements covered by insurance or reimbursed by third parties; (vi) repairs or other work (including rebuilding) occasioned by casualty or condemnation; (vii) repainting of the buildings; (viii) principal or interest on debt or amortization payments on any mortgages or deeds of trust or any other debt for borrowed money and amortization of improvements; (ix) depreciation of Landlord's original investment in the demised premises; (x) amounts paid by Landlord to affiliates of Landlord for services in connection with any common areas, to the extent such fees are in excess of the ordinary and reasonable fees paid in arm's length transaction; (xi) rents and other charges payable to underlying landlords including any charges arising due to violations of said leases; and (xii) the costs and expenses related to investigation of, testing for, removal and/or clean up of Hazardous Materials unless caused by Tenant.

There shall not be included in such Operating Expenses brokerage fees (including rental fees) related to the operation of the buildings; interest and depreciation charges incurred on the Property; or expenditures made by Tenant with respect to (i) cleaning, maintenance and upkeep of the demised premises.

If during the Term of this lease, Landlord shall make any capital expenditures reasonably necessary to maintain the parking lot or the parking lot lighting, the total amount of which is not properly included in Operating Expenses for the calendar year in which they were made, there shall nevertheless be included in Operating Expenses for each calendar year in which and after such capital expenditure is made the annual charge-off of such capital expenditure. (Annual charge-off shall be determined by (i) dividing the original cost of the capital expenditure by the number of years of useful life thereof [the useful life shall be reasonably determined by Landlord in accordance with generally accepted accounting principles and practices in effect at the time of acquisition of the capital item]; and (ii) adding to such quotient an interest factor computed on the unamortized balance of such capital expenditure based upon an interest rate reasonably determined by Landlord as being the interest rate then being charged for long term mortgages by institutional lenders on like properties within the locality in which the buildings are located).

Tenant's Share of Operating Expenses: One hundred percent (100%) of the Operating Expenses.

(2) Tenant shall not be obligated to pay the Operating Expenses for the period of time prior to May 1, 2001. Commencing on May 1, 2001 and thereafter during the Term, Tenant shall pay to Landlord, as additional rent, Tenant's Share of Operating Expenses, such amount to be apportioned on a per diem basis for any fraction of an Operating Year during which May 1, 2001 shall occur.

#### (D) MONTHLY PAYMENTS

Payment on account of the additional rent described in Sections (B) and (C) above shall be paid monthly on the first day of each and every month included in the Term commencing, however, on May 1, 2001. Promptly after the end of each Tax Year, Landlord shall make a determination of Tenant's share of real estate taxes and Operating Expenses. On or before the first day of April of each calendar year (the "Statement Deadline"), Landlord will deliver a statement (the "Operating Expenses Statement") to Tenant certified by Landlord's authorized representative showing: (i) the amount of the actual Operating Expenses for the preceding calendar year, with a breakdown of amounts by major categories of the Operating Expenses, and (ii) the amounts paid by Tenant toward the estimated Operating Expenses during the preceding calendar year; and if the aforesaid payments theretofore made for such period by Tenant exceed Tenant's share, such overpayment shall be credited against the payments thereafter to be made by Tenant pursuant to this Section (D); and if Tenant's share is greater than such payments theretofore made on account for such period, Tenant shall make a suitable payment to Landlord. The initial monthly payment on account of said additional rent shall be replaced after Landlord's determination of Tenant's share for the preceding Tax Year by a payment which is one-twelfth (1/12th) of Tenant's actual share thereof for the immediately preceding Tax Year, with adjustments as appropriate where such period is less than a full twelve-month period. Appropriate adjustments shall be made in said monthly payment if the real estate taxes upon the Property for the current Tax Year shall be known prior to the end of said Tax Year and/or if real estate taxes shall be payable to the taxing authority in installments, all to the end that as each payment of real estate taxes shall become payable Landlord shall have received from Tenant payments sufficient in amount to pay Tenant's share of the building's Share of Real Estate Taxes then payable by Landlord. At Landlord's election, Landlord may use its fiscal year rather than Tax Years for purposes of the adjustments described in this Section.

#### (E) ADDITIONAL RENT - ELECTRICITY, GAS, WATER & SEWER

(1) The demised premises shall have utility meters measuring the amount of the utilities consumed in the demised premises, and commencing upon the Commencement Date, Tenant shall pay to the utility companies furnishing such utilities, promptly upon the receipt of bills therefor, the cost of such utilities consumed in the demised premises.

(2) Tenant's use of electricity in the demised premises shall not at any time exceed the capacity of any of the electrical conductors or equipment in or otherwise serving the demised premises. Landlord warrants that 1,200 amp electrical service is provided to the Property.

### ARTICLE VI

#### TENANT'S COVENANTS

##### 6. TENANT'S COVENANTS DURING THE TERM

Tenant covenants during the Term and such other time as Tenant occupies any part of the demised premises:

(1) To pay when due (a) all Fixed Rent and additional rent, (b) all taxes which may be imposed on Tenant's personal property in the demised premises (including, without limitation, Tenant's fixtures and equipment) regardless to whomever assessed, and (c) all charges by any public utility for telephone and other utility services rendered to the demised premises;

(2) Except as otherwise provided in Article VIII and Section 4(A)(2), to keep the demised premises in good order, repair and condition, reasonable wear and tear only excepted; to replace all light bulbs as necessary; all cleaning and janitorial services for the demised premises; maintain and replace all interior glass; keep all utilities, pipes, conduits, drains and other installations used in connection with the demised premises, including, without limitation, the heating, ventilating and air conditioning systems in good order, condition and repair; and at the expiration or termination of this lease peaceably to yield up the demised premises and all changes and additions therein in such order, repair and condition, first removing all goods and effects of Tenant and those claiming under Tenant and any items the removal of which is required by any agreement between Landlord and Tenant (or specified therein to be removed at Tenant's election and which Tenant elects to remove), and repairing all damage caused by such removal and restoring the demised premises and leaving them clean and neat. Notwithstanding the foregoing, in the event that Tenant proposes to make any installation, alteration, addition or improvement to the demised premises, Tenant shall give written notice to Landlord no later than fifteen (15) business days prior to the proposed date of the commencement of construction of such installation, alteration, addition or improvement, together with plans and specifications therefor. Within ten (10) business days after the receipt by Landlord of such written notice and said plans and specifications, Landlord shall notify Tenant in writing whether it must remove the same at the expiration or termination of the Term of this lease, and the failure of Landlord to provide such written determination to Tenant within said ten (10) business days shall constitute Landlord's determination that such installation, alteration, addition and/or improvement need not be removed at the expiration or termination of the Term of this lease. If Tenant elects not to request Landlord's consent then Tenant shall remove from the demised premises (repairing any damage caused by such removal) any such installation, alteration, addition or improvement made without Landlord's consent and which Landlord requests Tenant remove within thirty (30) days after the expiration or termination of the Term of this lease. Such removal shall include returning the previously modified portions of the demised premises to their condition prior to the making of such installations, alterations, additions or improvements. Tenant's obligations hereunder shall survive the expiration or termination of the term of this lease. For purposes of this Section (2) the word "repairs" includes the making of replacements when necessary;

(3) Continuously from the Commencement Date, to use the demised premises only for the Permitted Use; and not to injure or deface the demised premises, buildings, or Lot; nor permit any use thereof which is improper, offensive, contrary to law or ordinances, or which is liable to invalidate any insurance on the buildings (or any portion thereof) or its contents, or liable to render necessary any addition to the buildings. Landlord acknowledges that Tenant's use of the demised premises as a biotechnology company, including, but not limited to pharmaceutical manufacturing, will not invalidate the insurance on the buildings;

(4) Intentionally Omitted;

(5) To keep the demised premises equipped with all safety appliances required by law or ordinance or any other regulation of any public authority and to procure all licenses and permits required because of any use made by Tenant and, if requested by Landlord, to do any work required because of such use, it being understood that the foregoing provisions shall not be construed to broaden in any way the Permitted Use;

(6) Not without the prior written consent of Landlord (which consent Landlord agrees that it shall not unreasonably withhold, delay or condition), to assign, hypothecate, pledge or otherwise encumber this lease, to make any sublease or to permit occupancy of the demised premises or any part thereof by anyone other than Tenant, voluntarily or by operation of law, and as additional rent, to reimburse Landlord promptly upon demand for reasonable legal and other expenses incurred by Landlord in connection with any request by Tenant for consent to assignment or subletting. If and whenever Tenant shall not be a so-called “publicly held” company, it is understood and agreed that the transfer of fifty percent (50%) or more of the stock in Tenant of any class (whether at one time or at intervals) shall constitute an “assignment” of Tenant’s interest in this lease. If there shall be any assignment or subletting by Tenant pursuant to the provisions of this paragraph, Tenant and Tenant’s Guarantor shall remain primarily liable for the performance and observance of the covenants and agreements herein contained on the part of Tenant to be performed and observed, such liability to be (in the case of any assignment) joint and several with that of such assignee. It is expressly understood and agreed that no assignment of Tenant’s interest in this lease shall be effective until such time as Tenant shall deliver to Landlord an agreement from the assignee, which agreement shall be reasonably satisfactory to Landlord in form and substance and shall provide that the assignee agrees with Landlord to be primarily liable for the performance and observance of the covenants and agreements herein contained on the part of Tenant to be performed and observed, such liability to be joint and several with that of Tenant. Landlord hereby agrees, however, that Tenant may, without Landlord’s consent, assign its interest in this lease or sublet the whole or part of the demised premises to (a) an entity which owns all of the outstanding stock of Tenant (“Tenant’s Parent”); (b) an entity wholly owned by Tenant or by Tenant’s Parent (“a Subsidiary”); (c) an entity resulting from the consolidation or merger of Tenant with any other entity; or (d) an affiliate of Tenant or Tenant’s Guarantor;

(7) To defend Landlord, with counsel acceptable to Landlord, save Landlord harmless from, and indemnify Landlord against any liability for injury, loss, accident or damage to any person or property and from any claims, actions, proceedings and expenses and costs in connection therewith (including, without implied limitation, reasonable counsel’s fees): (i) arising from the omission, fault, willful act, negligence or other misconduct of Tenant or anyone claiming under Tenant, or from any use made or thing done or occurring upon or about the demised premises but not due to the omission, fault, willful act, negligence or other misconduct of Landlord, or (ii) resulting from the failure of Tenant to perform and discharge its covenants and obligations under this lease. Landlord agrees that it will defend Tenant, with counsel acceptable to Tenant, save Tenant harmless from, and indemnify Tenant against any liability for injury, loss, accident or damage to any person or property and from any claims, actions, proceedings and expenses and costs in connection therewith (including, without implied limitation, reasonable counsel’s fees): (i) arising from the omission, fault, willful act, negligence or other misconduct of Landlord or anyone claiming under Landlord, or from any use made or thing done or occurring upon or about the demised premises but not due to the omission, fault, willful act, negligence or other misconduct of Tenant, or (ii) resulting from the failure of Landlord to perform and discharge its covenants and obligations under this lease, or (iii) arising from any hazardous material placed on the demised premises by Landlord or its agents or employees, or existing prior to Tenant’s occupancy of the demised premises. Landlord shall be responsible for remediating such hazardous material if required by law.

(8) To maintain public liability insurance upon the demised premises in amounts which shall, at the beginning of the Term, be at least equal to \$5,000,000.00 for bodily injury or death to one or more individuals and \$2,000,000.00 for damage to property, and from time to time during the Term, shall be for such higher limits, if any, as are customarily carried in the area in which the demised premises are located upon property similar in type and use to the demised premises. Such insurance shall name Landlord, Landlord’s Managing Agent, and Landlord’s Mortgagee as additional insureds. Tenant shall deliver to Landlord the policies of such insurance, or certificates thereof, not more than fifteen (15) days following the Commencement Date, and each renewal policy or certificate thereof, not more than fifteen (15) days following the expiration of the policy it renews. Each such policy shall be written by a responsible insurance company authorized to do business in the Commonwealth of Massachusetts and shall provide that the same shall not be modified or terminated without at least twenty (20) days’ prior written notice to each named insured;

(9) To keep all employees working in the demised premises covered by workmen’s compensation insurance in amounts required by law;

(10) To permit Landlord and its agents entry: to examine the demised premises at reasonable times and, if Landlord shall so elect, to make repairs, alterations and replacements; to remove, at Tenant's expense, any changes, additions, signs, curtains, blinds, shades, awnings, aerials, flagpoles, or the like not consented to in writing; and to show the demised premises to prospective tenants during the twelve months preceding the expiration of the Term and to prospective purchasers and mortgagees at all reasonable times. Tenant shall be allowed exclusive building mounted signage. Such signage shall be provided at Tenant's expense, subject to all applicable building codes and zoning by-laws. Further, subject to the receipt by Tenant of all necessary approvals (if any are so required), from the City of Chelsea, Tenant shall have the right to install communications devices on the roof of building A and/or building B. The size, location and method of attachment shall be subject to Landlord's prior review and approval and shall be in compliance with all state and local building codes and other applicable zoning restrictions. All costs associated with the installation, maintenance and removal of such rooftop installations shall be the sole responsibility of Tenant. Tenant shall in no event void Landlord's roof warranties and guaranties;

(11) Not to place a load upon any part of the floor of the demised premises exceeding that for which said floor was designed or in violation of what is allowed by law. Tenant's business machines and mechanical equipment which cause vibration or noise that may be transmitted to the building structure or to any other space in the buildings shall be placed and maintained by Tenant so as not to cause structural damage to the buildings;

(12) All the furnishings, fixtures, equipment, effects and property of every kind, nature and description of Tenant and of all persons claiming by, through or under Tenant which, during the continuance of this lease or any occupancy of the demised premises by Tenant or anyone claiming under Tenant, may be on the demised premises or elsewhere in the buildings or on the Lot shall be at the sole risk and hazard of Tenant, and if the whole or any part thereof shall be destroyed or damaged by fire, water or otherwise, or by the leakage or bursting of water pipes, steam pipes, or other pipes, by theft, or from any other cause, no part of said loss or damage is to be charged to or to be borne by Landlord, unless caused by the negligence or willful act of Landlord or its agents, servants, contractors or employees;

(13) To pay promptly when due the entire cost of any work done on the demised premises by Tenant and those claiming under Tenant; not to cause or permit any liens for labor or materials performed or furnished in connection therewith to attach to the demised premises; and immediately to discharge any such liens which may so attach;

(14) Intentionally Omitted;

(15) To pay to Landlord one and one half (1½) times the total of the Fixed Rent and additional rent then applicable for each month or portion thereof that Tenant shall retain possession of the demised premises or any part thereof after the termination of this lease, whether by lapse of time or otherwise; however, the provisions of this subsection shall not operate as a waiver by Landlord of any right of re-entry provided in this lease or as a matter of law;

(16) To insure the contents, equipment, and improvements of Tenant and those claiming under Tenant, under policies covering at least fire and the standard extended coverage risks, in amounts equal to the replacement cost thereof, the terms of which policies shall provide that such insurance shall not be canceled without at least twenty (20) days' prior written notice to Landlord. Copies of such insurance policy or policies, or certificates thereof, shall be delivered to Landlord not more than fifteen (15) days following the Commencement Date and each renewal policy or certificate thereof, not more than fifteen (15) days following the expiration of the policy it renews; and

(17) To pay Landlord's expenses, including reasonable attorney's fees, incurred in enforcing any obligation of Tenant in this lease. Landlord agrees that it shall pay Tenant's expenses including reasonable attorney's fees incurred in enforcing any obligation of Landlord in this lease.

## ARTICLE VII

### DEFAULT

#### 7. (A)EVENTS OF DEFAULT

(1) If Tenant shall default in the payment of Fixed Rent, additional rent or other payments required of Tenant, and if Tenant shall fail to cure said default within ten (10) days after receipt of notice of said default from Landlord, or (2) if Tenant shall default in the performance or observance of any other agreement or condition on its part to be performed or observed and if Tenant shall fail to cure said default within thirty (30) days after receipt of notice of said default from Landlord (but if longer than thirty (30) days shall be reasonably required to cure said default, then if Tenant shall fail to commence the curing of such default within thirty (30) days after receipt of said notice and diligently prosecute the curing thereof to completion), or (3) if any person shall levy upon, or take this leasehold interest or any part thereof upon execution, attachment or other process of law, or (4) if Tenant or Guarantor shall make an assignment of its property for the benefit of creditors, or (5) if Tenant or Guarantor shall be declared bankrupt or insolvent according to law, or (6) if any bankruptcy or insolvency proceedings shall be commenced by or against Tenant or Guarantor, or (7) if a receiver, trustee or assignee shall be appointed for the whole or any part of Tenant's or Guarantor's property, then in any of said cases, Landlord lawfully may immediately, or at any time thereafter, and without any further notice or demand except as is set forth herein and as required by law, enter into and upon the demised premises or any part thereof in the name of the whole, and hold the demised premises as if this lease had not been made, and expel Tenant and those claiming under it and remove its or their property without being taken or deemed to be guilty of any manner of trespass (or Landlord may send written notice to Tenant of the termination of this lease), and upon entry as aforesaid (or in the event that Landlord shall send Tenant notice of termination as above provided, on the fifth day next following the date of the sending of the notice), the term of this lease shall terminate. Notwithstanding the provisions of clause (1) of the immediately preceding sentence, if Landlord shall have rightfully given Tenant notice of default pursuant to said clauses twice during any twelve (12) month period, and if Tenant shall thereafter in such twelve (12) month period default in the payment of Fixed Rent, additional rent or other payments required of Tenant, then Landlord may exercise the right of termination provided for it in said immediately preceding sentence without first giving Tenant notice of such default and the opportunity to cure the same within the time provided in said clause (1). Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws in the event of Tenant being evicted or dispossessed for any cause, or in the event Landlord terminates this lease as provided in this Article.

#### (B) OBLIGATIONS THEREAFTER

In case of any such termination, Tenant will indemnify Landlord each month against all loss of Fixed Rent and additional rent and against all obligations which Landlord may incur by reason of any such termination between the time of termination and the expiration of the Term. It is understood and agreed that at the time of the termination or at any time thereafter Landlord may rent the demised premises, and for a term which may expire before or after the expiration of the Term, without releasing Tenant from any liability whatsoever, that Tenant shall be liable for any expenses incurred by Landlord in connection with obtaining possession of the demised premises, with removing from the demised premises property of Tenant and persons claiming under it (including warehouse charges), with putting the demised premises into good condition for reletting, and with any reletting, including, but without limitation, reasonable attorneys' fees and brokers fees, and that any monies collected from any reletting shall be applied first to the foregoing expenses and then to the payment of Fixed Rent, additional rent and all other payments due from Tenant to Landlord.

## ARTICLE VIII

### CASUALTY AND TAKING

#### 8. (A)CASUALTY AND TAKING

In case during the Term all or any substantial part of the demised premises, the buildings, or Lot or any one or more of them, are damaged by fire or any other casualty or by action of public or other authority or are taken by eminent domain, this lease shall terminate at Landlord's election, which may be made notwithstanding Landlord's entire interest may have been divested, by notice given to Tenant within thirty (30) days after the occurrence of the event giving rise to the election to terminate. Said notice shall, in the case of damage as aforesaid, specify the effective date of termination which shall be not less than thirty nor more than sixty days after the date of notice of such termination. In the case of any such taking by eminent domain, the effective date of the termination shall be the day on which the taking authority shall take possession of the taken property. Fixed Rent and additional rent shall be apportioned and adjusted as of the effective date of any such termination. If in any such case the demised premises are rendered unfit for use and occupation and this lease is not so terminated, Landlord shall use due diligence to put the demised premises, or, in the case of a taking, what may remain thereof (excluding any items which Tenant may be required or permitted to remove, from the demised premises at the expiration of the Term) into proper condition for use and occupation, but Landlord shall not be required to spend more than the net proceeds of insurance or award of damages it receives therefor, and a just proportion of the Fixed Rent and additional rent according to the nature and extent of the injury to the demised premises shall be abated until the demised premises or such remainder shall have been put by Landlord in such condition; and in case of a taking which permanently reduces the area of the demised premises, a just proportion of the Fixed Rent shall be abated for the remainder of the Term. Notwithstanding the foregoing, in the event that there is a fire or other casualty or a taking by eminent domain or by action of public or other authority, Landlord shall, within thirty (30) days of such event, make a good faith estimate of the anticipated restoration time. If pursuant to such estimate the damage to the base buildings or the Lot cannot be repaired and restored to substantially the same dimensions as prior to the casualty and as reasonably required for Tenant to conduct its business within eighteen (18) months from the occurrence of the same, Tenant shall have the right to terminate this lease by notice to this effect given to Landlord within thirty (30) days after receipt of Landlord's determination as aforesaid, and which termination shall be effective on the tenth (10th) day following the receipt by Landlord of said termination notice. If this lease shall not be terminated, as aforesaid, Landlord shall promptly commence to rebuild same provided, however, that if the buildings or Lot are not so restored within said eighteen (18) months, then Tenant shall have the right, as Tenant's sole remedy, to terminate this lease at any time thereafter but prior to the completion of the restoration. Further, if any such fire or other casualty or taking by eminent domain or by action of public or other authority occurs during the last two (2) years of the Term of this lease, and the demised premises are damaged or destroyed as a result thereof to the extent of fifteen percent (15%) or more of its insurable value, or if the square foot floor area of the demised premises are reduced by such taking during the last two (2) years of the Term by more than fifteen percent (15%), then Landlord and Tenant shall have the right to terminate this lease, by written notice given to the other party within thirty (30) days after the casualty or taking, and which termination shall, be effective on the tenth (10th) day following the delivery of said termination notice.

## (B) RESERVATION OF AWARD

Landlord reserves to itself any and all rights to receive awards made for damage to the demised premises, buildings or Lot and the leasehold hereby created, or any one or more of them, accruing by reason of any exercise of the right of eminent domain or by reason of anything done in pursuance of public or other authority. Tenant hereby releases and assigns to Landlord all of Tenant's rights to such awards, and covenants to deliver such further assignments and assurances thereof as Landlord may from time to time request. It is agreed and understood, however, that Landlord does not reserve to itself, and Tenant does not assign to Landlord, any damages payable for (i) movable equipment, trade fixtures, leasehold improvements, alterations and additions made by Tenant at Tenant's sole cost and expense, and personal property installed by Tenant or anybody claiming under Tenant at its own expense or (ii) relocation expenses, but in each case only if and to the extent that such damages are recoverable by Tenant from such authority in a separate action and without reducing Landlord's award of damages.

## ARTICLE IX

### MORTGAGEE

#### 9. (A) SUBORDINATION TO MORTGAGES

It is agreed that the rights and interest of Tenant under this lease shall be: (i) subject and subordinate to the lien of any present or future first mortgage and to any and all advances to be made thereunder, and to the interest thereon, upon the demised premises or any property of which the demised premises are a part, if the holder of such mortgage shall elect, by notice to Tenant, to subject and subordinate the rights and interest of Tenant under this lease to the lien of its mortgage; or (ii) prior to the lien of any present or future first mortgage, if the holder of such mortgage shall elect, by notice to Tenant, to give the rights and interest of Tenant under this lease priority to the lien of its mortgage. In the event of any of such elections, and upon notification by the holder of such mortgage to that effect, the rights and interest of Tenant under this lease shall be deemed to be subordinate to, or to have priority over, as the case may be, the lien of said mortgage, irrespective of the time of execution or time of recording of any such mortgage. Tenant agrees that it will, upon request of Landlord, execute, acknowledge and deliver any and all reasonable instruments deemed by Landlord necessary or desirable to evidence or to give notice of such subordination or priority and reasonably acceptable to Tenant. The word "mortgage" as used herein includes mortgages, deeds of trust or other similar instruments and modifications, consolidations, extensions, renewals, replacements and substitutes thereof. Whether the lien of any mortgage upon the demised premises or any property of which the demised premises are a part shall be superior or subordinate to this lease and the lien hereof, Tenant agrees that it will, upon request, attorn to the holder of such mortgage or anyone claiming under such holder and their respective successors and assigns in the event of foreclosure or similar action taken under such mortgage. Tenant further agrees that it shall not subordinate its interest in this lease to the lien of any junior mortgage, security agreement or lease affecting the demised premises, unless the holder of the first mortgage upon the demised premises or property which includes the demised premises shall consent thereto. Notwithstanding anything to the contrary contained in this Article 9, Tenant shall not be required to subordinate this lease and the lien hereof to the lien of any mortgage unless the holder of such mortgage shall enter into an agreement with Tenant, in a form reasonably acceptable to Tenant, recordable in form, to the effect that in the event of foreclosure of, or similar action taken under, such mortgage, all of the terms and conditions of this lease shall remain in effect and Tenant's possession of the demised premises shall not be terminated or disturbed by such mortgage holder or anyone claiming under such mortgage holder so long as Tenant shall not be in default under this lease beyond any applicable cure period. Landlord shall obtain such an agreement from the present mortgagee of the Property.

## (B) LIMITATION ON MORTGAGEE'S LIABILITY

Upon entry and taking possession of the mortgaged premises for any purpose, the holder of a mortgage shall have all rights of Landlord, and during the period of such possession Landlord, not such mortgage holder, shall have the duty to perform all of Landlord's obligations hereunder. No such holder shall be liable, either as a mortgagee or as holder of a collateral assignment of this lease, to perform, or be liable in damages for failure to perform, any of the obligations of Landlord unless and until such holder shall succeed to Landlord's interest herein through foreclosure of its mortgage or the taking of a deed in lieu of foreclosure, and thereafter such mortgage holder shall not be liable for the performance of any of Landlord's obligations hereunder, except for the performance of those obligations which arise during the period of time that such mortgage holder holds Landlord's right, title and interest in this lease or which arose prior thereto and are of a continuing nature, such liability to be limited to the same extent as Landlord's liability is limited pursuant to Section 10(E) hereof.

## (C) NO RELEASE OR TERMINATION

No act or failure to act on the part of Landlord which would entitle Tenant under the terms of this lease, or by law, to be relieved of any of Tenant's obligations hereunder or to terminate this lease, shall result in a release or termination of such obligations or a termination of this lease unless (i) Tenant shall have first given written notice of Landlord's act or failure to act to Landlord's mortgagees of record, provided Tenant has received written notice of such mortgagee, if any, specifying the act or failure to act on the part of Landlord which could or would be the basis of Tenant's rights and (ii) such mortgagees, after receipt of such notice, have failed or refused to correct or cure the condition complained of within the same time thereafter as allowed by Landlord, but nothing contained in this Section (C) shall be deemed to impose any obligation on any such mortgagee to correct or cure any such condition. Finally, Tenant agrees that so long as any present or future mortgage shall remain in effect Tenant shall not alter, modify, amend, change, surrender or cancel this lease nor pay the rent due hereunder in advance for more than thirty (30) days, except as may be required herein, without the prior written consent of the holder thereof, and Tenant will not seek to be made an adverse or defendant party in any action or proceeding brought to enforce or foreclose such mortgage.

## ARTICLE X

### GENERAL PROVISIONS

#### 10. (A) CAPTIONS

The captions of the Articles are for convenience and are not to be considered in construing this lease.

## (B) SHORT FORM LEASE

Upon request of either party both parties shall execute and deliver a short form of this lease in form appropriate for recording, and if this lease is terminated before the Term expires, an instrument in such form acknowledging the date of termination. No such short form lease shall contain any indication of the amount of the rentals payable hereunder by Tenant.

## (C) RELOCATION

Intentionally Omitted.

## (D) NOTICES

All notices and other communications authorized or required hereunder shall be in writing and shall be given by mailing the same by certified or registered mail, return receipt requested, postage prepaid, by mailing the same by Express Mail or by having the same delivered by a commercial delivery service such as Federal Express, UPS, Purolator Courier and the like. If given to Tenant the same shall be directed to Tenant at 64 Sidney Street, Cambridge, Massachusetts 42139, Attention: Chief Financial Officer, or to such other person or at such other address as Tenant may hereafter designate by notice to Landlord; and if given to Landlord the same shall be directed to Landlord at Landlord's Address, or to such other person or at such other address as Landlord may hereafter designate by notice to Tenant. In the event the notice directed as above provided shall not be received upon attempted delivery thereof to the proper address and shall be returned by the Postal Service or delivery service to the sender because of a refusal of receipt, the absence of a person to receive, or otherwise, the time of the giving of such notice shall be the first business day on which delivery was so attempted.

After receiving notice from Landlord or from any person, firm or other entity that such person, firm or other entity holds a mortgage which includes the demised premises as part of the mortgaged premises, no notice from Tenant to Landlord shall be effective unless and until a copy of the same is given by certified or registered mail to such holder, and the curing of any of Landlord's defaults by such holder shall be treated as performance by Landlord, it being understood and agreed that such holder shall be afforded the same period of time after the receipt of such notice as Landlord has in which to effect such cure.

## (E) SUCCESSORS AND ASSIGNS

The obligations of this lease shall run with the land, and this lease shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, legal representatives, successors and assigns, except that the Landlord named herein and each successive owner of Landlord's interest in this lease shall be liable only for the obligations of Landlord accruing during the period of its ownership. Whenever Landlord's interest in this lease is owned by a trustee or trustees, the obligations of Landlord shall be binding upon Landlord's trust estate, but not upon any trustee, beneficiary or shareholder of the trust individually. Without limiting the generality of the foregoing, and whether or not Landlord's interest in this lease is owned by a trustee or trustees, Tenant specifically agrees to look solely to Landlord's interest in the buildings and Lot (including any consideration received as part of a transfer of the Property and insurance proceeds and condemnation awards) for recovery of any judgment from Landlord, it being specifically agreed that neither Landlord, any trustee, beneficiary or shareholder of any trust estate for which Landlord acts nor any person or entity claiming by, through or under Landlord shall ever otherwise be personally liable for any such judgment. The foregoing shall not limit any injunctive relief to which Tenant may be entitled.

#### (F) NO SURRENDER

The delivery of keys to any employee of Landlord or to Landlord's agent or any employee thereof shall not operate as a termination of this lease or a surrender of the demised premises.

#### (G) WAIVERS AND REMEDIES

The failure of Landlord or of Tenant to seek redress for violation of, or to insist upon the strict performance of any covenant or condition of this lease shall not be deemed a waiver of such violation nor prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by Landlord of Fixed Rent or additional rent with knowledge of the breach of any covenant of this lease shall not be deemed a waiver of such breach by Landlord unless such waiver be in writing signed by Landlord. No consent or waiver express or implied, by Landlord or Tenant to or of any breach of any agreement or duty shall be construed as a waiver or consent to or of any other breach of the same or any other agreement or duty. No acceptance by Landlord of a lesser sum than the Fixed Rent and additional rent then due shall be deemed to be other than on account of the earliest installment of such rent due nor shall acceptance by Tenant of any lesser sum that may be due Tenant from Landlord be deemed to be other than on account of the full amount due, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as rent be deemed as accord and satisfaction, and Landlord or Tenant, may accept such check or payment without prejudice to Landlord's or Tenant's right to recover the balance of such installment or pursue any other remedy available to it. The specific remedies to which Landlord or Tenant may resort under the terms of this lease are cumulative and are not intended to be exclusive of any other remedies or means of redress to which it may be lawfully entitled in case of any breach or threatened breach by Tenant or Landlord of any provisions of this lease. In addition to the other remedies provided in this lease, Landlord and Tenant shall be entitled to the restraint by injunction of the violation or attempted or threatened violation of any of the covenants, conditions or provisions of this lease or to a decree compelling specific performance of any such covenants, conditions or provisions. If any term of this lease, or the application thereof to any person or circumstances shall be held, to any extent, to be invalid or unenforceable, the remainder of this lease, or the application of such term to persons or circumstances other than those as to which it has been held invalid or unenforceable, shall not be affected thereby, and each term of this lease shall be valid and enforceable to the fullest extent permitted by law. If any interest to be paid by Tenant hereunder shall exceed the highest lawful rate which Landlord may recover from Tenant, such interest shall be reduced to such highest lawful rate of interest.

#### (H) SELF-HELP

If Tenant shall at any time default in the performance of any obligation under this lease, Landlord shall have the right, but shall not be obligated, to enter upon the demised premises and to perform such obligation, notwithstanding the fact that no specific provision for such performance by Landlord is made in this lease with respect to such default. In performing such obligation, Landlord may make any payment of money or perform any other act. All sums so paid by Landlord (together with interest, from the time paid by Landlord until the time Tenant repays the same to Landlord at the Default Rate set forth in Section (A) of Article V above), shall be deemed to be additional rent and shall be payable to Landlord immediately on demand. Landlord may exercise the foregoing right without waiving any other of its rights or releasing Tenant from any of its obligations under this lease. If Landlord shall at any time default in the performance of any obligation under this lease, Tenant shall have the right, but shall not be obligated, to enter upon the demised premises and to perform such obligation, notwithstanding the fact that no specific provision for such performance by Tenant is made in this lease with respect to such default. In performing such obligation, Tenant may make any payment of money or perform any other act. All sums so paid by Tenant (together with interest, from the time paid by Tenant until the time Landlord repays the same to Tenant, Default Rate set forth in Section (A) of Article V above), shall be payable to Tenant immediately on demand. Tenant may exercise the foregoing right without waiving any other of its rights or releasing Landlord from any of its obligations under this lease. If Landlord shall not reimburse Tenant within thirty (30) days of Tenant's demand, Tenant may set off such sums from fifty percent (50%) of the monthly Fixed Rent payable by Tenant thereafter.

