

ACORDA THERAPEUTICS INC  
Form 10-K  
February 27, 2017

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, 2016

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)	13-3831168 (I.R.S. Employer Identification No.)
420 Saw Mill River Road, Ardsley, New York (Address of principal executive offices)	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	Name of each exchange on which registered
Common Stock \$0.001 par value	NASDAQ Global Market

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

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 (Do not check if a smaller reporting company) 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, 2016, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was \$518,498,297. 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, 2016 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, 2017, the registrant had 46,407,850 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 2017 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2016. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

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

Part III, Item 11, Executive Compensation.

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

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

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

ACORDA THERAPEUTICS, INC.

2016 FORM 10-K ANNUAL REPORT

## TABLE OF CONTENTS

	Page
<b>PART I</b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	40
Item 1B. <u>Unresolved Staff Comments</u>	65
Item 2. <u>Properties</u>	66
Item 3. <u>Legal Proceedings</u>	66
Item 4. <u>Mine Safety Disclosures</u>	69
<b>PART II</b>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	70
Item 6. <u>Selected Financial Data</u>	73
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	75
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	102
Item 8. <u>Financial Statements and Supplementary Data</u>	102
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	102
Item 9A. <u>Controls and Procedures</u>	102
Item 9B. <u>Other Information</u>	104
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	105
Item 11. <u>Executive Compensation</u>	105
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	105
Item 13. <u>Certain Relationship and Related Transactions, and Director Independence</u>	105
Item 14. <u>Principal Accounting Fees and Services</u>	105
<b>PART IV</b>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	106
<b><u>SIGNATURES</u></b>	



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 Biotie and Civitas transactions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg 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 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, any other products under development, or the products that we acquired with the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator Biogen in connection therewith; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this Annual Report, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We and our subsidiaries own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks "Acorda Therapeutics," our stylized Acorda Therapeutics logo, "Biotie Therapies," "Ampyra," "Zanaflex," "Zanaflex Capsules," "Qutenza" and "ARCUS." Also, our mark "Fampyra" is a registered trademark 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 focused on developing therapies that restore function and improve the lives of people with neurological disorders. We market three U.S. Food and Drug Administration (FDA)-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. Ampyra 2016 net revenue was \$492.8 million, an increase of approximately 13% over 2015. We also market Zanaflex Capsules and tablets, FDA-approved as short-acting drugs for the management of spasticity, and Qutenza, an FDA-approved dermal patch for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain.

We have five Orange Book-listed patents providing protection for Ampyra up to 2027. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange Book-listed patents that we rely on for Ampyra. These legal proceedings are described in further detail in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights.

We have a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, migraine and MS. CVT-301 is our most advanced clinical program and our highest priority. CVT-301 is a self-administered inhaled formulation of levodopa, or L-dopa, using our proprietary ARCUS drug delivery technology, in Phase 3 development for the treatment of OFF periods in people with Parkinson's disease. On February 9, 2017, we announced efficacy and safety clinical data from a Phase 3 clinical trial that we completed in 2016. The data shows a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. The safety profile of CVT-301 in the trial was consistent with that observed in a prior Phase 2b clinical trial. We plan to file a New Drug Application, or NDA, with the FDA in the U.S. by the end of the second quarter of 2017, pending data from ongoing long-term safety studies. We also plan to file a Marketing Authorization Application, or MAA, in Europe by the end of 2017 pending additional data analyses. We project that, if approved, CVT-301 could generate peak annual U.S. net revenue of more than \$500 million.

In 2016, we acquired Biotie Therapies Corp., and pursuant to the acquisition we acquired worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. Further expanding our pipeline, we also obtained global rights to SYN120, an oral, 5-HT6/5-HT2A dual receptor antagonist in Phase 2 development with support from the Michael J. Fox Foundation for Parkinson's-related dementia. We believe these acquired Biotie clinical stage programs, together with our CVT-301 clinical development program, position Acorda as a leader in Parkinson's disease therapeutic development.

Concurrently with the announcement of the Biotie transaction, we announced two separate financing transactions. The first was a private placement of 2,250,900 shares of our common stock in January 2016 for an aggregate purchase price of approximately \$75 million. We used the net proceeds from the private placement to fund, in part, the acquisition of Biotie described above. We also announced a commitment from JPMorgan Chase, N.A. for an asset-based credit facility for up to \$60 million, which we entered into on June 1, 2016. Availability under the facility is subject to a borrowing base, which is based on our and certain of our U.S. subsidiaries' eligible accounts receivable, inventory and equipment, after adjusting for customary factors that are subject to modification from time to time by the administrative agent under the facility at its discretion (not to be exercised unreasonably). Based on our eligible



accounts receivable and inventory and other components of the borrowing base, the availability under the facility was approximately \$60 million as of December 31, 2016.

Our strategy is to continue growing as a fully integrated biopharmaceutical company, focusing primarily in the areas of Parkinson's disease, migraine and MS. Our priorities for 2017 include advancing our late stage Parkinson's disease development programs, continuing to grow Ampyra and defending our Ampyra patents, and pursuing partnering or out-licensing transactions for some of our earlier-stage programs.

1

---

## Company Highlights

### Ampyra

Ampyra is the first product for which we completed clinical development. Ampyra, an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), was approved by the FDA in January 2010. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). To our knowledge, Ampyra is the first and only product indicated to improve walking in people with MS. Ampyra was made commercially available in the U.S. in March 2010, using our own specialty sales force, and had net revenue of \$493 million for the year ended December 31, 2016. Since the March 2010 launch of Ampyra, approximately 120,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. Seven years after approval, Ampyra continues to grow, reflecting the continued unmet medical need among people with MS for a treatment to improve walking. Our 60-day free trial program provides eligible patients with two months of Ampyra at no cost.

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial formulary. Approximately 75% of insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

Approximately 400,000 people in the U.S. suffer from MS, and each year approximately 10,000 people in the U.S. are newly diagnosed. In a poll of more than 2,000 people with MS, 87% said they experienced some limitation to their walking ability and limited activities that involved walking. Among MS patients diagnosed within the last 5 years, 58% report experiencing mobility issues at least twice a week. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra available in additional markets in 2017. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones.

### Ampyra/Fampyra Patents and Legal Proceedings

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

- The first is U.S. Patent No. 8,007,826, with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the USPTO, this patent will extend into 2027.
- The second is U.S. Patent No. 5,540,938, the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In April 2013, this patent received a five year patent term extension under the patent restoration provisions of the Hatch-Waxman Act. With a five year patent term extension, this patent will expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan's Drug Technologies business).

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

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

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

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who have submitted Abbreviated New Drug Applications, or ANDAs, with the FDA seeking marketing approval for generic versions of Amypra (dalfampridine) Extended Release Tablets, 10mg. 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 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016 and we are waiting for the Court's decision. In February 2017, we announced that we had reached a settlement agreement with one of these four generic companies. Our Orange Book-listed patents for Ampyra are also subject to inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). These IPR petitions challenge four of the five Orange Book-listed patents. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange Book-listed patents that we rely on for Ampyra. These legal proceedings are described in further detail in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

#### CVT-301, CVT-427 and ARCUS Technology

CVT-301 is self-administered, inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease causes a range of symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease.

CVT-301 delivers a precise dose of dry-powder formulation of L-dopa to the lung. Oral medication can be absorbed with slow and variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before

reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain shortly thereafter, bypassing the digestive system. CVT-301 is based on our proprietary ARCUS platform, a dry-powder pulmonary drug delivery technology 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, breath-actuated proprietary inhaler. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents.

In 2016, we completed a Phase 3 efficacy and safety clinical trial of CVT-301 for the treatment of OFF periods in Parkinson's disease. On February 9, 2017, we announced efficacy and safety data from this clinical trial, showing a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. The

3

---

clinical trial had three arms: CVT-301 84 mg and 60 mg doses (equivalent to 50 mg and 35 mg fine particle doses, respectively), and placebo. The trial met its primary outcome measure of improvement in motor function as measured by the Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS Part III) in people with Parkinson's disease experiencing OFF periods. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment. The primary endpoint was measured at 30 minutes post-treatment for the 84 mg dose at the 12-week visit. UPDRS Part III change was -9.83 compared to -5.91 for placebo with a p value of 0.009. The magnitude of CVT-301's benefit versus baseline was consistent with the data from the prior Phase 2b clinical trial, further described below, and represents a moderate to large clinically important difference. The placebo-adjusted difference was lower in the Phase 3 clinical trial than the Phase 2b clinical trial but still represented a clinically important difference.

The safety profile of CVT-301 in the trial was consistent with that observed in a prior Phase 2b clinical trial. Adverse events reported in any study arm at greater than 5% were cough, upper respiratory tract infection, throat irritation, nausea and sputum discoloration. Cough was the most common adverse event, reported by approximately 15% of subjects who received CVT-301. When reported, it was typically mild and reported once per participant during the course of treatment. Three of 227 participants receiving CVT-301 discontinued the study due to cough. Reports of serious adverse events were: 3, or 2.7% in the placebo arm, 6, or 5.3% in the 60 mg arm, and 2, or 1.8% in the 84 mg arm. There was one death in the study, a suicide in the 60 mg group, judged by the investigator not to be related to drug. We are currently conducting two additional Phase 3 studies to assess the long-term safety profile of CVT-301. Up to 12-month data from these studies are expected by the end of the first quarter of 2017.

We had a pre-NDA (New Drug Application) meeting with the FDA during the third quarter of 2016 and have received the FDA's minutes of that meeting. We plan to file an NDA with the FDA in the U.S. by the end of the second quarter of 2017, pending data from the ongoing long-term safety studies. We also plan to file a Marketing Authorization Application, or MAA, in the EU by the end of 2017 pending additional data analyses. 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®. We believe the Phase 3 efficacy and safety clinical trial, combined with data from the two additional Phase 3 studies and supported by existing Phase 2b data, will be sufficient for filing an NDA. We are projecting that, if approved, annual peak net revenue of CVT-301 in the U.S. alone could exceed \$500 million. We are actively seeking to partner this program outside of the U.S., the EU and certain other countries.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF period, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured. In April 2016, data from this clinical trial were one of six platform presentations highlighted during the Movement Disorders Invited Science Session at the 68th Annual Meeting of the American Academy of Neurology. In June 2016, data from this clinical trial was also presented in three posters during the 20th International Congress of Parkinson's Disease and Movement Disorders (MDS). In October 2016, we announced that results from Phase 1, Phase 2a and preclinical studies of CVT-301 were featured in the current edition of Science Translational Medicine.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS drug delivery 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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS drug delivery technology. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates.

Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in nasally delivered formulations. However, based on available data, we believe that nasally delivered triptans generally have an onset of action similar to orally administered triptans.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. In June 2016, at the 58th Annual Scientific Meeting of the American Headache Society, we presented pharmacokinetic data from the Phase 1 trial which showed increased bioavailability and faster absorption

compared to oral and nasal administration of the same active ingredient in healthy adults. In particular, the data showed that CVT-427 had a median T<sub>max</sub> of about 12 minutes for all dose levels compared to 1.5 hours for the oral tablet and 3.0 hours for the nasal spray. There were no serious adverse events, dose-limiting toxicities, evidence of acute bronchoconstriction or discontinuations due to adverse events reported in this study. The most commonly reported treatment-emergent adverse events were cough, chest discomfort, headache, and feeling hot. Apart from cough, single dose CVT-427 tolerability was generally consistent with the known safety profile of zolmitriptan. We have also completed a special population study to evaluate safe inhalation of CVT-427 in patients with asthma and in smokers. Some subjects in this study showed evidence of acute, reversible bronchoconstriction, post-inhalation. We plan to discuss these results with outside advisors and the FDA and, pending agreement, to advance the program into Phase 2 study by the end of 2017.

#### Biotie Acquisition; Tozadenant, SYN120 and BTT1023

In 2016, we acquired Biotie Therapies Corp. pursuant to a combination agreement with Biotie for a purchase price of approximately \$376 million. On September 30, 2016, we completed the acquisition of 100% of the capital stock of Biotie. Previously, in April and May, 2016, we had acquired approximately 97% of the fully diluted capital stock of Biotie pursuant to public tender offers. On September 30, 2016, we acquired shares representing the remaining approximately 3% of Biotie's fully diluted capital stock pursuant to compulsory redemption proceedings under Finnish law that we had initiated in April 2016. Pursuant to these redemption proceedings, we were entitled to acquire these remaining Biotie shares in exchange for our provision of a cash security deposit pending a final determination and payment of the redemption price for these shares. In November 2016, the arbitration tribunal administering the redemption proceedings rendered a decision in our favor, confirming that the price for the remaining unpaid shares would be the same as the price per share set forth in the combination agreement and offered and paid to the other Biotie shareholders. We made the remaining payments in January 2017. The arbitration decision was not appealed and became final and binding in February 2017.