#### (I) ESTOPPEL CERTIFICATE

Tenant agrees from time to time after the Commencement Date, upon not less than ten (10) business days' prior written request by Landlord, to execute, acknowledge and deliver to Landlord a statement in writing certifying that this lease is unmodified and in full force and effect; that Landlord has completed Landlord's Required Work; that Tenant has no defenses, offsets or counterclaims against its obligations to pay the Fixed Rent and additional rent and to perform its other covenants under this lease; that there are no uncured defaults of Landlord or Tenant under this lease (or, if there have been any modifications, that this lease is in full force and effect as modified and stating the modifications, and, if there are any defenses, offsets, counterclaims, or defaults, setting them forth in reasonable detail); and the dates to which the Fixed Rent, additional rent and other charges have been paid. Any such statement delivered pursuant to this Section (I) may be relied upon by any prospective purchaser or mortgagee of premises which include the demised premises or any prospective assignee of any such mortgagee. Landlord shall upon not less than ten (10) business days prior written request of Tenant deliver to Tenant a similar statement as requested herein.

#### (J) WAIVER OF SUBROGATION

(1) Tenant hereby releases Landlord to the extent of Tenant's insurance coverage, and to the full extent in the event Tenant elects to self insure for Tenant's personal property as permitted herein, from any and all liability for any loss or damage caused by fire or any of the extended coverage casualties or any other casualty insured against, even if such fire or other casualty shall be brought about by the fault or negligence of Landlord or its agents.

(2) Landlord hereby releases Tenant, to the extent of the Landlord's insurance coverage and to the extent required to be carried pursuant to this lease, from any and all liability for any loss or damage caused by fire or any of the extended coverage casualties or any other casualty insured against, even if such fire or other casualty shall be brought about by the fault or negligence of Tenant or its agents.

#### (K) BROKERS

Tenant hereby represents and warrants to Landlord that it has dealt with no broker in connection with this lease other than Burgess Properties, Inc., and Meredith & Grew ("the Listed Brokers"), and there are no other brokerage commissions or other finders' fees payable in connection herewith. Tenant hereby agrees to hold Landlord harmless from, and indemnified against, all loss or damage (including without limitation, the cost of defending the same) arising from any claim by any broker other than the Listed Brokers, claiming to have dealt with Tenant. Landlord shall pay the brokerage commission due the Listed Brokers by separate agreement, Landlord hereby represents and warrants to Tenant that it has dealt with no broker in connection, with this lease other than Burgess Properties, Inc., and Meredith & Grew ("the Listed Brokers"), and there are no other brokerage commissions or other finders' fees payable in connection herewith. Landlord hereby agrees to hold Tenant harmless from and indemnified against, all loss or damage (including without limitation, the cost of defending the same) arising from any claim by any broker other than the Listed Brokers, claiming to have dealt with Landlord.

#### (L) LANDLORD'S DEFAULTS

Landlord shall not be deemed to have committed a breach of any obligation to make repairs or alterations or perform any other act unless: (1) it shall have made such repairs or alterations or performed such other act negligently; or (2) it shall have received notice from Tenant designating the particular repairs or alterations needed or the other act of which there has been failure of performance and shall have failed to make such repairs or alterations or performed such other act within a thirty (30) days after the receipt of such notice (provided, however that if it shall reasonably require longer than thirty (30) days, then such longer period provided Landlord commences such curing within said thirty (30) days and prosecutes same to completion with due diligence); and in the latter event Landlord's liability shall be limited to the cost of making such repairs or alterations or performing such other act. Tenant may, following such thirty (30) day (or longer) period make such repairs or perform such act and Tenant may set off the costs thereof from fifty percent (50%) of the monthly Fixed Rent payable by Tenant thereafter. The foregoing shall not limit any injunctive relief to which Tenant may be entitled.

#### (M) EFFECTIVENESS OF LEASE

The submission of this lease for examination does not constitute a reservation of, or option for, the demised premises, and this lease becomes effective as a lease only upon execution and unconditional delivery thereof by both Landlord and Tenant.

## (N) HAZARDOUS MATERIALS

Tenant shall not (either with or without negligence) cause or permit the escape, disposal or release of any biologically or chemically active or other hazardous substances, or materials. Tenant shall not allow the storage or use of such substances or materials in any manner not sanctioned by the applicable permits, or by law or by the highest standards prevailing in the industry for the storage and use of such substances or materials, nor allow to be brought into the Lot any such materials or substances except to use in the ordinary course of Tenant's business, and then only after written notice is given to Landlord of the identity of such substances or materials. Tenant shall obtain and maintain all proper permits required by applicable law or ordinance for the storage and use of hazardous materials, and Tenant shall furnish evidence of same upon request. Without limitation, hazardous substances and materials shall include those described in the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. Section 9601 et seq., the Resource Conservation and Recovery Act, as amended, 42 U.S.C. Section 6901 et seq., any applicable state or local laws and the regulations adopted under these acts. If any lender or governmental agency shall ever require testing to ascertain whether or not there has been any release of hazardous materials, and if it is determined that there has been a release of hazardous materials attributable to Tenant, then the reasonable costs thereof shall be reimbursed by Tenant to Landlord upon demand as additional rent. In addition, Tenant shall execute affidavits, representations and the like from time to time at Landlord's request concerning Tenant's best knowledge and belief regarding the presence of hazardous substances or materials on the demised premises. In all events, Tenant shall indemnify Landlord in the manner elsewhere provided in this lease from any release of hazardous materials on the demised premises occurring while Tenant is in possession or elsewhere if caused by Tenant or persons acting under Tenant. The within covenants shall survive the expiration or earlier termination of the Term of this lease. Landlord acknowledges that Tenant may use and store certain hazardous materials provided Tenant uses, stores and removes same in accordance with all applicable laws. Tenant shall in all events remove any such hazardous materials upon the expiration of the Term of this lease. Landlord shall have the right, at reasonable times and upon prior reasonable notice (but in any event not less than 48 hours prior notice), to inspect the demised premises to determine the use, storage and removal of such hazardous materials. Upon request, Tenant shall give Landlord a list of the hazardous materials used, stored and removed from the demised premises. Notwithstanding any provision of this lease to the contrary, Landlord shall solely be responsible for the remediation (or to cause such removal or remediation) and all costs thereof to the extent required by and in compliance with all legal requirements of any hazardous material present in, on or under the demised premises existing prior to the date Landlord delivers the demised premises to Tenant, whether now known or discovered hereafter, or to the extent caused by Landlord, or its servants or agents. Landlord shall indemnify and hold Tenant harmless from any claims, damages, liabilities, penalties, fines and costs arising directly out of any condition caused or created by Landlord's failure to comply with its obligations under this Section. The foregoing indemnification of Tenant by Landlord includes, without limitation, all costs incurred by or imposed upon Tenant in connection with any judgments, damages, penalties, fines, liabilities or losses (including, without limitation, sums paid in settlement of claims, reasonable attorneys' fees, consultant fees and expert fees). Landlord's obligations under this Section will survive the termination or early expiration of this lease.

## (O) DELAYS

In any case where either party hereto is required to do any act (other than make a payment of money), delays caused by or resulting from Act of God, war, civil commotion, fire or other casualty, labor difficulties, shortages of labor, materials or equipment, government regulations or other causes beyond such party's reasonable control (other than such party's financial condition) shall not be counted in determining the time during which such act shall be completed, whether such time, be designated by a fixed date, a fixed time or "a reasonable time".

## ARTICLE XI

### SECURITY DEPOSIT

11. INTENTIONALLY OMITTED.

## ARTICLE XII

12. INTENTIONALLY OMITTED.

## ARTICLE XIII

### OPTION

#### 13. (A)OPTION TERM

Tenant shall have the right, at its election, to extend the Original Term of this lease for an additional period of five (5) years commencing upon the expiration of the Original Term, provided that Landlord shall receive written notice from Tenant of the exercise of its election at least nine (9) months prior to the expiration of the Original Term and provided further that Tenant shall not be in default beyond any applicable cure period at the time of Landlord's receipt of such notice in the payment of any Fixed Rent due Landlord by Tenant. Tenant shall have the right, at its election, to further extend the Original Term as previously extended for one (1) additional period of five (5) years commencing upon the expiration of the Original Term as previously extended, provided that Landlord shall receive written notice from Tenant of the exercise of its election at least nine (9) months prior to the expiration of the Original Term as previously extended and provided further that Tenant shall not be in default beyond any applicable cure period at the time of Landlord's receipt of such notice in the payment of any Fixed Rent due Landlord by Tenant. The expression "the original term" means the period of fifteen (15) years referred to in Section (A) of Article 1 of this lease. Prior to the exercise by Tenant of either of said elections to extend the Original Term, the expression "the term of this lease" or any equivalent expression shall mean the Original Term; after the exercise by Tenant of one or both of the aforesaid elections, the expression "the term of this lease" or any equivalent expression shall mean the Original Term as it may have been then extended. Except as expressly otherwise provided in this lease, all the agreements and conditions in this lease contained shall apply to the additional period or periods to which the Original Term shall be extended as aforesaid. If Landlord shall receive notice of the exercise of an election in the manner and within the time provided aforesaid, the Term shall be extended upon the receipt of the notice without the requirement of any action on the part of Landlord.

#### (B) OPTION RENT

During each of the additional periods for which the Original Term of this lease may be extended as set forth in Section (A) of this Article XIII above, the Fixed Rent payable hereunder shall be adjusted so as to equal the greater of (a) the Fixed Rent payable immediately prior thereto, or (b) the "fair market rent", as mutually determined by Landlord and Tenant through the process of negotiation. Notwithstanding anything to the contrary contained herein, however, if for any reason whatsoever Landlord and Tenant shall not agree in writing upon the "fair market rent" for the additional period in question at least six (6) months prior to the expiration of the Original Term, or the first additional period, as the case may be, then the fair market rent for premises of the size and nature of the demised premises shall be determined by licensed real estate appraisers having at least ten (10) years' experience in the appraisal of commercial real estate in Greater Boston, Massachusetts, one such appraiser to be designated by each of Landlord and Tenant. If either party shall fail to designate its appraiser by giving notice of the name of such appraiser to the other party within fifteen (15) days after receiving notice of the name of the other party's appraiser, then the appraiser chosen by the other party shall determine the fair market rent and his determination shall be final and conclusive. If the appraisers designated by Landlord and Tenant shall disagree as to the fair market rent, but if the difference between their estimates of fair market rent shall be five percent (5%) or less of the greater of the estimates, then the average of their estimates shall be the fair market rent for purposes hereof. If the appraisers designated by Landlord and Tenant shall disagree as to the amount of fair market rent, and if their estimates of fair market rent shall vary by more than five percent (5%) of the greater of said estimates, then they shall jointly select a third appraiser meeting the qualifications set forth above, and his estimate of fair market rent shall be the fair market rent for purposes hereof if it is not greater than the greater of the other two estimates and not less than the lesser of the other two estimates. If said third appraiser's estimate is greater than the greater of the other two estimates, then the greater of the other two estimates shall be the fair market rent for purposes hereof; and if the estimate of the third appraiser shall be less than the lesser of the other two estimates, then the lesser of the other two estimates shall be the fair market rent for purposes hereof. Each of Landlord and Tenant shall pay for the services of its appraiser, and if a third appraiser shall be chosen, then each of Landlord and Tenant shall pay for one-half of the services of the third appraiser. In determining fair market rent, any improvements made by Tenant in the demised premises and not otherwise reimbursed by Landlord shall not be considered, such that the appraisal shall be based on the condition of the demised premises as same existed on the delivery date as improved by Landlord's Construction



## ARTICLE XIV

### TITLE TO PREMISES

Landlord represents and warrants to Tenant that Landlord is the owner of the demised premises, and that there are no other individuals or entities having an ownership interest in the demised premises whatsoever except as expressly stated in this lease, and that Landlord has full right, power and authority, corporate and otherwise, to execute this lease, to lease the demised premises and to perform the obligations of Landlord under this lease. Landlord shall provide Tenant with its most recent commitment of title insurance or other proof adequate to Tenant, to insure that Landlord has title to the demised premises, unencumbered by claims which may disturb Tenant's enjoyment of the demised premises and that no tax liens exist against the demised premises.

Landlord warrants to Tenant that, by paying the rent provided for in this lease and performing Tenant's obligations under this lease, Tenant will be entitled to peaceably and quietly enjoy the demised premises and all rights and appurtenances thereto during the lease Term, without molestation or hindrance of any person whomsoever.

EXECUTED as a sealed instrument in two or more counterparts as of the day and year first above written.

**LANDLORD:**  
**H & N ASSOCIATES, LLC**

/s/Harold C. Garnick  
Harold C. Garnick, Manager

**TENANT:**  
**ADVANCED INHALATION RESEARCH, INC.**

By /s/James M. Frates  
James M. Frates  
Vice President

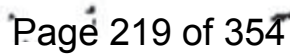
**ATTEST:**

By /s/Patricia Allen  
Director of Finance and Asst Secretary

(Corporate Seal)

**EXHIBIT A**

**PLAN SHOWING THE DEMISED PREMISES**



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## **EXHIBIT B**

### **LANDLORD'S REQUIRED WORK**

Landlord, at its expense, will complete the following improvements to the Property:

1. Completion of the passenger elevator upon installation by Tenant of Tenant's telephone service; and completion of the office lobby within one hundred fifty (150) days of Commencement Date provided, however, Landlord will provide a \$5,000.00 allowance to Tenant if Tenant chooses to install its own floor covering and ceiling in the 600 square foot lobby;
  2. All exterior parking lot paving, including the rear access drive (1.5" finish coat and preliminary coat if not already done), finish/landscape around the new drive, pave all around the smokestack area (including over concrete area), and lighting on or before May 21, 2001; and striping by a mutually agreed upon date;
  3. Relocation of the light pole in the parking lot on or before May 31, 2001;
  4. Remove all equipment from building C and professionally clean the interior of building C and restore the restrooms within one hundred fifty (150) days of Commencement Date, failing which, the proportionate rent for building C shall abate until the equipment is removed, the building interior is cleaned and the restrooms are restored;
  5. Provide industrial heating and lighting to building D and provide electrical service thereto. The work set forth in this paragraph 5 shall be completed within one hundred fifty (150) days of Commencement Date provided, however, if Tenant elects to perform same, Landlord shall give Tenant an allowance of \$6,100.00;
  6. Landlord shall replace the structure linking building D to building A within one hundred fifty (150) days of Commencement Date, failing which the proportionate rent for building D shall abate until said structure is replaced. Said structure shall thereafter be considered a building;
  7. Replace/fix chainlink fence around both rear parking lots by May 31, 2001;
  8. Two (2) new double doors in building D by January 30, 2001;
  9. Smooth building D floor with concrete skim coat or comparable product within one hundred fifty (150) days of Commencement Date;
  10. Clean up trash and remove all weeds around the buildings and garage area by May 31, 2001, and clean out the garage and secure and fix the doors thereto within one hundred fifty (150) days of Commencement Date; and
  11. Install steps at back of building C to rear parking lot by May 31, 2001.
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## **EXHIBIT C**

### **TENANT'S WORK**

Except as otherwise set forth on Exhibit B, all work needed to prepare the demised premises for Tenant's occupancy shall be Tenant's responsibility and is herein called "Tenant's Work". Except to the extent (if any) expressly provided to the contrary in Exhibit B hereof, Tenant's Work shall include, without limitation, furnishing any distribution facilities within the demised premises for utilities (including, without limitation, electricity, water and sewerage) required to meet Tenant's needs.

Tenant shall submit to Landlord for its approval plans and specifications for Tenant's Work. Landlord shall have twenty (20) days from the date of submission to approve or disapprove such plans and specifications. In the event of disapproval, Landlord shall give written notice of the same to Tenant and within fifteen (15) days from the date of such notice, Tenant shall submit new plans and specifications for Landlord's approval, corrected so as to satisfy Landlord's objections. Landlord shall not unreasonably withhold approval of plans and specifications, and Landlord agrees to cooperate with Tenant in the correction of disapproved plans and specifications.

All of Tenant's Work shall be done at Tenant's sole risk and expense. Landlord shall not be a party to nor incur any liability as a result of any contract to perform any of Tenant's Work. Tenant shall obtain lien waivers from all of its contractors commencing work in the demised premises so that no mechanics' or materialmen's liens shall attach to the demised premises or the buildings as a result of Tenant's Work.

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## **EXHIBIT D**

### **LANDLORD'S SERVICES**

Landlord shall cause the parking areas, driveways, walkways and outdoor stairs and the Lot to be kept reasonably free and clear of snow, ice and refuse and shall cause the landscaped areas (if any) of the Lot to be maintained in a reasonably attractive appearance. Landlord shall also cause the parking areas of the Lot to be kept lighted during hours of darkness to the extent reasonably required for the business operations conducted upon the Lot. Landlord shall cause the elevator to be regularly serviced and maintained. In the event Landlord shall on more than two (2) occasions in any twelve (12) month period fail to provide said services in a satisfactory manner within thirty (30) days following notice to Landlord by Tenant of such failure, Tenant may thereafter perform such services as Landlord has failed to perform with an appropriate adjustment in the management fee payable pursuant to Section (C) of Article 5 above.

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**EXHIBIT E**

**RULES AND REGULATIONS**

**INTENTIONALLY OMITTED**

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## EXHIBIT F

### LEGAL DESCRIPTION OF LOT

The premises are bounded and described as follows:

That certain parcel of land on the southerly side of Carter Street and the westerly side of Vale Street in Chelsea, Suffolk County, Massachusetts, being shown as Lot 1 on a “Subdivision Plan of Land in Chelsea, Mass., dated August 15, 1973, made by John Marion, Registered Land Surveyor”, recorded with the Suffolk County Registry of Deeds in Book 8687, Page 246, and being bounded and described, in accordance with said Plan, as follows:

NORTHWESTERLY      by Carter Street, 269 feet;

NORTHEASTERLY      by Vale Street, 543.16 feet;

SOUTHEASTERLY,  
EASTERLY AND  
NORTHEASTERLY      by Lot 5, by three lines 66.60 feet, 22.10 feet and 46.50 feet, respectively;

SOUTHWESTERLY      by land now or formerly of the Boston and Maine Corporation, 333.62 feet; and

WESTERLY AND  
SOUTHWESTERLY      by Lot 2, by three lines, 132.40 feet, 80.20 feet, and 157 feet, respectively.

## **SIDE LETTER**

1. Reference is made to lease dated December 6, 2000, by and between H&N Associates, LLC, a Massachusetts Limited Liability Company, as Landlord and Advanced Inhalation Research, Inc., a Delaware Corporation, as Tenant, with respect to premises known as Brickyard Square, Chelsea, Massachusetts. Said lease is hereinafter referred to as "the Lease".

2. Tenant agrees that it shall submit an application for tax relief substantially in the form as attached as Exhibit A to this Side Letter to the City of Chelsea on or before December 4, 2000. Upon approval of such application for tax relief by the City of Chelsea, Tenant shall cause the City of Chelsea to submit same for approval to the Economic Development Incentive Program of the Commonwealth of Massachusetts on or before December 21, 2000. In the event approval of such plan is not secured on or before February 28, 2001, Tenant shall have the right to terminate the Lease for such failure to obtain approval of the tax relief plan by a notice to this effect given to Landlord on or before February 28, 2001 and all Fixed Rent, additional rent and any other monies paid by Tenant to Landlord shall be returned immediately. Failing the giving of said notice to Landlord by said date, the Lease shall remain in full force and effect in accordance with its terms and Tenant shall have no further right to terminate the Lease except as may be provided for therein. Upon such approval, Tenant's right to terminate the Lease for such reason shall lapse.

The provisions of Exhibit B of the Lease to the contrary notwithstanding, upon notification from Tenant to Landlord that Tenant has obtained all of the approvals described above or that Tenant has waived its termination right set forth above, each item of Landlord's Required Work to be completed within one hundred fifty (150) days shall instead be completed within the earlier of ninety (90) days after Tenant's notification or one hundred fifty (150) days after the Commencement Date.

This Side Letter shall be binding upon the undersigned and their respective legal representatives, successors and assigns.

Executed as an instrument under seal as of 6<sup>th</sup> day of December, 2000.

**LANDLORD:**  
**H & N ASSOCIATES, LLC**

/s/ Harold C. Garnick  
Harold C. Gamick  
Manager

**TENANT:**  
**ADVANCED INHALATION RESEARCH, INC.**

By /s/ James M. Frates  
James M. Frates  
Vice President

**ATTEST:**  
By /s/ Patricia Allen  
Patricia Allen  
Director of Finance and Asst  
Secretary

(Corporate Seal)

**AGREED TO AND ACCEPTED ALKERMES, INC.,  
AS GUARANTOR**

By James M. Frates  
James M. Frates  
CFO, Vice President &  
Treasurer

**AMENDMENT A**

August 22, 2002

1. Reference is made to Lease dated December 6, 2000, by and between H&N Associates, LLC, a Massachusetts Limited Liability Company, as Landlord ("Landlord"), and Advanced Inhalation Research, Inc., a Delaware Corporation, as tenant ("Tenant"), with respect to premises known as Brickyard Square, 190 Everett Avenue, Chelsea, Massachusetts. Said Lease is hereinafter referred to as "the Lease".

2. Landlord and Tenant hereby agree that the Lease is hereby amended in the following respects:

(A) Landlord shall perform the work set forth on that Proposal of Multi-State Roofing, Inc. attached hereto and made a part hereof as Exhibit A, all at Tenant's sole cost and expenses. Tenant shall pay to Landlord the amount set forth on any invoice of Multi-State Roofing, Inc., upon presentation of such invoice. Tenant shall also pay for the cost of any change orders approved by tenant prior to work being begun. Landlord shall give to Tenant the benefit of any and all warranties that Landlord may have from Multi-State Roofing, Inc. pursuant to the work set forth on Exhibit A.

(B) Notwithstanding the provisions of subsection (2) of Section (A) of Article 4 of the lease, Tenant shall repair the roof and keep same in good order and in serviceable condition.

3. Except as expressly modified herein the Lease shall remain unmodified and in full force and effect.

4. The provisions of this Amendment A shall be binding upon and shall inure to the benefit of Landlord and Tenant and their respective legal representatives, successors and assigns.

In Witness Whereof, Landlord and Tenant have caused this Amendment A to be executed as an instrument under seal as of the day and year first above written.

**LANDLORD:**  
**H & N ASSOCIATES, LLC**

/s/ Harold C. Garnick  
Harold C. Garnick, Manager

**TENANT:**  
**ADVANCED INHALATION RESEARCH, INC.**

By /s/ James M. Frates  
Name: James M. Frates  
Title:

By  
Name:  
Title:

## AMENDMENT B

December 4, 2006

1. Reference is made to Lease dated December b, 2000, by and between H&N Associates, LLC, a Massachusetts Limited Liability Company, as landlord ("Landlord"), and Advanced Inhalation Research, Inc., a Delaware Corporation, as tenant ("Tenant"), with respect to premises known as Brickyard Square, 190 Everett Avenue, Chelsea, Massachusetts. Said lease, as amended by Amendment A dated August 22, 2002, is hereinafter referred to as "the Lease."

2. Landlord and Tenant are in dispute as to certain amounts owed by and between Landlord and Tenant pursuant to the Lease. Landlord and Tenant desire to resolve all claims relating to Section (B) of Article III of the Lease and Exhibit B of the Lease existing between them as of the date of this Amendment B. Accordingly, Landlord and Tenant hereby agree that the Lease is amended in the following respects:

The Fixed Rent payable pursuant to Article V of the Lease for the months of November and December, 2006, January and February, 2007, January and February, 2008, and January, February and March, 2009, shall be reduced on a dollar for dollar basis by the Fixed Rout payable for said months in an amount not to exceed \$52,700.00 per month for each of the aforesaid months, and Landlord shall pay to Tenant a single payment on or before March 31, 2009 in the amount of \$25,700.00. Notwithstanding the aforementioned, in the event the Fixed Rent payable is suspended or not otherwise payable under the Lease, Landlord's financial obligation to Tenant shall exist and shall be satisfied on the timelines set forth in this paragraph until Landlord has paid an aggregate of \$500,000 to Tenant.

3. Except as expressly modified herein the Lease shall remain unmodified and in full force and effect.

4. The provisions of this Amendment B shall be binding upon and shall inure to the benefit of Landlord and Tenant and their respective legal representatives, successors and assigns.

Signatures On Next Page Following

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IN WITNESS WHEREOF, Landlord and Tenant have caused this Amendment B to be executed as an instrument under seal as of the day and year first above written.

LANDLORD:  
H & N ASSOCIATES, LLC

TENANT:  
ADVANCED INHALATION RESEARCH, INC.

By: /s/ Harold C. Garnick  
Harold C. Garnick  
Manager

By /s/ Michael Landine  
Name: Michael Landine  
Title: Vice President

Agreed to and Approved:  
MORTGAGOR

By: /s/ Goran C. Finley  
Name: Goran C. Finley  
Title: Senior Vice President



SUBLEASE

This Sublease (the “Sublease”) is made as of the 27th day of December 2010 by and between ALKERMES, INC., a Pennsylvania corporation having an address at 852 Winter Street, Waltham, Massachusetts 02451-1420 (“Sublandlord”), and CORREGIDOR THERAPEUTICS, INC., a Delaware corporation having an address at 384 Powder Mill Road, Concord, MA 01742 (“Subtenant”).

WITNESSETH:

WHEREAS, by that certain Lease dated December 6, 2000 (the “Original Lease”), as amended by that certain (a) Side Letter dated December 6, 2000 (the “Side Letter”), (b) Amendment A dated August 22, 2002 (“Amendment A”) and (c) Amendment B dated December 4, 2006 (“Amendment B,” and together with the Original Lease, the Side Letter and Amendment A, the “Overlease”) (a copy of which Overlease is attached as Exhibit A hereto), H&N Associates, LLC, a Massachusetts limited liability company (“Overlandlord”), as landlord thereunder, leases to Sublandlord, successor-by-merger to Advanced Inhalation Research, Inc., a Delaware corporation, as tenant thereunder, the land and improvements commonly known as Brickyard Square and described in Article I of the Overlease as being located at 190 Everett Avenue, Chelsea, Massachusetts (the “Demised Premises”); and

WHEREAS, Subtenant desires to sublease from Sublandlord and Sublandlord desires to sublease to Subtenant, all of the Demised Premises (hereinafter referred to as the “Subleased Premises”).

NOW, THEREFORE, in consideration of the mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. DEMISE OF SUBLEASED PREMISES. Sublandlord hereby demises and subleases to Subtenant, and Subtenant hereby hires and takes from Sublandlord, exclusive possession of the Subleased Premises for the term and upon the conditions hereinafter set forth.

2. TERM.

(a) The term of this Sublease (the “Term”) shall commence on the date (the “Commencement Date”) of mutual execution and delivery of this Sublease by Sublandlord and Subtenant and expire on the Expiration Date (as hereinafter defined). On or before the expiration of the Free-Rent Period (as defined in Section 4(c) below), Subtenant shall deliver to Sublandlord a certificate of insurance as set forth in Sections 6.(8) and 6.(16) of the Overlease. In addition to the requirements in Section 6.(8), such certificate shall also name Sublandlord as an additional insured.

(b) The term “Expiration Date” as used herein means (i) December 31, 2015, or if one or more Extension Options (as defined in Section 2(c) below) have been exercised hereunder, the expiration of the last Extension Period (as defined in Section 2(c) below) pursuant

thereto, or (ii) such earlier date upon which this Sublease is terminated pursuant to the provisions hereof.

(c) Under the Overlease, Sublandlord has two options to extend the term of the Overlease by a period of five years (each an "Overlease Extension Option" and collectively the "Overlease Extension Options"). The extended term under each Overlease Extension Option shall be an "Overlease Extension Period." Subtenant shall have two options (each an "Extension Option" and collectively the "Extension Options") to extend the Term of this Sublease for a period of time coterminous with each Overlease Extension Period (each an "Extension Period"). Subtenant may exercise one or more Extension Options by providing Sublandlord with written notice of Subtenant's desire for such extension of the term hereof twelve (12) months prior to the expiration of the then current Term (including any Extension Period) of this Sublease; *provided* Subtenant provides Sublandlord with the Extension Period Security (as defined below). Sublandlord shall, within five (5) business days of the date of such notice, deliver written notice to Overlandlord exercising the applicable Overlease Extension Option, pursuant to the requirements set forth in the Overlease. Sublandlord shall provide Subtenant with a copy of such notice within five (5) business days of when Sublandlord provides such notice to Overlandlord. Each Extension Period shall be on the same terms and conditions as set forth in this Sublease. In connection with the determination of the Fixed Rent during the Extension Period pursuant to Section 13.(B) of the Overlease, Subtenant shall have the right to participate and make any decisions in connection with such process as if it were Tenant under the Overlease. Sublandlord shall not agree to any Fixed Rent for any Extension Period without the prior written consent of Subtenant. In the event that Subtenant shall not direct Sublandlord to exercise an Extension Option, this Sublease shall expire at the end of the then current Term.

Additionally, in connection with a sale of the Manufacturing Facility Equipment (as defined in Section 17 below), Sublandlord shall exercise any then unexercised and exercisable Extension Option to accordingly extend the Term; *provided* Subtenant provides Sublandlord with the Extension Period Security.

The "Extension Period Security" shall be a letter of credit or other arrangement acceptable to Sublandlord and Subtenant, in an amount not to exceed the sum of the Fixed Rent, Direct Expenses and utilities for the applicable Extension Period, which amount shall reduce quarterly to reflect the amount of time remaining in the Extension Period.

### 3. SUBORDINATION TO AND INCORPORATION OF THE OVERLEASE.

(a) This Sublease is in all respects subject and subordinate to the terms and conditions of the Overlease and to the matters to which the Overlease, including any amendments thereto, is or shall be subordinate. Subtenant agrees that Subtenant has reviewed and is familiar with the Overlease, and will not do or suffer or permit anything to be done which would result in a default or breach of the Overlease (beyond any applicable cure period) on the part of Sublandlord under the Overlease or cause the Overlease to be terminated. If, however, the Overlease is terminated prior to its scheduled expiration, for any reason whatever, this Sublease shall likewise terminate without further notice and without further obligation or liability on the part of the parties, except as otherwise set forth herein. Sublandlord shall promptly

provide Subtenant with a copy of any notice of default delivered to Sublandlord pursuant to the Overlease.

(b) Except as otherwise expressly provided in this Sublease, the terms, covenants, conditions, rights, obligations, remedies and agreements of the Overlease are incorporated into this Sublease by reference and made a part hereof as if fully set forth herein and shall constitute the terms of this Sublease, *mutatis mutandis*, Sublandlord being substituted for “Landlord” thereunder, Subtenant being substituted for “Tenant” thereunder, and “Subleased Premises” being substituted for “Premises” and “demised premises” thereunder, except to the extent that such terms do not relate to the Subleased Premises or are inapplicable to, or specifically inconsistent with the terms of this Sublease.

(c) The following provisions of the Overlease shall not be incorporated herein by reference and are expressly excluded from the terms of this Sublease: Sections 3.(A), 3.(B), 3.(C), 3.(E), 4.(A), 4.(B) (the portion of paragraph 1 beginning with the words “including without limitation” and ending with the words “repairs or alterations.”, paragraphs 2 and 3 only), 5.(A), 6.(2) (but only with respect to the restoration and removal provisions thereof as they relate to installations, alterations, additions and improvements existing as of the Commencement Date), 8.(A), 9, 10.(B), 10.(D), 10.(E), 10.(I), 10.(K), 10.(L), 10.(M), 13.(A), 13.(B), Article XIV (paragraph 1 only) and Exhibits B, C and D of the Original Lease, the Side Letter, Amendment A and Amendment B provided, however, that notwithstanding such non-incorporation, this Sublease remains subject and subordinate to all of the foregoing provisions as provided in Section 3 (a) above. Notwithstanding the non-incorporation of the provisions set forth in this Section 3(c), Subtenant shall have the benefit of all services of the Overlandlord to be provided pursuant to the Overlease.

(d) Any capitalized terms not defined herein shall have the meaning set forth in the Overlease.

#### 4. RENT.

(a) From and after the Commencement Date, Subtenant shall pay to Sublandlord annual fixed rent (the “Fixed Rent”) in the amounts set forth on Schedule 4 attached hereto. Fixed Rent shall be payable in advance in the monthly installments set forth on Schedule 4, pro-rated on a per diem basis in the case of any partial months during the Term. Except as otherwise set forth herein, each monthly installment of Fixed Rent shall be payable on or before the first day of each month, without notice or demand and without abatement, set-off or deduction.