Pursuant to the acquisition, we acquired worldwide rights to tozadenant, an oral adenosine A<sub>2a</sub> receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. A<sub>2a</sub> receptor antagonists have the potential to be the first new class of drug approved in the U.S. for improvement of motor symptoms in Parkinson's disease in over 20 years. We believe that tozadenant would be complementary to our other Phase 3 product for Parkinson's disease, CVT-301, because while tozadenant is being developed as a chronic therapy for reducing overall OFF time, CVT-301 is being developed for episodic use for rapid improvement of OFF periods when they occur. Biotie is currently conducting a Phase 3 clinical trial in which tozadenant is taken along with a person's other Parkinson's disease therapies. The trial, which is being conducted under a special protocol assessment, or SPA, from the FDA, is assessing improvement of motor function and activities of daily living in people with Parkinson's disease while taking tozadenant. We believe that this trial, if successful, together with data from a prior Phase 2b clinical trial, will provide sufficient efficacy data to file an NDA. We expect efficacy data from this trial in the first quarter of 2018. A separate open-label safety study is expected to begin enrollment in the first half of 2017.

Further expanding our pipeline, through Biotie we also obtained global rights to SYN120, an oral, 5-HT<sub>6</sub>/5-HT<sub>2A</sub> dual receptor antagonist in Phase 2 development with support from the Michael J. Fox Foundation for Parkinson's-related dementia. We expect to complete an ongoing Phase 2 exploratory study in the second half of 2017 and we expect data from this trial in the first quarter of 2018.

Biotie is also developing BTT1023 (timolumab), a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. There are no approved drug therapies for PSC, and liver transplant is the only treatment. Interim data from an ongoing Phase 2 proof-of-concept clinical trial of BTT1023 for PSC are expected in the second half of 2017. We are seeking to out-license this program.



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

#### Remyelinating Antibodies

We are developing rHIgM22, a remyelinating antibody, 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 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also included several exploratory clinical, imaging and biomarker measures. We announced top-line safety and

tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHlgM22, found no dose-limiting toxicities at any of the five dose levels studied. In April 2015, we presented additional safety data from this trial showing that rHlgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHlgM22 penetrates the central nervous system. We are currently enrolling a Phase 1 trial using one of two doses of rHlgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the second half of 2017. We are actively seeking a partner for further development of this program after completion of this trial.

#### Cimaglermin alfa/Neuregulins

Cimaglermin alfa is our lead product candidate for our neuregulin program. We completed a 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 report of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting FDA Drug-Induced Liver Injury Guidance (FDA 2009) stopping rules was also identified in the highest planned dose cohort, which resolved over two to three weeks. In 2015, we presented new analyses of data from this trial, which found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In 2013, we commenced a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In 2015, we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting the FDA guidelines referenced above. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within two to three weeks, as was the case with the one case of hepatotoxicity reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial have completed the pre-planned one year of follow up. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to further define the nature of the bilirubin signal. We have met with the FDA to present analysis of the data from the cimaglermin studies, as well as data from non-clinical studies, as part of our request that the program be removed from the clinical hold. We are seeking to out-license this program.

#### Ampyra/Dalfampridine Development Program

We have been studying the use of dalfampridine in patients who experience post-stroke walking difficulties, or PSWD, after experiencing an ischemic stroke. In 2016, we made the decision to stop enrollment in an ongoing Phase 3 clinical trial and conduct an unblinded analysis of the trial data. In November 2016, we announced we were discontinuing our PSWD program after reviewing the unblinded data and concluding that the results did not show sufficient efficacy to support further development. We have also been exploring a once-daily (QD) formulation of dalfampridine for use in our PSWD clinical program. A multi-dose pharmacokinetic study confirmed that we have developed a potentially viable QD formulation of dalfampridine.

#### Plumiaz

Plumiaz is a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs, or AEDs, who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures. In 2013, we submitted a New Drug Application, or NDA, for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. In May 2015, we announced that we completed discussions with the FDA, and thereafter we continued to advance development of Plumiaz. Based on these discussions, we were conducting three clinical trials for Plumiaz. However, in May 2016 we announced that we were discontinuing the program because data from clinical trials did not demonstrate Plumiaz's bioequivalence to Diastat<sup>®</sup> rectal gel. Specifically, the data demonstrated unexpectedly lower nasal mucosa absorption of diazepam in persons with epilepsy compared to studies in healthy volunteers.

## Corporate Update

In January 2016, we engaged Burkhard Blank, M.D., to assume the responsibilities of Chief Medical Officer on an interim basis, and in July 2016, we appointed Dr. Blank as our Chief Medical Officer. Dr. Blank has more than 25 years of industry experience, holding senior leadership positions with responsibility for managing international clinical trial programs, as well as heading regulatory affairs, statistics, drug safety and related departments.

In October 2016, we announced the departure of Mr. Michael Rogers, our former Chief Financial Officer. In connection with Mr. Rogers' departure, David Lawrence, previously Chief of Business Operations, assumed the role of Chief, Business Operations and Principal Accounting Officer. In that role, he is carrying out principal financial officer responsibilities. Andrew Hindman, the Company's Chief Business Development Officer, assumed responsibility for Financial Planning and Analysis and Investor Relations.

## Our Strategy

Our strategy is to continue to grow as a fully integrated biopharmaceutical company and to become a leading neurology company dedicated to the identification, development and commercialization of therapies that restore function and improve the lives of people with neurological disorders. We are seeking to leverage our scientific, clinical and commercial expertise in neurology and focusing on Parkinson's disease, migraine and MS. Following are our 2017 strategic priorities:

- ◆ Advancing our late stage Parkinson's disease programs, including: CVT-301, a self-administered, inhaled formulation of levodopa, or L-dopa, using our proprietary ARCUS drug delivery technology, in Phase 3 development for the treatment of OFF periods in people with Parkinson's disease; and tozadenant, an oral adenosine A2a receptor antagonist in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time.
- ◆ Maximizing the value of Ampyra, including defending our intellectual property relating to Ampyra and continuing to grow sales by bringing the therapy to appropriate patients who have not yet had the opportunity to benefit from it.
- ◆ Pursuing expansion of our pipeline and commercial geographic reach through strategic transactions, such as acquisitions of late stage or near commercial or commercial neurology development programs, and partnering or out-licensing late-stage development programs in certain foreign markets.
- ◆ Pursuing partnering and out-licensing opportunities for some of our early stage clinical programs such as BTT1023 and rHIgM22.

## Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Ampyra	MS	FDA-approved and marketed in the U.S.	Acorda (U.S.)
Fampyra	MS	Approved in a number of countries across Europe, Asia and the Americas	Biogen (outside U.S.)
Zanaflex Capsules and an authorized generic version of the capsules	Spasticity	FDA-approved	Acorda (U.S.); authorized generic marketed by Actavis
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
Qutenza	Post Herpetic Neuralgia	FDA-approved	Acorda (U.S. Canada, Latin America and certain other countries)
Selincro	Alcohol Dependence	EMA-approved	Lundbeck

## Research and

## Proposed

## Development

Programs	Therapeutic Area(s)	Stage of Development	Marketing Rights
CVT-301	Parkinson's disease OFF periods	Phase 3 clinical trial complete	Acorda/Worldwide; seeking to out-license outside of U.S., Europe and certain other territories
Tozadenant	Parkinson's disease OFF time	Phase 3 clinical trial ongoing	Acorda (Biotie)/Worldwide
SYN120	Parkinson's disease-related dementia	Phase 2 clinical trial ongoing	Acorda (Biotie)/Worldwide
BTT1023 (timolumab)	Primary Sclerosing Cholangitis	Phase 2 clinical trial ongoing	Acorda (Biotie)/Worldwide; seeking to out-license
CVT-427	Migraine	Phase 1 clinical trial completed	Acorda/Worldwide
rHIgM22	MS	Second Phase 1 clinical trial ongoing	Acorda/Worldwide; seeking to out-license
Cimaglermin alfa	Heart failure	Phase 1b clinical trial on hold	Acorda/Worldwide; seeking to out-license
Chondroitinase Program	Spinal cord injury	Research	Acorda/Worldwide
NP-1998	No current plans for development	Phase 3, but no current plans for development	Acorda (U.S. Canada, Latin America and certain other countries)

## Background on Neurological Conditions

We are a biopharmaceutical company focused on developing therapies that restore function and improve the lives of people with neurological disorders. Where our neurology programs may also show promise for disorders outside of the nervous system, we may elect to pursue these opportunistically as well. Currently, we are focused on developing and marketing therapeutics 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. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

#### Parkinson's Disease

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

As Parkinson's disease progresses, even optimized regimens of oral carbidopa/levodopa are associated with increasingly wide variability in the timing and amount of absorption into the bloodstream. This results in the unreliable control of symptoms, leading to motor complications including OFF periods. OFF periods, which are characterized by a re-emergence of Parkinson's disease symptoms, can increase in frequency and severity during the course of the disease. OFF periods remain one of the most challenging aspects of the disease despite optimized regimens with current therapeutic options and strategies. About half of people with Parkinson's disease treated with L-dopa therapy experience OFF periods within five years of initiating treatment. For the approximately 350,000 people in the U.S. and 420,000 in Europe who experience them, OFF periods are inadequately addressed by available therapies and are considered one of the greatest unmet medical needs facing people with Parkinson's disease. OFF periods can be very disruptive to the lives of people with Parkinson's disease, their families and caregivers.

According to recent studies following people with Parkinson's disease over the entire course of their illness, approximately 50-80% may experience dementia. Some studies have reported that the average time from onset of Parkinson's disease to developing dementia is about 10 years. Dementia is a physical change in the brain that causes a decline in the brain's ability to process and understand information, and can affect thinking, perception, and mood. As Parkinson's disease progresses over time, Parkinson's disease-related dementia can cause problems with: memory loss and forgetfulness; speaking and communicating with others; problem solving and understanding of complex ideas; paying attention; emotional control, mood, and motivation; confusion, anxiety, and hallucinations.

#### Migraine

Migraine is a neurological syndrome characterized by pain, nausea, abnormal sensitivity to sound and abnormal sensitivity to light. It is believed to affect over 10% of the global population. In the U.S., the National Institutes of Health estimates 12% of the population, or approximately 37 million people, suffer from migraine, with women being nearly three times more affected than men. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in

poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in nasally delivered formulations. However, based on available data, we believe that nasally delivered triptans generally have an onset of action similar to orally administered triptans.

#### 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.

## 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 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. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who have submitted Abbreviated New Drug Applications (ANDA) with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. 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 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016 and we are waiting for the Court’s decision. In February 2017, we announced that we had reached a settlement agreement with one of these four generic companies. Our Orange Book-listed patents for Ampyra are also subject to inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). These IPR petitions challenge four of the five Orange Book-listed patents. The USPTO held an oral argument regarding the IPR petitions on January 19, 2016, and a ruling on the IPR petitions is expected in March 2017. An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange Book-listed patents that we rely on for Ampyra. These legal proceedings are described in further detail in Part I, Item 3 of this report. We will vigorously defend our intellectual property rights.

Ampyra is marketed as Famprya outside the U.S. by Biogen under a 2009 license and collaboration agreement. Famprya has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Famprya available in additional markets in 2017.

## Background

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

## Clinical Studies and Safety Profile

Our New Drug Application, or NDA, for Ampyra was based on data from a comprehensive development program assessing the safety and efficacy of Ampyra, including two Phase 3 trials that involved 540 people with MS. The

primary measure of efficacy in our two Phase 3 MS trials was walking speed (in feet per second) as measured by the Timed 25-foot Walk (T25FW), using a responder analysis. A responder was defined as a patient who showed faster walking speed for at least three visits out of a possible four during the double-blind period than the maximum speed achieved in the five non-double-blind, no treatment visits (four before the double-blind period and one after). A significantly greater proportion of patients taking Ampyra 10 mg twice daily were responders compared to patients taking placebo, as measured by the T25FW (Trial 1: 34.8% vs. 8.3%; Trial 2: 42.9% vs. 9.3%). The increased response rate in the Ampyra group was observed across all four major types of MS. During the double-blind treatment period, a significantly greater proportion of patients taking Ampyra 10 mg twice daily had increases in walking speed of at least 10%, 20%, or 30% from baseline, compared to placebo. In both trials, the consistent improvements in walking speed were shown to be associated with improvements on a patient

self-assessment of ambulatory disability, the 12 item Multiple Sclerosis Walking Scale (MSWS-12), for both drug and placebo treated patients. However, a drug vs. placebo difference was not established for that outcome measure.