(b) From and after the Commencement Date, Subtenant agrees to pay to Sublandlord, as additional rent hereunder, an amount equal to all of the Real Estate Taxes (as defined in Section 5.(B)(1) of the Overlease) and Operating Expenses (as defined in Section 5.(C)(1) of the Overlease) due from Sublandlord to Overlandlord pursuant to Sections 5.(B) and 5.(C) of the Overlease, respectively (collectively, “Direct Expenses”). Sublandlord shall provide Subtenant with evidence of its payment of the Direct Expenses to Overlandlord within five (5) business days of the date Sublandlord makes such payment to Overlandlord.

(c) So long as Subtenant is not then in material default under this Sublease (beyond any applicable notice and cure period), Fixed Rent and Direct Expenses shall be abated for the period (the "Free-Rent Period") beginning on the Commencement Date and continuing through March 31, 2011. In addition, during the Free-Rent Period, Sublandlord shall pay all utilities and other operating costs for the Subleased Premises. In the event of a termination of this Sublease prior to December 31, 2015, as a result of any default by or on behalf of Subtenant, any such Fixed Rent and Direct Expenses previously abated hereunder shall be immediately due and payable from Subtenant to Sublandlord.

(d) In addition to the Fixed Rent and Direct Expenses, Subtenant agrees to pay to Sublandlord all Subtenant Surcharges (as hereinafter defined) as additional rent hereunder. As used herein, the term "Subtenant Surcharges" shall mean any and all amounts which become due and payable by Sublandlord to the Overlandlord under the Overlease (without additional charge or profit to Sublandlord) as "Additional Rent" (as such term is defined in the Overlease) which would not have become due and payable but for the acts and/or failures to act of Subtenant under this Sublease or which are otherwise attributable to the Subleased Premises, including, but not limited to: (i) any increases in the Overlandlord's fire, rent or other insurance premiums resulting from any act or omission of Subtenant, and (ii) any additional rent or charges under the Overlease payable by Sublandlord on account of any other additional service as may be provided under the Overlease, or with the consent of the Overlandlord, Subtenant shall pay any Subtenant Surcharge within fifteen (15) business days after Subtenant's receipt of the Overlandlord's statements from Sublandlord. In the event that Subtenant disputes the Subtenant Surcharges, Sublandlord agrees to cooperate with Subtenant in seeking a reduction of such disputed amount from the Overlandlord, and if such reduction is obtained, the corresponding reduction of the Subtenant Surcharge shall be refunded to Subtenant within thirty (30) days thereof.

(e) Any failure or delay by Sublandlord in billing any sum set forth in this Section 4 shall not constitute a waiver of Subtenant's obligation to pay the same in accordance with the terms of this Sublease; provided, however, that the fifteen (15) day period set forth in Section 4(d) above shall not commence until the Subtenant is in receipt of the Overlandlord's statements.

(f) The Fixed Rent, Direct Expenses and Subtenant Surcharges, and any other amounts payable pursuant to this Sublease, shall be paid by Subtenant to Sublandlord at the address set forth for notices below, or at such other place as Sublandlord may hereafter designate from time to time in writing delivered in accordance with Section 11 below, in lawful money of the United States of America, by a good unendorsed check or other immediately available funds, subject to collection, as and when the same become due and payable, without demand therefor and without any deduction, set-off or abatement whatsoever. Any other amounts of additional rents and other charges herein reserved and payable shall be paid by Subtenant in the manner and to the persons set forth in the statement from Sublandlord describing the amounts due as applicable. All Direct Expenses, Subtenant Surcharges and all other costs, charges and expenses which Subtenant assumes, agrees or is obligated to pay to Sublandlord pursuant to this Sublease shall be additional rent and in the event of nonpayment thereof Sublandlord shall have all the rights and remedies with respect thereto as are herein provided for in case of nonpayment of the Fixed Rent reserved hereunder.

(g) In the event that the “Fixed Rent”, “Real Estate Taxes”, “Operating Expenses” (as each such term is defined in the Overlease) or any other costs or expenses payable by Sublandlord under the Overlease are abated, the Fixed Rent, Real Estate Taxes, Operating Expenses and any other costs or expenses payable by Subtenant hereunder shall abate correspondingly.

5. SECURITY DEPOSIT. Within two (2) days after Subtenant’s execution and delivery of this Sublease, Subtenant shall deliver to Sublandlord an initial security deposit in the amount of One Million Dollars (\$1,000,000) (the “Initial Security Deposit”, and together with any Extension Security Deposit held from time to time, the “Security Deposit”) in the form of an unconditional, irrevocable standby letter of credit without documents, i.e., no obligation on Sublandlord’s part to present anything but a sight draft, with Sublandlord as beneficiary, drawable in whole or in part, providing for payment in Boston, Massachusetts, on presentation of Sublandlord’s drafts on sight, providing for multiple draws and multiple successors and otherwise both from a bank and in a form reasonably acceptable to Sublandlord (an “LC”). Notwithstanding the foregoing, Subtenant may elect to initially deliver the Initial Security Deposit in cash form, provided that Subtenant delivers an LC to Sublandlord to replace the cash Initial Security Deposit within forty-five (45) days of the effective date of this Sublease, and upon Sublandlord’s receipt of such LC, Sublandlord shall promptly return the cash balance of the Initial Security Deposit to Subtenant. If any portion of the Security Deposit is used or applied pursuant to this Section 5, Sublandlord shall provide Subtenant with written notice setting forth the amounts so used or applied and the purpose therefor, and Subtenant shall, within ten (10) days after receipt of such notice, deposit cash or a replacement letter of credit (in form and substance subject to the same requirements as the original letter of credit) in an amount sufficient to restore the Security Deposit to the required balance hereunder at such time. Subtenant’s failure to do so shall be a material default and breach of this Sublease by Subtenant.

The Security Deposit shall be held by Sublandlord as security for the faithful performance by Subtenant of all the terms, covenants, and conditions of this Sublease applicable to Subtenant. If Subtenant defaults with respect to any provision of this Sublease beyond all applicable periods of notice and cure, including but not limited to the provisions relating to the condition of the Subleased Premises upon the Expiration Date, Sublandlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any amount which Sublandlord may spend by reason of Subtenant’s default. The rights of Sublandlord pursuant to this Section are in addition to any rights which Sublandlord may have pursuant to Section 10 below.

Upon the expiration of the initial term (without giving effect to any Extension Periods) hereof or earlier termination of this Sublease, and when all then-existing defaults hereunder have been cured, Sublandlord shall return the Initial Security Deposit or any balance thereof (without interest) to Subtenant within three (3) months of such expiration or termination. Failure of Subtenant to deliver a replacement letter of credit to Sublandlord at least thirty (30) days prior to the expiration date of any current letter of credit shall constitute a separate default entitling Sublandlord, following written notice and an opportunity to cure by Subtenant, to draw down immediately and entirely on the current letter of credit and the proceeds shall constitute a cash Initial Security Deposit.

With respect to any Extension Period, Subtenant shall provide to Sublandlord the Extension Security Deposit applicable thereto. Upon expiration or earlier termination of any Extension Period and when all then-existing defaults hereunder have been cured, Sublandlord shall return the Extension Security Deposit or any balance thereof (without interest) to Subtenant within three (3) months of such expiration or earlier termination.

Notwithstanding anything in this Section 5 to the contrary, if the expiration of the initial term or any Extension Period shall also represent the occurrence of the Expiration Date, then upon expiration or earlier termination of this Sublease, Sublandlord shall return any Security Deposit or any balance thereof (without interest) to Subtenant within three (3) months of such expiration or earlier termination, and after Subtenant has vacated the Subleased Premises and all then-existing defaults hereunder have been cured.

6. CONDITION OF SUBLEASED PREMISES. It is agreed that on the Commencement Date Sublandlord shall deliver the Subleased Premises to the Subtenant, and Subtenant will accept the Subleased Premises from Sublandlord, "as is" in its present condition and Sublandlord has no obligation to perform any work therein or contribute to the cost of any work.

7. FAILURE OF OVERLANDLORD TO PERFORM OBLIGATIONS. Sublandlord represents and warrants that the Overlease is in full force and effect and that Sublandlord is not currently in default under the Overlease, nor is there any condition that, with the provision of notice or the passage of time or both, would constitute a default thereunder. Sublandlord shall not do nor permit to be done, nor fail to take any action, required under the Overlease that results in a breach or default under the Overlease. Subtenant acknowledges and agrees that Sublandlord shall have no obligation to provide any services to the Subleased Premises or to perform the terms, covenants, conditions or obligations contained in the Overlease on the part of Overlandlord to be performed, except as expressly provided herein. Subtenant agrees to look solely to Overlandlord for the furnishing of such services and the performance of such terms, covenants, conditions or obligations. In the event that Overlandlord shall fail to furnish such services or to perform any of the terms, covenants, conditions or obligations contained in the Overlease on its part to be performed, Sublandlord shall be under no obligation or liability whatsoever to Subtenant for such failure. In any event, Subtenant shall not be allowed any abatement or diminution of rent under this Sublease because of Overlandlord's failure to perform any of its obligations under the Overlease, except to the extent that the rent and other sums due under the Overlease are abated, in which case the rent and other sums due hereunder shall abate correspondingly. Sublandlord agrees, however, that in the event that Overlandlord shall fail to provide the services or perform the obligations to be provided or performed by it pursuant to the terms of the Overlease, Sublandlord shall, upon written notice from Subtenant, make demand upon Overlandlord pursuant to the terms of the Overlease and to otherwise reasonably cooperate with Subtenant to enforce Overlandlord's obligations. If such cooperation shall require the expenditure of funds by Sublandlord, Sublandlord shall promptly undertake such action upon the written request of Subtenant if Subtenant agrees to make such expenditure of funds.

8. CASUALTY AND CONDEMNATION. Notwithstanding anything to the contrary contained in this Sublease or in the Overlease, Subtenant shall not have the right to

terminate this Sublease as to all or any part of the Subleased Premises, or be entitled to an abatement of Fixed Rent or any other item of rental, by reason of a casualty or condemnation affecting the Subleased Premises unless Sublandlord is entitled to terminate the Overlease or is entitled to a corresponding abatement with respect to its corresponding obligation under the Overlease. If Sublandlord is entitled to terminate the Overlease for all or any portion of the Subleased Premises by reason of casualty or condemnation, Sublandlord shall provide Subtenant with notice of such right within five (5) business days of Sublandlord's receipt of the Overlandlord's determination (as more fully described in Section 8.(A) of the Overlease) and Subtenant may terminate this Sublease as to any corresponding part of the Subleased Premises by written notice to Sublandlord given at least five (5) business days prior to the date(s) Sublandlord is required to give notice to Overlandlord of such termination under the terms of the Overlease.

9. CONSENTS. In all provisions of the Overlease requiring the approval or consent of the "Landlord," Subtenant shall be required to obtain the approval or consent of both Overlandlord and Sublandlord (which consent of Sublandlord shall not be unreasonably withheld, delayed or conditioned). In no event shall Sublandlord be liable for failure to give its consent or approval in any situation where consent or approval has been withheld or refused by Overlandlord, whether or not such withholding or refusal was proper. Notwithstanding the foregoing, Sublandlord and Subtenant shall cooperate in good faith to obtain any such consent of Overlandlord.

10. DEFAULTS. Subtenant covenants and agrees that in the event that it shall default in the performance of any of the terms, covenants and conditions of this Sublease or of the Overlease as incorporated herein (in each case beyond any applicable notice and cure period), Sublandlord shall be entitled to exercise any and all of the rights and remedies to which it is entitled by law, including, without limitation, the remedy of summary proceeding, and also any and all of the rights and remedies specifically provided for in the Sublease and in the Overlease, which are incorporated herein and made a part hereof, with the same force and effect as if herein specifically set forth in full, and that wherever in the Overlease rights and remedies are given to Overlandlord therein named, the same shall be deemed to refer to Sublandlord herein. The notice and cure periods set forth in Section 7.(A) of the Overlease shall apply to all obligations under this Sublease.

11. NOTICE. Whenever, by the terms of this Sublease, any notice, demand, request, approval, consent or other communication (each of which shall be referred to as a "Notice") shall or may be given either to Sublandlord or to Subtenant, such Notice shall be in writing and shall be sent by hand delivery, reputable overnight courier, or by registered or certified mail, return receipt requested, postage prepaid, addressed as follows (or to such other address or addresses as may from time to time hereafter be designated by Sublandlord or Subtenant, as the case may be, by like Notice):

(a) If intended for Sublandlord, Alkermes, Inc.

to:

852 Winter Street  
Waltham, Massachusetts 02451-1420  
Attn: General Counsel

(b) If intended for Subtenant, to: Corregidor Therapeutics, Inc.  
384 Powder Mill Road  
Concord, Massachusetts 01742  
Attn: Chief Executive Officer

All such Notices shall be deemed to have been served on the date of actual receipt or rejection thereof (in the case of hand delivery), or one (1) business day after such Notice shall have been deposited with a reputable overnight courier, or three (3) business days after such Notice shall have been deposited in the United States mails within the continental United States postage prepaid (in the case of mailing by registered or certified mail as aforesaid).

12. BROKER. Each of Sublandlord and Subtenant represents and warrants to the other that it has not dealt, either directly or indirectly, with any real estate agent or broker in connection with this Sublease other than Colliers Meredith & Grew (the "Broker") and Sublandlord shall be solely responsible for all fees of the Broker. Each of Sublandlord and Subtenant shall indemnify the other from and against any and all loss, costs and expenses, including reasonable attorney's fees, incurred as a result of a breach of such representation and warranty, and Sublandlord shall indemnify Subtenant for any and all loss, costs and expenses, including reasonable attorney's fees, incurred in connection with or arising from its obligation to pay all fees of the Broker.

13. COUNTERPARTS. This Sublease may be executed in one or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The parties acknowledge and agree that the signatures of the parties hereto may be delivered via facsimile or email and that such signatures shall be effective to the same extent as delivery of an original signature.

14. SUBTENANT TERMINATION RIGHT. So long as Subtenant is not then in material default under this Sublease (beyond any applicable notice and cure period), Subtenant shall have the one-time right to terminate this Sublease upon written notice (the "Early Termination Notice") to Sublandlord and the payment to Sublandlord of a fee (the "Early Termination Fee") in the amount of \$1,000,000. If Subtenant shall provide the Early Termination Notice, then on the date set forth on the Early Termination Notice (the "Termination Date") that is no less than one hundred eighty (180) days after the date of the Early Termination Notice, this Sublease shall automatically terminate as if the Termination Date were the scheduled date for expiration of the term of this Sublease. Sublandlord may retain all or any remaining portion of the Security Deposit in satisfaction of the payment of the Early Termination Notice (but not in excess of the amount of the Early Termination Fee). Subtenant shall have no further obligations hereunder.

15. TERMINATION BY SUBLANDLORD. Sublandlord shall have the right, for a period of one hundred eighty (180) days following any Termination Event (as defined below), to terminate this Sublease upon written notice to Subtenant. If Sublandlord shall so exercise its termination right, then on the date that is one hundred eighty (180) days after the date of Sublandlord's notice to Subtenant, without anything further, this Sublease shall terminate as if such date were the scheduled date for expiration of the term of the Sublease. Subtenant shall

have no further obligations hereunder. On such date, Subtenant shall pay to Sublandlord a penalty (the "Early Termination Penalty") in the amount of \$1,000,000, and Sublandlord may retain all or any remaining portion of the Security Deposit in satisfaction of the payment of the Early Termination Penalty (but not in excess of the Early Termination Penalty).

A "Termination Event" shall mean any one of the following: (a) a termination of that certain Asset Purchase and License Agreement between the parties dated December 27, 2010 (the "Asset Purchase Agreement"), (b) the failure of Subtenant to exercise its option under the Asset Purchase Agreement to purchase the Manufacturing Facility Equipment, (c) an "Event of Default" by Subtenant under that certain Promissory Note in the amount of \$30MM issued by Subtenant to Sublandlord pursuant to the Asset Purchase Agreement, or (d) an "Event of Default" by Subtenant under that certain Loan and Security Agreement between the parties entered into pursuant to the Asset Purchase Agreement.

16. SUBLANDLORD'S STORAGE AND ACCESS. Notwithstanding anything in this Sublease to the contrary, during the Free-Rent Period Sublandlord shall have the right to store Sublandlord's furniture, equipment and other materials in the Subleased Premises and to access the Subleased Premises from time to time as Sublandlord shall reasonably require in order to manage and/or dispose of such furniture, equipment and other materials.

17. FURNITURE FIXTURES AND EQUIPMENT. So long as Subtenant is not then in material default under this Sublease (beyond any applicable notice and cure period), in consideration of the payment of Fixed Rent by Subtenant to Sublandlord, and without any additional consideration, Sublandlord hereby grants to Subtenant a license to use the machinery, equipment, instruments, laboratory equipment and apparatus, fixtures, tools, and other tangible assets described on Exhibit B attached hereto and owned by Sublandlord (the "Manufacturing Facility Equipment"). Subtenant acknowledges and agrees that the Manufacturing Facility Equipment is provided in "as-is" condition without any warranty, implied or express, of any kind whatsoever, including any warranty as to the design, quality or condition of the Manufacturing Facility Equipment, any warranty of merchantability or fitness of the Manufacturing Facility Equipment for any particular purpose or as to any other matter relating to the Manufacturing Facility Equipment or any part thereof. Subtenant shall have the right to use the Manufacturing Facility Equipment solely for the Development, Commercialization and Manufacture of Licensed Products on its own behalf or on behalf of its Affiliates or Collaboration Partners (as such terms are defined in the Asset Purchase Agreement), with such activities to be conducted solely at the Subleased Premises, and for no other purpose without the prior written consent of Sublandlord, which shall not be unreasonably withheld. Subtenant covenants and agrees with Sublandlord that Subtenant shall not use the Manufacturing Facility Equipment in contravention of the foregoing. In addition Subtenant shall not use the Manufacturing Facility Equipment to manufacture any penicillins, cephalosporins, beta lactams, "biological products" (as defined in 21 CFR 600.3(h)), high potency compounds or non-pharmaceutical products.

Subtenant shall maintain the Manufacturing Facility Equipment at its own expense so as to keep the Manufacturing Facility Equipment in compliance with all applicable laws and in as good condition as the same shall be as of the Commencement Date, reasonable wear and tear and damage by fire or other casualty excepted, and Subtenant shall not remove the Manufacturing Facility Equipment from the Subleased Premises; provided, however, that upon prior written

notice to Sublandlord, Subtenant may (a) remove any item of Manufacturing Facility Equipment that is broken and (b) improve the Manufacturing Facility Equipment. Subtenant shall insure the Manufacturing Facility Equipment in appropriate amounts for damage or loss.

So long as Subtenant is not then in material default under this Sublease (beyond any applicable notice and cure period), Subtenant shall have the right to purchase the Manufacturing Facility Equipment pursuant to the terms of the Asset Purchase Agreement. Following any such purchase, the provisions of this Section 17 will be of no further force or effect.

18. ENVIRONMENTAL INDEMNITY, Notwithstanding the incorporation of Section 14.(N) of the Overlease pursuant to the provisions of Section 3(b) of this Sublease, Subtenant shall not have any liability to Sublandlord in connection with the presence of any hazardous substances or materials (“Hazardous Materials”) introduced onto the Demised Premises by Sublandlord prior to the Commencement Date (a “Pre-Existing Condition”), except to the extent that any willful, negligent or unlawful act or omission of Subtenant shall exacerbate such Pre-Existing Condition. In addition, with respect to any Pre-Existing Condition, Sublandlord shall indemnify, defend and hold harmless Subtenant and its officers, directors, employees and agents from and against any costs and expenses (including reasonable investigation expenses, legal expenses and attorneys’ fees), liabilities, fines, damages, assessments and/or other losses incurred by any of them and arising from a Pre-Existing Condition. Sublandlord’s obligation to indemnify, defend and hold harmless pursuant to this Section 18 shall survive any termination or expiration of this Sublease.

19. SUCCESSORS AND ASSIGNS. The covenants, conditions and agreements herein contained shall inure to the benefit of and be binding upon Sublandlord, its successors and assigns, and shall be binding upon Subtenant, its successors and assigns, and shall inure to the benefit of Subtenant and only such assigns of Subtenant to whom the assignment by Subtenant has been completed in accordance with the provisions of this Sublease and the Overlease.

*[signatures on following page]*

IN WITNESS WHEREOF, Sublandlord and Subtenant herein have duly executed this instrument on the day and year first above written.

SUBLANDORD:

ALKERMES, INC.

By: /s/ Gordon Pugh

Name: Gordon Pugh

Its: Senior Vice President

SUBTENANT :

CORREGIDOR THERAPEUTICS, INC.

By: /s/ Glenn Batchelder

Name: Glenn Batchelder

Its: Chief Financial Officer

**SIGNATURE PAGE TO SUBLEASE**

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SCHEDULE 4  
FIXED RENT SCHEDULE

<u>Period</u>	<u>Annual Fixed Rent</u>	<u>Monthly Fixed Rent</u>
Commencement Date through December 31, 2010	\$632,401.75	\$52,700.15
January 1, 2011 through December 31, 2015	\$722,105.25	\$60,175.44
Any Extension Period	Fixed Rent as in the Overlease	Fixed Rent as in the Overlease

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EXHIBIT A  
OVERLEASE  
*[attached]*

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EXHIBIT B  
MANUFACTURING FACILITY EQUIPMENT

Description	FEC ID#
GEA FES SYSTEMS CHILLER, 30 TON CAPACITY MODEL 02261091 WITH 75 HP GRASSO COMPRESSOR, RATED 49.7 GPM, 5 F TO -30 F TEMP RANGE, R 507 REFRIGERANT, 576 CU METERS/HR, 2002	BYS060
SARTORIOUS BALANCE, MODEL CISL1-U	
SARTORIOUS BALANCE, MODEL CISL1-U	
ELECTROL SPECIALISTS CIP SKID WITH STORAGE TANK, HEAT EXCHANGER AND CIRCULATION PUMP WITH CONTROLS	BYS061
GILSON SIEVE, MODEL SS-8R IN ENCLOSURE, SERIAL# 4855	BYS030
TELESIS PIN STAMP MARKING SYSTEM, MODEL TMP1700, SERIAL# 10751	BYS032
FLOW SCIENCES BENCH HOOD WITH HELA, MODEL 18X30, SERIAL# 100307-01	BYS036
FLOW SCIENCES BENCH HOOD WITH HELA, MODEL 18X30, SERIAL# 100307-01	BYS037
CONSOLIDATED STERILIZER, SINGLE DOOR, 24" X36" CHAMBER, RATED 36 PSI AT 300 F INTERNAL, JACKETED FOR 60 PSI AT 300 F WITH CONTROLS, SERIAL#5902-80, 2007	BYS028
BELLIMED GLASS WASHER, MODEL WD230, STAINLESS STEEL WITH PUMP AND RESERVOIR	BYS029
BECKER DUAL VACUUM SYSTEM, WITH (2) U4100 SA/K PUMPS, 5 HP ON TANK, 2007	BYS027
MARCOR PURIFICATION LAB WATER GENERATOR, WITH AQUAFINN TOC REDUCTION AND AQUA FINN ULTRAVIOLET UNIT, SERIAL# 13079	BYS026
HACH ULTRA ANALYTICS PARTICAL COUNTER, MODEL MET 13400, MODEL 3415, 5UM MIN SIZE, 1 CFM, SERIAL#	BYS010
MILLIPORE M AIR T ISOLATION PUMP	BYS011
HACH ULTRA ANALYTICS PARTICAL COUNTER, MODEL MET 13400, MODEL 3415, 5 UMMIN SIZE, 1 CFM, SERIAL# 080301149	BYS009
BINDER INCUBATOR, MODEL SCHUTZART IP20 BF720, DUAL DOOR, 100 C/212 F, 115 VOLT, 60 HERTZ, #058937, SERIAL# 9010-0244	BYS002

BINDER INCUBATOR. MODEL BF720, DUAL DOOR. 115VOLT, 60 HERTZ, SERIAL# 05-83877	BYS003
BINDER INCUBATOR, MODEL BF115, 100 C, SERIAL# 04-73041	BYS007
NUAIRE HOOD, 6', MODEL NU-425-600, SERIES 30, CLASS II, TYPE A2, SERIAL#114883051007, 2007	BYS005
SIEVERS 900 LAB TOC ANALYZER, MODEL TOC900 LAB WITH AUTOSAMPLER AND COMPUTER, SERIAL# 07072000	BYS021
SIEVERS 900 LAB TOC ANALYZER. MODEL TOC900 LAB WITH AUTOSAMPLER AND COMPUTER, SERIAL# 07071995	BYS020
VWR OVEN, MODEL 1350GM, 110/120 VOLT, SERIAL# 08036007	BYS014
VWR OVEN, MODEL 1350GM, 110/120 VOLT, SERIAL# 09070207	BYS015
FLOW SCIENCES BENCH HOOD WITH HELA, MODEL 18 X 30, SERIAL# 10-10-07-03	
MOCROVOID LAMINAIR HOOD, 6', MODEL 4F-55-PP-NM-6', PLASTIC, SERIAL@ 11812	BYS024
TRANE EARTH WISE CENTRAVA CENTRIFUGAL WATER CHILLER, MODEL CVHE450, APPROX 450 TON, 480 VOLT, SERIAL3 LO2F100171, 2002	BYS038
TRANE EARTH WISE CENTRAVA CENTRIFUGAL WATER CHILLER, MODEL CVHE450, APPROX 450 TON, 480 VOLT, SERIAL# LO2F 100170, 2002	BYS039
BUDZAR HEATING SKID TRANSFER PACKAGE, MODEL IWT-S1100/DSP, RANGE TO 225 F TEMP RANGE, WITH (2) 40 HP PUMPS, RATED 1100 GPM AT 92' HEAD, 480 VOLT, SERIAL# 200203-5587, 2002	BYS040
CLEAVER BROOKS STEAM BOILER, MODEL CB1700 250/150, 150 PSI, 10,206,000 BTU, GAS FIRED WITH SURGE TANK, SERIAL# OC102026, 2002	BYS046
CLEAVER BROOKS STEAM BOILER, MODEL CB1700 250/150, ORIGINALLY 150 PSI CONVERTED TO 15 PSI STEAM, 10,206,000 BTU, GAS FIRED WITH SURGE TANK, SERIAL# OC102025, 2002	BYS047
SINGLE BAG DUST FILTER, STAINLESS STEEL, DESIGNED FOR (1) 5.5" DIAMETER X36" LONG CAGE	
SINGLE BAG DUST FILTER, STAINLESS STEEL, DESIGNED FOR (1) 5.5" DIAMETER X36" LONG CAGE	
Circulating Pump, 5Hp.	3040339

Glove Box, Single Sided With Light, Unused, New 2008	3340256
REFRIGERATOR	3040246
Refrigerator, Model Sp5Akt-22V2, 115 Volt, Cart Recorder	3040247
KOBELCO ROTARY SCREW AIR COMPRESSOR, KNW SERIES, MODEL KNOW-C/H, OIL FREE, 2-STAGE, 75 HP, 480 VOLT, 3 PHASE, SERIAL# 02J0208	BYS042
KOBELCO ROTARY SCREW AIR COMPRESSOR, KNW SERIES, MODEL KNOW-C/H, OIL FREE, 2-STAGE, 75 HP, 480 VOLT, 3 PHASE, SERIAL# 02J0207	BYS043
AIRTEK DUAL DESSICANT DRYER, MODEL TWB600, SERIAL# T02979-07G	BYS044
QUINCY AIR COMPRESSOR ON TANK, MODEL QT7CCDT00083, DUAL 5 HP PUMPS, SERIAL# 20080812-0001	BYS045
5' X 5' GSE FLOOR SCALE, 460 VOLT WITH RAMP AND READOUT	BYS081
STERIS FINN AQUA STERILIZER, MODEL 6121-D-B, S/S, 24" X 48" X 48" CHAMBER, PASS THRU, 480 VOLT, (2) CARTS, ALLEN BRADLEY PLC CONTROLS, SERIAL# COA41728	BYS075
MGR AMERICA MODEL G100 PRE WEIGHT ROTARY CAPSULE FILLER, S/S, METTLER BALANCES, VACUUM SYSTEM AND CREATIVE DISIGNS TOTE LIFT, 480 VOLT, MG2 SERIAL# 4462, 2002	BYS078
STERIS GLASS WASHER, MODEL 580	BYS076
8' GEA NIRO SPRAY DRYER, MODEL PSD-4N-CC, 316 S/S CONTACT SURFACES, 304 S/S NON CONTACT SURFACES, ELECTRO POLISHED INSIDE AND OUTSIDE, 2500MM DIAMETER X 2000MM STRAIGHT SIDE, 60 DEGREE CONE BOTTOM, ELECTRICALLY HEATED WITH 100 KW HEATER RATED 350 C MAX INLET TEMP, CHAMBER RATED .03 BAR TO .1 BAR AT -10 C TO + 230 C, WITH MULTIPLE PRESSURE AND FLUID NOZZEL ATOMIZERS, DUST COLLECTOR, (4) HEPA FILTERS, BLOWERS AND INTER CONNECTING DUCT WORK QAND VALVING, RATED 1250 KG/HR AT 200 C INLET TEMPM 20-100KG/HR WATER EVAPORATION RATE, FAB#099-0020 NDK091-0010-00, NEW 2002	BYS063
TECHNOPHAR TUBLE DRYER, MODEL TD-8X, 8 S/S, 8 BASKET, 110/108 VOLT, 3.22 HP MOTOR DRIVE WITH SPARE BASKETS, SERIAL#06-02	BYS079
275 LITER FELMEIER KETTLE, 316L S/S, 304L S/S JACKET, 50PSI AND FULL VACUUM AT 350 F INTERNAL, 150PSI FULL VACUUM AT 350 F JACKET, SERIAL# S50906, NATIONAL BOARD# 3502, 2006	BYS071
230 LITER FELMEIER PRESSURE TANK, 316L S/S, 24" DIAMETER X 31" STRAIGHT SIDE, DISHED REMOVABLE TOP, DISH BOTTOM, SERIAL #S109806	BYS072

275 LITER FELMEIER KETTLE, 316L S/S, 304L S/S JACKET, AND FULL VACUUM AT 350 F INTERNAL, 150PSI AND FULL VACUUM AT 350 F JACKET, SERIAL# S50806, NATIONAL BOARD# 3501, 2006	BYS070
800 LITER FELMEIER REACTOR. 316L 304L S/S JACKET, 50psi AND FULL VACUUM AT 302 F INTERNAL, 100 PSI AND FULL VACUUM AT 302 F JACKET WITH TOP MOUNTED .5 HP CHEMINEER AGITATOR DRIVE, SERIAL# SO2002, NATIONAL BOARD# 2512, 2002	BYS066
150 LITER FELMEIER REACTOR, 316L S/S, 304L S/S JACKET, 50 PSI AND FULL VACUUM AT 302 F INTERNAL, 100PSI AND FULL VACUUM AT 302 F JACKET WITH TOP MOUNTED .5 HP CHEMINEER AGITATOR DRIVE, SERIAL# SO1802, NATIONAL BOARD# 2510, 2002	BYS067
500 LITER FELMEIER REACTOR, 316L S/S, 304L S/S JACKET, 50 PSI AND FULL VACUUM AT 302 F INTERNAL, 100PSI AND FULL VACUUM AT 302 F JACKET WITH TOP MOUNTED .5 HP CHEMINEER AGITATOR DRIVE, SERIAL# SO1902, NATIONAL BOARD# 2511, 2002	BYS064
150 LITER FELMEIER REACTOR, 316L S/S, 304L S/S JACKET, 50 PSI AND FULL VACUUM AT 302 F INTERNAL, 100PSI AND FULL VACUUM AT 302 F JACKET WITH TOP MOUNTED .5 HP CHEMINEER AGITATOR DRIVE, SERIAL# SO1702, NATIONAL BOARD# 2509, 2002	BYS065
2500 LITER FELMEIER REACTOR, 316L S/S, 304L S/S JACKET, 56" DIAMETER X 68" STRAIGHT SIDE DISH TOP AND BOTTOM, 50PSI AND FULL VACUUM AT 350 F INTERNAL, 150 PSI AND FULL VACUUM AT 350 F JACKET WITH TOP MOUNTED 1 HP SHARPE AGITATOR DRIVE, SERIAL# S51006, NATIONAL BOARD# 3511, 2007	BYS069
2500 LITER FELMEIER REACTOR, 316L S/S, 304L S/S JACKET, 56" DIAMETER X 68" STRAIGHT SIDE DISH TOP AND BOTTOM, 50PSI AND FULL VACUUM AT 350 F INTERNAL, 150 PSI AND FULL VACUUM AT 350 F JACKET WITH TOP MOUNTED 1 HP SHARPE AGITATOR DRIVE, SERIAL# S51106, NATIONAL BOARD# 3512, 2007	BYS068
2415 GALLON DIVERSIFIED METALS PRESSURE TANK, 304 S/S, 6' DIAMETER X 5'6" STRAIGHT SIDE, 2:1 ELLIPTICAL TOP AND BOTTOM, RATED 14.9 PSI AND FULL VACUUM AT 348 F, ON 4 S/S LEGS WITH TOP CENTER MOUNTED AGITATOR, 24" SIDE BOTTOM MANWAY WITH LADDER, SERIAL# P1911-1VE-2921	BYS062
HOWORTH AIRTECH LTD DOWN FLOW CONTAINMENT BOOTH, SAFE AREA CLASS, FINE DUST AND HEPA FILTER, 128" WIDE X 120" DEEP X 9' HIGH, STAINLESS STEEL, SERIAL# 04237, 2007 NEVER USED	BYS073
(18) PROCESS SOLUTIONS IBC CONTAINERS, APPROX 5 CU FT, S/S, 30" X 30" X 30" CONE, FORK LIFT ACCESS, 6" OPENING	BYS074

(12) COPLEY CONTROLS	
SKID WITH (4) PLASTIC FUME HOODS	
KIOCKNER EAS BLISTER PACK UNIT, WITH CAPSULE FEEDER AND CHILLER, SERIAL# 448, 220 VOLT, NEW 2000	SID91
ETS CONTROL ENVIROMENTAL CHAMBER, TEMP AND HUMIDITY CONTROLS	SID102
PUMP STAND	
MILLIPORE BUBBLE POINT DIFFUSION AND HYDRO TEST UNIT, MODEL XITXACTP1 INTEGRITEST EXACTA	SID075
REVCO FREEZER, MODEL ULT2140-3-A35, R404A AND R134A REFIGERANT, SERIAL# V26M596638-WM	SID113
FLOW SCIENCE FUME HOOD WITH METTLER TOLEDO BALANCE AND HEPA FILTER	
BUCHI INERT LOOP CHILLER, MODEL B295, 1000 WATTS, 60 HERTZ, RATED TO -25c	SID044A
(2) FLOW SCIENCE FUME HOODS WITH HEPA FILTER	
(2) FLOW SCIENCE FUME HOODS WITH HEPA FILTER	
(2) FLOW SCIENCE FUME HOODS WITH HEPA FILTER	
HARRO HOFLIGER CAPSULE FILLER, TYPE MODU-C 100% CONTROL WITH AUTOMATIC CAPSULE FEEDER WITH WEIGH CHECK, SIZE 2 AND 00 CHANGE PARTS, UNIT RATED UP TO 100,000 CAPSULES/HOUR WHEN NOT IN 100 % CONTROL MODE, 480 VOLT, 3 PHASE MACHINÉ# HH-0006.008, NEW 2007	SID096
LING ELECTRONICS, MODEL ACG D390-2" STROKE CONV , VIBRATION, MODEL390, WITH L390 COMBO BASE SLIP TABLE, SERIAL# 9809-825-9-B, VIBRATION SERIAL# 40, MACHINE SERIAL# 9809-le-40	SID039
50 LITER PRECISION STAINLESS REACTOR, 316L STAINLESS STEEL, RATED 50 PSI AND FULL VACUUM AT +302/-302 F INTGERNAL AND JACKET, .25 HP NETTCO AGITATOR DRIVE, 230/460 VOLT, SERIAL# 991066, NATIONAL BOARD# 8343, NEW 1999	BYS 109
HARRO HOFLIGER CAPSULE FILLER, TYPE KFMIII-C, SIZE 2 CHANGE PARTS 480 VOLT, 3 PHSE, MACHINE#0003.009, NEW 2001	SID060

GRANITE TABLE	
SCHENEK GRAVAMETRIC FEEDER, MECHATRON, 5 HP, 220 VOLT WITH TWO SPOUTS SERIAL# 92935-01A-VFD	BYS119
MULTITON ELECTRIC PALLET JACK, MODEL QMAX3000#, EME30	BYS052
8794 GALLON DIVERSIFIED METALS, PRESSURE TÄNK, 304 S/S, 102” DIAMETER X 222” STRAIGHT SIDE, 2:1 ELLIPTICAL HEADS, RATED 14.9 PSI AND FULL VACUUM AT 348 F, ON 4 S/S LEGS, SERIAL# P2+22-2VE-1101, NEW 2002, WEIGHT 11,900#	BYS049
9326 GALLON DIVERSIFIED METALS PRESSURE TANK, 304 S/S, 102” DIAMETER X 222” STRAIGHT SIDE, 2:1 ELLIPTICAL HEADS, RATED 14.9 PSI AND FULL VACUUM AT 348 F, ON 4 S/S LEGS, SERIAL# P1911-3VE-111, NEW 2002, WEIGHT 12,600#	BYS048
CAT GENSET WITH FUEL TANK, MODEL DMO634-02, 700 KW, 875 KVA	BYS041
BAC COOLING TOWER, MODEL33315JSQW, SERIAL# u0253782, 2002	BYS050
BAC COOLING TOWER, MODEL33315JSQW, SERIAL# U0253782, 2002	BYS051
COPLEY HCP5	

**ASSET PURCHASE AND LICENSE AGREEMENT**

**BY AND BETWEEN**

**ALKERMES, INC.**

**AND**

**CORREGIDOR THERAPEUTICS, INC.**

**DECEMBER 27, 2010**

CERTAIN PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS [ ] AND AN ASTERISK\*, HAVE BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

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<b>EXHIBIT D</b>	<b>Security Agreement</b>

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

## ASSET PURCHASE AND LICENSE AGREEMENT

This Asset Purchase and License Agreement (the “Agreement”) is made effective as of the 27th day of December 2010 (the “Effective Date”) by and between Alkermes, Inc., a Pennsylvania corporation having a principal place of business at 852 Winter Street, Waltham, Massachusetts 02451 (“Alkermes”), and Corregidor Therapeutics, Inc., a Delaware corporation with its principal place of business located at 384 Powder Mill Road, Concord, MA 01742 (“Corregidor”). Alkermes and Corregidor are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

### RECITALS

**WHEREAS**, Alkermes has been engaged in the research, development and manufacture of certain pulmonary delivery products (the “Business,” as defined herein); and

**WHEREAS**, Alkermes is willing to sell, transfer and assign to Corregidor, and Corregidor desires to purchase and acquire, certain assets which are employed or held by Alkermes specifically in connection with the Business, and Corregidor also desires to assume certain obligations and liabilities in connection therewith; and

**NOW, THEREFORE**, based on the premises and the mutual covenants and obligations set forth below, and intending to be bound hereby, the Parties agree as follows:

### ARTICLE 1

#### DEFINITIONS

Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or Schedule or Exhibit to, this Agreement, unless another agreement is specified, (b) the word “including” will be construed as “including without limitation,” (c) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulations, in each case, as amended or otherwise modified from time to time, (d) words in the singular or plural form include the plural and singular form, respectively, (e) words of any gender include each other gender, (f) “or” is disjunctive but not necessarily exclusive, (g) the word “will” shall be construed to have the same meaning and effect as the word “shall,” (h) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified, (i) references to a particular Person include such Person’s successors and assigns to the extent not prohibited by this Agreement, and (j) defined terms used, but not defined, in the Schedules shall have the meaning set forth in this Agreement. The following terms shall have the following meanings as used in this Agreement:

**1.1 “Acquisition Event”** shall mean the assignment by Corregidor of this Agreement pursuant to Section 12.5 hereof to a Person that acquires all or substantially all of Corregidor’s business to which this Agreement relates, whether in a merger, consolidation, reorganization, acquisition, sale or otherwise.

**1.2 “Active Component”** shall mean any product other than a Licensed Product which performs an identifiable therapeutic or prophylactic function when combined with a Licensed Product.

**1.3 “Acusphere Agreements”** shall mean (i) the Settlement Agreement dated February 8, 2008 between Alkermes and Acusphere, Inc. and (ii) the Settlement Agreement dated July 15, 2008 between Alkermes and Acusphere, Inc.

**1.4 “Affiliate”** shall mean, except as provided below, a Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with the party being referenced. For purposes of this definition, “control” shall mean the possession, direct or indirect, of the power to cause the direction of the management and policies of a Person, whether through ownership of fifty percent (50%) or more of the voting securities of such Person, by contract or otherwise.

**1.5 “Agreement”** shall mean this Asset Purchase and License Agreement dated December 27, 2010 by and between Alkermes and Corregidor.

**1.6 “Alkermes”** shall have the meaning ascribed to it in the opening paragraph of this Agreement.

**1.7 “Alkermes Dry Powder Inhalation Product”** shall mean any pharmaceutical product for the delivery by inhalation of epinephrine, L-Dopa (levodopa) or apomorphine, whether alone or in combination with other active ingredients.

**1.8 “Alkermes Know-How”** shall mean (i) all Know-How that is Controlled by Alkermes on the Effective Date and that is described or embodied in the Manufacturing Facility Equipment or in the Equipment, Documentation, Pulmonary INDs and Inhalers transferred to Corregidor pursuant to Section 2.1, and (ii) all Know-How Controlled by Alkermes that is necessary or reasonably useful for the pulmonary delivery of pharmaceutical products and that is disclosed to Corregidor during the Transition Period. Alkermes Know-How that may be disclosed during the Transition Period will include only such Know-How described in subsection (ii) that is (A) disclosed in writing and clearly marked as Alkermes Know-How or (B) that is disclosed orally or visually, and Alkermes, within [\*\*\*] after such disclosure, delivers to Corregidor a written document or documents stating that such Know-How is Alkermes Know-How and referencing the place and date of such oral or visual disclosure. Alkermes Know-How does not include Alkermes Patents.

**1.9 “Alkermes Patents”** shall mean the (i) Pulmonary Patents and (ii) MIT Patents.

**1.10 “Applicable Law”** shall mean the laws, rules and regulations, including the FDCA and any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time anywhere in the world that are relevant to activities under this Agreement.

**1.11 “Assets”** shall have the meaning ascribed to it in Section 2.1 of this Agreement.

**1.12 “Assignee”** shall mean any Affiliate or Third Party to which Corregidor makes an Assignment pursuant to Section 3.7.

**1.13 “Assumed Liabilities”** shall have the meaning ascribed to it in Section 2.4 of this Agreement.

**1.14 “Bankruptcy Code”** shall have the meaning ascribed to it in Section 10.5 of this Agreement.

**1.15 “Bill of Sale”** shall mean a Bill of Sale substantially in the form of the agreement attached hereto as Exhibit A.

**1.16 “Business”** shall mean the business conducted by Alkermes prior to the Effective Date of researching, developing and manufacturing Licensed Products, but only to the extent that Alkermes owns, has the right to grant a license to, or has the right to disclose the assets, including the intellectual property, used by Alkermes in the conduct of such business (in each case without paying any consideration to any Third Party); *provided, however*, that Licensed Products shall exclude, for purposes of this definition, for the avoidance of doubt, Licensed Products for delivery of trospium.

**1.17 “Business Day”** shall mean any day other than a Saturday or Sunday when banks are open for business in Boston, Massachusetts.

**1.18 “Calendar Quarter”** shall mean a three-month period ending on March 31, June 30, September 30, or December 31.

**1.19 “Calendar Year”** shall mean a twelve-month period ending on December 31.

**1.20 “Change in Control”** shall mean a merger, reorganization or consolidation of a Party with or into another entity in which all of the issued and outstanding stock of such Party is converted into or exchanged for cash, securities of another entity, or other property; or a sale of all or substantially all of such Party’s assets or business; or the sale of all of the issued and outstanding stock of such Party; provided, in each case, that (A) the stockholders of such Party immediately before any such transaction or series of related transactions do not, immediately thereafter, beneficially own (as such term is used in Rule 13d-3 under the Securities Exchange Act of 1934, as amended) a majority of the outstanding equity of the entity that acquires such Party’s assets or stock or of the surviving or resulting entity in such a merger or consolidation, and (B) the primary purpose of such transaction or series of related transactions is not for financing.

**1.21 “Collaboration Partner”** shall mean (i) a sublicensee under the license granted to Corregidor pursuant to Section 3.8 of this Agreement; (ii) a licensee or sublicensee under the Pulmonary Patents; (iii) an Assignee under Corregidor’s rights under the Pulmonary Patents pursuant to Section 3.7 of this Agreement, *provided* the Assignment to such Assignee is permitted pursuant to Section 3.7 of this Agreement (but excluding any assignee of Corregidor pursuant to Section 12.5 of this Agreement); or (iv) any other Third Party to which Corregidor, its Affiliates, an Assignee, their licensees or sublicensees grants any right, or that is otherwise enabled by these parties, to Commercialize a Licensed Product; *provided, however*, that Collaboration Partner shall exclude (i) any Distributor and (ii) any Third Party engaged to perform activities on behalf of Corregidor or its Affiliates on a reasonable fee for service basis, unless such Third Party is distributing, marketing or selling Licensed Products to other Third Parties, and Corregidor or its Affiliates, directly or indirectly, have an interest in, or share in, the profits from the sale of Licensed Products by such Third Party.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**1.22 “Collaboration Partner Revenue”** shall mean consideration that is received by or on behalf of Corregidor or its Affiliates both (i) from a Collaboration Partner for a license, sublicense or other right to conduct the Development, Manufacture or Commercialization of a Licensed Product, and (ii) after the Launch of such Licensed Product, excluding all Milestone Payments received by or on behalf of Corregidor or its Affiliates from such Collaboration Partner. Collaboration Partner Revenue shall not include (A) [\*\*\*]; (B) [\*\*\*], (C) [\*\*\*], and (D) [\*\*\*]. For clarity, Collaboration Partner Revenue excludes all payments received by or on behalf of Corregidor or its Affiliates from a Collaboration Partner prior to the Launch of Licensed Products.

**1.23 “Combination Product”** shall have the meaning ascribed to it in Section 5.3 of this Agreement.

**1.24 “Commercial Capsule”** shall mean a capsule containing drug substance formulated for pulmonary delivery, which capsule is incorporated into, or is, a Licensed Product.

**1.25 “Commercialization”** (including variations such as **“Commercialize”** and **“Commercializing”**) shall mean the performance of those activities relating to promoting, marketing, importing, distributing, selling or offering to sell (including pre-marketing), sampling, conducting medical activities and post-marketing drug surveillance of or for Licensed Products.

**1.26 “Commercially Reasonable Efforts”** shall mean the level of efforts and resources required to Develop and Commercialize a Licensed Product in a diligent and sustained manner consistent with the efforts and resources a similarly situated biotechnology or pharmaceutical company would typically devote to a product of similar market potential, profit potential and strategic value resulting from its own research efforts, based on conditions then prevailing, but without taking into account amounts such as Royalties required to be paid to Alkermes pursuant to this Agreement.

**1.27 “Confidential Information”** shall mean all confidential or proprietary information received or otherwise obtained by either Party from the other Party or its Affiliates pursuant to this Agreement, other than that portion of such information or materials which:

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(a) is now, or hereafter becomes, generally available to the public through no fault of the receiving Party or its Permitted Recipients;

(b) the receiving Party already possesses without obligations of confidentiality with respect thereto, as evidenced by its written records, predating receipt thereof from the other Party;

(c) is obtained from a Third Party without restriction who had the legal right to disclose the same to the receiving Party; or

(d) has been independently developed by the receiving Party without the aid, application or use of Confidential Information, as demonstrated by competent written proof.

**1.28 “Confidentiality Agreement”** shall mean that Confidential Disclosure Agreement between the Parties dated July 7, 2009.

**1.29 “Controlled”** shall mean with respect to Alkermes Patents, Alkermes Know-How and other intellectual property that Alkermes, in whole or in part, owns or has a license to such Alkermes Patents, Alkermes Know-How or intellectual property and has the ability to grant a license or a sublicense, as applicable, or to otherwise disclose proprietary or trade secret information, to Corregidor, without paying any consideration to any Third Party and without either misappropriating the proprietary or trade secret information of a Third Party or violating the terms of any agreement or other arrangement with any Third Party existing and in effect at the time Alkermes would be required hereunder to grant Corregidor such license or sublicense.

**1.30 “Corregidor”** shall have the meaning ascribed to it in the opening paragraph of this Agreement.

**1.31 “Default”** shall mean with respect to either Party (i) that any representation or warranty of such Party set forth in Section 6.1 or Section 6.2 of this Agreement, respectively, shall have been untrue in any material respect as of the Effective Date, (ii) that such Party, such Party’s Affiliate or such Party’s Collaboration Partners shall have failed to perform any material obligation set forth herein, or (iii) that such Party shall have failed to pay to the other Party any payment hereunder in any material respect on or before the last day when such payment is due.

**1.32 “Development”** (including variations such as “Develop” and “Developing”) shall mean the performance of any and all activities relating to obtaining Regulatory Approval of a Licensed Product and to supporting and expanding such Regulatory Approval, including activities relating to developing the ability to manufacture and to continue to manufacture the Licensed Product.

**1.33 “Direct Sale Event”** shall mean the [\*\*\*] of the date of Manufacture of the first Commercial Capsule by or on behalf of Corregidor or its Affiliates that is incorporated into, or that is, a Licensed Product intended for sale by Corregidor or its Affiliates.

**1.34 “Dispute”** shall have the meaning ascribed to it in Section 11.1 of this Agreement.

**1.35 “Distributor”** shall mean any Third Party appointed by Corregidor, its Affiliates or Collaboration Partners to perform distribution, marketing and/or sales of Licensed Products, where neither Corregidor nor its Affiliates or Collaboration Partners have an interest in, or share in, the profits from the sale of Licensed Products by such Third Party.

**1.36 “Documentation”** shall have the meaning ascribed to it in Section 2.1.3 of this Agreement.

**1.37 “Dollar”** shall mean a United States dollar, and “\$” shall be interpreted accordingly.

**1.38 “Effective Date”** shall have the meaning ascribed to it in the opening paragraph of this Agreement.

**1.39 “EMA”** shall mean the European Medicines Agency, or any successor thereto.

**1.40 “Equipment”** shall have the meaning ascribed to it in Section 2.1.2 of this Agreement.

**1.41 “Equity Investment Agreements”** shall mean (i) the Amended and Restated Certificate of Incorporation of Corregidor, filed on or about the Effective Date, (ii) the Investors’ Rights Agreement dated as of the Effective Date by and among Corregidor and certain investors, (iii) the Voting Rights Agreement dated as of the Effective Date by and among Corregidor and certain investors and stockholders, (iv) the Series A Preferred Stock Purchase Agreement dated as of the Effective Date by and among Corregidor and certain investors and (v) the Right of First Refusal and Co-Sale Agreement dated as of the Effective Date by and among Corregidor and certain investors and stockholders,

**1.42 “FDA”** shall mean the United States Food and Drug Administration, or any successor thereto.

**1.43 “FDCA”** shall mean the U.S. Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 et seq.

**1.44 “IND”** shall mean an Investigational New Drug Application, as defined in the FDCA, or similar application or submission that is required to be filed with any Regulatory Authority before beginning clinical trials of a Licensed Product.

**1.45 “Inhalers”** shall have the meaning ascribed to it in Section 2.1.4 of this Agreement.

**1.46 “Instrument of Assignment and Assumption”** shall mean an Instrument of Assignment and Assumption substantially in the form of the agreement attached hereto as Exhibit B.

**1.47 “Know-How”** shall mean all proprietary data, devices, information, know-how, inventions, discoveries, trade secrets, processes, techniques, compositions, materials, methods, formulas or improvements, whether patentable or not.

**1.48 “Launch”** shall mean as to a given Licensed Product, the first commercial sale of such Licensed Product by Corregidor, its Affiliates or Collaboration Partners to a Third Party in any country following the receipt of Regulatory Approval in that country.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**1.49 “Lease”** shall mean the Lease dated December 6, 2000 between H&N Associates, LLC and Alkermes, as amended, for the Manufacturing Facility,

**1.50 “Licensed Product”** shall mean a product, the manufacture, use, sale, offer for sale or import of which (i) is covered by a Valid Claim of an Alkermes Patent or (ii) utilizes the Alkermes Know-How.

**1.51 “Losses”** shall mean costs and expenses (including reasonable investigation expenses, legal expenses and attorneys’ fees), liabilities, fines, damages, assessments and/or other losses arising from a Third-Party claim, suit, action or demand.

**1.52 “Manufacturing”** (including variations such as **“Manufacture”**) shall mean the performance of any and/or all activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality control, quality assurance, testing and release, shipping and warehousing of Licensed Products.

**1.53 “Manufacturing Facility”** shall mean the manufacturing facility located at Brickyard Square, 190 Everett Avenue, Chelsea, Massachusetts.

**1.54 “Manufacturing Facility Equipment”** shall mean the machinery, equipment, instruments, laboratory equipment and apparatus, fixtures, tools, and other tangible assets that are listed in Exhibit B to the Sublease.

**1.55 “Milestone Payment”** shall mean a payment due upon achievement of a certain level of cumulative Net Sales or upon achievement of certain events occurring after Launch of a Licensed Product that are related to the Development or Commercialization of such Licensed Product.

**1.56 “MIT Patent License Agreement”** shall mean the Patent License Agreement between the Massachusetts Institute of Technology ( “MIT”) and Alkermes, Inc. dated August 15, 1997, as amended.

**1.57 “MIT Patents”** shall mean the patents and patent applications licensed to Alkermes pursuant to the MIT Patent License Agreement.

**1.58 “Multi-Product Contract”** shall mean a contract between Corregidor, its Affiliates and/or Collaboration Partners, on the one hand, and a Third Party, on the other hand, for the sale of a Licensed Product and one or more products other than a Licensed Product.

**1.59 “New Drug Application” or “NDA”** means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314, a Biological License Application (BLA) pursuant to 21 C.F.R. § 601.2, or any equivalent or corresponding application for Regulatory Approval (including pricing and reimbursement approval required by Applicable Law prior to sale of a pharmaceutical product) in any country or regulatory jurisdiction other than the United States.

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**1.60 “Net Sales”** shall mean [\*\*\*]. Each of such deductions will only be applicable to the extent it is determined in accordance with U.S. GAAP as consistently applied by Corregidor for pharmaceutical products other than a Licensed Product, provided that Net Sales by Collaboration Partners that do not use U.S. GAAP shall be calculated with the equivalent accounting standards applicable to such Collaboration Partners. [\*\*\*]

**1.61 “Option Agreement”** shall mean the Option Agreement dated September 28, 2010 between the Parties.

**1.62 “Option Effective Date”** shall mean the date on which the earliest of the following events occurs (i) the Acquisition Event; (ii) the Resale Event; or (iii) the Direct Sale Event.

**1.63 “Parties”** shall have the meaning ascribed to it in the opening paragraph of this Agreement.

**1.64 “Party”** shall have the meaning ascribed to it in the opening paragraph of this Agreement.

**1.65 “Penn State License Agreement”** shall mean the License Agreement between The Penn State Research Foundation (“Penn State”) and Alkermes, dated January 28, 2004.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**1.66 “Permitted Recipients”** shall have the meaning ascribed to it in Section 9.1 of this Agreement.

**1.67 “Person”** shall mean an individual, corporation, limited liability company, partnership, association, trust, unincorporated organization, other entity or group.

**1.68 “Phase 1 Clinical Trial”** means, as to a specific pharmaceutical product, a clinical trial of safety of such product in healthy volunteers or a limited patient population, or clinical studies directed toward understanding the pharmacokinetic properties of the product, as further defined in 21 C.F.R. § 312.21(a), or the corresponding regulation in jurisdictions other than the United States. A Phase 1 Clinical Trial shall be deemed initiated upon the first dosing of the first patient.

**1.69 “Phase 3 Clinical Trial”** means, as to a specific pharmaceutical product, a pivotal clinical trial performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of an NDA by a Regulatory Authority and to provide an adequate basis for physician labeling, as described in 21 C.F.R. § 312.21(c), or the corresponding regulation in jurisdictions other than the United States. A Phase 3 Clinical Trial shall be deemed initiated upon the first dosing of the first patient.

**1.70 “Promissory Note”** shall mean a promissory note that may be issued by Corregidor to Alkermes in the original principal amount of Thirty Million Dollars (\$30,000,000) as described in Section 3.13, which shall be substantially in the form set forth in Exhibit C hereto.

**1.71 “Pulmonary INDs”** shall have the meaning ascribed to it in Section 2.1.5 of this Agreement.

**1.72 “Pulmonary Patents”** shall have the meaning ascribed to it in Section 2.1.1 of this Agreement.

**1.73 “Regulatory Approval”** shall mean any approvals (including supplements, amendments, pre- and post-approvals and price approvals), licenses, registrations, designations or authorizations of any supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the distribution, use or sale of a Licensed Product in a regulatory jurisdiction in the Territory.

**1.74 “Regulatory Authority”** shall mean any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council, or other government entity involved in granting of Regulatory Approval for a pharmaceutical or biologic product in a regulatory jurisdiction in the Territory, including the FDA and the EMA.

**1.75 “Resale Event”** shall mean the Manufacture of the first Commercial Capsule by or on behalf of Corregidor or its Affiliates that is incorporated into, or that is, a Licensed Product and intended for sale by a Collaboration Partner.

**1.76 “Retained Liabilities”** shall have the meaning ascribed to it in Section 2.3 of this Agreement.

**1.77 “Royalty” or “Royalties”** shall mean those amounts payable as royalties by Corregidor to Alkermes pursuant to Section 5.2 of this Agreement.

**1.78 “Security Agreement”** shall mean a Loan and Security Agreement providing the terms of and securing the Promissory Note, which shall be substantially in the form set forth in Exhibit D hereto.

**1.79 “Sublease”** shall mean the Sublease dated as of the Effective Date by and between the Parties.

**1.80 “Term”** shall have the meaning ascribed to it in Section 10.1 of this Agreement.

**1.81 “Territory”** shall mean all the countries of the world.

**1.82 “Third Party”** shall mean any Person other than Alkermes or Corregidor or an Affiliate of either of them.

**1.83 “Third-Party Dry Powder Inhalation Product”** shall mean any pharmaceutical product for the delivery by inhalation of epinephrine, L-Dopa (levodopa) or apomorphine, or salts or hydrates of any of the foregoing, whether alone or in combination with other active ingredients.

**1.84 “Transition Period”** shall mean the period beginning on [\*\*\*] and ending on [\*\*\*].

**1.85 “Trigger Transaction”** shall have the meaning ascribed to it in Section 5.2.1 of this Agreement.

**1.86 “United States”** shall mean the United States of America, its territories and possessions, including the Commonwealth of Puerto Rico.

**1.87 “U.S. GAAP”** shall mean generally accepted accounting principles in the United States.

**1.88 “Valid Claim”** shall mean a claim or pending claim of an Alkermes Patent, which claim or pending claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been cancelled, withdrawn from consideration, determined to be unallowable, abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer; *provided, however*, that if the holding of such court or agency is later reversed by a court or agency with overriding authority, the claim shall be reinstated as a Valid Claim with respect to Net Sales made after the date of such reversal; *provided further, however*, on a country-by-country basis, a claim of a patent application pending for more than [\*\*\*] shall not be considered to be a Valid Claim for purposes of this Agreement unless and until a patent with respect to such application issues with such claim, in which case such claim will be reinstated and be deemed to be a Valid Claim, but only as of the date of issuance of such patent.

## ARTICLE 2

### ASSETS AND LIABILITIES

**2.1. Assets to be Acquired .** Subject to the terms and conditions hereof (including Article 3), effective as of December 27, 2010, subject to Alkermes' retained right, title and interest in and to the Alkermes Know-How that is described in or embodied in the Equipment, Documentation, Pulmonary INDs and Inhalers, Alkermes hereby sells, assigns, transfers, conveys and delivers to Corregidor, and Corregidor hereby purchases, acquires and accepts from Alkermes, all of Alkermes' other right, title and interest on the Effective Date in and to the following assets (collectively, the “Assets”):

**2.1.1. Patents and Patent Applications .** The patents and patent applications that are listed on Schedule 2.1.1; any substitutions, extensions (including supplementary protection certificates), registrations, confirmations, reissues, continuations, divisionals, continuations-in-part, reexaminations, renewals or the like thereof or thereto; any patents or patent applications claiming priority from the patents and patent applications listed on Schedule 2.1.1; and all foreign counterparts of any of the foregoing (the “Pulmonary Patents”);

**2.1.2. Equipment and Instruments .** Certain machinery, equipment, instruments, laboratory equipment and apparatus, fixtures, tools, and other tangible assets that are listed on Schedule 2.1.2 (the “Equipment”);

**2.1.3. Documentation .** Copies of certain documentation directly related to the Business, including regulatory correspondence and meeting minutes; reports from preclinical, clinical, manufacturing process development, and feasibility studies; toxicology reports; pharmacology reports; design reports; testing protocols; formulation recipes and methods; analytical methods; process specifications; standard operating procedures; and manufacturing batch records, that are listed on Schedule 2.1.3 (the “Documentation”);

**2.1.4. Inhalers .** Certain inhalers, associated molds and tools and assembly equipment employed or held for use by Alkermes specifically in connection with the Business that are listed on Schedule 2.1.4 (the “Inhalers”);

**2.1.5. Pulmonary INDs .** Certain INDs filed with the FDA pursuant to which Alkermes conducted clinical trials of Licensed Products in the United States that are listed on Schedule 2.1.5 (the “Pulmonary INDs”); and

**2.1.6. Contracts .** The MIT Patent License Agreement, the Penn State License Agreement and the Acusphere Agreements.

**2.2. Technology Ownership .** Alkermes retains the sole right, title and interest, subject only to the license granted in Sections 3.8 of this Agreement, to the Alkermes Know-How. Except as expressly provided in this Agreement, no rights in any other technology, intellectual property or assets of Alkermes are granted to Corregidor by implication, estoppel or otherwise.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**2.3. Retained Obligations and Liabilities .** The Parties acknowledge and agree that except as expressly provided in this Agreement or the Option Agreement, as between the Parties, Alkermes shall remain responsible for all obligations and liabilities arising out of the Business, or the Assets or their use, in each case prior to the Effective Date (the “Retained Liabilities”).

**2.4. Assumed Obligations and Liabilities .** The Parties acknowledge and agree that Corregidor shall assume and perform all obligations and liabilities arising out of the Assets or their use on and after the Effective Date (the “Assumed Liabilities”).

### ARTICLE 3

#### ASSIGNMENT AND TRANSFER

**3.1. Bill of Sale and Instrument of Assignment and Assumption .** On the Effective Date, the Parties shall execute and deliver the Bill of Sale and Instrument of Assignment and Assumption.

**3.2. Sublease .** On the Effective Date, the Parties shall execute and deliver the Sublease.

**3.3. Contracts .** On the Effective Date, Alkermes shall assign to Corregidor Alkermes’ rights, and Corregidor shall assume Alkermes’ obligations, under the MIT Patent License Agreement, the Penn State License Agreement and the Acusphere Agreements, except to the extent such rights and obligations relate to performance or non-performance under such agreements prior to the Effective Date. Corregidor agrees to be bound on and after the Effective Date by all the terms and conditions set forth in the MIT Patent License Agreement, the Penn State License Agreement and the Acusphere Agreements.

**3.4. Inhalers and Documentation .** As soon as practicable after the Effective Date, but in any event within [\*\*\*] after the Effective Date, Alkermes shall ship to Corregidor any Inhalers and Documentation not already located at the Manufacturing Facility. Corregidor shall be responsible for all costs incurred, including freight, transportation and insurance, in connection with the shipment of the Inhalers and Documentation. Likewise, Corregidor shall bear the risk of loss for such Inhalers and Documentation upon delivery of such Inhalers and Documentation to Corregidor’s common carrier by Alkermes.

**3.5. Pulmonary INDs .** As soon as practicable after the Effective Date, but in any event within [\*\*\*] days after the Effective Date, Alkermes shall (i) notify the FDA of, and as soon as is reasonably practicable thereafter take all actions reasonably necessary to effect or evidence, the transfer of the Pulmonary INDs to Corregidor, and (ii) provide to Corregidor copies of the Pulmonary INDs.

**3.6. Pulmonary Patents .** After the Effective Date, Alkermes shall execute, or procure the execution of, such formal documents of sale and/or assignment as are required consistent with the terms and conditions of this Agreement to formally record the change of title to the Pulmonary Patents to Corregidor in a timely manner. Alkermes shall instruct its patent counsel that the Pulmonary Patents have been assigned to Corregidor, subject to this Agreement including Section 3.7 hereof, and that such counsel must look to Corregidor for further instructions with respect to the Pulmonary Patents, which instructions shall be undertaken at Corregidor’s expense.