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

The FDA's approval letter included certain post-marketing study requirements and confirmed certain commitments made by us with respect to Ampyra, all of which we have now completed. The post-marketing requirements included additional animal toxicology studies to evaluate certain impurities, in-vitro receptor binding and abuse potential studies in animals, and an evaluation of clinical adverse events related to abuse 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 Actavis (a Teva Pharmaceuticals subsidiary) following the launch by Apotex Inc. of its generic tizanidine hydrochloride capsules. In March 2013, Mylan Laboratories also launched generic tizanidine hydrochloride capsules.

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

#### Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the U.S., Canada, Latin America and certain other territories. Grunenthal GmbH (as the assignee of 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 a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, migraine and MS. We have three clinical-stage programs in Parkinson's disease, including CVT-301, our most advanced clinical program and our highest priority, as well as our tozadenant and SYN120 programs which we acquired with Biotie. We believe these three clinical development programs position Acorda as a leader in Parkinson's disease therapeutic development. These programs and the other programs in our pipeline are described below.

### CVT-301, CVT 427 and ARCUS Technology

CVT-301 is a self-administered, inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease causes a range of symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease.

CVT-301 delivers a precise dose of dry-powder formulation of L-dopa to the lung. Oral medication can be absorbed with slow and variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain shortly thereafter, bypassing the digestive system. CVT-301 is based on our proprietary ARCUS platform, a dry-powder pulmonary drug delivery technology 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, breath-actuated proprietary inhaler. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents.

In 2016, we completed a Phase 3 efficacy and safety clinical trial of CVT-301 for the treatment of OFF periods in Parkinson's disease. On February 9, 2017, we announced efficacy and safety data from this clinical trial, showing a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. The clinical trial had three arms: CVT-301 84 mg and 60 mg doses (equivalent to 50 mg and 35 mg fine particle doses, respectively), and placebo. The trial met its primary outcome measure of improvement in motor function as measured by the Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS Part III) in people with Parkinson's disease experiencing OFF periods. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment. The primary endpoint was measured at 30 minutes post-treatment for the 84 mg dose at the 12-week visit. UPDRS Part III change was -9.83 compared to -5.91 for placebo with a p value of 0.009. The magnitude of CVT-301's benefit versus baseline was consistent with the data from the prior Phase 2b clinical trial, further described below, and represents a moderate to large clinically important difference. The placebo-adjusted difference was lower in the Phase 3 clinical trial than the Phase 2b clinical trial but still represented a clinically important difference.

The safety profile of CVT-301 in the trial was consistent with that observed in a prior Phase 2b clinical trial. Adverse events reported in any study arm at greater than 5% were cough, upper respiratory tract infection, throat irritation, nausea and sputum discoloration. Cough was the most common adverse event, reported by approximately 15% of subjects who received CVT-301. When reported, it was typically mild and reported once per participant during the course of treatment. Three of 227 participants receiving CVT-301 discontinued the study due to cough. Reports of serious adverse events were: 3, or 2.7% in the placebo arm, 6, or 5.3% in the 60 mg arm, and 2, or 1.8% in the 84 mg arm. There was one death in the study, a suicide in the 60 mg group, judged by the investigator not to be related to

drug. We are currently conducting two additional Phase 3 studies to assess the long-term safety profile of CVT-301. Up to 12-month data from these studies are expected by the end of the first quarter of 2017.

We had a pre-NDA (New Drug Application) meeting with the FDA during the third quarter of 2016 and have received the FDA's minutes of that meeting. We plan to file an NDA with the FDA in the U.S. by the end of the second quarter of 2017, pending data from the ongoing long-term safety studies. We also plan to file a Marketing Authorization Application, or MAA, in the EU by the end of 2017 pending additional data analyses. 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®. We believe the Phase 3 efficacy and safety clinical trial, combined with data from the two additional Phase 3 studies and supported by existing Phase 2b data, will be sufficient for filing an NDA. We are projecting that, if approved, annual peak net revenue of

12

---

CVT-301 in the U.S. alone could exceed \$500 million. We are actively seeking to partner this program outside of the U.S., the EU and certain other countries.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF period, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured. In April 2016, data from this clinical trial were one of six platform presentations highlighted during the Movement Disorders Invited Science Session at the 68<sup>th</sup> Annual Meeting of the American Academy of Neurology. In June 2016, data from this clinical trial was also presented in three posters during the 20th International Congress of Parkinson's Disease and Movement Disorders (MDS). In October 2016, we announced that results from Phase 1, Phase 2a and preclinical studies of CVT-301 were featured in the current edition of Science Translational Medicine.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS drug delivery 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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS drug delivery technology. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in nasally delivered formulations. However, based on available data, we believe that nasally delivered triptans generally have an onset of action similar to orally administered triptans.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. In June 2016, at the 58th Annual Scientific Meeting of the American Headache Society, we presented pharmacokinetic data from the Phase 1 trial which showed increased bioavailability and faster absorption compared to oral and nasal administration of the same active ingredient in healthy adults. In particular, the data showed that CVT-427 had a median T<sub>max</sub> of about 12 minutes for all dose levels compared to 1.5 hours for the oral tablet and 3.0 hours for the nasal spray. There were no serious adverse events, dose-limiting toxicities, evidence of acute bronchoconstriction or discontinuations due to adverse events reported in this study. The most commonly reported treatment-emergent adverse events were cough, chest discomfort, headache, and feeling hot. Apart from cough, single dose CVT-427 tolerability was generally consistent with the known safety profile of zolmitriptan. We have also completed a special population study to evaluate safe inhalation of CVT-427 in patients with asthma and in smokers. Some subjects in this study showed evidence of acute, reversible bronchoconstriction, post-inhalation. We plan to discuss these results with outside advisors and the FDA and, pending agreement, to advance the program into Phase 2 study by the end of 2017.

In July 2015, the Bill & Melinda Gates Foundation awarded us a \$1.4 million grant to support the development of a formulation and delivery system for a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome, or RDS. The formulation will be based on our proprietary ARCUS drug delivery technology, and will be produced in collaboration with the Massachusetts Institute of Technology. RDS is a condition affecting newborns in which fluid collects in the lungs' air sacs; it most commonly affects infants born prematurely. It can be fatal, or lead to severe, chronic health issues caused by a lack of oxygen getting to the baby's brain and other organs.

The syndrome is caused by the infants' inability to produce enough surfactant, a liquid lining the inside of the lungs. Delivering liquid surfactant to the lungs via intubation is the standard of care. This grant will support the development of a portable and easily administered inhaled form of surfactant, which may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. This program is not aimed at developing a commercial product, but our work on this program could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

#### Tozadenant

We own (through Biotie) worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. A2a receptor



antagonists have the potential to be the first new class of drug approved in the U.S. for improvement of motor symptoms in Parkinson's disease in over 20 years. We believe that tozadenant would be complementary to our other Phase 3 product for Parkinson's disease, CVT-301, because while tozadenant is being developed as a chronic therapy for reducing overall OFF time, CVT-301 is being developed for episodic use for rapid improvement of OFF periods when they occur.

Biotie previously conducted a Phase 2b clinical trial of tozadenant in people with Parkinson's disease who have motor fluctuations on levodopa, among other chronic medicines. The study compared four individual dose arms versus a placebo arm. The primary outcome was a reduction in OFF time, as determined by a patient diary. The clinical trial showed statistically significant and clinically meaningful reductions in OFF time.

Biotie is currently conducting a Phase 3 clinical trial in which tozadenant is taken along with a person's other Parkinson's disease therapies. The trial is being conducted under a special protocol assessment, or SPA, from the FDA and is comparing two of the dose arms of tozadenant that were studied in the Phase 2b clinical trial versus placebo. The trial is assessing improvement of motor function and activities of daily living in people with Parkinson's disease while taking tozadenant. We believe that this trial, if successful, together with data from the prior Phase 2b clinical trial, will provide sufficient efficacy data to file an NDA with the FDA. We expect efficacy data from this trial in the first quarter of 2018. A separate open-label safety study is expected to begin enrollment in the first half of 2017.

#### SYN120

We own (through Biotie) worldwide rights to SYN120, an oral, 5-HT<sub>6</sub>/5-HT<sub>2A</sub> dual receptor antagonist in Phase 2 development with support from the Michael J. Fox Foundation for Parkinson's-related dementia. Dementia is a physical change in the brain that causes a decline in the brain's ability to process and understand information, and can affect thinking, perception and mood. As Parkinson's disease progresses over time, Parkinson's disease-related dementia can cause problems with: memory loss and forgetfulness; speaking and communicating with others; problem solving and understanding of complex ideas; paying attention; emotional control, mood, and motivation; and confusion, anxiety, and hallucinations. According to recent studies following people with Parkinson's disease over the entire course of their illness, approximately 50-80% may experience dementia. Some studies have reported that the average time from onset of Parkinson's disease to developing dementia is about 10 years. We expect to complete an ongoing Phase 2 exploratory study in the second half of 2017 and we expect data from this trial in the first quarter of 2018.

#### BTT1023

We own (through Biotie) worldwide rights to BTT1023 (timolumab), a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC. PSC is a rare, chronic disease that damages the bile ducts over time. Bile fluid is an essential aid to digestion that is made in the liver. In people with PSC, the bile ducts become blocked due to inflammation and scarring (fibrosis). This causes bile to accumulate in the liver, where it gradually damages liver cells and eventually results in liver failure. There are no approved drug therapies for PSC and liver transplant is the only treatment.

Although the mechanism of action is not fully elucidated, BTT1023 is a fully human monoclonal antibody that targets VAP-1 (vascular adhesion protein-1). Biotie conducted multiple preclinical and clinical studies suggesting VAP-1 may play a role in inflammatory and fibrotic diseases. Inflammatory diseases, such as rheumatoid arthritis, inflammatory bowel disease and psoriasis, are the result of the immune system mistakenly attacking the body's own cells and tissue. Fibrotic diseases, such as PSC and cirrhosis of the liver, are characterized by the formation of scar tissue that prevents normal function of the body's organs.

A Phase 2 proof-of-concept clinical trial is ongoing and is being funded through the Efficacy and Mechanism Evaluation (EME) Program, a Medical Research Council and National Institute for Health Research partnership in the United Kingdom. Interim data from this clinical trial are expected in the second half of 2017.

BTT1023 has been granted orphan drug designation for PSC by FDA and the European Medicines Agency (EMA). We are seeking to out-license this program.

#### 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 rHIgM22, a remyelinating antibody, as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions. In April 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also included several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. In April 2015, we presented additional safety data from this trial showing that rHIgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system.

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

#### Ampyra/Dalfampridine Development Programs

We have been studying the use of dalfampridine in patients who experience post-stroke walking difficulties, or PSWD, after experiencing an ischemic stroke. In 2016, we made the decision to stop enrollment in an ongoing Phase 3 clinical trial and conduct an unblinded analysis of the trial data. In November 2016, we announced we were discontinuing our PSWD program after reviewing the unblinded data and concluding that the results did not show sufficient efficacy to support further development. We have also been exploring a once-daily (QD) formulation of dalfampridine for use in our PSWD clinical program. A multi-dose pharmacokinetic study confirmed that we have developed a potentially viable QD formulation of dalfampridine.

#### Cimaglermin alfa/Neuregulins

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

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.

Cimaglermin alfa is our lead product candidate for our neuregulin program. 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. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting report of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting FDA Drug-Induced Liver Injury Guidance (FDA 2009) stopping rules was

also identified in the highest planned dose cohort, which resolved over two to three weeks. Further analyses of data from this trial found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In 2013, we commenced a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. 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. In 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting the FDA guidelines referenced above. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within two to three weeks, as was the case with the one case of hepatotoxicity reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial have completed the pre-planned one year of follow up. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to further define the nature of the bilirubin signal. We have met with the FDA to present analysis of the data from the cimaglermin studies, as well as data from non-clinical studies, as part of our request that the program be removed from clinical hold. We are seeking to out-license this program.

#### Chondroitinase Program

This program is focused on researching the potential use of chondroitinase as a treatment of injuries to the spinal cord and brain, as well as other neurotraumatic indications. Published research has demonstrated that a matrix of scar tissue that develops from injury to the central nervous system, or CNS, 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.

This 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 were assessing for the treatment of neuropathic pain. We acquired rights to NP-1998 from NeurogesX, Inc. in 2013 in connection with our purchase of Qutenza, an FDA-approved dermal patch containing 8% prescription strength capsaicin. We acquired development and commercialization rights in the U.S., Canada, Latin America and certain other territories. Grunenthal GmbH (as the assignee of Astellas Pharma Europe Ltd.) has an option to develop NP-1998 in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland certain countries in Eastern Europe, the Middle East and Africa.

We made certain upfront payments to acquire the Qutenza and NP-1998 assets from NeurogesX, and may also make up to \$5.0 million in payments contingent upon the achievement of certain regulatory and sales milestones related to

NP-1998. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, we have no current plans to invest in further development of NP-1998 for neuropathic pain.

#### Plumiaz

We had been developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy on stable regimens of antiepileptic drugs, or AEDs, who experience bouts of increased seizure activity, also known

as seizure clusters or acute repetitive seizures, or ARS. In 2013, we submitted a New Drug Application, or NDA, for Plumiaz to the FDA. Plumiaz was filed under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from a therapy previously approved by the FDA (DIASTAT® Rectal Gel) and providing pharmacokinetic data comparing the reference product to Plumiaz. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. In May 2015, we announced that we completed discussions with the FDA, and thereafter we continued to advance development of Plumiaz. Based on these discussions, we were conducting three clinical trials for Plumiaz. However, in May 2016 we announced that we were discontinuing the program because data from clinical trials did not demonstrate Plumiaz's bioequivalence to Diastat® rectal gel. Specifically, the data demonstrated unexpectedly lower nasal mucosa absorption of diazepam in persons with epilepsy compared to studies in healthy volunteers. Our Neuronex, Inc. subsidiary is a party to a license agreement with SK Biopharmaceuticals Co., Ltd. relating to Plumiaz.

### Sales, Marketing and Market Access

#### Ampyra

Since the March 2010 launch of Ampyra, approximately 120,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. Seven years after approval, Ampyra continues to grow, reflecting the continued unmet medical need among people with MS for a treatment to improve walking. As of December 31, 2016, 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 60-day free trial program. Our 60-day free trial program provides eligible patients with two months of Ampyra at no cost. During 2016, on average, approximately 80% of new Ampyra patients enrolled in 60-day free trial. The program is in its sixth year, and data show that 60-day free trial participants have higher compliance and persistency rates over time compared to patients not in the program. Approximately 50% of patients who initiate therapy with the 60-day free trial free trial program convert to paid prescriptions.

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 Market Access Account Directors who provide information and assistance to payers and physicians on Ampyra; National Trade Account Directors who work with our limited network of specialty pharmacies; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of our strategic initiatives.

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

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

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



lives. In addition to these efforts, we have implemented a comprehensive series of educational and promotional programs to support Ampyra.

Ampyra is distributed in the U.S. exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. The distribution process through specialty pharmacy providers is well established within the MS community, and physicians and patients are familiar with this model. This distribution process is intended to provide the best possible patient experience, improve patient adherence to the required drug regimen, including dosage, and assist in educating patients regarding the risks associated with Ampyra. The specialty pharmacy providers that deliver Ampyra by mail, and Kaiser Permanente, are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar days, and some have agreed to hold a minimum of 10 business days of inventory.

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial formulary. Approximately 75% of insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

#### Zanaflex

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

#### Qutenza

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

#### CVT-301

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

Material and Other Collaborations and License Agreements

Biogen (Fampyra)

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

18

---

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

Ampyra is marketed as Fampyra outside the U.S. by Biogen. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra available in additional markets in 2017.

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

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

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

The Collaboration Agreement will terminate upon the expiration of Biogen's royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of expiration of the last-to-expire patent covering a licensed product, fifteen years following first commercial sale of such licensed product, the expiration of regulatory exclusivity and the existence of certain levels of sales by competing products. The Collaboration Agreement and the Supply Agreement will automatically terminate upon the termination of our license agreement with Alkermes in its entirety or with respect to all countries outside of the U.S. We cannot

terminate our license agreement with Alkermes without Biogen's prior written consent under certain circumstances. Biogen may terminate the Collaboration Agreement in its entirety or on a country-by-country basis at any time upon 180 days' prior written notice, subject to our right to accelerate such termination. The Collaboration Agreement may also be terminated by either party if the other party fails to cure a material breach under the agreement, which termination will be limited to a particular country or region under certain circumstances. However, if Biogen has the right to terminate the Collaboration Agreement due to our material uncured breach, Biogen may instead elect to keep the agreement in effect, but decrease the royalty rates they pay us by a specified percentage. We may also terminate the Collaboration Agreement if Biogen does not commercially launch a licensed product within a specified time period after receiving regulatory approval for such licensed product or otherwise fails to meet certain commercialization obligations. In addition, we may terminate the Collaboration Agreement under certain circumstances if (i) Biogen, its affiliates or its sublicensees challenge certain of our patents or (ii) there is a change in control of Biogen or its parent company or certain dispositions of assets by Biogen, its parent or its affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen's territory of more than a specified percentage

within a certain period of time after such change in control or disposition. The Supply Agreement may be terminated by either party if the other party fails to cure a material breach under the Supply Agreement. In addition, the Supply Agreement will terminate automatically upon termination of the Collaboration Agreement, and the Collaboration Agreement will terminate automatically if the Supply Agreement is terminated for any reason other than for a material breach that we are responsible for. To the extent permitted by law, each party may terminate the Collaboration Agreement and the Supply Agreement if the other party is subject to bankruptcy proceedings.

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

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

In connection with the entry into the Collaboration Agreement, Biogen and Alkermes entered into a Consent Agreement with us. Under the Consent Agreement, Alkermes consented to our sublicense of rights to Biogen, and the three parties agreed to set up a committee to coordinate activities under our agreements with Alkermes with respect to the development, supply and commercialization of the licensed products for Biogen's territory. The Consent Agreement also amended our agreements with Alkermes by, among other things, permitting us to allow Biogen to grant sublicenses to certain unaffiliated distributors; permitting us to allow Biogen to package the licensed products and to work directly with Alkermes with respect to certain supply-related activities; and, requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

#### Alkermes (Ampyra)

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.

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

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

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

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

Subject to the early termination provisions, the Alkermes license terminates on a country-by-country basis 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.

#### 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.

We agreed to pay Rush a license fee, milestone payments of up to \$1.1 million and royalties based on net sales of the product for neurological indications. We have made or accrued an aggregate of \$1.1 million in milestone payments and \$48.1 million in royalties under this agreement through December 31, 2016. 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 patent 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.

#### Roche (Tozadenant and SYN120)

Our Biotie subsidiary is a party to an amended and restated license agreement with Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd. (the "Roche Entities"), pursuant to which Biotie obtained exclusive, royalty-bearing, worldwide licenses under the Roche Entities' patent rights and know-how to develop, manufacture and commercialize products incorporating specified Roche Entities compounds, including tozadenant and SYN120 (classified into tiered programs). Under the license agreement, tozadenant is a Tier 2 compound and SYN120 is a Tier 1 compound. Biotie's license with respect to products containing Tier 2 compounds, or Tier 2 products, extends to the field of any and all uses to treat or prevent human diseases and disorders. Biotie's license with respect to products containing Tier 1 compounds, or Tier 1 products, is limited to the field of any and all uses to treat or prevent central nervous system diseases and disorders. Under the terms of the Roche license agreement, following the completion of certain studies, the Roche Entities had the right to opt-in to obtain an exclusive right to develop and commercialize the Tier 1 products and terminate the license granted to Biotie with respect to such Tier 1 products. In June 2012, following Biotie's completion of the specified studies, the Roche Entities notified Biotie of their decision not to exercise their opt-in right for SYN120. Following the Roche Entities' decision not to exercise their opt-in right, Biotie retains its licensed global development and commercialization rights to SYN120 under the Roche license agreement.

Pursuant to the Roche license agreement, Biotie is obligated to make certain milestone payments to the Roche Entities on the achievement of specified regulatory and commercial milestones, totaling up to \$37 million for Tier 1 products, including SYN120 and \$29 million for Tier 2 products, including tozadenant. Biotie is also obligated to pay the Roche Entities tiered single-digit royalties, starting in the low single digits and increasing to the high single digits, on net sales of licensed products. Biotie's obligation to pay royalties to the Roche Entities will expire on a product-by-product and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the licensed Roche Entities patents, Biotie's patent rights or patent rights jointly owned with the Roche Entities that cover the composition, use or manufacture of the applicable product in such country or 10 years from the first commercial sale of such product in such country. Biotie is required to exercise commercially reasonable efforts to perform the activities set forth in an agreed upon development plan for SYN120 and must use commercially reasonable efforts to develop and commercialize, either directly or through affiliates or sublicensees, SYN120 and tozadenant in the U.S. and Europe and in such other markets as Biotie deems commercially reasonable.

The term of the Roche license agreement will expire on the date of the expiration of all payment obligations of both parties under the agreement. Upon expiration of the Roche license agreement, all licenses granted to each party that were in effect immediately prior to such expiration will be retained on a nonexclusive, fully paid, royalty-free basis. The Roche Entities may terminate the Roche license agreement either on a program-by-program basis for certain programs or in its entirety, for any reason or no reason upon 90 days' written notice. In the event of the Roche Entities' unilateral termination of the Roche license agreement without cause, all licenses and other rights granted by the Roche Entities to Biotie will remain in full force and effect in accordance with their respective terms. Biotie may also terminate the Roche license agreement either on a program-by-program basis for certain of the programs or in its entirety, for any reason or no reason upon 90 days' written notice. In the event of Biotie's unilateral termination without cause, all licenses granted to Biotie with respect to the compounds and products in the terminated program (or, in the case of termination of the entire agreement, all compounds and products) will terminate. Either party may terminate

the Roche license agreement for cause in the event of a breach by the other party of any material provision of the agreement if such breach has continued for 60 days after notice was provided (or a reasonably longer time if a party is diligently pursuing cure of a breach that was not susceptible of cure within the 60 day notice period). In the case of agreement disputes, specified officers must attempt resolution, and if no resolution is achieved, the matter may be referred to binding arbitration for final settlement as the exclusive forum for dispute resolution except for certain matters relating to patents and other intellectual property rights.

#### UCB Termination and Transition Agreement (Tozadenant)

Our Biotie subsidiary was previously a party to a collaboration agreement with UCB Biopharma S.P.R.L. relating to the development and commercialization of tozadenant. In 2014, Biotie and UCB entered into a termination and transition

agreement pursuant to which UCB's participation in tozadenant development and commercialization was terminated. Under the terms of the collaboration agreement, as terminated by the termination and transition agreement, Biotie received a nonexclusive, worldwide, perpetual, sublicensable, royalty-free license to any blocking patents controlled by UCB as of the date of termination of the collaboration agreement in 2014, that would be infringed by the further development or exploitation of tozadenant products, solely to the extent necessary to develop and commercialize tozadenant products in the form described in UCB's regulatory filings.

Pursuant to the UCB termination and transition agreement, UCB also granted to Biotie an undivided, one-half ownership interest in all know-how related to tozadenant jointly developed by Biotie and UCB under the UCB collaboration agreement, as well as a worldwide, royalty-free license under UCB's intellectual property rights in certain product data and regulatory documentation to use and reference the same for the purposes of exploiting tozadenant. UCB reserved the right to use such product data and regulatory documentation, subject to certain limitations. UCB provided Biotie with certain development funding under the UCB termination and transition agreement, and Biotie is obligated to repay such funding out of any future income Biotie receives from tozadenant. Biotie and UCB each agreed to release the other party from all claims arising out of the other party's development activities with respect to tozadenant prior to the date of the termination and transition agreement, as well as UCB's exploitation of tozadenant prior to that date. Biotie also agreed to indemnify UCB against any losses in connection with third-party claims arising from the continued exploitation of tozadenant by Biotie or its licensees.