**3.7. No Assignment of Pulmonary Patents .** Until the end of the Term, no right, title or interest in or to the Pulmonary Patents may be sold, transferred, leased, assigned, or otherwise disposed of by Corregidor or its Affiliates (an “Assignment”) other than to an Affiliate of Corregidor, or pursuant to a transaction permitted pursuant to Section 12.5, without the prior written consent of Alkermes to the proposed Assignee, such consent not to be unreasonably withheld, delayed or conditioned; *provided, however*, that any such Assignment to an Affiliate shall terminate at such time as the Affiliate to which the Pulmonary Patents are sold, transferred, leased, assigned, or otherwise disposed of ceases to be an Affiliate of Corregidor, unless Alkermes provides its prior written consent to the continuation of such Assignment. For the avoidance of doubt, the activities prohibited by this Section 3.7 shall not include granting a license or sublicense under the Pulmonary Patents pursuant to Section 3.9. Notwithstanding the foregoing, Corregidor may not make an Assignment to any Third Party until [\*\*\*]. Corregidor shall promptly notify Alkermes of any intended Assignment and provide to Alkermes a copy of the agreement under which Corregidor intends to make such Assignment, which may be redacted to omit information unrelated to the Assignment of the Pulmonary Patents or the performance of obligations under this Agreement. Corregidor shall include in any Assignment permitted by this Section 3.7 express language that the terms, conditions and obligations of any such Assignment are subject to the terms, conditions and obligations of this Agreement.

**3.8. Know-How License to Corregidor .** Subject to the terms and conditions of this Agreement, Alkermes hereby grants to Corregidor, as of the Effective Date, a non-exclusive, worldwide license, with the right to grant sublicenses (subject to Section 3.9), under the Alkermes Know-How, to use the Alkermes Know-How for the sole purposes of making, having made, using, selling, offering for sale and importing Licensed Products in the Territory.

**3.9. Licenses or Sublicenses .** Corregidor may grant licenses or sublicenses under the Pulmonary Patents and the Alkermes Know-How to its Affiliates or to Third Parties in accordance with the terms of this Section 3.9. Notwithstanding the licensing or sublicensing of all or part of Corregidor’s rights and obligations hereunder, Corregidor shall remain responsible for the full and complete performance of all of Corregidor’s obligations and duties under this Agreement. In the event Corregidor grants a license or sublicense of the Pulmonary Patents or the Alkermes Know-How, Corregidor shall promptly notify Alkermes thereof and provide to Alkermes a copy of the agreement under which Corregidor granted such license or sublicense, which may be redacted to omit information unrelated to the licensing or sublicensing of the Pulmonary Patents or the Alkermes Know-How or the performance of obligations under this Agreement. Any license or sublicense arrangement shall include express language that the terms, conditions and obligations of any such license or sublicense are subject to the terms, conditions and obligations of this Agreement. Subject to any necessary and appropriate adjustment of such terms, conditions and obligations in light of the type and scope of the license or sublicense granted, such license or sublicense (i) shall include diligence, royalty payment and

reporting, records and audit, and confidentiality obligations consistent with the terms, conditions and obligations of this Agreement; (ii) shall include indemnification and insurance obligations equivalent to the indemnification and insurance obligations of Corregidor herein, and shall provide that such indemnification and insurance obligations shall run to and be for the benefit of Alkermes; and (iii) shall name Alkermes as an intended third party beneficiary of the obligations of the licensee or sublicensee without imposing any obligation or liability on the part of Alkermes to the licensee or sublicensee; *provided, however*, that Alkermes' rights as a third party beneficiary under such license or sublicense shall be exercisable only to the extent necessary for Alkermes to prevent or address any material adverse impact upon Alkermes which Corregidor fails to use reasonable efforts to prevent or address, and in any event Alkermes' status as an intended third party beneficiary under such license or sublicense shall expire upon the [\*\*\*]. Any subsequent sublicense of the Pulmonary Patents or the Alkermes Know-How by any such licensee or sublicensee, or any license or sublicense thereof by any Assignee, shall also be subject to the terms and conditions of this Section 3.9.

**3.10. Limitations on Alkermes' Licensing, Transfer or Use of the Alkermes Know-How.** Upon and after the Effective Date, without Corregidor's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned, Alkermes shall not license, sublicense or otherwise transfer the Alkermes Know-How to a Third Party for the express purpose of such Third Party Developing, Manufacturing or Commercializing a Third-Party Dry Powder Inhalation Product. In addition, upon and after the Effective Date, without Corregidor's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned, Alkermes shall not itself, or through its Affiliates, practice or use the Alkermes Know-How to Develop, Manufacture or Commercialize an Alkermes Dry Powder Inhalation Product. Notwithstanding the foregoing, the limitations on Alkermes' rights to practice and use the Alkermes Know-How that are set forth in the second sentence of this Section 3.10 shall expire upon any Change in Control of Alkermes.

**3.11. Access to Personnel, Information and Records.** From time to time after the Effective Date, Alkermes will, at Corregidor's reasonable request and expense, make available to Corregidor's agents and representatives (i) information, books, records and other documents relating to the Assets, including copies thereof, as Corregidor may reasonably request, and (ii) individuals in Alkermes' employ having knowledge of the Assets. Corregidor will pay Alkermes, at Alkermes' then current full-time equivalent (FTE) hourly rate, for all work performed by Alkermes at Corregidor's request, subject to the last sentence of this Section 3.11. Before Alkermes commences any work pursuant to this Section 3.11 at Corregidor's expense, the Parties will agree in advance on the scope of such work and the amount that Corregidor will be obligated to pay Alkermes for such work. At the end of each month during the period any such work is being performed by Alkermes at Corregidor's request and expense, as provided in this Section 3.11, Alkermes will invoice Corregidor for any such work that has been performed during such month and any costs that Alkermes has incurred, and Corregidor will pay all such invoices within [\*\*\*] of the invoice date. Notwithstanding the foregoing, during the Transition Period, Alkermes will provide Corregidor, at Corregidor's reasonable request and at Alkermes' expense, a reasonable amount of information and support with respect to the Assets and the transfer thereof from Alkermes to Corregidor.

**3.12. Later Identified Documentation .** If after the Effective Date Alkermes discovers and confirms the characterization of any documentation or items described in Section 2.1.3 (without regard to the requirement that such items be listed on Schedule 2.1.3) as necessary for or directly related to the Development, Manufacture or Commercialization of Licensed Products and such documentation or items are not also used in Alkermes business operations unrelated to the Business, then Alkermes shall so notify Corregidor in writing. Any such documentation and items shall automatically be included within the definition of Documentation upon Corregidor's receipt of such notice from Alkermes, and Alkermes will promptly transfer such documentation and items to Corregidor, at Corregidor's expense.

**3.13. Option to Purchase Manufacturing Facility Equipment .**

**3.13.1. Option .** In accordance with the terms of this Section 3.13, Alkermes hereby grants Corregidor an option to purchase the Manufacturing Facility Equipment (the "Option"). The term of the Option shall begin on the Option Effective Date and expire [\*\*\*] thereafter (the "Option Exercise Period"). Corregidor shall promptly notify Alkermes of the occurrence of the Option Effective Date, identifying the event triggering the Option Effective Date. If Corregidor elects to exercise the Option, Corregidor shall provide written notice to Alkermes of such election during the Option Exercise Period; *provided, however*, that Corregidor may not exercise the Option if the Term (as defined in the Sublease) of the Sublease (including any Extension Periods, as defined in the Sublease) has expired or if Corregidor is in material default under the Sublease (after giving effect to any applicable notice and cure period with respect to such default).

**3.13.2. Acquisition Event Trigger .** If the event triggering the Option is the Acquisition Event, then, within [\*\*\*] following Alkermes' receipt of Corregidor's Option exercise notice, Alkermes shall sell, assign and transfer the Manufacturing Facility Equipment to Corregidor, and in consideration for such sale, assignment, and transfer of the Manufacturing Facility Equipment, Corregidor shall pay Alkermes Thirty Million Dollars (\$30,000,000). In connection with such sale, assignment and transfer, the Parties shall execute and deliver a bill of sale containing representations and warranties comparable to those set forth in Section 6.1 (i) hereof, and Alkermes shall exercise any exercisable options contained in Article XIII of the Lease in accordance with the terms and conditions set forth in the Sublease.

**3.13.3. Resale Event or the Direct Sales Event Trigger .** If the event triggering the Option is the Resale Event or the Direct Sales Event, then, within [\*\*\*] following Alkermes' receipt of Corregidor's Option exercise notice, Alkermes shall sell, assign and transfer the Manufacturing Facility Equipment to Corregidor and in consideration for such sale, assignment, and transfer of the Manufacturing Facility Equipment, Corregidor will issue Alkermes the Promissory Note substantially in the form set forth in Exhibit C hereto. The Promissory Note will be secured by the Manufacturing Facility Equipment pursuant to the Security Agreement substantially in the form set forth in Exhibit D hereto. In connection with such sale, assignment and transfer, the Parties shall execute and deliver the Bill of Sale for the Manufacturing Facility Equipment attached to the Security Agreement, and Alkermes shall exercise any exercisable options contained in Article XIII of the Lease in accordance with the terms and conditions set forth in the Sublease. In addition during such [\*\*\*] period, the Parties will amend this Agreement to add the "Cost of Goods Manufactured" definition set forth in the Security Agreement so as to provide for reporting of the number of units of Commercial Capsules sold and their Cost of Goods Manufactured pursuant to Section 5.4, and to provide for the audit of Cost of Goods Manufactured and payments made under the Security Agreement and Promissory Note pursuant to Section 8.1.

**3.13.4. Failure to Exercise the Option .** If Corregidor does not exercise the Option during the Option Exercise Period, and if the term of the Sublease has not already expired or terminated, then Alkermes will have the right to terminate the Sublease, in its sole discretion, as provided in Section 15 of the Sublease.

## ARTICLE 4

### DEVELOPMENT AND COMMERCIALIZATION

**4.1. Development and Commercialization Efforts .** Corregidor shall, itself or with or through its Affiliates and Collaboration Partners, use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products.

**4.2. Corregidor's Minimum Development Performance Obligations .** Notwithstanding the Development obligations set forth in Section 4.1, Corregidor will have the following minimum performance obligations [\*\*\*]:

- (a) Prior to [\*\*\*], Corregidor will have [\*\*\*]; and
- (b) Prior to [\*\*\*], Corregidor will either (i) [\*\*\*], or (ii) [\*\*\*].

If either of the obligations set forth in Sections 4.21(a) or ( b ) has not been fulfilled prior to the deadline therefor, and Corregidor cannot reasonably demonstrate that this failure resulted from technical, regulatory, scientific or business causes that had an unforeseen adverse impact, which could not reasonably be mitigated, on the Development or Manufacture of the Licensed Products, then Alkermes shall have the right, which may be exercised in its sole discretion, upon notice to Corregidor delivered at any time following the deadline, to terminate this Agreement for Default.

**4.3. Status Reports .** During the Term within [\*\*\*] after the end of each Calendar Year, Corregidor will provide Alkermes with an annual status report that describes the Development efforts performed by or on behalf of Corregidor during the Calendar Year at issue. Such report will include a general summary of important events and/or milestones achieved and other matters about which Corregidor believes Alkermes should be informed.

**4.4. Patent Prosecution .** Corregidor shall file, prosecute and maintain the Alkermes Patents in the United States and in such foreign countries as it selects, based on reasonable commercial and patent prosecution strategy considerations, in accordance with commercially reasonable practices for obtaining intellectual property protection for pharmaceutical products comparable to the Licensed Products (but without taking into account amounts such as Royalties required to be paid to Alkermes based on the Alkermes Patents), provided that the foregoing obligations, as to the MIT Patents, shall be subject to the terms and conditions of the MIT Patent License Agreement.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**4.5. No Conflict .** Corregidor will not enter into any agreement with any Third Party that is in conflict with this Agreement in any material respect, and will not take any action that would prevent it from performing any material obligation under this Agreement, or that would otherwise materially conflict with or materially adversely affect the performance of its obligations under this Agreement.

**4.6. Compliance with Applicable Laws .** Corregidor agrees that its Development, Commercialization and Manufacture of Licensed Products will be carried out in compliance with all Applicable Laws.

## **ARTICLE 5**

### **CONSIDERATION**

**5.1. Corregidor Stock .** In partial consideration for the sale, assignment, and transfer of the Assets and the grant of the license under this Agreement, Corregidor agrees, on the Effective Date, to provide to Alkermes shares of Corregidor's Series A Preferred Stock pursuant to the terms and conditions set forth in Equity Investment Agreements.

#### **5.2. Royalties .**

**5.2.1. Royalty Calculation .** In partial consideration for the sale, assignment, and transfer of the Assets and the grant of the license under this Agreement, Corregidor shall pay to Alkermes the following Royalties for each Licensed Product (after giving effect to Sections 5.2.3 and 5.3, to the extent applicable):

(i) for all Licensed Products sold by, on behalf of, or under the authority of Corregidor or its Affiliates (other than those Licensed Products sold by, on behalf of or under the authority of Corregidor's Collaboration Partners), Corregidor will pay Alkermes [\*\*\*] of Net Sales of such Licensed Products; and

(ii) for all Licensed Product sold by or on behalf of, or under the authority of a given Collaboration Partner, Corregidor will pay Alkermes the lower of: (A) [\*\*\*] of Net Sales of such Licensed Products in a given Calendar Year, or (B) [\*\*\*] of all Collaboration Partner Revenue received by or on behalf of Corregidor or its Affiliates from such Collaboration Partner in such Calendar Year, Notwithstanding the foregoing, for any Licensed Product sold by, on behalf of or under the authority of any such Collaboration Partner, Corregidor will not pay Alkermes less than [\*\*\*] of Net Sales of such Licensed Products in a given Calendar Year. For clarity, sales of Licensed Products by Distributors shall not be included in Net Sales and shall not be subject to Royalty payments under this Section 5.2.1.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Corregidor shall not enter into a transaction with a Collaboration Partner which is structured to require the Collaboration Partner to pay to Corregidor, its Affiliates, or any other designee of Corregidor or its Affiliates, Milestone Payments that are materially in excess of those typically included in comparable arrangements for similar pharmaceutical or biotechnology products of similar market potential (a “Trigger Transaction”). Upon entering into a transaction with a Collaboration Partner, whether pursuant to Sections 3.7 and 3.9 or otherwise, Corregidor shall promptly notify Alkermes thereof and provide Alkermes with a copy of the agreement governing such transaction. Within [\*\*\*] of receiving any such agreement between Corregidor and a Collaboration Partner, if Alkermes believes that Corregidor has entered into a Trigger Transaction with such Collaboration Partner, it may submit the issue for resolution by binding arbitration in accordance with Section 11.2. If the arbitrator determines that Corregidor entered into a Trigger Transaction with a given Collaboration Partner, then Corregidor shall pay to Alkermes, beginning on the effective date of the Trigger Transaction, instead of the amount Corregidor is obligated to pay pursuant to the paragraph immediately preceding this paragraph, an amount equal to the lower of (X) [\*\*\*] of Net Sales of the relevant Licensed Products sold by or on behalf of, or under authority of, such Collaboration Partner in a given Calendar Year; or (Y) (1) [\*\*\*] of the Milestone Payments deemed to have caused the Trigger Transaction that are received by Corregidor or its Affiliates from such Collaboration Partner with respect to such Licensed Products in such Calendar Year, plus (2) [\*\*\*] of all Collaboration Partner Revenue received by Corregidor or its Affiliates from such Collaboration Partner in such Calendar Year, but in any event not less than [\*\*\*] of Net Sales of the relevant Licensed Products sold by or on behalf of, or under authority of, such Collaboration Partner in such Calendar Year. If the arbitrator determines that Corregidor did not enter into a Trigger Transaction, then Alkermes will receive the Royalty that it would have otherwise received pursuant to Section 5.2.1(ii) with respect to such Collaboration Partner. For clarity, this paragraph describes a mutually agreed upon exclusive mechanism for resolving disputes regarding Trigger Transactions, and accordingly, Alkermes may not terminate this Agreement under Section 10.2 solely on the basis that Corregidor entered into a Trigger Transaction.

**5.2.2. Duration of Royalty Payments .** Corregidor will pay the Royalties to Alkermes, as referenced in Section 5.2.1, for each Licensed Product, on a Licensed Product-by-Licensed Product and country-by-country basis until the later of (i) the expiration of the Alkermes Patents containing Valid Claims covering such Licensed Product in such country, or (ii) twelve (12) years and six (6) months after the Launch of such Licensed Product in such country.

**5.2.3. Reduction in Royalty .** The Royalty payments due to Alkermes pursuant to this Section 5.2 shall be reduced by [\*\*\*] of the amounts otherwise due pursuant to Section 5.2.1 on a Licensed Product-by-Licensed Product and country-by-country basis for any Licensed Product that is not covered by a Valid Claim of the Alkermes Patents in a given country at the time such Licensed Product is sold in such country. Such reductions shall apply for purposes of determining the amounts due to Alkermes pursuant to Section 5.2.1.

**5.3. Combination Products .** Net Sales of any Licensed Product sold as part of a product which consists of the Licensed Product in combination with one or more Active Components (“Combination Product”), for purposes of determining the Royalties payable to Alkermes under Section 5.2, shall be calculated as follows:

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

(a) In the event each of the Active Components and Licensed Product are sold separately, the Net Sales shall be calculated by [\*\*\*].

(b) If the Active Component(s) in the Combination Product are not sold separately in the Territory, but the Licensed Product is sold separately in the Territory, Net Sales shall be calculated by [\*\*\*].

(c) If the Licensed Product is not sold separately in the Territory, Net Sales of a Combination Product shall be determined in good faith by the Parties taking into account the relative values of the Active Components and the Licensed Product contained therein.

For purposes of this Section 5.3, the term “Net Sales” as it relates to Combination Products shall have the same meaning as Net Sales except that “Combination Product” shall be substituted for “Licensed Product” in the definition of Net Sales, before performing the calculations set forth in this Section 5.3.

**5.4. Royalty Payments and Reports .** Within [\*\*\*] after the end of each month during which Licensed Products are sold pursuant to this Agreement, Corregidor will deliver to Alkermes a report setting forth Corregidor’s good faith estimate of the following for the Territory in the aggregate: (i) the amount of gross sales of Licensed Products during such month, (ii) the number of units and dosage strengths of Licensed Products sold during such month, (iii) the amount of Net Sales of Licensed Products sold during such month; (iv) the currency conversion rates used during such month, and (v) the Dollar-equivalent of Net Sales during such month. In addition, within [\*\*\*] after the end of each Calendar Quarter for which Royalties are payable by Corregidor to Alkermes pursuant to Section 5.2, Corregidor will deliver to Alkermes a true and accurate report providing in reasonable detail an accounting of all Net Sales made in the Territory during such Calendar Quarter (each a “Quarterly Sales Report”), including, on an country-by-country basis and for the Territory in the aggregate: (A) the amount of gross sales of Licensed Products during such Calendar Quarter, (B) the number of units and dosage strengths of Licensed Products sold during such Calendar Quarter, (C) the amount of Net Sales of Licensed Products sold during such Calendar Quarter, (D) the currency conversion rates used during such Calendar Quarter, (E) the Dollar-equivalent of such Net Sales during such Calendar Quarter, and (F) a calculation of the amount of the Royalty payment due on such Net Sales for such Calendar Quarter. Notwithstanding the

foregoing, such Calendar Quarter report may include a reasonable estimate of this information for Net Sales by Corregidor's Collaboration Partners rather than a true and correct report thereof. Within [\*\*\*] after delivery of this report to Alkermes, Corregidor will pay to Alkermes the Royalty payment due on Net Sales as described in such report. If necessary, after receipt of information on Net Sales of Corregidor's Collaboration Partners that is inconsistent with any estimated information previously disclosed to Corregidor, Corregidor shall make any necessary reconciling payments or take any necessary reconciling credits against amounts due to Alkermes based on Net Sales by Corregidor's Collaboration Partners, to reflect the amount actually due pursuant to Section 5.2.1 (ii). Any such reconciling payments shall be made within [\*\*\*] after the end of the Calendar Quarter in which such information was received and any such reconciling credits shall be taken against amounts due to Alkermes during the next Calendar Quarter. If the Royalty payable to Alkermes is calculated on the basis of Collaboration Partner Revenue or Milestone Payments rather than Net Sales, within [\*\*\*] after the end of each Calendar Quarter for which such Royalties are payable by Corregidor to Alkermes pursuant to Section 5.2.1(ii), Corregidor will deliver to Alkermes a true and accurate report of all Collaboration Partner Revenue actually received by or on behalf of Corregidor or its Affiliates from Collaboration Partners in such Calendar Quarter, and within [\*\*\*] after delivery of this report to Alkermes, Corregidor will pay to Alkermes the Royalty payment due on Collaboration Partner Revenue or Milestone Payments as described in such report.

**5.5. Manner of Payments .** All consideration payable to Alkermes under this Agreement shall be paid in Dollars. All sums due to Alkermes under this Article 5 will be payable by bank wire transfer in immediately available funds to such bank account(s) as Alkermes may designate from time to time. Corregidor will endeavor to notify Alkermes as to the date and amount of any such wire transfer in no event later than the Business Day of such transfer.

**5.6. Withholding .** Alkermes shall be responsible for any and all income or other taxes required by law to be withheld or deducted from any of the Royalty and other payments made hereunder (" Withholding Taxes "), and Corregidor may deduct from any amounts that Corregidor is required to pay pursuant to Section 5.4 an amount equal to such Withholding Taxes. Alkermes shall provide Corregidor any information necessary to determine the Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for Alkermes' account and evidence of such payment shall be secured and sent to Alkermes within [\*\*\*] of such payment. Corregidor will give notice of its intention to begin withholding any Withholding Taxes hereunder in advance of such withholding. In the event of such withholding, the Parties agree to confer regarding other reasonable, lawful measures to minimize such withholding.

**5.7. Foreign Exchange .** Whenever for the purposes of calculating the Royalties payable under Section 5.4 conversion from any foreign currency shall be required, all amounts shall first be calculated in the currency of sale and then converted into Dollars by applying the rate of exchange listed in the New York edition of *The Wall Street Journal* for the last Business Day of each month during the applicable Calendar Quarter.

**5.8. Late Payments .** Without limitation on other available rights or remedies, any payments or portions thereof due hereunder that are not paid at the latest [\*\*\*] following the date such payments are due under this Agreement will bear interest at the lower of (i) [\*\*\*] above the overnight London Inter-Bank Offer Rate (LIBOR) rate in effect on the due date, or (ii) the maximum rate permitted by Applicable Law, calculated on the number of days such payment is delinquent.

**5.9. Third Party Payments .** Without making any reduction in the Royalties payable pursuant to Section 5.2 hereof, Corregidor shall be responsible for obtaining any licenses to, and paying compensation for the use of, any patents, patent applications and other intellectual property rights owned by Third Parties and necessary or useful for the manufacture, use, sale, offer for sale or import of any Licensed Product in the Territory and that are not licensed hereunder to Corregidor.

## **ARTICLE 6**

### **REPRESENTATIONS AND WARRANTIES**

**6.1. Representations and Warranties of Alkermes .** Alkermes hereby represents and warrants to Corregidor as of the Effective Date as follows:

**(a) Corporate Existence and Power .** Alkermes is a corporation duly organized, validly existing and in good standing under the laws of the State of Pennsylvania, and has full corporate power and authority to own and operate its property and assets and to carry on its business as it is now being conducted.

**(b) Authority and Binding Agreement .** Alkermes has the corporate power and authority to enter into this Agreement and perform its obligations hereunder. Alkermes has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered by Alkermes and constitutes a legal, valid and binding obligation of Alkermes that is enforceable against it in accordance with its terms; except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition law, penalties and jurisdictional issues including conflicts of law).

**(c) No Conflict .** The execution, delivery and performance of this Agreement by Alkermes does not conflict with, and would not result in a breach or violation of or constitute a default under (i) any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound; (ii) the provisions of its charter or operative documents or bylaws; (iii) any material license, franchise, permit or other similar authorization related to the transactions contemplated hereby; or (iv) any material Applicable Law, or any judgment, decree or order of any court, governmental body or administrative or other agency having jurisdiction over it.

**(d) Brokers .** No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Alkermes.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

(e) **Title to Pulmonary Patents** . Except as set forth in Schedule 6.1(e) hereof, Alkermes is conveying to Corregidor good and marketable title to the Pulmonary Patents existing as of the Effective Date free and clear of restrictions on, or conditions to, transfer or assignment and free and clear of mortgages, security interests, licenses, liens, encumbrances, or rights of others to possession or use.

(f) **Patent Invalidity and Unenforceability; No Other Patents** . Except as set forth in Schedule 6.1(f) hereof, no Third Party has filed (such that it is pending as of the Effective Date), or to the actual knowledge of the General Counsel of Alkermes, as of the Effective Date threatened in writing to file, any claim, lawsuit, charge, complaint or other action alleging that the Alkermes Patents are invalid or unenforceable, and the Alkermes Patents are not subject to a pending interference, opposition or appeal of an opposition. Except as set forth in Schedule 6.1(f) hereof, the Alkermes Patents constitute all patent applications and patents Controlled by Alkermes immediately prior to the Effective Date that claim the manufacture, use or composition of matter of the Licensed Products that are within the scope of the Business.

(g) **Contracts** . The MIT Patent License Agreement, the Penn State License Agreement, and the Acusphere Agreements are in full force and effect. With respect to each such agreement, Alkermes is not in material breach or default with respect to its obligations thereunder. Except as set forth in Schedule 6.1(g) hereof, to the actual knowledge of the General Counsel of Alkermes, no counterparty to any of these agreements is in material breach or default with respect to such party's obligations thereunder.

(h) **Right to License** . Alkermes has the right to grant the license under the Alkermes Know-How granted hereunder and has not assigned, transferred, conveyed, sublicensed or otherwise encumbered any right, title and interest in the Alkermes Know-How inconsistent with the terms of this Agreement.

(i) **Title to Equipment and Inhalers** . Except as set forth in Schedule 6.1(i) hereof and subject to Alkermes' retained right, title and interest in and to the Alkermes Know-How that is described in or embodied in the Equipment and the Inhalers, Alkermes is conveying to Corregidor good and marketable title to the Equipment and Inhalers free and clear of restrictions on, or conditions to, the transfer or assignment thereof, free and clear of mortgages, security interests, licenses, liens, encumbrances, or rights of others to possession or use; *provided, however* , that all Equipment and Inhalers are transferred to Corregidor on an "as is" "where is" basis without any other representation or warranty of any kind, either expressed or implied, including any warranty as to the design, quality or condition of the Equipment or Inhalers, any warranty of merchantability or fitness of the Equipment or Inhalers for any particular purpose or as to any other matter relating to the Equipment or the Inhalers or any part thereof.

(j) **Third Party Claims** . Except for claims that were settled pursuant to the Acusphere Agreements, Alkermes has not received any written claims from any Third Party that the manufacture, use or sale of Licensed Products that are within the scope of the Business infringe any patents or patent applications of such Third Party.

Except as set forth in this Section 6.1, Alkermes makes no representations or warranties of any kind. Specifically Alkermes does not warrant the validity or enforceability of the Alkermes Patents, and makes no representations whatsoever with regard to the scope of the Alkermes Patents, or that the Alkermes Patents and Alkermes Know-How may be exploited without infringing other patents or other intellectual property rights of Third Parties. Alkermes MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE of any subject matter defined by the claims of the Alkermes Patents and Alkermes Know-How. References in the foregoing representations and warranties to “actual knowledge” mean the actual knowledge of the referenced person with respect to the specified matter as of the time the representation is made, after making reasonable inquiry of other members of his/her department and reviewing the files of his/her department that he/she reasonably expects would contain relevant information.

**6.2. Representations and Warranties of Corregidor .** Corregidor hereby represents and warrants to Alkermes as of the Effective Date as follows:

(a) **Corporate Existence and Power .** Corregidor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and has full corporate power and authority to own and operate its property and assets and to carry on its business as it is now being conducted.

(b) **Authority and Binding Agreement .** Corregidor has the corporate power and authority to enter into this Agreement and perform its obligations hereunder. Corregidor has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered by Corregidor and constitutes a legal, valid and binding obligation of Corregidor that is enforceable against it in accordance with its terms; except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors’ rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition law, penalties and jurisdictional issues including conflicts of law).

(c) **No Conflict .** The execution, delivery and performance of this Agreement by Corregidor does not conflict with, and would not result in a breach or violation of or constitute a default under (i) any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound; (ii) the provisions of its charter or operative documents or bylaws; (iii) any material license, franchise, permit or other similar authorization related to the transactions contemplated hereby; or (iv) any Applicable Law, or any judgment, decree or order of any court, governmental body or administrative or other agency having jurisdiction over it.

(d) **Brokers .** No broker, finder or investment banker is entitled to any brokerage, finder’s or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Corregidor.

Except as set forth in this Section 6.2, Corregidor makes no representations or warranties of any kind.

## ARTICLE 7

### INDEMNIFICATION

**7.1. Indemnification by Alkermes .** Alkermes hereby agrees to defend, hold harmless and indemnify (collectively, “Indemnify”) Corregidor and its officers, directors, agents and employees (collectively, the “Corregidor Indemnitees”) from and against any and all Losses arising out of (i) any of Alkermes’ representations and warranties set forth in Section 6.1 of this Agreement being untrue in any material respect on the Effective Date; (ii) the failure to perform, in any material respect, any covenant or agreement of Alkermes set forth in this Agreement; (iii) the Retained Liabilities or (iv) the research, development, making, having made, using, or importing of Licensed Products by, on behalf of, or under the authority of Alkermes prior to the Effective Date. Third-Party claims, suits, actions or demands subject to indemnification and hold harmless obligations hereunder shall not include any claims, suits, actions or demands asserted by any agent of Alkermes.

**7.2. Indemnification by Corregidor .** Corregidor hereby agrees to Indemnify Alkermes and its officers, directors, agents and employees (collectively, the “Alkermes Indemnitees”) from and against any and all Losses arising out of (i) any of Corregidor’s representations and warranties set forth in Section 6.2 of this Agreement being untrue in any material respect on the Effective Date; (ii) the failure to perform, in any material respect, any covenant or agreement of Corregidor set forth in this Agreement; (iii) the Assumed Liabilities or (iv) except to the extent such Losses are required to be indemnified by Alkermes pursuant to Section 7.1(iv) hereof, the research, development, making, having made, using, importing, selling, or offering for sale of Licensed Products by, on behalf of, or under the authority of Corregidor, its Affiliates or Collaboration Partners. Third-Party claims, suits, actions or demands subject to indemnification and hold harmless obligations hereunder shall not include any claims, suits, actions or demands asserted by any agent or Collaboration Partner of Corregidor.

**7.3. Indemnification Procedures .** The following procedures shall apply to any Third Party claim, suit, action or demand for which the Corregidor Indemnitees or Alkermes Indemnitees, as the case may be (the “Indemnified Party”), may be entitled to indemnification under this Article 7 (a “Claim”). To be eligible to be Indemnified for a Claim, the Indemnified Party shall (i) provide the Party required to Indemnify the Indemnified Party (the “Indemnifying Party”) with prompt written notice of the Claim giving rise to the indemnification obligation under this Article 7, *provided that*, the failure to provide prompt notice shall not relieve the Indemnifying Party of any of its obligations under this Article 7 except to the extent the Indemnifying Party is actually prejudiced thereby; (ii) provide the Indemnifying Party with the exclusive ability to defend (with the reasonable cooperation of the Indemnified Party) against the Claim; and (iii) not settle, admit or materially prejudice the Claim, without the Indemnifying Party’s prior written consent. The Indemnified Party shall reasonably cooperate with the Indemnifying Party, at the Indemnifying Party’s expense, in the defense of any Claim. Notwithstanding the foregoing, the Indemnified Party shall have the right to participate in and

have counsel selected by it participate, at the Indemnified Party's expense, in any action for which the Indemnified Party seeks to be Indemnified by the Indemnifying Party. The Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment with respect to, any Claim, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld or delayed; *provided that*, the Indemnifying Party may settle or compromise any Claim in its absolute discretion if the settlement or compromise provides for an unconditional release of, and does not impose any requirements on or have any material adverse effect on, the Indemnified Party.

**7.4. Limitations on Indemnification** . A Party's obligation to Indemnify the Alkermes Indemnitees or Corregidor Indemnitees, as the case may be, pursuant to this Article 7 shall not apply to the extent of (i) any Losses that arise from the negligence, bad faith or intentional misconduct of an Alkermes Indemnatee if the party seeking indemnification is an Alkermes Indemnatee or a Corregidor Indemnatee if the party seeking indemnification is a Corregidor Indemnatee; (ii) any Losses that arise from the breach of this Agreement by an Alkermes Indemnatee if the party seeking indemnification is an Alkermes Indemnatee or a Corregidor Indemnatee if the party seeking indemnification is a Corregidor Indemnatee; or (iii) the failure by the party seeking indemnification to take reasonable action to mitigate any Losses.