#### Other License Agreements

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

- We have an exclusive, worldwide license from the Canadian Spinal Research Organization for specified patents and know-how relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.
- We have an exclusive, worldwide license from Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King's College London to specified patents and patent applications for products related to enzymatic methods, including chondroitinase, of treating central nervous system disorders. Under the same license, we also have non-exclusive rights to these patents and patent applications for products related to small molecule inhibitors for use in treating central nervous system disorders.
- We have an exclusive, worldwide license from the Mayo Foundation for Education and Research, or Mayo Clinic, to specified patents, patent applications, and other intellectual property on certain antibodies relating to our research on the therapeutic use of these antibodies, specifically myelination and remyelination in MS and spinal cord injury.
- We have an exclusive, worldwide sublicense from Paion AG (formerly CeNeS Pharmaceuticals plc) to certain patents, patent applications and know-how relating to cimaglermin alfa or fragments thereof and non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sublicense 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.
- Our Biotie subsidiary has an exclusive, worldwide license from Medarex, Inc. to certain patents and know-how relating to BTT1023.



Our Neuronex, Inc. subsidiary is a party to a license agreement with SK Biopharmaceuticals Co., Ltd., relating to Plumiaz, a proprietary nasal spray formulation of diazepam that we were developing as a treatment for certain epilepsy patients. In 2016 we announced that we were discontinuing our Plumiaz development program.

#### 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 and us, Alkermes consented to our sublicense of our rights under our agreements with Alkermes to Biogen. The three parties agreed to set up a committee to coordinate activities under these agreements with respect to the development, supply and commercialization of the licensed products for Biogen's territory. The Consent Agreement also amended our agreements with Alkermes by, among other things, permitting us to allow Biogen to grant sublicenses to certain unaffiliated distributors, permitting us to allow Biogen to package the licensed products and to work directly with Alkermes with respect to certain supply-related activities, and requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

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

##### Once-Daily (QD) Formulation of Dalfampridine

We have been exploring a once-daily (QD) formulation of dalfampridine for use in our post-stroke walking difficulties, or PSWD, clinical program. In November 2016, we announced we were discontinuing our PSWD program. As part of this development program, we conducted Phase 1 pharmacokinetic studies on prototypes and these studies confirmed we have a potentially viable QD formulation of dalfampridine.

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

##### CVT-301, CVT-427 and ARCUS Technology

Our 2014 acquisition of Civitas included its 90,000 square foot subleased manufacturing facility located in Chelsea, Massachusetts. The facility was built specifically for the commercial-scale manufacture of ARCUS products. Prior to Civitas's acquisition of this facility from Alkermes, the facility produced more than 36 million human doses of ARCUS-based products for use in clinical trials by Alkermes's collaborator in indications other than Parkinson's disease. Civitas subsequently took steps to recommission the facility, which has been certified by the EU regulatory authority (known as the Qualified Person, or QP, audit). Civitas produced current good manufacturing practices, or cGMP-quality human doses of CVT-301 for Phase 1, Phase 2 and Phase 3 clinical trials. As we are already at commercial scale, we believe that this will

support rapid commercialization should we receive marketing approval from the FDA. However, if we obtain approval from the FDA, we anticipate the need to expand our manufacturing operations at the Chelsea facility after product launch to meet demand depending on the timing and extent of sales growth. The ARCUS dry powder aerosol particles are generated by applying our proprietary and multi-step spray drying process to active pharmaceutical ingredient. The application of spray drying in the pharmaceutical industry is highly specialized, and the process of manufacturing ARCUS particles requires significant expertise in dry powder manufacture and handling and capsule filling.

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

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

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

#### Cimaglermin alfa

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

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

#### rHIgM22

We contracted with BioVest International, now Cell Culture Company, and CMC Biologics in 2009 for production and purification, respectively, of rHIgM22. All manufacturing was performed under cGMPs. Acorda and CMC Biologics developed analytical methods and characterization assays to support manufacturing and stability testing of the drug substance. A pilot lot of drug substance was tested in GLP studies for safety and toxicology.

The final drug product for rHIgM22 for clinical studies was produced at Althea Technologies, now Ajinomoto Althea, Inc., using material produced by CMC Biologics as described above. The manufacturing process for drug substance and drug product, along with initial stability data for both, was submitted to FDA as part of an IND application

originally filed in August 2012.

#### Other Products in Development

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

25

---



## Intellectual Property

We have patent portfolios relating to: Ampyra/aminopyridines; CVT-301, CVT-427 and the ARCUS drug delivery technology; tozadenant, SYN120, BTT1023; cimaglermin alfa/neuregulins; remyelinating antibodies/antibodies relating to nervous system disorders; chondroitinase; 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.

The intellectual property relating to our programs is owned or licensed either directly by Acorda or indirectly through subsidiaries, including for example subsidiaries we acquired in connection with our 2014 acquisition of Civitas Therapeutics, Inc. and our 2016 acquisition of Biotie Therapies Corp. Throughout this report, we may refer to any and all such intellectual property, and the corresponding research and development programs as, “our” or “Acorda’s” programs.

### Ampyra/aminopyridines

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

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

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who have submitted Abbreviated New Drug Applications with the FDA seeking marketing approval for generic versions of Amypra (dalfampridine) Extended Release Tablets, 10mg. 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 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016 and we are waiting for the Court’s decision. In February 2017, we announced that we had reached a settlement agreement with one of these four generic companies. Our Orange Book-listed patents for Ampyra are also subject to inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). These IPR petitions challenge four of the five Orange Book-listed patents. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange Book-listed patents that we rely on for Ampyra. These legal proceedings are described in

further detail in Part I, Item 3 of this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm

26

---

Arzneimittel GmbH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

#### CVT-301, CVT-427 and ARCUS Technology

The intellectual property portfolio that we acquired with Civitas has over 100 issued U.S. and foreign patents relating to CVT-301 and the ARCUS drug delivery technology. This includes over 15 issued U.S. patents relating to CVT-301 directed to compositions of the drug product, the inhaler, methods of delivery of L-dopa, and manufacturing processes. The latest of the issued patents expires in 2032. The CVT-427 program, which also utilizes the ARCUS drug delivery technology, has pending applications directed to formulations, which, if granted would expire in 2036 absent any patent term adjustment.

#### Tozadenant

The tozadenant patent portfolio includes both Roche and Biotie owned patent families. The portfolio exclusively licensed from Roche includes two granted U.S. patents set to expire in 2021 and 2025, with claims directed to compositions of matter. The U.S. Patent set to expire in 2025 has foreign counterparts including a granted European patent with claims directed to composition of matter and methods of use. This European patent is also set to expire in 2025. The Biotie owned patent family includes pending U.S. and European patent applications with claims directed to method of use which, if granted would expire in 2030 and 2031 respectively. The Biotie owned patent family also includes pending and granted counterparts in other countries.

#### SYN120

We have an exclusive license from Roche for patents and patent applications relating to SYN120. This includes four granted U.S. patents set to expire in 2025 and 2026. The license also includes foreign counterparts, including two granted European patents, set to expire in 2025. The claims are directed to compositions of matter and methods of use.

#### BTT1023

The BTT1023 portfolio includes two patent families. The first family is owned by Biotie and includes two granted U.S. patents set to expire in 2028 and foreign counterparts including a granted European patent set to expire in 2028. The claims are directed to composition of matter and methods of use. The second family is co-owned by Biotie with the University of Birmingham and includes pending U.S. and European patent applications which, if granted, would expire in 2030. This family also includes pending and granted counterparts in other countries. The claims of this family are directed to use of VAP-1 inhibitors for treatment of fibrotic conditions. The University of Birmingham has licensed their rights in this patent family back to Biotie.

#### 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 granted and pending U.S. and foreign patent applications directed to additional antibodies and their use. With regard to remyelinating

antibodies, the portfolio includes granted European patents as well as other granted foreign counterparts.

#### Cimaglermin alfa/Neuregulins

We are the exclusive licensee under a license agreement with Paion AG (formerly CeNeS Pharmaceuticals, plc), of its worldwide portfolio of patents, patent applications and IP rights related to products of neuregulin genes, including cimaglermin alfa. Collectively, these patents claim the use of particular neuregulins to treat various pathophysiological

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

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

#### Chondroitinase

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

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

#### 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. An application for patent term extension (“PTE”) for this patent was filed on December 18, 2009 under the Hatch-Waxman law that allows for a patent to be extended for up to five additional years to compensate for regulatory delays stemming from the FDA approval process. We believe there is the potential for the patent to be extended to June 2021. We are waiting the FDA's final determination of the regulatory review period followed by the final determination from the USPTO confirming the length of the patent term extension and issuance of a patent term extension certificate from the USPTO. The original expiration date for Patent No. 6,239,180 was November 6, 2016. As the PTE request is still under review, we filed a request for an interim extension of time for this patent with the USPTO. The USPTO granted the request and the term of the patent is now extended to November 6, 2017. Securing further interim extensions is possible as we await issuance of the patent term extension certificate from the USPTO.

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, “Biotie Therapies,” “Ampyra,” “Zanaflex,” “Zanaflex Capsules,” “Qutenza” and “ARCUS.” We also have trademark registrations for “Fampyra” “Kampyra” and pending trademark applications therefore, in numerous foreign jurisdictions. In addition, our trademark portfolio includes several trademark registrations and pending trademark applications for potential product names and for disease awareness activities.

## Competition

The market for developing and marketing pharmaceutical products is highly competitive. We are aware of many biotechnology and pharmaceutical companies that are engaged in development and/or marketing of therapeutics for a broad range of central nervous system conditions, including multiple sclerosis, or MS, Parkinson's disease, or PD, and migraine. Many of our competitors have substantially greater financial, research and development, human and other resources than we

28

---

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, Tysabri, Plegridy and Tecfidera from Biogen, Betaseron from Bayer AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Merck Serono, Gilenya and Extavia from Novartis AG, Aubagio and Lemtrada from Genzyme Corporation (a Sanofi company), Glatopa from Sandoz International GmbH (a Novartis AG company), Zinbryta from Biogen and AbbieVie, and Rituxan from F. Hoffman-La Roche 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. We are aware that Adamas Pharmaceuticals, Inc. is developing ADS-5102 (amantadine hydrochloride) in patients with MS who have walking impairment, which may compete with Ampyra. Catalyst Pharmaceuticals, Inc. is developing a 3,4-diaminopyridine product, licensed from Biomarin, that also may compete with Ampyra.

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

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

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

Ampyra could become subject to competition from generic drug manufacturers. Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who have submitted Abbreviated New Drug Applications with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. 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 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016 and we are waiting for the Court's decision. In February 2017, we announced that we had reached a settlement agreement with one of these four generic companies. Our Orange Book-listed patents for Ampyra are also subject to inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). These

IPR petitions challenge four of the five Orange Book-listed patents. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange Book-listed patents that we rely on for Ampyra. These legal proceedings are described in further detail in Part I, Item 3 of this report. We will need to devote significant resources to these legal proceedings, and if we are not successful our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of these legal proceedings.



#### CVT-301/Parkinson's Disease

If approved for the treatment of OFF periods (re-emergence of symptoms), CVT-301 would compete against on-demand therapies that aim to specifically address Parkinson's disease symptoms. Currently, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF periods. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Sunovion Pharmaceuticals Inc. is developing a sublingual, or under the tongue, formulation of apomorphine. This program is in Phase 3 clinical development and could potentially be commercially launched ahead of CVT-301.

The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and the amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. CVT-301 may face competition from therapies that can limit the occurrence of OFF periods. Approaches to achieve consistent levodopa plasma concentrations include new formulations of carbidopa/levodopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of levodopa. Impax Laboratories has received FDA approval for RYTARY, an extended-release formulation of oral carbidopa/levodopa, and extended release formulations of oral and patch carbidopa/levodopa are being developed by others including Impax Depomed Inc., Intec Pharma and NeuroDerm Ltd. Also, Abbvie Inc. has developed a continuous administration of a gel-containing levodopa through a tube that is surgically implanted into the intestine. This therapy, known as Duopa, has been approved by the FDA and is approved in the EU.

#### Tozadenant

There is no cure or disease modifying treatment currently available for Parkinson's disease. Available therapies fall into two categories, those that can limit the occurrence of OFF periods (re-emergence of symptoms) and other therapies for the on-demand treatment of OFF periods. If approved, tozadenant would be the first new class of drugs approved in the U.S. for improvement of motor symptoms in Parkinson's disease in over 20 years. Broadly, current therapies and those in development 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. We believe these therapies are complementary, since tozadenant is positioned as an adjunct to levodopa-based regimens. However, we cannot predict how the improvement in existing or development of new therapeutics for the treatment of Parkinson's disease might affect demand for an adjunctive therapy such as tozadenant.

If approved for the reduction of OFF time, Tozadenant would compete with other adjunctive therapies in late stage development. For example, Safinamide is being developed by Newron Pharmaceuticals S.p.a as add-on therapy to treat mid-late stage Parkinson's disease patients. We believe that Newron Pharmaceuticals could receive approval from the FDA for their NDA as early as March 2017. Also, Opicapone (BIA 9-1067) is a Parkinson's disease therapy developed by BIAL currently approved in Europe and in Phase 1 development in the U.S. for use as adjunctive therapy in levodopa treated Parkinson's disease patients. Istradefylline, another A2a antagonist therapy for Parkinson's disease, being developed by Kyowa Hakko Kirin, is approved in Japan, but future plans for this product in the U.S. market are unknown.

#### Zanaflex/Spasticity

Zanaflex Capsules and Zanaflex tablets contain tizanidine hydrochloride, one of the two leading active ingredients used for the management of spasticity, a symptom suffered by, among others, both MS and spinal cord injury patients. Tizanidine hydrochloride is approved by the FDA as a short-acting drug for the management of spasticity. There are currently a number of generic version of both Zanaflex tablets and Zanaflex Capsules on the market, including our own authorized generic version of Zanaflex Capsules that we launched in 2012. Our net revenue from Zanaflex

products, particularly Zanaflex Capsules, has declined significantly due to competition from generic versions, and we expect it will continue to decline in 2017 and beyond.

#### Qutenza/Post-Herpetic Neuralgia

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

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

## Government Regulation

### FDA Regulation of Drugs and Drug Product Approval

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

In the U.S., Ampyra, Zanaflex Capsules, Zanaflex tablets, Qutenza, and our product candidates are regulated by the FDA as drugs. Some of our product candidates are potentially regulated both as drugs, drug/medical device combinations and as biological products. Drugs, biologics, and medical devices primarily are regulated under the Federal Food, Drug, and Cosmetic Act, as amended, the Public Health Service Act, as amended, and the regulations of the FDA. These products 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 drug and biological 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 does not guarantee FDA approval even if the SPA is followed. For example a substantial scientific issue essential to determining the safety or effectiveness of the drug could be identified after the testing has begun. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses, or approval with restricted distribution or other burdensome post-approval requirements or limitations.

Federal and state law requires the submission of registry and results information for most clinical trials to a publicly available database at [www.clinicaltrials.gov](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., for most drugs and biologics, 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/or the clinical sponsor for compliance with Good Clinical Practice, or GCP. If the FDA determines that one or more of our clinical trials were not conducted in accordance with GCP, the agency may determine not to consider effectiveness data generated from such clinical trials in support of our applications for marketing approval.

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 are 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 in the U.S. by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including requirements relating to record-keeping, labeling, packaging, reporting of adverse experiences and other reporting, advertising and promotion, distribution, cGMPs, and import/export, as well as any other requirements imposed by the applicant's NDA or BLA. The FDA's rules for advertising and promotion require, among other things, that our promotion be truthful, fairly balanced and adequately substantiated, and that our labeling bears adequate directions for all intended uses of the product. 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

33

---



safety profile. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Foreign drug manufacturers must comply with similar local requirements and may be subject to inspections by the FDA or local regulatory agencies. We cannot be certain that we or our present or future suppliers will be able to comply with 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 on 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 laws and/or regulations may be enacted which could impose additional burdens or limitations on our ability to obtain approval of our product candidates or market our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in government scrutiny or new regulations that could harm our business. For example, recent significant price increases by certain drug manufacturers have received considerable scrutiny from U.S. Congress, in some cases forcing those companies to dramatically reduce those prices. 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 spinal cord injury. The number of people affected by MS now exceeds 200,000. However, this does not affect Ampyra's orphan drug designation in the United States, as it was granted prior to the increase in prevalence above 200,000.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, and reduced filing fees for marketing applications. If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity for that use. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. The FDA may approve a subsequent application from another sponsor if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior or demonstrates a major contribution to patient care, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves another 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" that has already been 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. It also must contain certifications with respect to all patents that are listed for the reference listed drug in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

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, the 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 hybrid applications that rely 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. ANDA applicants and 505(b)(2) applicants must certify to all patents listed in the Orange Book for the reference listed drug (i.e., the innovator NDA). An ANDA (or 505(b)(2) application) may be submitted to FDA after four years if it contains a certification of patent invalidity or non-infringement to one of those listed patents. 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, the 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 the FDA because full NDAs do not rely on a pioneer's data.

Special procedures apply when an ANDA contains one or more certifications stating that a listed patent is invalid or not infringed. This is known as a "Paragraph IV" certification. 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 Paragraph IV 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 length of the automatic stay depends on when the ANDA is filed. No company can file an ANDA on a reference listed drug that the 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 a Paragraph IV patent certification. If an ANDA containing a Paragraph IV certification is filed five or more years after FDA approval of the NCE, then the stay duration is 30 months. However, if an ANDA (with a Paragraph IV certification) 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.

35

---

If the stay is either lifted or expires and the FDA approves the ANDA, the generic manufacturer may decide to begin selling its product even if patent litigation is pending. However, if the generic manufacturer launches before patent litigation is resolved, the launch is at the risk of the generic manufacturer being later held liable for patent infringement damages.

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

While the question of substitutability is one of state law, most states look to the FDA to determine whether a generic is substitutable. The FDA lists therapeutic equivalence ratings in 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. Drug products that the FDA considers to be therapeutically equivalent to other drug products receive one of various types of “A” ratings. For example, solid oral dosage form drug products that are considered therapeutically equivalent are generally rated “AB” in the Orange Book, while therapeutically equivalent solutions and powders for aerosolization generally receive an “AB” or an “AN” rating depending on how bioequivalence was demonstrated.

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 branded 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.

The process described above is not applicable to drugs where the pioneer product was approved pursuant to a BLA, rather than an NDA. A separate process exists for follow-on versions of such products and is discussed in the section entitled “Biosimilars,” below.

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

The FDA regulates, among other things, the development, testing, manufacturing, labeling, safety, effectiveness, storage, record keeping, marketing, import, export, 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 post market surveillance, and specific FDA guidance. Most Class III medical devices are assessed individually through an extensive Premarket Review application, or PMA. As a result, although they are subject to General Controls, they generally are not subject to Special Controls. Instead,

most Class III devices have additional requirements and conditions of use imposed on them through the individualized PMA review and approval process.

Although we do not manufacture or market stand-alone medical devices, some of our product candidates rely on device components to deliver drug product to patients. In general, the FDA regulates such products as “combination products.” The FDA assigns combination products for review by the drug or device center based on a determination of the product’s “primary mode of action.” If the FDA determines that the product achieves its therapeutic effect through drug component, it will be assigned to the Center for Drugs (CDER) or the Center for Biologics (CBER) for review and approval.

By contrast, if the FDA determines that the device component is the primary mode of action, then the product will be reviewed and approved by the center for devices (CDRH). We anticipate that to the extent that any of our pipeline products are regulated as combination products, the FDA likely will find that the primary mode of action is through the drug component, and therefore the product will be reviewed by CDER. In that case, however, CDER/CBER will consult with CDRH on the drug component and we will still have to comply with certain requirements applicable to medical devices.

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

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

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

### Biosimilars

The Affordable Care Act amended the Public Health Service Act to authorize the FDA to approve “biosimilars” (follow-on versions of pioneer products approved pursuant to a BLA) via a separate, abbreviated pathway. Under this abbreviated pathway, the biosimilar applicant must demonstrate that its product is “highly similar” to the “reference product,” and that there are no “clinically meaningful differences” between the biosimilar and the reference product. Unlike ANDAs, biosimilars are not, in general, automatically substitutable for the reference product at the pharmacy. Instead, the FDA must make a separate finding of “interchangeability.” To date, the trend in state law has been to permit or require substitution only of those biosimilars that have also been deemed by the FDA to be interchangeable.

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



## Other Regulations

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products, as well as medical devices, are potentially subject to regulation and oversight by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, the Drug Enforcement Administration (DEA), and state and local governments. For example, controlled substances that are scheduled by the DEA are subject to additional regulatory requirements including, among other things, special security and handling requirements, and potential restrictions on distribution, sales, marketing. For example, sales, marketing, scientific/educational grant programs and other Acorda interactions with healthcare professionals, must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, and may be affected by the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and/or the Veterans Health Care Act of 1992, as amended. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services on behalf of the states and must regularly submit certain pricing information to CMS. Under the Veterans Health Care Act, or VHCA, we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Administration and the Department of Defense, or DOD, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal health care programs including Medicare and Medicaid. In addition, under legislative changes made in 2009, discounted prices must also be offered for certain DOD purchases for its TRICARE retail pharmacy program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic disclosures on sales, marketing, pricing, and other activities, and/or register their sales representatives, 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 (ACA), pharmaceutical manufacturers are subject to federal reporting requirements with regard to payments or other transfers of value made to physicians and teaching hospitals. Reports submitted under these requirements are 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, our collaborator for Ampyra, would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls, by law, and to drug reimbursement programs with varying price control mechanisms.

In the U.S., there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the U.S., federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public healthcare

programs such as Medicaid. Various states have adopted further mechanisms under Medicaid and other programs that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Recent heightened scrutiny of the prices of several drug products have led to numerous other proposals, at both the federal and state level, to address perceived issues related to drug pricing.

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.

The new Administration and the majority party in both Houses of the U.S. Congress have indicated their desire to repeal the ACA. It is unclear whether, when and how that repeal will be effectuated and what the effect on the healthcare sector will be. 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. In the EU, for example, there is extensive regulation of pharmaceutical pricing and reimbursement through health 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 based on the results of health economic assessments. Others control the price of pharmaceutical products through reference pricing approaches where the reimbursement price is determined by the price in other jurisdictions. 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 20, 2017, we had 597 employees. Of the 597 employees, 147 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 450 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 2017 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2017 Proxy Statement within 120 days after the end of our 2016 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 2017 Proxy Statement.

### Item 1A. Risk Factors.

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

#### Risks related to our business

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

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

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

As of December 31, 2016, we had an accumulated deficit of approximately \$244.0 million. We had a net loss of \$34.6 million for the year ended December 31, 2016. We had net income of \$11.1 million for the year ended December 31, 2015, and \$17.7 million for the year ended December 31, 2014. We may not achieve or 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:

- Successfully defending our intellectual property relating to Ampyra; maintaining our sales levels for Ampyra in the U.S.; and supporting Biogen's efforts to successfully obtain and maintain regulatory approval for Fampyra (as Fampridine Prolonged Release tablets) in the EU and other markets outside the U.S.;
- successfully advancing our late-stage programs, including: our Phase 3 program to develop CVT-301, a self-

40

---

administered, inhaled formulation of levodopa using our proprietary ARCUS drug delivery technology, for the treatment of OFF periods in people with Parkinson's disease; and our Phase 3 program to develop tozadenant, an oral adenosine A2a receptor antagonist, as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time;

• continuing to advance and/or out-license our earlier-stage clinical development programs; 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 2017 we expect to invest a significant amount to support our CVT-301 and tozadenant clinical trial programs.

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

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

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

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

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

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

• the occurrence of any side effects, adverse reactions, customer complaints or misuse (or any unfavorable publicity relating thereto) stemming from the use of Ampyra or our other products or identified in ongoing or future studies of dalfampridine;

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

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

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

Ampyra is marketed as Fampyra outside the U.S. by Biogen pursuant to a conditional approval obtained from the European Commission in 2011. The conditional approval must be reassessed and renewed annually, and pursuant to

the requirements of the conditional approval Biogen may be required to carry out additional studies on the long-term effectiveness and safety of Fampyra. A failure to conduct these additional studies, or adverse results from them, could jeopardize Biogen's ability to maintain the European Commission approval for Fampyra. Also, regardless of the status of the



European Commission approval for Fampyra, market acceptance of Ampyra in the U.S. and elsewhere could be harmed if additional studies fail to show efficacy or are inconclusive on efficacy of Fampyra. Also, market acceptance of Ampyra in the U.S. could be harmed if additional studies demonstrate safety concerns that are inconsistent with our clinical trial results and post-marketing experience in the U.S. Such adverse safety results from additional studies could also potentially affect continued FDA approval of Ampyra. If additional studies produce safety findings that are inconsistent with the trial results we previously submitted to the FDA, we would be obligated to report those findings to the FDA. In 2016, Biogen completed its ENHANCE clinical trial, required under the conditional approval. The results of this study are under review by the EMA, and the safety data has been submitted to the FDA.