**7.5. Overlapping Claims** . Notwithstanding Section 7.1 and Section 7.2, in the event a Claim relates to periods or matters for which both of Alkermes and Corregidor may have responsibility or for which each of the Parties may have indemnification obligations to the other under this Article 7, (i) if either Party elects to join the defense of such Claim to be commenced by the other Party, then (A) Corregidor and Alkermes shall jointly select counsel to represent the Parties in the defense of the Claim and the Parties shall share all attorneys' fees and legal costs related to the Claim based on the portion of the matter or period underlying the Claim for which each Party has responsibility and, if necessary, a Party shall reimburse the other Party for any payment for attorneys' fees and legal costs related to the Claim in excess of such other Party's proportional share; (B) Corregidor and Alkermes shall jointly decide upon all matters, including strategy, related to the defense of the Claim; (C) the Parties shall provide all reasonable cooperation to each other and the selected counsel in the defense of such Claim; (D) each Party shall have the right to have independent counsel selected by it participate, at such Party's sole expense, in the preparation of, and discussions related to, the defense of such Claim; (E) neither Party shall settle or compromise, or consent to the entry of any judgment with respect to, any such Claim, without the prior written consent of the other Party, which will not be unreasonably withheld or delayed; and (F) each Party shall pay that portion of any damages or settlement amounts resulting from any such Claim which relates to the period(s) or matter(s) for which it has responsibility under this Agreement; or (ii) if a Party elects not to join the defense of such Claim to be commenced by the other Party, then (A) such other Party shall defend against such Claim, and the Parties shall share all attorneys' fees and legal costs related to the Claim based on the portion of the matter or period underlying the Claim for which each Party has responsibility and, if necessary, a Party shall reimburse the other Party for any payment for attorneys' fees and legal costs related to the Claim in excess of such other Party's proportional share; (B) the Parties shall reasonably cooperate in the defense of any such Claim; (C) such Party shall have the right to subsequently participate in and have counsel selected by it participate, at such Party's expense, in any action or dispute resolution related to such Claim; (D) the other Party shall not settle or compromise, or consent to the entry of any judgment with respect to, any such Claim, without

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

the prior written consent of such Party, which will not be unreasonably withheld or delayed; and (E) each Party shall pay that portion of any damages or settlement amounts resulting from any such Claim which relates to the period(s) or matter (s) for which it has responsibility under this Agreement. Notwithstanding the foregoing, nothing in this Section 7.5 shall give either Party a right to obtain or receive Confidential Information of the other Party whose disclosure is not otherwise contemplated by this Agreement.

**7.6. Insurance .** Each Party shall at its own expense procure, within [\*\*\*] of the Effective Date, and maintain during the Term, insurance policy/policies, including (i) Commercial General Liability insurance, including coverage for products and completed operations and contractual liability (including coverage for advertising and personal injury), and (ii) Product Liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. All such policies will be written by insurance companies with an A.M. Best's rating (or its equivalent) of A or better. Notwithstanding the foregoing, beginning on the date Corregidor initiates a Phase 1 Clinical Trial, Corregidor shall procure and maintain Commercial General Liability insurance, including coverage for products and completed operations and contractual liability (including coverage for advertising and personal injury), and Product Liability insurance (each policy to be maintained for a period of at least [\*\*\*] after the expiration or termination of this Agreement, in the event the policy is a claims made form) in each case with a limit of no less than [\*\*\*] for each occurrence. Any insurance shall not be construed to create a limit of the insuring Party's liability with respect to its indemnification obligations under this Article 7. Each Party shall provide the other Party with written evidence of such insurance upon request, Each Party shall provide the other with written notice at least [\*\*\*] prior to a cancellation, suspension, non-renewal or material change in such insurance which would reasonably be expected to materially adversely affect the rights of the other Party hereunder. Each Party's insurance hereunder shall be primary with respect to the obligations for which such Party is liable hereunder and non-contributing with respect to the obligations for which such Party is to be indemnified by the other Party.

**7.7. Non-Duplicative Payments .** In calculating amounts payable to an Indemnified Party, the amount of the Indemnified Losses shall not be duplicative of any other Loss for which an indemnification claim has been made and shall be computed net of (i) payments recovered by the Indemnified Party under any insurance policy with respect to such Losses, and (ii) any recovery by the Indemnified Party from any Person with respect to such Losses.

**7.8. Limitation of Liability .** Except pursuant to their indemnification and hold harmless obligations set forth in Sections 7.1 and 7.2, neither Party shall be responsible to the other Party for any special, indirect, incidental, exemplary, punitive or consequential damages arising out of or resulting from this Agreement.

**7.9. Survival .** The representations and warranties of the Parties contained in Sections 6.1 and 6.2 shall survive the Effective Date for [\*\*\*]. The Parties intend for the preceding sentence to shorten the otherwise applicable statute of limitations and agree that no claims (other than claims of, or causes of action arising from, fraud) may be brought based upon, directly or indirectly, any of the representations and warranties contained in this Agreement on or after the date that is [\*\*\*] after the Effective Date.

## ARTICLE 8

### RECORDS; AUDIT

**8.1. Financial Statements .** Corregidor shall deliver to Alkermes the following financial statements of Corregidor:

(a) within [\*\*\*] after the end of each month, Corregidor shall use reasonable efforts to deliver unaudited statements of income and of cash flows for such month, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such month all prepared in accordance with U.S. GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with U.S. GAAP);

(b) within [\*\*\*] after the end of each Calendar Quarter, Corregidor shall deliver unaudited statements of income and of cash flows for such Calendar Quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such Calendar Quarter all prepared in accordance with U.S. GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with U.S. GAAP); and

(c) within [\*\*\*] after the end of each Calendar Year, Corregidor shall deliver: (i) a balance sheet as of the end of such Calendar Year, (ii) statements of income and of cash flows for such Calendar Year, and a comparison between (x) the actual amounts as of and for such Calendar Year and (y) the comparable amounts for the prior Calendar Year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such Calendar Year, and (iii) a statement of stockholders' equity as of the end of such Calendar Year, all such financial statements audited and certified by independent public accountants of nationally or regionally recognized standing selected by Corregidor and approved by Alkermes, which approval shall not be unreasonably withheld or delayed.

With respect to each of the financial statements called for in this Section 8.1, Corregidor shall deliver to Alkermes, an instrument executed by the chief financial officer and chief executive officer of Corregidor (or person having equivalent functional responsibility) certifying that such financial statements were prepared in accordance with U.S. GAAP consistently applied with prior practice for earlier periods (except as otherwise set forth in Sections 8.1(a) or 8.1(b)) and fairly present the financial condition of Corregidor and its results of operation for the periods specified therein. In addition, with respect to the financial statements called for in Section 8.1(c), Corregidor shall deliver to Alkermes the auditor's report, including opinions, scorecards, recorded changes and other ancillary documents. If, for any period, Corregidor has any subsidiary whose accounts are consolidated with those of Corregidor, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of Corregidor and all such consolidated subsidiaries.

**8.2. Royalty Records; Audit .** Corregidor shall keep or cause to be kept such records as are required to determine, in a manner consistent with U.S. GAAP, as applicable, the accuracy of the calculation of all Net Sales and Royalties payable under this Agreement; provided that any Collaboration Partner that does not keep records in accordance with U.S. GAAP shall keep such records in accordance with the equivalent accounting practices to which it adheres. Such records shall be retained for no less than a [\*\*\*] period following the year in which any payments of Royalties were made hereunder. Not more than once per Calendar Year, and once within [\*\*\*] after the end of the Term, Alkermes shall have the right to engage, at its own expense, an independent certified public accountant appointed by Alkermes and reasonably acceptable to Corregidor, to examine, in confidence, the records of Corregidor as may be necessary to determine, with respect to any Calendar Year or portion thereof, the correctness or completeness of any payment required to be made by Corregidor under this Agreement; *provided, however* , that the books and records for any particular Calendar Year shall only be subject to one such audit. Such independent public accountant shall enter into an appropriate confidentiality agreement with Corregidor. All information contained in any report of such independent public accountant to Alkermes shall be deemed Confidential Information of Corregidor hereunder. A copy of such report will be provided to Corregidor at the same time it is provided to Alkermes. Such report shall not disclose any information except that which should properly be contained in a Royalty report required under this Agreement, but may include, in the event the accountant shall be unable to verify the correctness of any or all of such payment, the unverifiable amount of such payment and information relating to why any or all of such payment is unverifiable. If any audit performed evidences an underpayment by Corregidor of any amounts or payments owing hereunder, Corregidor shall promptly pay the amount of such underpayment to Alkermes with interest thereon calculated in accordance with Section 5.8. If any audit performed under this Section 8.2 discloses an underpayment of [\*\*\*] or more from the amount due to Alkermes hereunder for the period under audit, Corregidor shall bear the full cost of the performance of such audit. Any overpayment shall be fully creditable against amounts subsequently payable by Corregidor to Alkermes under this Agreement. Each Collaboration Partner shall be required to keep and maintain records and to permit them to be audited by Alkermes to the same extent required by this Section 8.2.

## ARTICLE 9

### CONFIDENTIALITY

**9.1. Treatment of Confidential Information .** The Parties agree that during the Term, and for a period of [\*\*\*] after this Agreement expires or terminates, a Party receiving Confidential Information of the other Party shall (i) maintain in confidence such Confidential Information; (ii) not disclose such Confidential Information to any Third Party without prior written consent of the disclosing Party, except for disclosures to its and its Affiliates' employees, actual or potential Collaboration Partners, independent contractors, advisors, investors, actual or potential acquirers and agents who have a need to know such Confidential Information to perform such Party's obligations hereunder and who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Section 9.1 ("Permitted Recipients"); and (iii) not use such Confidential Information for any purpose other than the performance of this Agreement. Each Party shall be responsible for any breach of the obligations set forth in this Article 9 by its Permitted Recipients.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**9.2. Authorized Disclosure** . Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party to the extent and to the Persons as required by Applicable Law, legal process, court order or the rules of the National Association of Securities Dealers or of a Regulatory Authority; *provided, however* , that the Party required or intending to disclose the other Party's Confidential Information shall, to the extent permitted by such Applicable Law, process, order or rules, first have given prompt notice to such other Party to enable it to seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in such efforts by the other Party. Notwithstanding anything to the contrary in Section 9.1, Corregidor may also disclose the Confidential Information of Alkermes to the extent required in its reasonable judgment to Develop, Manufacture and Commercialize Licensed Products pursuant to this Agreement, including to (i) prosecute patent applications directed to Licensed Products and as otherwise contemplated in this Agreement, (ii) make filings and submissions to, or correspond or communicate with, Regulatory Authorities, (iii) conduct discussions with actual or potential investors, Collaboration Partners, acquirers or Distributors, and (iv) secure, operate and maintain appropriate facilities and capabilities to support, and otherwise to conduct, the Development, Manufacture and Commercialization of Licensed Products pursuant to this Agreement.

Notwithstanding the foregoing, in the event that Corregidor discovers in the Documentation any Confidential Information of Alkermes that it believes may comprise any Confidential Information of Eli Lilly and Company, then Corregidor shall promptly provide such Confidential Information to Alkermes. If Alkermes confirms that such Confidential Information comprises Confidential Information of Eli Lilly and Company, then Corregidor shall maintain such Confidential Information in confidence and not disclose it to any Third Party.

In addition, notwithstanding the foregoing, in the event that Corregidor discovers any Confidential Information of Alkermes that it believes comprises detailed information relating to pharmaceutical product formulations or pharmaceutical product manufacturing processes that does not fall within the exceptions set forth in Sections 1.27 (a) through (d) (“Alkermes Proprietary Information”), and if Corregidor wishes to disclose such Confidential Information to a Third Party in connection with disclosures permitted pursuant to subsections (iii) and (iv) above, then Corregidor may disclose such Confidential Information pursuant to a written agreement with a Third Party that imposes an obligation of non-use for any purpose other than the Development, Manufacture or Commercialization of Licensed Products or for the conduct of Corregidor's business, and imposes obligations of confidentiality and non-disclosure, all for a period of at least [\*\*\*] from the date of disclosure (a “Proprietary Information CDA”). If Corregidor desires to confirm whether such Confidential Information of Alkermes constitutes Alkermes Proprietary Information, Corregidor may provide such Confidential Information to Alkermes for review at least [\*\*\*] prior to the date of its intended disclosure to obtain such confirmation; *provided, however* , that if Corregidor provides to Alkermes an amount of Confidential Information for review that is greater in quantity than the amount of material that could reasonably be reviewed during a [\*\*\*] period, such period shall be extended accordingly. If during such [\*\*\*] (or appropriately extended) period, Alkermes confirms that such Confidential Information comprises Alkermes Proprietary Information, then Alkermes will notify Corregidor of such confirmation prior to expiration of such [\*\*\*] (or appropriately extended) period. Following the receipt of such confirmation, Corregidor may only disclose such Confidential Information pursuant to Proprietary Information CDA. If Alkermes does not confirm that such Confidential Information comprises Alkermes Proprietary Information during such time period, then Corregidor shall be free to make such disclosure of such Confidential Information to such Third Party without a Proprietary Information CDA.

**9.3. Publicity; Terms of Agreement .** The Parties agree that the existence of and the material terms of this Agreement shall be considered Confidential Information of both Parties. Except as otherwise required by Applicable Law or applicable stock exchange requirements as set forth below, or as expressly permitted by the terms of this Agreement, neither Alkermes nor Corregidor shall, and each of them shall cause their respective representatives and agents not to, issue or cause the publication of any press release or public announcement with respect to the transactions contemplated by this Agreement without the express prior approval of the other Party, which approval shall not be unreasonably withheld or delayed. The Parties agree to issue a joint press release in a form that is mutually agreed to by the Parties to announce the execution of this Agreement. Routine references to this Agreement and the terms hereof in the context of disclosures or publications regarding a Party's business in general will be allowed in the usual course of a Party's business. If in the reasonable opinion of a Party's legal counsel, a public announcement is required by Applicable Law or applicable stock exchange requirements, then, to the extent permissible by Applicable Law, the disclosing Party will provide the other Party notice reasonable under the circumstances of such intended announcement and will consult with the other Party with respect to the nature and scope of such intended announcement. In addition to the foregoing, with respect to complying with the disclosure requirements of the Securities and Exchange Commission ("SEC"), in connection with any required SEC filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement by such agencies.

## ARTICLE 10

### TERM AND TERMINATION

**10.1. Term .** Subject to the following provisions, this Agreement shall commence on the Effective Date and, unless sooner terminated as provided in Section 4.2 or as provided in this Article 10, will continue in effect until the expiration of all Corregidor's Royalty payment obligations as set forth in this Agreement (such period, the "Term").

**10.2. Termination by Alkermes .** Upon any Default by Corregidor under this Agreement, Alkermes may notify Corregidor in writing of such Default and require that Corregidor cure such Default within forty-five (45) days of Alkermes' notice. In the event Corregidor shall not have cured the Default by the end of the forty-five (45) day grace period, Alkermes may elect to terminate this Agreement effective upon a second written notice to Corregidor. No Default as defined in Section 1.31(i) shall be deemed to have occurred by Corregidor under this Section 10.2 unless Alkermes shall have given notice thereof to Corregidor under this Section 10.2 prior to the eighteen (18) month anniversary of the Effective Date. Notwithstanding the foregoing, if Corregidor commits a Default with respect to (i) any obligation to provide information or reports to Alkermes pursuant to this Agreement or (ii) any obligation pursuant to Section 9.2 with respect to the disclosure of Alkermes Proprietary Information, Alkermes shall not have the right to terminate this Agreement pursuant to this Section 10.2

unless such Default has a material adverse effect on Alkermes. In addition, if Corregidor commits a Default under Section 4.4 of this Agreement, Alkermes shall not have the right to terminate this Agreement but instead may select the remedy established by Section 10.7. For clarity, notwithstanding Section 12.1, Alkermes shall not have the right to terminate this Agreement pursuant to this Section 10.2 for any default by Corregidor under the Sublease or the Equity Investment Agreements, or the Promissory Note or the Security Agreement if the latter two agreements become effective; *provided, however*, that (i) any failure to issue Series A Preferred Stock of Corregidor to Alkermes pursuant to Section 1.2(b) or 1.3(a) of the Series A Preferred Stock Purchase Agreement (which is one of the Equity Investment Agreements) after the Effective Date, or (ii) any failure of the requisite number of Stockholders and Key Holders (each as defined in the Voting Agreement (which is also one of the Equity Investment Agreements)) to vote, or cause to be voted, their Shares (as defined in the Voting Agreement) to elect a person designated by Alkermes to the Board of Directors of Corregidor pursuant to the terms of the Voting Agreement, which failure leads to the Alkermes designee not becoming or remaining a member of the Board of Directors of Corregidor, shall be deemed to be a Default by Corregidor hereunder, except in the event of (i) a written waiver by Alkermes of its right to designate a member of the Board of Directors of Corregidor, (ii) a written agreement by Alkermes to amend the Voting Agreement to eliminate its board designation rights or (iii) the termination of the Voting Agreement pursuant to its terms.

### **10.3. Termination by Corregidor .**

**10.3.1. Termination for Convenience.** Commencing one hundred eighty (180) days after the Effective Date, Corregidor will have the right to terminate this Agreement at any time by providing ninety (90) days prior written notice to Alkermes.

**10.3.2. Termination upon Default by Alkermes.** Upon any Default by Alkermes under this Agreement, Corregidor may notify Alkermes in writing of such Default and require that Alkermes cure such Default within forty-five (45) days of Corregidor's notice. In the event Alkermes shall not have cured the Default by the end of the forty-five (45) day grace period, Corregidor may elect to terminate this Agreement effective upon a second written notice to Alkermes. No Default as defined in Section 1.31(i) shall be deemed to have occurred by Alkermes under this Section 10.3 unless Corregidor shall have given notice thereof to Alkermes under this Section 10.3 prior to the eighteen (18) month anniversary of the Effective Date.

**10.4. Right to Terminate Upon Bankruptcy .** Either Party may, in addition to any other remedies available to it by Applicable Law or in equity, terminate this Agreement, in whole or in part as the terminating Party may determine, by notice to the other Party in the event (i) the other Party has become bankrupt or has made an assignment for the benefit of its creditors; (ii) there has been appointed a trustee or receiver for the other Party or for all or a substantial part of its property; or (iii) any case or proceeding has been commenced or other action taken by or against the other Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other Applicable Law of any jurisdiction now or hereafter in effect, and any such event has continued for sixty (60) days undismissed, unbonded and/or undischarged.

**10.5. Survival of License to Corregidor upon Alkermes' Bankruptcy .** All rights and licenses granted under this Agreement by Alkermes to Corregidor are, and shall otherwise be deemed to be, for purposes of Section 365 (n) of the United States Bankruptcy Code, as amended from time to time (the “Bankruptcy Code”), licenses of rights to “intellectual property” as defined under Section 101 (35A) of the Bankruptcy Code. The Parties agree that Corregidor, as licensee of such rights, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code in the event of a bankruptcy of Alkermes.

**10.6. Effects of Termination .** Upon termination of this Agreement pursuant to Sections 10.2, 10.3, or 10.4 :

(a) **License Grant.** Upon the termination of this Agreement, all licenses and rights granted to Corregidor hereunder will terminate, and except as provided herein, Corregidor shall immediately cease all Development, Commercialization and Manufacture of Licensed Products.

(b) **Termination of Sublease .** Upon the termination of the Agreement, at Alkermes' request, the Sublease will terminate.

(c) **Promissory Note .** With respect to any termination of this Agreement, the Promissory Note, if then in force, will be governed by the terms and conditions set forth therein.

(d) **Corregidor Obligations .** Following the effective date of termination of this Agreement, Corregidor shall perform each of the following obligations, but only at Alkermes' request:

(i) Corregidor shall transfer and assign to Alkermes all of Corregidor's right, title and interest in and to the Pulmonary Patents. Corregidor shall promptly execute, or procure the execution of, such formal documents of sale and/or assignment as may be required consistent with the terms and conditions of this Agreement to formally record the change of title to the Pulmonary Patents to Alkermes. Corregidor shall instruct its patent counsel that the Pulmonary Patents have been assigned to Alkermes and that the counsel must look to Alkermes for further instructions with respect to the Pulmonary Patents, which instructions shall be undertaken at Alkermes' expense;

(ii) Corregidor shall transfer and assign to Alkermes all of Corregidor's right, title and interest in and to the Equipment and any other machinery, equipment, instruments, laboratory equipment and apparatus, fixtures, tools, and other tangible assets purchased by Corregidor specifically in connection with the Licensed Products;

(iii) Corregidor shall transfer and assign to Alkermes all of Corregidor's right, title and interest in and to the Inhalers (to the extent such inhalers then exist and are owned or controlled by Corregidor) and any other inhalers developed by or on behalf of Corregidor for use with any Licensed Product;

(iv) Corregidor shall ship to Alkermes any equipment and inhalers identified in Sections 10.6 d (ii) and (iii) that Alkermes designates for shipment (to the extent such inhalers then exist and are owned or controlled by Corregidor). Alkermes shall be responsible for all costs incurred, including freight, transportation and insurance, in connection with the shipment of such equipment and inhalers. Likewise, Alkermes shall bear the risk of loss for such equipment and inhalers upon delivery thereof to Alkermes' carrier by Corregidor;

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

(v) Corregidor shall transfer and assign to Alkermes Corregidor's rights, and Alkermes shall assume Corregidor's obligations under, the MIT Patent License Agreement, the Penn State License Agreement and the Acusphere Agreements, except to the extent such rights and obligations relate to performance or non-performance under such agreements prior to the effective date of termination;

(vi) Corregidor shall transfer and assign to Alkermes all of Corregidor's right, title and interest in and to the Documentation, and any other manufacturing documentation directly related to the Licensed Products, including standard operating procedures, facility documentation and manufacturing batch records. Corregidor shall promptly transfer to Alkermes copies of such documentation;

(vii) Corregidor shall promptly transfer and assign to Alkermes all of Corregidor's and its Affiliates' right, title and interest in and to the Pulmonary INDs and any other INDs Corregidor or its Affiliates have filed with respect to any Licensed Product in any country in the Territory. Corregidor and its Affiliates will execute all documents and take all actions that may be necessary to transfer the title to such INDs to Alkermes. Corregidor will also promptly, at Alkermes' request, transfer to Alkermes copies of such INDs;

(viii) Corregidor shall promptly transfer and assign to Alkermes all of Corregidor's and its Affiliates' right, title and interest in and to any Regulatory Approvals for any Licensed Product in any country in the Territory. Corregidor and its Affiliates will execute all documents and take all actions that may be necessary to transfer the title to such Regulatory Approvals to Alkermes. Corregidor will also promptly, at Alkermes' request, transfer to Alkermes copies of such materials as well as copies of Corregidor's and its Affiliates' records of all communications with Regulatory Authorities relating to Licensed Products;

(ix) Corregidor shall promptly transfer to Alkermes a copy of the content of all safety and clinical databases relating to all Licensed Products existing as of the effective date of termination, to the extent owned or controlled by Corregidor at such time. In addition, Corregidor shall promptly transfer to Alkermes copies of all other material safety, pre-clinical and clinical data and information in its or its Affiliates' possession or control as of the effective date of termination relating to the Licensed Products, including all information required to be maintained by Corregidor or its Affiliates in connection with clinical trials of the Licensed Products conducted, sponsored or supported by or on behalf of Corregidor or its Affiliates;

(x) Corregidor and its Affiliates shall promptly assign to Alkermes or its nominee such agreements as Alkermes designates between Corregidor or its Affiliates, on the one hand, and Third Parties (excluding Collaboration Partners), on the other hand, that are freely assignable and relate solely to the Development, Commercialization or Manufacture of Licensed Products in the Territory; and

(xi) Corregidor shall execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate to transfer to Alkermes the foregoing rights and items.

(e) Notwithstanding anything to the contrary in this Section 10.6, if at the time of any such termination, Corregidor has a Collaboration Partner, and such Collaboration Partner is then in compliance with the agreement between Corregidor and such Collaboration Partner under which such Collaboration Partner has obtained a license, sublicense or other right to Develop and Commercialize Licensed Products, such Collaboration Partner shall be entitled, if it so elects by written notice to Alkermes within thirty (30) days after such termination of this Agreement becomes effective, to enter into a direct agreement with Alkermes pursuant to which such Collaboration Partner would be granted by Alkermes a license, sublicense or other right to continue to practice the rights granted to such Collaboration Partner by Corregidor; *provided, however*, that such license, sublicense or other rights would be no different in nature or scope than the rights granted to such Collaboration Partner by Corregidor under the rights and licenses granted by Alkermes to Corregidor pursuant to this Agreement. Notwithstanding the foregoing, if such Collaboration Partner did not, at the time of such termination of this Agreement, have the right to make the Licensed Products that are subject to the relevant license or sublicense from Corregidor, and such Collaboration Partner requires a license under the Alkermes Know-How and the Alkermes Patents (to the extent then owned or controlled by Alkermes) to manufacture Licensed Products to enjoy the benefit of the other rights granted to such Collaboration Partner by Corregidor, then, unless Alkermes, in its sole discretion, is willing to manufacture and supply such Licensed Products to such Collaboration Partner on the terms pursuant to which Corregidor was obligated to manufacture Licensed Products for such Collaboration Partner, Alkermes will grant to such Collaboration Partner a license under the Alkermes Know-How and the Alkermes Patents (to the extent then owned or controlled by Alkermes) to manufacture the relevant Licensed Products to the extent necessary to permit the Collaboration Partner to enjoy the benefit of such rights, *provided, however*, that such arrangement would not impose upon Alkermes any obligations that would be different in nature or scope from Alkermes' obligations to Corregidor hereunder. Alkermes shall use commercially reasonable efforts to negotiate in good faith and enter into such a direct agreement within sixty (60) days after such termination becomes effective provided that such Collaboration Partner also uses commercially reasonable efforts to do the same.

**10.7. Remedy for Default in Patent Prosecution or Maintenance .** In the event Corregidor Defaults under Section 4.4 of this Agreement by failing to file, prosecute or maintain an Alkermes Patent in accordance with the terms and conditions of Section 4.4, then the Alkermes Patent that was the subject of such Default (the “ Relevant Alkermes Patent ”) shall be deemed to have issued or granted on the date of such Default in the relevant country or countries. In such case, all claims of such Relevant Alkermes Patent that were in existence on the date of such Default shall be deemed to be Valid Claims. In consequence, if a Licensed Product sold in a country is covered by such deemed Valid Claims of such Relevant Alkermes Patent, the duration and amount of Royalty payments by Corregidor to Alkermes pursuant to Sections 5.2.2 and 5.2.3 shall be calculated during the Deemed Term (as defined below) of such deemed Valid Claims in such country accordingly. The Parties acknowledge that Corregidor, to avoid Alkermes exercising its alternative remedy of terminating the Agreement upon a Default by Corregidor of Section 4.4, has proposed the payment of Royalties on the terms set forth in this

Section 10.7., without regard for whether the Licensed Product that is effected by the Default is covered by an actual Valid Claim of an Alkermes Patent. Alkermes accepted Corregidor's proposal, and the Royalty rates and Royalty duration applied to such sales of such Licensed Product reflect the mutual agreement of the Parties as to the value of Alkermes foregoing its alternative remedy of termination of this Agreement. A "Deemed Term" shall mean (i) for a Relevant Alkermes Patent that was issued in the relevant country on the date of such Default, the time period equal to the remaining term of such Relevant Alkermes Patent in such country had such Default not occurred, or (ii) for a Relevant Alkermes Patent that was a pending patent application on the date of such Default, the time period expiring upon the date that is [\*\*\*] following the Launch of the Licensed Product in such country.

**10.8. Return of Confidential Information .** Upon expiration or termination of this Agreement, each Party shall within [\*\*\*] thereafter destroy all Confidential Information of the other Party in its possession and/or under its control; *provided that* , each Party shall have the right to retain one archival copy of Confidential Information for its legal files for the sole purposes of establishing its rights and determining its obligations under this Agreement. At the request of the other Party, a Party shall deliver a certification, executed by an officer of such Party, that all Confidential Information of the other Party has been destroyed as set forth in this Section 10.8., subject to the right to retain one archival copy as set forth in this Section 10.8.

**10.9. Survival .** The following provisions shall survive any expiration or termination of this Agreement: Sections 5.4-5.9 and Articles 7, 8, 9, 10 11 and 12., in each case only in the event and to the extent applicable, and subject to the terms and conditions stated therein. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement will also survive, but only to the extent required for the full performance of this Agreement. Upon termination of this Agreement, for a period of [\*\*\*] thereafter Corregidor, its Affiliates and Collaboration Partners shall have a continuing limited right to sell the Licensed Products that as of the effective date of termination are held in inventory by or on behalf of such parties; *provided that* , Corregidor, its Affiliates and Collaboration Partners shall only have such right for the sole purpose of selling such inventory; *provided further* , that with respect to any such Licensed Products, Corregidor shall pay the Royalties due under Section 5.2 of this Agreement and shall comply with all terms and conditions of this Agreement with respect thereto. Termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. The remedies provided in this Article 10 are not exclusive of any other remedies a Party may have in law or equity, including rights and remedies under the Bankruptcy Code.

## ARTICLE 11

### DISPUTE RESOLUTION

#### 11.1. Disputes.

**11.1.1. Objective .** The Parties recognize that disputes, controversies or claims arising out of or relating to this Agreement, or the interpretation, breach, termination or invalidity hereof (each a "Dispute"), may from time to time occur during the Term. It is the objective of the Parties to establish procedures to facilitate the resolution of Disputes occurring with respect to this Agreement, in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 11 if and when a Dispute occurs with respect to this Agreement.

**11.1.2. Resolution by Senior Executives .** Unless otherwise specifically recited in this Agreement, any Disputes relating to the Agreement shall be first referred to the Chief Operating Officer of Alkermes and the Chief Executive Officer of Corregidor (the “Senior Executives”) for resolution by one Party (the “Complaining Party”) providing a dispute notice (the “Dispute Notice”) to the Senior Executives and the other Party. The Dispute Notice shall set concisely forth the Dispute, the Parties’ respective positions, and the specific relief requested. Within [\*\*\*] after receipt of the Dispute Notice, the other Party (the “Responding Party”) shall provide a concise written response (the “Response”) to the Dispute Notice to the Senior Executives and the Complaining Party. The Senior Executives shall attempt to resolve the Dispute within [\*\*\*] after their receipt of the Response. In the event that the Senior Executives cannot resolve a Dispute within this period, unless otherwise agreed by the Parties, then any Dispute may be referred by either Party to arbitration in accordance with Section 11.2 upon written notice to the other Party. Notwithstanding the foregoing any Dispute relating to the scope, validity or enforceability of an Alkermes Patent may only be determined in accordance with Section 11.4 hereof.

**11.2. Arbitration .** The Parties agree that any Dispute referred for arbitration by a Party pursuant to Section 11.1 or referred by Alkermes pursuant to Section 5.2 shall be resolved through binding arbitration in accordance with the CPR International Institute for Conflict Prevention and Resolution Rules for Non-Administered Arbitration, as amended from time to time (the “CPR Rules”). The Neutral Organization designated to perform the functions specified in the CPR Rules will be the CPR International Institute for Conflict Prevention and Resolution, or its successor organization. Any Dispute in which either Party seeks in excess of [\*\*\*] in damages, or in which any equitable relief is sought by either Party, will be resolved by an arbitral tribunal consisting of three (3) arbitrators, one of whom will be designated by each Party in accordance with the CPR Rules, and a third arbitrator who will chair the tribunal and who will be selected as provided in the CPR Rules. The Parties shall use commercially reasonable efforts to select the arbitrator or arbitrators within [\*\*\*] after such Dispute is referred for arbitration under this Section 11.2. Any other Dispute, including any Dispute referred by Alkermes pursuant to Section 5.2, will be submitted to a sole arbitrator, who shall be an individual with relevant experience in the biotechnology/pharmaceutical industry and who shall be appointed pursuant to the CPR Rules. The arbitrator(s) shall be instructed by the Parties to complete the arbitration within [\*\*\*] after selection of the sole or final arbitrator. The arbitrator(s) shall, within [\*\*\*] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. Arbitration pursuant to this Section 11.2 shall be governed by the Federal Arbitration Act, 9 U.S.C. § § 1-16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The arbitration proceedings shall be conducted in Boston, Massachusetts. Each Party shall continue to perform its obligations under the Agreements pending final resolution of any Dispute unless to do so would be impossible or

impracticable under the circumstances. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. The Parties agree that they shall share equally the cost of arbitration filing and hearing fees, and the cost of the arbitrator(s). Each Party must bear its own attorney's fees and associated costs and expenses. Notwithstanding the foregoing, with respect to any Dispute referred by Alkermes pursuant to Section 5.2, the Party whose judgment about whether or not the transaction at issue was a Trigger Transaction is determined by the arbitrator to be incorrect shall pay the cost of arbitration filing and hearing fees, and the cost of the arbitrator. Nothing contained in this Agreement shall deny or limit any relief, remedy or recovery to which a Party may otherwise be entitled under the Sublease, the Equity Investment Agreements, the Promissory Note or the Security Agreement.