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

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

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

In general, under the Internal Revenue Code of 1986, as amended, a corporation is subject to limitations on its ability to utilize net operating losses, or NOLs, to offset future taxable income. As of December 31, 2016, we had approximately \$253 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. 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 U.S. and Puerto Rico, as well as certain European countries where we have subsidiaries and/or subsidiary operations. Significant judgment is required in determining our tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service,

or other taxing authority, disagrees with the positions taken by us, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. In addition, the U.S. government may adopt tax reform measures that significantly increase our worldwide tax liabilities, which could materially harm our business, financial condition and results of operations.

We operate in the highly-regulated pharmaceutical industry.

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

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

The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Any regulatory approvals may be for fewer or narrower indications than we request, may include distribution restrictions, or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow a special risk evaluation and mitigation strategy, or REMS, to monitor and manage potential safety issues, all of which may eliminate or reduce the drug's market potential. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Some of our investigational products may be regulated as combination products, which will require that we satisfy FDA that both the drug and device component of our products satisfy FDA requirements. Failure to satisfy the FDA's requirements for either the drug or device component of such combination products could delay approval of our products or result in such products not receiving FDA approval.

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

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

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

• suspension of review or refusal to approve pending applications.

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, controlled substances

and we may be subject to other local, state, federal and foreign regulations. We cannot predict the impact of those regulations on us, although they could impose significant restrictions on our business and we may have to incur additional expenses to comply with them.

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

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

We cannot be certain that we can reach agreement with (or renew existing agreements with) needed third party manufacturers or suppliers on reasonable terms, if at all. Manufacturers or suppliers may choose not to conduct business with us at all, for example if they determine that our particular business requirements would be unprofitable or otherwise not appropriate for their business. Even if we have agreements with third parties, they may not perform their obligations to us and/or they may be unable or unwilling to establish or increase production capacity commensurate with our needs. Also, third party manufacturers and suppliers are subject to their own operational and financial risks that are outside of our control, including macro-economic conditions that may cause them to suffer liquidity or operational problems and that could interfere with their business operations.

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

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

inspections by foreign regulatory authorities. Failure to pass such inspections by foreign regulatory authorities could impede our ability to manufacture product needed for clinical trials or impede our ability to secure product approvals.

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

manufacture our products or product candidates or the API or other components of such products or product candidates may be unique or proprietary to the original manufacturer or supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a backup or alternative supplier, or we may be unable to transfer such skills at all.

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

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

We similarly rely on Alkermes and other third parties for the manufacture of our Zanaflex and authorized tizanidine hydrochloride generic products and the supply of tizanidine hydrochloride, Qutenza, and the API in those products. Also, we intend to rely on third-party manufacturers to make the inhaler and to supply the API in CVT-301, and any failure by a third-party manufacturer or supplier may delay or impair our ability to complete clinical trials or commercialize CVT-301. We have manufactured the capsules containing formulized levodopa, or L-dopa, for our preclinical studies, Phase 1 clinical trials, Phase 2 clinical trials, and Phase 3 clinical trials of CVT-301 in our own manufacturing facility. 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.

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

We currently manufacture all clinical supply of CVT-301 at our Chelsea, Massachusetts manufacturing facility that we occupy under a lease that expires in December 2025, which we may extend for up to ten years. We intend to manufacture all commercial supplies of CVT-301, if approved for commercial sale, as well as supplies of all additional ARCUS inhaled therapeutic candidates that we may develop, in this manufacturing facility. However, our Chelsea manufacturing facility has not been inspected by the FDA. Prior to commercialization of CVT-301, the FDA

will likely conduct a pre-approval inspection. If, during this inspection, the FDA determines that the systems or facility do not meet FDA current good manufacturing practices, or cGMP, requirements, the FDA may not grant marketing approval for our product. If we obtain approval from the FDA for CVT-301, we anticipate the need to expand our manufacturing operations at the Chelsea facility after product launch to meet demand depending on the timing and extent of sales growth.

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.

We may incur significant liability if we fail to comply with stringent FDA marketing and promotion regulations.

Our advertising and promotion activities are subject to stringent FDA rules and oversight. Among other requirements, our advertising and promotional materials must not be false or misleading in any particular respect, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of our products. We must submit all promotional materials to the FDA by 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 may be required to provide corrective information. Should we fail to comply with these requirements, we may be subject to significant liability including civil and administrative remedies as well as criminal sanctions.

For example, in June 2012, we received an untitled letter from the FDA stating that one of our Ampyra promotional videos was misleading because it overstated the efficacy of, and minimized important risk information associated with, Ampyra. In July 2013, we received a warning letter from the FDA stating that one of our consumer print advertisements 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 a written response to the warning letter we committed to take appropriate corrective action. In June 2014, FDA sent us a close-out letter to the July 2013 warning letter, stating that FDA considers the matter closed.

Each of our products is approved with specific indications and other conditions of use that inform our ability to promote our products. For example, Ampyra is indicated “to improve walking in patients with multiple sclerosis (MS). 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 reactions, 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 or other products 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.

We face significant risks if we promote our drugs “off-label,” i.e., for uses other than those that the FDA has approved for our products. 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, it traditionally has prohibited companies from promoting their drugs for off-label uses. Several recent federal court cases, based on First Amendment principles, have called into question the FDA’s ability to enforce against companies solely on the basis of truthful and non-misleading off-label promotion of their drugs. It is unclear, however, how the courts ultimately will resolve this issue or how the FDA’s policies may (or may not) change in light of developing case law. Furthermore, off-label promotion of our products could violate advertising and promotion requirements such as the prohibition against false or misleading advertising and/or labeling, or the requirement that approved labeling bear “adequate directions” for all of the product’s “intended uses.” Accordingly, we potentially face significant risk of enforcement should we promote Ampyra or any of our other products in the U.S. for any uses that are not consistent with the products’ approved labeling. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations regulating promotion of approved drugs as well as the promotion of products for which marketing approval has not been obtained. A company that is found to have violated these requirements may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the above-described regulatory restrictions, 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 and investigational products are in compliance with advertising and promotional regulations, the FDA or another regulatory or enforcement authority may disagree.

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 and an October 2016 label change adding vomiting as a side effect of Ampyra.

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, regulatory authorities, third party payers or patients may perceive or conclude that the risks associated with use of Ampyra outweigh the benefits, which could cause FDA to seek to withdraw Ampyra's regulatory approvals or impact the availability of adequate reimbursement by third-party payers;
- we may be required to reformulate the product, conduct additional preclinical or clinical studies, or make changes in labeling or changes to or reapprovals of manufacturing facilities;
- the FDA may impose a new risk evaluation and mitigation strategy, or REMS, on Ampyra or otherwise restrict its distribution and use;
- our reputation in the marketplace may suffer; and
- government investigations and lawsuits, including class action suits, may be brought against us.

The above occurrences could impair our business by harming or possibly preventing sales of Ampyra, causing sales to fall below projections, and increasing our expenses. We face similar risks with respect to our other marketed products.

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

Under FDA regulations, we are required to monitor the safety of Ampyra and inform healthcare professionals about the risks of drug-associated seizures with Ampyra. We are required to document and investigate reports of adverse events, and to report them to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in FDA withdrawal of marketing authorization or other regulatory action, civil actions against us, or criminal penalties, any of which could harm our business. Since 2010, we have submitted some late reports, including instances where specialty pharmacies that dispense Ampyra or a marketing partner have failed to timely report to us some of the reports of adverse events that they received. We reported these adverse events to the FDA immediately upon receipt. However, because these adverse events were not reported to us in a timely manner, they were considered late reports to the FDA. Also, FDA inspections have identified issues with our adverse event reporting which have led to Form 483s and a warning letter, which are further described below. If the specialty pharmacies that we rely upon to sell Ampyra in the

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

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

If we receive a notice of inspectional observations or deficiencies on FDA Form 483, or inspectional observations from foreign regulatory authorities, we may be required to undertake corrective and preventive actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses. Failure to adequately address the FDA's, or foreign regulatory agency's, concerns could expose us to enforcement and administrative actions.

For example, between 2010 and 2014, FDA conducted a number of inspections focusing on our pharmacovigilance program. These inspections resulted in a series of FDA Form 483s with observations relating to timeliness of adverse event reporting and other aspects of our quality program. We also received a written warning letter, based on the inspections, and citing Acorda for violations of its pharmacovigilance obligations. We provided FDA with formal written responses to each 483 as well as the warning letter. These responses advised FDA of corrective actions we were taking to address all of the issues raised by the inspectional observations and the warning letter. These corrective actions have all been completed. In February 2016, the FDA conducted what it classified as a biennial routine inspection. The inspection focused on pharmacovigilance reporting and product complaint handling, and resulted in one FDA Form 483 observation related to Ampyra "lack of effect" complaint trends analysis. 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 has not yet issued a "close-out" letter to the 2012 warning letter. Although it does not always do so, the FDA may issue a close-out letter when it determines that a company has completed corrective actions that adequately address all of the issues raised by the warning letter. Therefore, 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 administrative, civil, or criminal penalties. 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. In some cases, our third-party suppliers' drug manufacturing sites may also be subject to inspection by foreign regulatory authorities. We face similar risks to our business if those third-party manufacturers are unable to comply with foreign regulatory requirements. We and our third-party suppliers are generally required to maintain compliance with cGMPs and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In addition, the FDA must approve certain changes to our suppliers or manufacturing methods. If we or our third-party suppliers cannot demonstrate ongoing cGMP compliance, we may be required to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of our third-party suppliers, to pass regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties, shut-down of manufacturing facilities, or other civil or criminal sanctions. Non-compliance could increase our costs, cause us to lose revenue, and damage our reputation.

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

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

We are dependent on our collaboration with Biogen to commercialize Ampyra outside of the U.S. (known as Fampyra outside the U.S.)

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

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates or to their marketing and distribution;
- collaborators may not be successful in their efforts to obtain regulatory approvals or adequate product reimbursement in a timely manner, or at all, as discussed in further detail below in these risk factors;
- 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.

49

---



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

Our collaborator, Biogen, will need to obtain and maintain regulatory approval in foreign jurisdictions where it seeks to market or is currently marketing Fampyra.

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

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

A conditional approval must be reassessed and renewed annually, and there can be no assurance that Biogen will be able to satisfy the requirements for maintaining the approval. As part of its conditional approval, Biogen may be required to carry out additional studies on the long-term effectiveness and safety of Fampyra. The requirements to conduct supplemental trials add to the cost and risks of development and approval, and a failure to conduct these additional studies or adverse results from them, could jeopardize Biogen's ability to maintain the European Commission approval for Fampyra. These studies appear to support the safety and effectiveness of the drug as described in the current label and have been submitted to the European Commission for final approval. These additional or supplemental trials with respect to Fampyra or other product candidates could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA. Adverse safety results from additional studies could potentially affect continued FDA approval of Fampyra. In 2016, Biogen completed its ENHANCE clinical trial, required under the conditional approval. The results of this study are under review by the EMA, and the safety data has been submitted 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,

including a once-daily (QD) formulation of dalfampridine. 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.

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 both by the FDA and similar foreign regulatory authorities;
- difficulties in obtaining sufficient quantities of our product candidates, or where applicable comparator product or other ancillary materials needed, manufactured under cGMP;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board (or ethics committee), or a data safety monitoring board, or clinical holds placed upon the trials by the FDA or similar foreign regulatory authorities;
- approval by FDA and/or foreign regulatory authorities of new drugs that are more effective than our product candidates;
- change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and
- change in our financial position.

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

Clinical trials are subject to oversight by institutional review boards (or similar ethics committees), data safety monitoring boards, the FDA, and similar foreign regulatory authorities to ensure compliance with good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any of those standards are not complied with in a clinical trial, the resulting data from the clinical trial may not be usable or we, an institutional review board, the FDA, or a similar foreign regulatory authority may suspend or terminate a trial, which would severely delay our development and possibly end the development of the product candidate.