**11.3. Jurisdiction** . For the purposes of this Article 11, the Parties agree to accept the jurisdiction of the federal courts located in the Commonwealth of Massachusetts for the purposes of enforcing awards entered pursuant to this Article and for enforcing the agreements reflected in this Article 11.

**11.4. Determination of Disputes Relating to Patents and Other Intellectual Property** . Notwithstanding the foregoing, any Dispute relating to the determination of scope, validity or enforceability of an Alkermes Patent shall be submitted exclusively to a court having jurisdiction over the disputed patent.

## ARTICLE 12

### MISCELLANEOUS

**12.1. Entire Agreement; Amendment.** This Agreement, including the Exhibits, the Schedules, the Bill of Sale, the Instrument of Assignment and Assumption, the Sublease, the Equity Investment Agreements, the Promissory Note (if applicable) and the Security Agreement (if applicable), constitute the entire agreement between the Parties related to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof; on the Effective Date of this Agreement, the Confidentiality Agreement is hereby superseded, provided that all Confidential Information disclosed therein shall be treated as if disclosed under, and shall be subject to the terms of, this Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter hereof other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to a writing referencing this Agreement and signed by an authorized officer of each Party.

**12.2. Notices** . Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes (i) when delivered, if sent by recognized overnight courier or personally delivered, or (ii) upon confirmation of receipt, if sent by facsimile transmission (provided a duplicate hard copy is promptly delivered by one of the other foregoing means), in each case using the mailing addresses of the Parties as set forth below (or such other mailing addresses of which a Party is notified pursuant to this Section 12.2):

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

For Corregidor:

Corregidor Therapeutics, Inc.  
384 Powder Mill Road  
Concord, Massachusetts 01742  
Facsimile: 978-405-5142  
Attn: Chief Executive Officer

With a copy to:

Faber Daeufer & Rosenberg  
Bay Colony Corporate Center  
950 Winter Street, Suite 4500  
Waltham, MA 02451  
Facsimile: 781-795-4747  
Attn: Joseph Faber

For Alkermes:

Alkermes, Inc.  
852 Winter Street  
Waltham, Massachusetts 02451  
Facsimile: 781-890-6425  
Attn: General Counsel

**12.3. Governing Law .** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements executed and performed entirely within the Commonwealth of Massachusetts, without regard to any applicable principles of conflicts of law.

**12.4. Interpretation .** In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

**12.5. Assignment .** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder, by operation of law or otherwise, without the prior written consent of the other Party, except that either Party may make such an assignment of all its rights and obligations hereunder, without the other Party's consent, to a Person that acquires all or substantially all of its business to which this Agreement relates, whether in a merger, consolidation, reorganization, acquisition, sale or otherwise. This Agreement shall be binding on the permitted successors and assigns of the assigning Party, and the name of a Party appearing herein shall be deemed to include the name(s) of such Party's permitted successors and assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 12.5 shall be null and void and of no legal effect.

**12.6. Counterparts .** This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement will become binding when any one or more counterparts hereof, individually or taken together, bear the signatures of both Parties. For the purposes hereof, an electronic or facsimile copy of this Agreement, including signed signature pages hereto, shall be deemed an original.

**12.7. Severability .** In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable provision in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided, however* , that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto shall be enforceable to the fullest extent permitted by law.

**12.8. Headings .** The heading for each article and section in this Agreement has been inserted for convenience of reference only and is not intended to limit or expand on the meaning of the language contained in the particular article or section.

**12.9. Further Actions .** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

**12.10. Independent Contractors .** The relationship between Corregidor and Alkermes created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other Party except as expressly set forth in this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party.

**12.11. Use of Name .** Except as expressly set forth in this Agreement, neither Party shall have the right to use in advertising, publicity, other promotional activities or otherwise any name, trade name, trademark, corporate logo or other designation of the other Party hereto or its Affiliates, including any contraction or abbreviation of any of the foregoing, unless the express written permission of such other Party has been obtained or as required by Applicable Law.

**12.12. No Waiver .** The Parties understand and agree that no failure or delay in exercising any right, power or privilege hereunder will operate as a waiver thereof, nor will any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder. To be effective hereunder, any waiver of any right, power or privilege hereunder shall be in writing and signed by the Party against whom the waiver is sought to be enforced.

**12.13. Fees and Expenses .** Regardless of whether or not the transactions contemplated by this Agreement are consummated, each Party shall bear its own fees and expenses incurred in connection with the negotiation and execution of this Agreement.

**12.14. Force Majeure .** Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement (other than obligations to pay any amounts due hereunder to the other Party), only if and to the extent that such failure or delay is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence and the delayed or non-performing Party notifies the other Party promptly when such circumstances arise, giving an indication of the likely extent and duration thereof, and promptly uses and continues to use all commercially reasonable efforts to resume performance of its obligations as soon as practicable.

**12.15. No Set-Off .** Neither Party shall have any right to set-off any amount owed to such first Party by the other Party under this Agreement, another agreement or otherwise from any amount owed by such first Party to the other Party hereunder, without the prior written consent of the other Party.

**12.16. Nonsolicitation .** During the Term, each Party agrees that it will not (i) recruit, solicit or induce any employee of the other Party to terminate his or her employment with such other Party, or (ii) hire or attempt to hire such employee. However, nothing set forth in this Section 12.16 shall prohibit a Party from indirectly recruiting, soliciting or inducing such employees to leave the other Party through the use of advertisements in trade journals, or hiring any employees who leave the other Party under such conditions.

**12.17. Parties in Interest .** This Agreement shall be binding upon and inure solely to the benefit of each Party hereto and its respective permitted successors and assigns, and nothing in this Agreement, express or implied, is intended to or shall confer upon any other Person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

**12.18. No Other Rights .** The Parties acknowledge and agree that, except as expressly set forth in this Agreement, neither Party (i) grants any rights or licenses to the other Party under this Agreement and (ii) shall have any rights or obligations under this Agreement except as expressly set forth herein.

*[signature page follows]*

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**IN WITNESS WHEREOF** , the Parties have executed and delivered this Agreement by their duly authorized representatives as of the Effective Date.

**ALKERMES, INC.**

By: /s/ Michael Landine  
Print Name: Michael Landine  
Title: Senior Vice President  
By: /s/ Gordon Pugh  
Print Name: Gordon Pugh  
Title: Senior Vice President

**CORREIGIDOR THERAPEUTICS, INC.**

By: /s/ Glenn Batchelder  
Print Name: Glenn Batchelder  
Title: CEO

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission. Where nineteen pages of material have been omitted, the redacted material is marked with [†].

**Schedule 2.1.1**

**to**

**Asset Purchase and License Agreement**

**between Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

<i>Country Name</i>	<i>Sub</i>	<i>Status</i>	<i>App #</i>	<i>Patent #</i>	<i>Issue Date</i>	<i>Comments</i>
---------------------	------------	---------------	--------------	-----------------	-------------------	-----------------

[†]

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission. Where three pages of material have been omitted, the redacted material is marked with [●].

**Schedule 2.1.2**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

Description	FEC ID#
[●]	

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Device	Location	Qty	Model	Additional Description
***	***	***	***	***
Network Device	Location	Qty	Model	
***	***	***		***
Device	Location	Qty	Model	Additional Description
***	***	***	***	***

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Schedule 2.1.3

to

Asset Purchase and License Agreement

between

Alkermes, Inc.

and

Corregidor Therapeutics, Inc.

AIR System

1.1.	Deposition Study		
-	***	***	***
-	***	***	***
-	***	***	***
1.2.	p MDI w/Bud&EPI		
-	***	***	***
1.3.	Tech Report – Formulation		
-	***	***	***
-	***	***	***
1.4.	C2S Inhaler DMF		
-	***	***	***

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission. Where thirty one pages of material have been omitted, the redacted material is marked with [•••].

**Brickyard Square Facility- 31**

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2.1. [***]
[•••]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission. Where eighty eight pages of material have been omitted, the redacted material is marked with [ ¥ ].

Excipients

3.	-	Excipients	-	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-
-	***	***	***	-

[ ¥ ]

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission. Where eight pages of material have been omitted, the redacted material is marked with [†].

## **Legacy Documents – SOPs**

[†]

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**Schedule 2.1.4**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

**Molds**

<i>Mold #</i>	<i>Description</i>
***	
<b>Assembly Equipment</b>	

\*\*\*

**Inspection Gages/Fixtures**

<i>Gage ID</i>	<i>Description</i>
***	

**Inhalers**

\*\*\*

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Schedule 2.1.5

to

Asset Purchase and License Agreement

between

Alkermes, Inc.

and

Corregidor Therapeutics, Inc.

Project	IND #	Date IND submitted	Current Status
***	***	***	***
***	***	***	***

--

**Schedule 6.1(e)**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc .**

[\*\*\*]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**Schedule 6.1(f)**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

[\*\*\*]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

**Schedule 6.1(g)**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

[\*\*\*]

---

**Schedule 6.1(i)**

**to**

**Asset Purchase and License Agreement**

**between**

**Alkermes, Inc.**

**and**

**Corregidor Therapeutics, Inc.**

[\*\*\*]

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## **Exhibit A**

### **BILL OF SALE**

KNOW ALL MEN BY THESE PRESENTS that as of December 27, 2010, the undersigned, Alkermes, Inc., a Pennsylvania corporation (“Seller”), for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, does hereby sell, assign, transfer, convey and deliver to Corregidor Therapeutics, Inc., a Delaware corporation (“Buyer”), all right, title and interest of Seller in and to the Assets (as defined in that certain Asset Purchase and License Agreement dated as of December 27, 2010 (the “Purchase Agreement”) by and between Seller and Buyer), subject to Seller’s retained right, title and interest in and to the Alkermes Know-How that is described in or embodied in certain of these Assets, as set forth in Section 2.1 of the Purchase Agreement. All capitalized terms not defined herein shall have the meanings ascribed to them in the Purchase Agreement.

TO HAVE AND TO HOLD the aforesaid Assets unto Buyer to and for Buyer’s own proper use and benefit forever.

At any time or from time to time after the date hereof, at Buyer’s reasonable request and without further consideration, Seller shall execute and deliver to Buyer such other instruments of sale, assignment, transfer, conveyance and delivery, provide such materials and information and take such other actions as Buyer may reasonably deem necessary or desirable in order more effectively to sell, assign, transfer, convey and deliver to Buyer, and to confirm Buyer’s title to, the aforesaid Assets, and, to the full extent permitted by law, to put Buyer in actual possession and operating control of the aforesaid Assets and to assist Buyer in exercising all rights with respect thereto.

Nothing set forth in the foregoing shall limit, expand or otherwise affect the rights and obligations of Buyer and Seller as set forth in the Purchase Agreement. In the event of any conflict between the terms and conditions of this Bill of Sale and a term or condition of the Purchase Agreement, the term or condition of the Purchase Agreement shall control.

[Signature Page Follows]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

IN WITNESS WHEREOF, the undersigned has executed and delivered this Bill of Sale as of the date first set forth above.

ALKERMES, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

\_\_\_\_\_

## **Exhibit B**

### **INSTRUMENT OF ASSIGNMENT AND ASSUMPTION**

THIS INSTRUMENT OF ASSIGNMENT AND ASSUMPTION is executed and delivered this 27th day of December 2010, by Alkermes, Inc., a Pennsylvania corporation (“Seller”), in favor of Corregidor Therapeutics, Inc., a Delaware corporation (“Buyer”). Capitalized terms used but not defined herein shall have the respective meanings ascribed to them in the Asset Purchase Agreement (defined below).

WHEREAS, Seller and Buyer are parties to an Asset Purchase and License Agreement, dated as of December 27, 2010 (the “Asset Purchase Agreement”), pursuant to the terms of which (a) Seller agreed to sell, assign, transfer, convey and deliver to Buyer, and Buyer agreed to purchase, acquire and accept from Seller, the Assets and (b) Seller and Buyer acknowledged and agreed that Buyer would assume and perform all Assumed Liabilities;

WHEREAS, Seller is contemporaneously herewith transferring the Assets to Buyer pursuant to the terms of the Asset Purchase Agreement; and

WHEREAS, in partial consideration therefor, the Asset Purchase Agreement requires Buyer to assume the Assumed Liabilities described in Section 2.4 of the Asset Purchase Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Seller does hereby sell, assign, transfer, convey and deliver to Buyer all right, title and interest of Seller in and to the Assets, subject to Seller’s ongoing right, title and interest in and to the Alkermes Know-How described in or embodied in certain of these Assets, as set forth in Section 2.1 of the Asset Purchase Agreement.
  2. As of the date hereof, Buyer hereby assumes the Assumed Liabilities and agrees to perform all obligations and liabilities arising out of the Assumed Liabilities as and when due and performable.
  3. Except as specifically provided in Section 2 above, and except as may otherwise be expressly provided in the Asset Purchase Agreement, Buyer has not assumed and shall not be bound by any liabilities of Seller.
  4. The assumption of the Assumed Liabilities by Buyer shall not enlarge any rights of third parties and nothing herein or in any instrument of transfer shall prevent Buyer from contesting in good faith the claim of any third party with respect to any of the Assumed Liabilities. Nothing set forth in the foregoing shall limit, expand or otherwise affect the rights and obligations of Buyer and Seller as set forth in the Asset Purchase Agreement. In the event of any conflict between the terms and conditions of this Instrument and a term or condition of the Asset Purchase Agreement, the term of the Asset Purchase Agreement shall control.
-

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

5. At the reasonable request of Seller, Buyer shall (without compensation or charge) execute and deliver all such further instruments or perform all such further acts as may be reasonably necessary or desirable in order to effectively transfer and assign all the Assumed Liabilities to Buyer.

6. This Instrument shall be binding upon Buyer and its successors and permitted assigns and shall inure to the benefit of Seller and its successors and permitted assigns.

7. This Instrument may be executed in counterparts, all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties thereto.

[ *Signature Page Follows* ]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

IN WITNESS WHEREOF, Buyer and Seller have caused this instrument to be duly executed by its duly authorized representative as of the day and year above written.

**BUYER:**

CORREGIDOR THERAPEUTICS, INC.

By: \_\_\_\_\_

Name:

Title:

**SELLER:**

ALKERMES, INC.

By: \_\_\_\_\_

Name:

Title:

\_\_\_\_\_

## Exhibit C

### PROMISSORY NOTE

\$30,000,000.00 [ \_\_\_\_\_ ], 201[ \_\_ ]

For value received, the undersigned, Corregidor Therapeutics, Inc., a Delaware corporation (“Obligor”), hereby promises to pay to the order of Alkermes, Inc., a Pennsylvania corporation (“Lender”), whose principal office is at 852 Winter Street, Waltham, Massachusetts 02451, the original principal sum of \$30,000,000.00 together with interest accruing in arrears from and including the date set forth above (the “Effective Date”) on the unpaid principal balance hereunder, computed daily and compounded quarterly, at the rate of [\*\*\*] above LIBOR calculated on the first day of each calendar year during the remaining term hereof (the “Interest Rate”), payable as set forth below. At the option of Lender and to the extent permitted by applicable law, the rate of interest on any unpaid principal or interest not paid when due and payable hereunder, or otherwise from and after the occurrence and during the continuation of an Event of Default, shall be [\*\*\*] per annum above the Interest Rate. Interest shall be calculated on the basis of actual number of days elapsed and a year of 360 days. Notwithstanding any other provision of this Note, Lender does not intend to charge and Obligor shall not be required to pay any interest or other fees or charges in excess of the maximum permitted by applicable law; any payments in excess of such maximum shall be credited to reduce principal hereunder. All payments received by Lender hereunder will be applied first to costs of collection, if any, then to interest and the balance to principal.

This Note is issued in connection with that certain Asset Purchase and License Agreement by and between the Lender and Obligor, dated as of December 27, 2010 (as amended or restated from time to time, the “Purchase Agreement”), and is subject to the terms thereof. In Hoaddition, this Note is secured by, entitled to the benefits of, and governed by the terms and conditions of that certain Loan and Security Agreement by and between Obligor and Lender, of even date herewith (as amended or restated from time to time, the “Security Agreement”). Defined terms used but not defined herein shall have the meanings ascribed thereto in the Security Agreement.

Principal and interest hereunder shall be paid pursuant to and in accordance with the terms provided in the Security Agreement.

Payments shall continue on each successive Quarterly Due Date until all principal and interest hereunder have been paid in full.

This Note may be prepaid at any time, without premium or penalty, in whole or in part. Any prepayment of principal shall be accompanied by a payment of accrued interest in respect of the principal being prepaid.

All payments (including prepayments) to be made by Obligor shall be made in immediately available funds in U.S. dollars, without setoff or counterclaim to the Lender Account before 1:00 p.m. (Eastern Time) on the date when due. All payments received by the Lender after 1:00 p.m. (Eastern Time) on any Business Day or at any time on a day that is not a Business Day shall be deemed to be received on the next Business Day. Whenever any required payment would otherwise be due on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension. All payments due to the Lender shall be effected by bank wire transfer to the Lender Account.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Any outstanding principal and any accrued and unpaid interest hereunder shall become immediately due and payable upon a Change in Control of the Obligor.

Upon the occurrence of any Event of Default, Lender may declare any or all Obligations of Obligor to Lender (including the unpaid principal hereunder and any interest due thereon), immediately due and payable without presentment, demand, protest or notice.

If this Note is not paid in accordance with its terms, Obligor shall pay to Lender, in addition to principal and accrued interest thereon, all costs of collection of the principal and accrued interest, including, but not limited to, reasonable attorneys' fees, court costs and other costs for the enforcement of payment of this Note.

No waiver of any obligation of Obligor under this Note shall be effective unless it is in a writing signed by Lender. A waiver by Lender of any right or remedy under this Note on any occasion shall not be a bar to exercise of the same right or remedy on any subsequent occasion or of any other right or remedy at any time.

This Note is delivered in and shall be enforceable in accordance with the internal domestic laws of the Commonwealth of Massachusetts (without regard to the conflicts of law provisions thereof), and shall be construed in accordance therewith, and shall have the effect of a sealed instrument.

This Note, and the indebtedness of Obligor to Lender evidenced hereby, shall not be subject to any setoff, recoupment, reduction, counterclaim or defense to payment, each of which is hereby expressly waived by Obligor. Obligor hereby expressly waives presentment, demand, and protest, notice of demand, dishonor and nonpayment of this Note, and all other notices or demands of any kind in connection with the delivery, acceptance, performance, default or enforcement hereof, and hereby consents to any delays, extensions of time, renewals, waivers or modifications that may be granted or consented to by the holder hereof with respect to the time of payment or any other provision hereof or of the Security Agreement.

CORREGIDOR THERAPEUTICS, INC.

By:  
Name:  
Title:

Attested:  
By:  
Name:  
Title:

## **Exhibit D**

### **SECURITY AGREEMENT**

#### **LOAN AND SECURITY AGREEMENT**

This LOAN AND SECURITY AGREEMENT (the “Agreement”) is made and entered into as of [ \_\_\_\_], 201[ \_\_] by and between Corregidor Therapeutics, Inc., a Delaware corporation (the “Obligor”), and Alkermes, Inc., a Pennsylvania corporation (the “Lender”).

#### **RECITALS**

WHEREAS, the Lender and the Obligor are party to that certain Asset Purchase and License Agreement, dated as of December 27, 2010 (as amended and/or restated from time to time, the “Purchase Agreement”), pursuant to which the Lender granted to the Obligor an option to purchase the Manufacturing Facility Equipment (the “Option”) upon the occurrence of certain triggering events, including the Resale Event and the Direct Sale Event;

WHEREAS, a Resale Event or a Direct Sale Event has occurred and the Obligor has exercised its Option to purchase the Manufacturing Facility Equipment pursuant to Section 3.13 of the Purchase Agreement and has, among other required actions, delivered to the Lender an Option exercise notice;

WHEREAS, the Purchase Agreement provides that in consideration of the sale, assignment, and transfer of the Manufacturing Facility Equipment, Obligor will issue to the Lender a promissory note in the form set forth as Exhibit A hereto (the “Note”), such Note to be in the original principal amount of \$30,000,000.00 and to be secured by the Manufacturing Facility Equipment; and

WHEREAS, concurrently herewith, the Lender and the Obligor are entering into an amendment to the Purchase Agreement to (i) add the “Cost of Goods Manufactured” definition set forth herein to Article 1 of the Purchase Agreement, (ii) to provide for reporting of the number of units of Commercial Capsules sold and their Cost of Goods Manufactured in Section 5.4 of the Purchase Agreement, and (iii) to provide for the audit of Cost of Goods Manufactured, payments made hereunder and payments made under the Note in Section 8.2 of the Purchase Agreement.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Obligor and the Lender hereby agree as follows:

1. Defined Terms. Unless otherwise defined herein, terms which are defined in the Purchase Agreement and used herein are so used as so defined, and terms which are defined in the Uniform Commercial Code in effect in the Commonwealth of Massachusetts on the date hereof are used herein as therein defined, and the following terms shall have the following meanings:

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

“Code” means the Uniform Commercial Code as from time to time in effect in the Commonwealth of Massachusetts.

“Collateral” shall have the meaning assigned to it in Section 4 of this Agreement.

“Commercial Capsule” shall mean a capsule containing drug substance formulated for pulmonary delivery, which capsule is incorporated into a Licensed Product.

“Cost of Goods Manufactured” shall mean one hundred percent (100%) of Obligor’s fully burdened Manufacturing cost of any Commercial Capsule incorporated into a Licensed Product, including but not limited to the cost of goods produced as determined by the Person performing (or contracting with a Third Party to perform) each stage of the Manufacturing process, including but not limited to facility costs, depreciation of capital expenditures, direct labor and equipment costs, material costs, product quality assurance/control costs (including testing), process improvements, manufacturing scale-up, manufacturing site qualification, manufacturing support costs conversion costs and overhead costs, all to the extent reasonably attributable to the Manufacture of such Commercial Capsules, as well as any other costs borne by the Manufacturing Person for transport, customs clearance and storage of Commercial Capsules, and inventory adjustments incurred in the normal course of business; provided, however, that “Cost of Goods Manufactured” shall not include the cost of any Protein and shall not exceed \$[\*\*\*] per Commercial Capsule. The Cost of Goods Manufactured shall exclude all costs of manufacturing any other components of Licensed Products other than the Commercial Capsule, such as but not limited to any Inhalers and kit components, and all final packaging for Commercial Capsules or Licensed Products. All components of Cost of Goods Manufactured shall be calculated in accordance with the applicable Person’s internal accounting policies and principles, which shall be in accordance with U.S. GAAP and applied consistently.

“Equity Investment Agreements” shall mean those Equity Investment Agreements as contemplated and defined in the Purchase Agreement.

“Lender Account” shall mean such bank accounts as the Lender may designate in writing to Obligor from time to time.

“LIBOR” shall mean the overnight London Inter-Bank Offer Rate.

“Obligations” means the unpaid principal amount of, and interest on, the Note and all other obligations and liabilities of the Obligor to the Lender, whether direct or indirect, absolute or contingent, due or to become due, or now existing or hereafter incurred, whether arising under, out of or in connection with this Agreement and the Note, or otherwise, including, but not limited to, any and all costs of collection, including, but not limited to, reasonable attorneys’ fees, court costs and other costs arising from enforcement of the terms and conditions of this Agreement and the Note.

“Permitted Lien” shall mean (a) liens for taxes if obligations with respect to such taxes are not delinquent or are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted; and (b) statutory liens of landlords of carriers, warehousemen, mechanics, repairmen, workmen and materialmen, and other liens imposed by law, in each case incurred in the ordinary course of business (i) for amounts not yet overdue or (ii) for amounts that are overdue and that (in the case of any such amounts overdue for a period in excess of five (5) days) are being contested in good faith by appropriate proceedings, so long as such reserves or other appropriate provisions, if any, as shall be required by U.S. GAAP shall have been made for any such contested amounts.

“Protein” shall mean the protein component of the drug substance contained within a Commercial Capsule.

2. Promise to Pay; Issuance of Note.

(a) Subject to and in reliance upon the representations, warranties, covenants, terms and conditions of this Agreement, the Lender agrees to issue the Note to the Obligor and to deliver to the Obligor a Bill of Sale in substantially the form attached hereto as Exhibit B.

(b) The Obligor unconditionally promises to pay the Lender the Obligations when due in accordance with this Agreement and the Note, and Obligor shall execute and deliver the Note to the Lender in connection herewith.

3. Interest and Repayment.

(a) Interest. The principal amount of the Note shall accrue interest in arrears from and including the date hereof (the “Effective Date”) until the Note is fully repaid, computed daily and, to the extent not repaid, compounded annually, at a rate of [\*\*\*] above LIBOR, calculated for each following calendar year on the first Business Day of such year (the “Interest Rate”). Interest shall be calculated on the basis of actual number of days elapsed and a year of 360 days. Each determination of an interest rate hereunder shall be made by the Lender and shall be conclusive, binding and final for all purposes, absent manifest error.

(b) Payment Reports and Due Dates. From and after the Effective Date, the Obligor will make Payments (as defined below) within fifteen (15) days after delivery of the Quarterly Sales Report (the “Quarterly Due Date”) which Quarterly Sales Report shall be delivered as provided in the Purchase Agreement.

(c) Payments of Principal and Interest. From and after the Effective Date, principal and interest under the Note shall be paid by the Obligor to the Lender in quarterly installments on each Quarterly Due Date, commencing on the first Quarterly Due Date following the Effective Date, in an amount equal to the Cost of Goods Manufactured for Commercial Capsules sold during such Calendar Quarter as reported on the Quarterly Sales Report (each, a “Payment” and collectively, the “Payments”). Payments shall be first applied to accrued but uncapitalized interest and then to principal.

(d) Term. Payments shall continue on each successive Quarterly Due Date until all Obligations have been paid in full.

(e) Payments. All payments (including prepayments) to be made by Obligor under the Note shall be made in immediately available funds in U.S. dollars, without setoff or counterclaim to the Lender Account before 1:00 p.m. (Eastern Time) on the date when due. All payments received by the Lender after 1:00 a.m. (Eastern Time) on any Business Day or at any time on a day that is not a Business Day shall be deemed to be received on the next Business Day. Whenever any payment required under the Note would otherwise be due on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension. All payments due to the Lender under the Note shall be effected by bank wire transfer to the Lender Account.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

(f) Payment Upon Change in Control. The then-outstanding principal and any accrued and unpaid interest under the Note shall become immediately due and payable upon a Change in Control of the Obligor.

(g) Withholdings. All Payments shall be made free and clear of any taxes, withholdings, duties, impositions or other charges such that the Lender shall receive the entire amount of all Payments so long as Lender has not changed its jurisdiction of incorporation or organization since December 27, 2010 in a manner that would result in a change in the taxes, withholdings, duties, impositions or other charges imposed upon Payments.

(h) Loan Records. The Lender shall maintain an account evidencing the Obligations of Obligor, including the amounts of principal and interest payable and paid to the Lender from time to time under the Note. The entries made in such account shall, to the extent permitted by applicable law, be prima facie evidence of the existence and amounts of the Obligations recorded therein; provided, however, that no error in such account and no failure of the Lender to maintain such account shall affect the obligations of Obligor to repay the Obligations in accordance with their terms.

(i) Prepayments. Obligor can voluntarily prepay the Note at any time, without premium or penalty, in whole or in part. Any prepayment of principal shall be accompanied by a payment of accrued interest in respect of the principal being prepaid.

(j) Default Rate. To the extent permitted by applicable law, the rate of interest on any unpaid principal or interest not paid when due and payable under the Note, or otherwise from and after the occurrence and during the continuation of an Event of Default (as defined below), shall be [\*\*\*] per annum above the Interest Rate (the “Default Rate”). The application of the Default Rate shall not be interpreted or deemed to extend any cure period or waive any Default or Event of Default or otherwise limit the Lender’s right or remedies hereunder. All interest payable at the Default Rate shall be payable on demand.

4. Grant of Security Interest. As collateral security for the prompt and complete payment and performance when due (whether at the stated maturity, by acceleration or otherwise) of the Obligations, the Obligor hereby grants to the Lender a security interest in all right, title and interest of the Obligor in the Manufacturing Facility Equipment (as defined in the Purchase Agreement), whether now owned or hereafter acquired, and Proceeds of the Manufacturing Facility Equipment (the “Collateral”). For the avoidance of doubt, the Collateral shall not include goods manufactured using the Manufacturing Facility Equipment or any rights to payments derived from the sale of such products.

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5. Rights of Lender; Limitations on Lender's Liability. Anything herein to the contrary notwithstanding and without limiting the Lender's right to consent in writing to any disposition or attempted disposition as provided in Section 7(i) hereof, the Obligor shall remain liable under each item of Collateral to observe and perform all the conditions and obligations to be observed and performed by it thereunder, all in accordance with the terms of any agreement with respect thereto. Prior to the exercise of remedies by the Lender, the Lender shall not have any obligation or liability under any item of Collateral (or any agreement with respect thereto) by reason of or arising out of this Agreement or the receipt by the Lender of any payment relating to item of Collateral pursuant hereto, nor shall the Lender be obligated in any manner to perform any of the obligations of the Obligor under or pursuant to any item of Collateral (or any agreement with respect thereto), to make any payment, to make any inquiry as to the nature or the sufficiency of any payment received by it or as to the sufficiency of any performance by any party under any item of Collateral (or any agreement with respect thereto), to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts which may have been assigned to it or to which it may be entitled at any time or times.

6. Representations and Warranties of Obligor. The Obligor represents and warrants to the Lender that:

(a) Corporate Existence and Power. The Obligor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and has full corporate power and authority to own and operate its property and assets and to carry on its business as it is now being conducted.

(b) Authority and Binding Agreement. The Obligor has the corporate power and authority to enter into this Agreement and perform its obligations hereunder and under the Note. The Obligor has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder and under the Note. This Agreement and the Note has each been duly executed and delivered by the Obligor and each constitutes a legal, valid and binding obligation of the Obligor that is enforceable against it in accordance with its terms; except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition law, penalties and jurisdictional issues including conflicts of law).

(c) No Conflict. The execution, delivery and performance of this Agreement and the Note by the Obligor does not conflict with, and does not on the date hereof result in a breach or violation of or constitute a default under (i) any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound; (ii) the provisions of its charter or operative documents or bylaws; (iii) any material license, franchise, permit or other similar authorization related to the transactions contemplated hereby; or (iv) any material applicable law, or any judgment, decree or order of any court, governmental body or administrative or other agency having jurisdiction over it.

(d) Required Consents. No filing, registration, qualification with, or approval, consent or withholding of objections from, any governmental authority or instrumentality or any other entity or person is required with respect to the entry into, or performance by the Obligor of, this Agreement or the Note, except any already obtained.

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

(e) Collateral. The Obligor represents and warrants to the Lender it has good title to all of the Collateral, free and clear of all liens, security interests and adverse interests in favor of any person or entity other than the Lender other than Permitted Liens.

7. Covenants. The Obligor covenants and agrees with the Lender that, from and after the date of this Agreement until all Obligations are paid in full:

(a) Further Documentation; Pledge. At any time and from time to time, upon the written request of the Lender, and at the sole expense of the Obligor, the Obligor will promptly and duly execute and deliver such further instruments and documents and take such further action as the Lender may reasonably request for the purpose of obtaining or preserving the full benefits of this Agreement and of the rights and powers herein granted. The Obligor hereby authorizes the Lender to file or record any financing or continuation statements under the Uniform Commercial Code in effect in any jurisdiction with respect to the security interests and liens created hereby. A copy or other reproduction of this Agreement shall be sufficient as a financing statement for filing in any appropriate jurisdiction. If any amount payable under or in connection with any of the Collateral shall be or become evidenced by any Instrument or Chattel Paper in excess of [\*\*\*], the Obligor shall immediately deliver or cause the delivery to the Lender of such Instrument or Chattel Paper, duly endorsed in a manner reasonably satisfactory to the Lender, to be held as Collateral pursuant to this Agreement.

(b) Notice to Lender. The Obligor shall provide the Lender with (a) notice of the occurrence of any Default or Event of Default, promptly, but in any event within [\*\*\*] days, after the date on which any officer of the Obligor obtains knowledge of the occurrence of any such event, (b) copies of all statements, reports and notices made available generally by Obligor to its securityholders and all documents filed with the Securities and Exchange Commission or any securities exchange or governmental authority exercising a similar function, promptly, but in any event within [\*\*\*] days of delivering or receiving such information to or from such persons, and (c) a report of any legal actions pending or threatened against Obligor or any subsidiary of Obligor that could reasonably be expected to result in damages or costs to Obligor of \$[\*\*\*] or more promptly, but in any event within [\*\*\*] days, upon receipt of notice thereof. The Obligor will promptly, but in any event within [\*\*\*] days, notify (in reasonable detail) the Lender of any damage to or loss (including loss of use) or destruction of any material Collateral.

(c) Indemnification. The Obligor agrees to pay, and to save the Lender harmless from, any and all liabilities, reasonable costs and expenses (including, without limitation, legal fees and expenses) (i) with respect to, or resulting from, any delay in paying, any and all excise, sales or other taxes which may be payable or determined to be payable with respect to any of the Collateral, (ii) with respect to, or resulting from, any delay in complying with any law, rule, regulation or order of any court, arbitrator or governmental entity, jurisdiction or authority applicable to any of the Collateral or (iii) with respect to the exercise of remedies by Lender.

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(d) Maintenance of Records. The Obligor will keep and maintain at its own cost and expense satisfactory and complete records of the Collateral. For the Lender's further security, the Obligor hereby grants to the Lender a security interest in all of the Obligor's books and records pertaining to the Collateral, and upon the occurrence and during the continuance of an Event of Default, the Obligor shall provide copies of any such books and records to the Lender or to its representatives at the request of the Lender.

(e) Right of Inspection. Not more than [\*\*\*] per year unless an Event of Default is continuing, upon reasonable prior notice and during normal business hours, the Lender and its representatives may examine the books and records related to the Collateral, take extracts therefrom and make photocopies thereof, and the Obligor agrees to render to the Lender, at the Obligor's cost and expense, such clerical and other assistance as may be reasonably requested with regard thereto. Not more than [\*\*\*] per year unless an Event of Default is continuing, the Lender and its representatives shall at all times also have the right during normal business hours, and upon reasonable prior notice, to enter into and upon any premises where any of the Manufacturing Facility Equipment is located for the purpose of inspecting the same or otherwise protecting its interests therein. For clarity, the limits on inspection of the Manufacturing Facility Equipment by Lender under this Section 7(e) shall not limit any rights of access to the premises on which such equipment is located that are provided to Lender pursuant to the Sublease.

(f) Compliance with Laws, etc. The Obligor will comply in all material respects with all material laws, rules, regulations and orders of any court, arbitrator or governmental entity, jurisdiction or authority applicable to the Collateral or any part thereof or to the operation of the Obligor's business; provided, however, that the Obligor may contest any such law, rule, regulation or order in any reasonable manner which shall not, in the reasonable opinion of the Lender, adversely affect the Lender's rights or the priority of its liens on the Collateral.

(g) Payment of Obligations. The Obligor will pay promptly when due all taxes, assessments and governmental charges or levies imposed upon the Collateral or in respect of its income or profits therefrom, as well as all claims of any kind (including, without limitation, claims for labor, materials and supplies) against or with respect to the Collateral (any such item, a "Charge"), except that no such Charge need be paid if (i) it is being contested in good faith by appropriate proceedings diligently conducted, (ii) the proceedings related to any Charge do not involve any material danger of the sale, forfeiture or loss of any of the Collateral or any interest therein and (iii) such Charge is adequately reserved against on the Obligor's books in accordance with U.S. GAAP.

(h) Limitation on Liens on Collateral. Except for Permitted Liens, the Obligor will not create, incur or permit to exist, will defend the Collateral against, and will take such other action as is necessary to remove, any lien, security interest, pledge, mortgage, deed of trust, levy, attachment, claim or other charge or encumbrance on or to the Collateral, and will defend the right, title and interest of the Lender in and to any of the Collateral against the claims and demands of all persons or entities whatsoever.

(i) Limitations on Dispositions of Collateral. The Obligor will not sell, convey, rent, lease, sublease, mortgage, license, transfer or otherwise dispose of any of the Collateral, or attempt, offer or contract to do so, without the prior written consent of Lender with the exception of (i) worn out or obsolete equipment and (ii) the negotiation of Instruments comprising the Proceeds of Collateral.

(j) Maintenance of Collateral. The Obligor will maintain each item of Manufacturing Facility Equipment in not worse condition than such Manufacturing Facility Equipment was in on December 27, 2010, ordinary wear and tear and immaterial impairments of value and damage by the elements excepted, and will provide all maintenance, service and repairs necessary for such purpose. The Obligor will keep and maintain at its own cost and expense satisfactory and complete records of the maintenance of the Collateral, including any reports, invoices or other service records or receipts it obtains in connection with the maintenance and/or repair of the Collateral. For the Lender's further security, the Obligor hereby grants to the Lender a security interest in all of such maintenance records pertaining to the Collateral, and upon the occurrence and during the continuance of an Event of Default, the Obligor shall turn over any such records to the Lender or to its representatives at the request of the Lender.

(k) Maintenance of Insurance. The Obligor will maintain, with financially sound and reputable insurance companies with an A.M. Best's rating (or its equivalent) of A:VIII or better, insurance policies (i) insuring the Collateral against loss by fire, explosion, theft and such other casualties as may be reasonably satisfactory to the Lender and (ii) insuring the Obligor and the Lender against liability for personal injury and property damage relating to such Collateral, such policies to be consistent with normal business practices of prudent companies similarly situated, with losses payable to the Obligor and the Lender as their respective interests may appear. All such insurance shall (i) provide that no termination, cancellation, material reduction in amount or material change in coverage thereof shall be effective until at least thirty (30) days after receipt by the Lender of written notice thereof, and (ii) name the Lender as an insured. From time to time upon the request of the Lender, the Obligor shall deliver to the Lender insurance policies, certificates or binders as the Lender may from time to time reasonably request.

8. Events of Default; Remedies. All Obligations under this Agreement and the Note shall, at the option of the Lender, become due and payable without notice or demand, upon the happening of any one of the following specified events (each a "Default," and the occurrence of such, an "Event of Default") by or with respect to Obligor (the "Accelerated Obligations") and the Accelerated Obligations shall bear interest at the Default Rate: (a) failure to pay any amount as set forth in this Agreement and/or the Note; (b) failure or omission to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement and/or under the Note, and such default is not cured within ten (10) days after written notice of such default from the Lender pursuant to Section 12; *provided, however*, with respect to failure to maintain the Manufacturing Facility Equipment pursuant Section 7(j), such period shall be [\*\*\*] days; (c) a material breach by the Obligor of the Purchase Agreement not cured within any applicable cure period, whether having occurred on or after the effective date thereof; (d) a material breach by the Obligor of the Equity Investment Agreements, as defined in the Purchase Agreement, not cured within any applicable cure period, whether having occurred on or after the effective date thereof; (e) the making of a general assignment for the benefit of creditors; (f) the filing of any petition or the commencement of any proceeding for any relief under any bankruptcy or insolvency laws, or any laws relating to the relief of debtors;

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(g) suspension of the transaction of the Obligor's usual business; or (9) a material breach by the Obligor of the Sublease not cured within any applicable cure period, whether having occurred on or after the effective date thereof, or cancellation, for whatever reason, of the Sublease. If an Event of Default shall occur and be continuing, the Lender may exercise, in addition to all other rights and remedies granted to it in this Agreement and in any other instrument or agreement securing, evidencing or relating to the Obligations, all rights and remedies of a secured party under the Code. Without limiting the generality of the foregoing, if an Event of Default shall have occurred and be continuing, the Lender, without demand of performance or other demand, presentment, protest, or notice of any kind (except any notice required by law referred to below) to or upon the Obligor or any other person or entity (all and each of which are hereby waived), may in such circumstances forthwith collect, receive, appropriate and realize upon the Collateral, or any part thereof, and/or may forthwith sell, lease, assign, give option or options to purchase, or otherwise dispose of and deliver the Collateral or any part thereof (or contract to do any of the foregoing), in one or more parcels at public or private sale or sales, at any exchange, broker's board or office of the Lender or elsewhere upon such terms and conditions as it may deem advisable and at such prices as it may deem best, for cash or on credit or for future delivery without assumption of any credit risk. The Lender shall have the right upon any such public sale or sales, and, to the extent permitted by law, upon any such private sale or sales, to purchase the whole or any part of the Collateral so sold, free of any right or equity or redemption in the Obligor, which right or equity is hereby waived or released. The Obligor further agrees, if an Event of Default shall have occurred and be continuing, at the Lender's request, to assemble the Collateral and make it available to the Lender at places which the Lender shall reasonably select, whether at the Obligor's premises or elsewhere. The Lender shall apply the net proceeds of any such collection, recovery, receipt, appropriation, realization or sale, after deducting all reasonable costs and expenses of every kind incurred therein or incidental to the care or safekeeping of any of the Collateral or in any way relating to the Collateral or the rights of the Lender hereunder, including, without limitation, reasonable attorneys' fees and disbursements, to the payment in whole or in part of the Obligations, in such order as the Lender may elect, and only after such application and after the payment by the Lender of any other amount required by any provision of law, including, without limitation, Section 9-615 of the Code, shall the Lender be required to account for the surplus, if any, to the Obligor. To the extent permitted by applicable law, the Obligor waives all claims, damages and demands it may acquire against the Lender arising out of the exercise by the Lender of any of its rights hereunder, provided that such release shall not apply to any claim, damage or demand resulting directly from the gross negligence, actual willful misconduct or bad faith of the Lender. If any notice of a proposed sale or other disposition of Collateral shall be required by law, such notice shall be deemed reasonable and proper if given at least [\*\*\*] days before such sale or other disposition. The Obligor shall remain liable for any deficiency if the proceeds of any sale or other disposition of the Collateral are insufficient to pay the Obligations and the fees and disbursements of any attorneys employed by the Lender to collect such deficiency.

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9. Powers.

(a) Power of Attorney. The Obligor hereby irrevocably constitutes and appoints the Lender and any officer or agent thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of the Obligor and in the name of the Obligor or in its own name, from time to time in the Lender's discretion, for the purpose of carrying out the terms of this Agreement, to take any and all appropriate action and to execute any and all instruments which may be necessary or desirable to accomplish the purposes of this Agreement, and, without limiting the generality of the foregoing, the Obligor hereby gives the Lender the power and right, on behalf of the Obligor, without notice to or assent by the Obligor, to do the following, at any time when an Event of Default shall have occurred and be continuing:

- (i) in the case of any Collateral, in the name of the Obligor or its own name, or otherwise, to take possession of and endorse and collect any checks, drafts, notes, acceptances or other instruments for the payment of moneys due under any item of Collateral or with respect to any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Lender for the purpose of collecting any and all such moneys due with respect to any Collateral whenever payable;
  - (ii) to pay or discharge taxes and liens levied or placed on or threatened against the Collateral, to effect any repairs or any insurance called for the terms of this Agreement and to pay all or any part of the premiums therefor and the costs thereof; and
  - (iii) (A) to direct any party liable for any payment under any of the Collateral to make payment of any and all moneys due or to become due thereunder directly to the Lender or as the Lender shall direct; (B) to ask or demand for, collect, receive payment of and receipt for, any and all moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral; (C) to sign and endorse any invoices, freight or express bills, bills of lading, storage or warehouse receipts, drafts against debtors, assignments, verifications, notices and other documents in connection with any of the Collateral; (D) to commence and prosecute any suits, actions or proceedings at law or in equity in any court of competent jurisdiction to collect the Collateral or any thereof and to enforce any other right in respect of any Collateral; (E) to defend any suit, action or proceeding brought against the Obligor with respect to any Collateral; (F) to settle, compromise or adjust any suit, action or proceeding described in clause (E) above and, in connection therewith, to give such discharges or releases as the Lender may deem appropriate; and (G) generally, to sell, transfer, pledge and make any agreement with respect to or otherwise deal with any of the Collateral as fully and completely as though the Lender were the absolute owner thereof for all purposes, and to do, at the Lender's option and the Obligor's expense, at any time, or from time to time, all acts and things which the Lender deems necessary to protect, preserve or realize upon the Collateral and the Lender's liens thereon and to effect the intent of this Agreement, all as fully and effectively as the Obligor might do.
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At the reasonable request of the Lender, at any time when an Event of Default shall have occurred and be continuing, the Obligor shall deliver to the Lender, one or more further documents ratifying any and all actions that said attorneys shall lawfully take or do or cause to be taken or done by virtue hereof. This power of attorney is a power coupled with an interest and shall be irrevocable.

(b) Other Powers. The Obligor also authorizes the Lender, at any time and from time to time, to execute, in connection with the sales permitted according to the terms hereof, any endorsements, assignments or other instruments of conveyance or transfer with respect to the Collateral.

(c) No Duty on Lender's Part. The powers conferred on the Lender hereunder are solely to protect the Lender's interests in the Collateral and shall not impose any duty upon it to exercise any such powers. The Lender shall be accountable only for amounts that it actually receives as a result of the exercise of such powers, and neither it nor any of its officers, directors, employees or agents shall be responsible to the Obligor for any act or failure to act hereunder, except for its own gross negligence or willful misconduct.

10. Performance by Lender of Obligor's Obligations. If the Obligor fails to perform or comply with any of its agreements contained herein and the Lender, as provided for by the terms of this Agreement or the Note, shall itself perform or comply, or otherwise cause performance or compliance, with such agreement, the expenses of the Lender incurred in connection with such performance or compliance, together with interest thereon at the Default Rate, shall be payable by the Obligor to the Lender on demand and shall constitute Obligations secured hereby.

11. Limitation on Duties Regarding Preservation of Collateral. The Lender's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession, under Section 9-207 of the Code or otherwise, shall be to deal with such Collateral in the same manner as the Lender deals with similar property for its own account. Neither the Lender nor any of its directors, officers, employees or agents shall be liable for failure to demand, collect or realize upon all or any part of the Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of the Obligor or otherwise.

12. Notices. Any notice required or permitted to be given under this Agreement or the Note shall be in writing, shall specifically refer to this Agreement and/or the Note, as applicable, and shall be deemed to have been sufficiently given for all purposes (i) when delivered, if sent by recognized overnight courier or personally delivered, or (ii) upon confirmation of receipt, if sent by facsimile transmission (provided a duplicate hard copy is promptly delivered by one of the other foregoing means), in each case using the mailing addresses of the parties as set forth below (or such other mailing addresses of which a party is notified pursuant to this section):

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For the Obligor:

Corregidor Therapeutics, Inc.  
384 Powder Mill Road  
Concord, Massachusetts 01742  
Facsimile: (978) 405-5142  
Attn: Chief Executive Officer

For the Lender:

Alkermes, Inc.  
852 Winter Street  
Waltham, Massachusetts 02451  
Facsimile: 781-890-6425  
Attn: General Counsel

13. Governing Law. This Agreement and the Note shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements executed and performed entirely within the Commonwealth of Massachusetts, without regard to any applicable principles of conflicts of law.

14. Interpretation. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement. Reference to the Obligor and the Lender shall be deemed to refer to any of their respective subsidiaries.

15. Powers Coupled with an Interest. All authorizations and agencies herein contained with respect to the Collateral are irrevocable and powers coupled with an interest.

16. Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder, by operation of law or otherwise, without the prior written consent of the other Party, except that Lender may make such an assignment of all its rights and obligations hereunder, without Obligor's consent, to a Person that acquires all or substantially all of its business to which this Agreement relates, whether in a merger, consolidation, reorganization, acquisition, sale or otherwise. This Agreement shall be binding on the permitted successors and assigns of the assigning Party, and the name of a Party appearing herein shall be deemed to include the name(s) of such Party's permitted successors and assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16 shall be null and void and of no legal effect.

17. Counterparts. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement will become binding when any one or more counterparts hereof, individually or taken together, bear the signatures of both parties. For the purposes hereof, an electronic or facsimile copy of this Agreement, including signed signature pages hereto, shall be deemed an original.

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18. Severability. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the parties hereto shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable provision in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; provided, however, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the parties hereto shall be enforceable to the fullest extent permitted by law.

19. Headings. The heading for each section in this Agreement has been inserted for convenience of reference only and is not intended to limit or expand on the meaning of the language contained in the particular article or section.

20. Further Actions. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement and to fulfill the obligations under the Note.

21. No Waiver; Cumulative Remedies. The Lender shall not by any act (except by a written instrument pursuant to Section 22 hereof), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default or in any breach of any of the terms and conditions hereof. No failure to exercise, nor any delay in exercising, on the part of the Lender, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Lender of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy that the Lender would otherwise have on any future occasion. The rights and remedies herein provided are cumulative, may be exercised singly or concurrently and are not exclusive of any rights or remedies provided by law.

22. Waivers and Amendments. None of the terms or provisions of this Agreement or the Note may be waived, amended, supplemented or otherwise modified except by a written instrument executed by the Obligor and the Lender, provided that any provision of this Agreement may be waived by the Lender in a written letter or agreement executed by the Lender or by an electronic or a facsimile transmission of such intention from the Lender to the Debtor.

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

IN WITNESS WHEREOF, the Obligor has caused this Agreement to be duly executed and delivered in favor of the Lender as of the date first above written.

OBLIGOR:  
Corregidor Therapeutics, Inc.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

LENDER:  
Alkermes, Inc.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

\_\_\_\_\_

EXHIBIT A

PROMISSORY NOTE

\$30,000,000.00

[ \_\_\_\_\_ ], 201[ \_\_ ]

For value received, the undersigned, Corregidor Therapeutics, Inc., a Delaware corporation (“Obligor”), hereby promises to pay to the order of Alkermes, Inc., a Pennsylvania corporation (“Lender”), whose principal office is at 852 Winter Street, Waltham, Massachusetts 02451, the original principal sum of \$30,000,000.00 together with interest accruing in arrears from and including the date set forth above (the “Effective Date”) on the unpaid principal balance hereunder, computed daily and compounded quarterly, at the rate of [\*\*\*] above LIBOR calculated on the first day of each calendar year during the remaining term hereof (the “Interest Rate”), payable as set forth below. At the option of Lender and to the extent permitted by applicable law, the rate of interest on any unpaid principal or interest not paid when due and payable hereunder, or otherwise from and after the occurrence and during the continuation of an Event of Default, shall be [\*\*\*] per annum above the Interest Rate. Interest shall be calculated on the basis of actual number of days elapsed and a year of 360 days. Notwithstanding any other provision of this Note, Lender does not intend to charge and Obligor shall not be required to pay any interest or other fees or charges in excess of the maximum permitted by applicable law; any payments in excess of such maximum shall be credited to reduce principal hereunder. All payments received by Lender hereunder will be applied first to costs of collection, if any, then to interest and the balance to principal.

This Note is issued in connection with that certain Asset Purchase and License Agreement by and between the Lender and Obligor, dated as of December 27, 2010 (as amended or restated from time to time, the “Purchase Agreement”), and is subject to the terms thereof. In addition, this Note is secured by, entitled to the benefits of, and governed by the terms and conditions of that certain Loan and Security Agreement by and between Obligor and Lender, of even date herewith (as amended or restated from time to time, the “Security Agreement”). Defined terms used but not defined herein shall have the meanings ascribed thereto in the Security Agreement.

Principal and interest hereunder shall be paid pursuant to and in accordance with the terms provided in the Security Agreement.

Payments shall continue on each successive Quarterly Due Date until all principal and interest hereunder have been paid in full.

This Note may be prepaid at any time, without premium or penalty, in whole or in part. Any prepayment of principal shall be accompanied by a payment of accrued interest in respect of the principal being prepaid.

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All payments (including prepayments) to be made by Obligor shall be made in immediately available funds in U.S. dollars, without setoff or counterclaim to the Lender Account before 1:00 p.m. (Eastern Time) on the date when due. All payments received by the Lender after 1:00 p.m. (Eastern Time) on any Business Day or at any time on a day that is not a Business Day shall be deemed to be received on the next Business Day. Whenever any required payment would otherwise be due on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension. All payments due to the Lender shall be effected by bank wire transfer to the Lender Account.

Any outstanding principal and any accrued and unpaid interest hereunder shall become immediately due and payable upon a Change in Control of the Obligor.

Upon the occurrence of any Event of Default, Lender may declare any or all Obligations of Obligor to Lender (including the unpaid principal hereunder and any interest due thereon), immediately due and payable without presentment, demand, protest or notice.

If this Note is not paid in accordance with its terms, Obligor shall pay to Lender, in addition to principal and accrued interest thereon, all costs of collection of the principal and accrued interest, including, but not limited to, reasonable attorneys' fees, court costs and other costs for the enforcement of payment of this Note.

No waiver of any obligation of Obligor under this Note shall be effective unless it is in a writing signed by Lender. A waiver by Lender of any right or remedy under this Note on any occasion shall not be a bar to exercise of the same right or remedy on any subsequent occasion or of any other right or remedy at any time.

This Note is delivered in and shall be enforceable in accordance with the internal domestic laws of the Commonwealth of Massachusetts (without regard to the conflicts of law provisions thereof), and shall be construed in accordance therewith, and shall have the effect of a sealed instrument.

This Note, and the indebtedness of Obligor to Lender evidenced hereby, shall not be subject to any setoff, recoupment, reduction, counterclaim or defense to payment, each of which is hereby expressly waived by Obligor. Obligor hereby expressly waives presentment, demand, and protest, notice of demand, dishonor and nonpayment of this Note, and all other notices or demands of any kind in connection with the delivery, acceptance, performance, default or enforcement hereof, and hereby consents to any delays, extensions of time, renewals, waivers or modifications that may be granted or consented to by the holder hereof with respect to the time of payment or any other provision hereof or of the Security Agreement.

CORREGIDOR THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

\_\_\_\_\_

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

Attested:

By:

Name:

Title:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_

## EXHIBIT B

### BILL OF SALE

KNOW ALL MEN BY THESE PRESENTS that as of [ \_\_\_\_\_ ], 201[ \_\_ ], the undersigned, Alkermes, Inc., a Pennsylvania corporation (“Seller”), for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, does hereby sell, assign, transfer, convey and deliver to Corregidor Therapeutics, Inc., a Delaware corporation (“Buyer”), all right, title and interest of Seller in and to the Manufacturing Facility Equipment (as defined in that certain Asset Purchase and License Agreement dated as of December 27, 2010 (the “Purchase Agreement”) by and between Seller and Buyer), subject to Seller’s retained right, title and interest in and to the Alkermes Know-How that is described in or embodied in this Manufacturing Facility Equipment. All capitalized terms not defined herein shall have the meanings ascribed to them in the Purchase Agreement.

TO HAVE AND TO HOLD the aforesaid Manufacturing Facility Equipment unto Buyer to and for Buyer’s own proper use and benefit forever.

Subject to Seller’s retained right, title and interest in and to the Alkermes Know-How that is described in or embodied in the Manufacturing Facility Equipment and subject to the restoration and removal provisions of the Sublease, Seller is conveying to Buyer good and marketable title to the Manufacturing Facility Equipment free and clear of restrictions on, or conditions to, the transfer or assignment thereof, free and clear of mortgages, security interests, licenses, liens, encumbrances, or rights of others to possession or use; *provided, however*, that all Manufacturing Facility Equipment is transferred to Buyer on an “as is” “where is” basis without any other representation or warranty of any kind, either expressed or implied, including any warranty as to the design, quality or condition of the Manufacturing Facility Equipment, any warranty of merchantability or fitness of the Manufacturing Facility Equipment for any particular purpose or as to any other matter relating to the Manufacturing Facility Equipment or any part thereof.

At any time or from time to time after the date hereof, at Buyer’s reasonable request and without further consideration, Seller shall execute and deliver to Buyer such other instruments of sale, assignment, transfer, conveyance and delivery, provide such materials and information and take such other actions as Buyer may reasonably deem necessary or desirable in order more effectively to sell, assign, transfer, convey and deliver to Buyer, and to confirm Buyer’s title to, the Manufacturing and Facility Equipment, and, to the full extent permitted by law, to put Buyer in actual possession and operating control of the Manufacturing and Facility Equipment and to assist Buyer in exercising all rights with respect thereto.

Nothing set forth in the foregoing shall limit, expand or otherwise affect the rights and obligations of Buyer and Seller as set forth in the Purchase Agreement. In the event of any conflict between the terms and conditions of this Bill of Sale and a term or condition of the Purchase Agreement, the term or condition of the Purchase Agreement shall control.

[Signature Page Follows]

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Commission.

IN WITNESS WHEREOF, the undersigned has executed and delivered this Bill of Sale as of the date first set forth above.

ALKERMES, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

CERTAIN PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS [ ] AND AN ASTERISK\*, HAVE BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

## AMENDMENT TO ASSET PURCHASE AND LICENSE AGREEMENT

THIS AMENDMENT (the “Amendment”) is made and entered into as of December 9, 2011 to the Asset Purchase and License Agreement (the “Agreement”) made and entered into as of December 27, 2010 by and between Civitas Therapeutics, Inc., a Delaware corporation having its principal office at 190 Everett Avenue, Chelsea, MA 02150 (“Civitas”), and Alkermes, Inc., a Pennsylvania corporation having its principal office at 852 Winter Street, Waltham, MA 02451 (“Alkermes”) (any terms used but not defined herein shall have the meaning set forth in the Agreement).

### RECITALS:

WHEREAS, Alkermes and Civitas have entered into the Agreement;

WHEREAS, Alkermes and Civitas now wish to amend the Agreement on the terms and conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

- 1. Schedule 2.1.1.** Schedule 2.1.1 of the Agreement shall be modified to include the patents listed in the attached Appendix A. The parties agree that despite the addition of these patents to Schedule 2.1.1 Alkermes shall not be deemed to be in breach of its representations in Section 6.1(e) or Section 6.1(f) of the Agreement.
- 2. Schedule 2.1.3.** Schedule 2.1.3 of the Agreement shall be modified to include the documentation listed in the attached Appendix B.
- 3. Equipment Use.** Civitas has requested the right to use for an unspecified period of time the Xceledose capsule filler owned by Alkermes (the “Capsule Filler”) for Civitas’ CVT-301 development program (the “Development Program”). Alkermes has agreed to lend the Capsule Filler to Civitas for this purpose, subject to the following conditions:
  - a) Civitas will be responsible for all costs incurred by Alkermes associated with packaging, insuring and transporting the Capsule Filler from Alkermes’ manufacturing facility in Wilmington, OH to the Manufacturing Facility. Alkermes will invoice Civitas for these costs, and Civitas will pay this invoice within thirty (30) days of receipt.

- b) Alkermes does not represent or warrant that the Capsule Filler is in working order or condition. Civitas shall use the Capsule Filler entirely at its own risk and shall, in accordance with the terms of the Agreement, Indemnify the Alkermes Indemnitees from and against any and all Losses arising out of the use of the Capsule Filler by, on behalf of, or under the authority of Civitas, its Affiliates or Collaboration Partners.
- c) Civitas will use the Capsule Filler only in connection with the Development Program and will maintain the Capsule Filler in at least the condition in which it was received by Civitas, ordinary wear and tear excepted. While the Capsule Filler is at the Manufacturing Facility, Civitas will insure it against damage or loss. Civitas will keep the Capsule Filler free and clear of all mortgages, security interests, liens, encumbrances, or rights of others to possession or use.
- d) At any time, upon sixty (60) days prior written notice, Alkermes may direct Civitas to return the Capsule Filler to Alkermes.
- e) Upon Alkermes' direction that the Capsule Filler be returned, or upon Civitas' decision to cease using the Capsule Filler, Civitas will be responsible for cleaning and packaging the Capsule Filler and insuring and delivering it, at Civitas' expense, to a facility of Alkermes' choosing. In the event Civitas decides to cease using the Capsule Filler, Civitas will provide Alkermes notice at least thirty (30) days prior to the intended delivery of the Capsule Filler.

**4. Governing Law.** This Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements executed and performed entirely within the Commonwealth of Massachusetts, without regard to any applicable principles of conflicts of law.

**5. Integration.** Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall continue in full force and effect as provided therein. This Amendment and the Agreement constitute the entire agreement between the Parties related to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to a writing referencing the Agreement and signed by an authorized officer of each Party.

**6. Execution in Counterparts.** This Amendment may be executed simultaneously in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. This Agreement will become binding when any one or more counterparts hereof, individually or taken together, bear the signature of both Parties. For the purposes hereof, an electronic or facsimile copy of this Agreement, including signed signature pages hereto, shall be deemed an original.

*[signature page follows]*

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the Parties have executed and delivered this Amendment by their duly authorized representatives as of the date first set forth above.

CIVITAS THERAPEUTICS, INC.

By: /s/Glenn Batchelder

Name: Glenn Batchelder

Title: CEO

ALKERMES, INC.

By: /s/Blair Jackson

Name: Blair Jackson

Title: Vice President, Business Development

Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## **Appendix A**

[\*\*\*]

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission. Where eighteen pages of material have been omitted, the redacted material is marked with [¥] .

## **Appendix B**

[¥]

CERTAIN PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS [ ] AND AN ASTERISK\*, HAVE BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

## SECOND AMENDMENT TO ASSET PURCHASE AND LICENSE AGREEMENT

THIS SECOND AMENDMENT (the “Amendment”) is made and entered into as of December 19, 2014 to the Asset Purchase and License Agreement (the “Agreement”) made and entered into as of December 27, 2010, as amended as of December 9, 2011 by the first amendment (“Amendment No. 1”), by and between Civitas Therapeutics, Inc., a Delaware corporation having its principal office at 190 Everett Avenue, Chelsea, MA 02150 (“Civitas”), and Alkermes, Inc., a Pennsylvania corporation having its principal office at 852 Winter Street, Waltham, MA 02451 (“Alkermes”) (capitalized terms used but not defined herein shall have the meaning set forth in the Agreement).

### RECITALS:

WHEREAS, Alkermes and Civitas have entered into the Agreement;

WHEREAS, Alkermes and Civitas now wish to amend the Agreement on the terms and conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Schedule 2.1.3** . Schedule 2.1.3 of the Agreement shall be modified to include the documentation listed in the attached Appendix A.
2. **Equipment Use**. Civitas had previously requested the right to use for an unspecified period of time the Xceledose capsule filler owned by Alkermes (the “Capsule Filler”) for Civitas’ CVT-301 development program. Pursuant to Amendment No. 1, Alkermes subsequently lent the Capsule Filler to Civitas for this purpose. Both Parties acknowledge that Civitas returned the Capsule Filler to Alkermes in May 2014 in full working condition.
3. **Governing Law** . This Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements executed and performed entirely within the Commonwealth of Massachusetts, without regard to any applicable principles of conflicts of law.
4. **Integration** . Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement and Amendment No. 1 shall continue in full force and effect as provided therein. This Amendment, Amendment No. 1 and the Agreement constitute the entire agreement between the Parties related to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof. No subsequent alteration, amendment, change or addition to this Amendment shall be binding upon the Parties unless reduced to a writing referencing this Amendment and signed by an authorized officer of each Party.

**5 . Execution in Counterparts .** This Amendment may be executed simultaneously in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. This Amendment will become binding when any one or more counterparts hereof, individually or taken together, bear the signature of both Parties. For the purposes hereof, an electronic or facsimile copy of this Amendment, including signed signature pages hereto, shall be deemed an original.

*[signature page follows]*

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the Parties have executed and delivered this Amendment by their duly authorized representatives as of the date first set forth above.

CIVITAS THERAPEUTICS, INC.

By: /s/ Rick Batycky  
Name: Rick Batycky  
Title: CTO Acorda

ALKERMES, INC.

By: /s/ Michael Landine  
Name: Michael Landine  
Title: Senior Vice President

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Certain portions of this Exhibit have been omitted pursuant to a confidential treatment request. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission. Where seven pages of material have been omitted, the redacted material is marked with [¥] .

## **Appendix A**

[¥]

**List of Subsidiaries of the Registrant**

**Civitas Therapeutics, Inc. (Delaware)**

**Neuronex, Inc. (Delaware)**

**Acorda Therapeutics Limited (UK)**

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

**Consent of Independent Registered Public Accounting Firm**

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

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

(1) Registration Statement (Form S-3 No. 333-196803)

(2) Registration Statement (Form S-8 Nos. 333-194375, 333-164626, 333-158085, 333-131846, 333-149726 , 333-174785, 333-179906, and 333-187091 )

of our reports dated February 27, 2015 with respect to the consolidated financial statements of Acorda Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Acorda Therapeutics, Inc. included in this Annual Report (Form 10-K) of Acorda Therapeutics, Inc. for the year ended December 31, 2014 filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 27 , 2015

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO**

**RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, Ron Cohen, certify that:

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

Date: February 27, 2015

/s/ RON COHEN

Ron Cohen

*Chief Executive Officer*

*(Principal Executive Officer)*



**CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO**

**RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, Michael Rogers, certify that:

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

Date: February 27, 2015

/s/ MICHAEL ROGERS

Michael Rogers

*Chief Financial Officer*

*(Principal Financial Officer)*



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

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ron Cohen, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ RON COHEN  
Chief Executive Officer  
(Principal Executive Officer)  
February 27, 2015

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

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

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Rogers, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ MICHAEL ROGERS  
Chief Financial Officer  
(Principal Financial Officer)  
February 27, 2015

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