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

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

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 regulations promulgated pursuant to the Health Insurance Portability and Accountability Act, as amended and similar state laws. Because of the breadth of these laws and the narrowness of safe harbors under these laws, it is possible that some of our business activities could be subject to challenge under one or more of these laws. All of these activities are also subject to federal and state consumer protection and unfair competition laws.

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim

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

Sanctions under these federal and state laws may include requirements to make payments to government-funded health plans to correct for insufficient rebates paid by us or overpayments made to us, civil monetary penalties, exclusion of

our products from reimbursement under government programs, criminal fines and imprisonment. We may also be subject to a corporate integrity agreement, deferred prosecution agreement, or similar arrangement.

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 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 Affordable Care Act, enacted in 2010, substantially changed 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 have affected existing government healthcare programs. Changes to the Affordable Care Act, or other federal legislation regarding healthcare access, financing, or delivery and other actions taken by individual states concerning the possible expansion of Medicaid could impact our financial position or results of operations.

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

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

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

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

The new U.S. Presidential administration and the majority party in both Houses of the U.S. Congress have indicated their desire to repeal the Affordable Care Act. It is unclear whether, when and how that repeal will be effectuated and



what the effect on the healthcare sector will be. In addition to the potential repeal of the Affordable Care Act, there are indications that the Medicaid program may be restructured, which could lead to revisions in Medicaid coverage for prescription drugs. The outlook for the healthcare sector is unclear, and we are unable to predict the future course of federal or state healthcare legislation and regulations. 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 and rebates to a greater number of third-party payers to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable. 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 implement utilization management techniques, such as prior authorization or quantity limits for Ampyra, 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 utilization management, 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. In addition, the Affordable Care Act contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. The Affordable Care Act requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.” Legislative or regulatory revisions to the Medicare Part D outpatient prescription drug benefit, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and harm our results of operations.

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

The commercial success in the EU of products approved there, including Fampyra, primarily depends on obtaining and maintaining government reimbursement because, in many European countries, patients may not have access to prescription drugs that are not reimbursed by their governments. In addition, participation in pricing and

reimbursement procedures and 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 collaborators, such as Biogen, to sell our products on a profitable basis. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of products by us or our collaborators, such as Biogen, and exert commercial pressure on pricing within a country.

In response to the downturn in global economic conditions in recent years, governments in a number of international markets have announced or implemented measures aimed at reducing healthcare costs to constrain the overall level of government expenditures. This includes Germany and other countries in the EU, where Biogen has obtained regulatory approval for Fampyra. The measures vary by country and include, among other things, mandatory rebates and discounts,

reimbursement limitations and reference pricing, price reductions and suspensions on pricing increases on pharmaceuticals. These measures may negatively impact net revenue from Biogen's sales of Fampyra and therefore the amount of the royalty we receive from Biogen. Furthermore, the adverse financial impact of these measures in any particular country, in addition to related reimbursement or regulatory constraints, could prevent the commercial launch or continued commercialization of Fampyra in that country.

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological conditions, including Parkinson's disease, or PD, migraine and multiple sclerosis, or MS.

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

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

Ampyra. We are aware that Adamas Pharmaceuticals, Inc. is developing ADS-5102 (amantadine hydrochloride) for patients with MS who have walking impairment, which may compete with Ampyra. Catalyst Pharmaceuticals, Inc. is developing a 3,4-diaminopyridine product, licensed from Biomarin, that also may compete with Ampyra. Also, several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates. In addition, in certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available.

CVT-301. If approved for the treatment of OFF periods, (re-emergence of symptoms) CVT-301 would compete against on-demand therapies that aim to specifically address Parkinson's disease symptoms. Currently, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF periods. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Sunovion Pharmaceuticals Inc. is developing a sublingual, or under the tongue, formulation of apomorphine. This program is in Phase 3 clinical development and could potentially be commercially launched ahead of CVT-301.

The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and the amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. CVT-301 may face competition from therapies that can limit the occurrence of OFF periods. Approaches to achieve consistent levodopa

plasma concentrations include new formulations of carbidopa/levodopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of levodopa. Impax Laboratories has received FDA approval for RYTARY, an extended-release formulation of oral carbidopa/levodopa, and extended release formulations of oral and patch carbidopa/levodopa are being developed by others including Impax Depomed Inc., Intec Pharma and NeuroDerm Ltd. Also, Abbvie Inc. has developed a continuous administration of a gel-containing levodopa through a tube that is surgically implanted into the intestine. This therapy, known as Duopa, has been approved by the FDA and is approved in the EU.

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 drug delivery 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.

Tozadenant. There is no cure or disease modifying treatment currently available for Parkinson's disease. Available therapies fall into two categories, those that can limit the occurrence of OFF periods (re-emergence of symptoms) and other therapies for the on-demand treatment of OFF periods. If approved, tozadenant would be the first new class of drugs approved in the U.S. for improvement of motor symptoms in Parkinson's disease in over 20 years. Broadly, current therapies and those in development 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. We believe these therapies are complementary, since tozadenant is positioned as an adjunct to levodopa-based regimens. However, we cannot predict how the improvement in existing or development of new therapeutics for the treatment of Parkinson's disease might affect demand for an adjunctive therapy such as tozadenant.

If approved for the reduction of OFF time, tozadenant would compete with other adjunctive therapies in late stage development. For example, Safinamide is being developed by Newron Pharmaceuticals S.p.a as add-on therapy to treat mid-late stage Parkinson's disease patients. We believe that Newron Pharmaceuticals could receive approval from the FDA for their NDA as early as March 2017. Also, Opicapone (BIA 9-1067) is a Parkinson's disease therapy developed by BIAL currently approved in Europe and in Phase 1 development in the U.S. for use as adjunctive therapy in levodopa treated Parkinson's disease patients. Istradefylline, another A2a therapy for Parkinson's disease, being developed by Kyowa Hakko Kirin, is approved in Japan, but future plans for this product in the U.S. market are unknown.

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

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

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence or assumption of debt and contingent liabilities, some of which may not be disclosed to us and may be difficult or impossible for us to identify at the time of acquisition;
- exposure to business risks or issues, or legal or regulatory compliance issues, such as with the FDA, associated with the acquired or in-licensed company, business or product candidate, which may not be disclosed to us and may be difficult or impossible for us to identify at the time of acquisition or licensing;
- difficulties in assimilating the personnel and/or operations of the acquired companies;
- diversion of our management's attention away from other business concerns;
- commencement of business in markets where we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed products or product candidates, for example by underestimating the investment required to advance research and development programs, or 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

57

---

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 to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment, which is included in the NDA approval for Zanaflex Capsules, was to be satisfied by February 2007. We provided retrospective pediatric safety data to the FDA in April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline due to delays in investigator recruitment and obtaining Institutional Review Board approvals. The study was completed and the final report submitted to the FDA in April 2008. The FDA reviewed our report against new standards set out in the Pediatric Research Equity Act (PREA) and reauthorized by both the 2007 FDA Amendments Act (FDAAA) and the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) and concluded that the report did not satisfy the commitment. The FDA has informed us that a series of studies designed to further characterize the pharmacokinetics and demonstrate the efficacy and long-term safety of Zanaflex Capsules in children are required to fulfill the pediatric commitment for Zanaflex Capsules. In June 2011, the FDA informally advised us that it would be amending the pediatric commitment for Zanaflex Capsules to require a non-clinical juvenile toxicology study, as well as formalize the timeline for the required pediatric studies. In December 2012, the FDA issued a formal written request that confirmed the information in its informal June 2011 request, and set forth specific deadlines for the required pediatric non-clinical and clinical studies. In January 2013, we submitted a request in writing to the FDA to extend the deadlines for these studies, and in September 2014 we received a "Denial of Deferral Request" letter from the FDA. We responded to this denial letter in October 2014, requesting the FDA to reconsider the denial, which the FDA again denied in March 2015. Subsequently in March 2015, we received a notice of non-compliance with PREA. In May 2016, the FDA denied our request for a full waiver of pediatric studies, and subsequently published a letter of non-compliance and our response to the FDA's letter of non-compliance under 505B99(d)(1) of the Federal Food, Drug and Cosmetic Act. While our request for full waiver of the pediatric studies was denied, in their May 2016 letter the FDA requested that we use existing data from previously completed studies to employ a modeling and simulation



approach to characterize the pharmacokinetics of tizanidine in pediatric subjects to select a dose for future study, and further the letter requested that these modeling and simulations be submitted to the FDA. We have initiated the modeling and simulation that were requested by the FDA and we continue to evaluate the letter of non-compliance and the additional actions we may take in response to the letter. Additionally, and separate from the pediatric commitment, the FDA asked for, and we have completed, a clinical electrocardiogram study in adult humans to investigate potential QT prolongation (heart rhythm measure). This post-marketing commitment has been fulfilled. The remaining studies could be more extensive and more costly than our prior studies and might result in new data that are not consistent with the current safety and efficacy profile of the drug, which might require us to change our product labeling and could harm product sales. We also may be subject to penalties for not meeting our pediatric study commitments, including a court-imposed injunction to conduct studies.

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

Many states have enacted laws governing the licensure of companies that manufacture and/or distribute prescription drugs, although the scope of these laws varies, particularly where out-of-state distributors are concerned. We have obtained licenses in all of the jurisdictions in which we believe we are required to be licensed. However, there can be no assurance that one or more of these states will not take action under these licensure laws.

Several states have also enacted legislation regarding promotional and other activities conducted by pharmaceutical companies. The specifics of these laws vary, but in general they require companies to establish marketing compliance programs; disclose various sales and marketing expenses and pricing information; refrain from providing certain gifts or other payments to healthcare providers; and/or ensure that their sales representatives in that state are licensed. Some states, including California, Connecticut, Massachusetts, Minnesota, and Vermont, 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, 2016, we had approximately \$158.5 million in cash and cash equivalents. 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. 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. Also, we operate a

manufacturing facility, which is subject to further environmental, health and safety laws and regulations, including those laws and regulations which govern the exposure of persons to hazardous substances, the emission of pollutants into the air, the discharge of pollutants into bodies of water, and the general health, safety and welfare of employees and members of the public. We may incur substantial costs in order to comply with current or future such laws and regulations, which may also impair our research, development and/or manufacturing efforts.

In connection with our R&D and manufacturing activities, we cannot completely avoid the risk of contamination or injury, and in such cases of contamination or injury, or in cases of failure to comply with environmental, health and safety laws and regulations, we could be held liable, and in some cases strictly liable, for any resulting damages. Moreover, the existence, investigation and/or remediation of contamination at properties currently or formerly owned, leased or operated by

us may result in costs, fines or other penalties. Furthermore, our third-party manufacturers are subject to the same or similar environmental, health and safety laws and regulations as those to which we are subject. It is possible that if our third-party manufacturers fail to operate in compliance with the applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages and/or experience a disruption in the manufacture and supply of our product candidates or products. Any such liability may result in substantial civil or criminal fines, penalties or other sanctions, which could exceed our assets and resources, as well as reputational harm.

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

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

#### Risks related to our intellectual property

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

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

We have patent portfolios relating to Ampyra/aminopyridines, CVT-301, CVT-427 and our ARCUS drug delivery technology, tozadenant, SYN120, BTT1023, cimaglermin alfa/neuregulins, remyelinating antibodies/antibodies relating to nervous system disorders, chondroitinase, 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 drug delivery 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, ten generic drug manufacturers have filed Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra with the FDA. Since 2015, we have reached settlement agreements with seven of the generic companies. In filing these ANDAs for Ampyra, the generic drug manufacturers have challenged all of the Orange Book-listed patents that protect the Ampyra franchise. As such, to protect our intellectual property rights we have initiated legal proceedings asserting the challenged Orange Book-listed patents against these generic drug manufacturers. As further described under Legal Proceedings in Part I, Item 3 of this report, there is currently a statutory stay which restricts the FDA from approving any remaining ANDAs, from the parties that have not settled with Acorda, until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date. If the stay is either lifted or expires, as described, and the generic drug manufacturers otherwise meet the FDA's requirements for the approval of ANDAs, the generic manufacturers may decide to begin selling a generic version of Ampyra even if our

lawsuits against these manufacturers are still pending and despite the fact that if we later win these lawsuits the generic manufacturers could be held liable for patent infringement damages. A bench trial against four generic companies was conducted in September 2016 (we have since reached a settlement agreement with one of those four companies) and we are currently awaiting the Court's decision. Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invents Act, specifically inter partes review and/or post grant review before the U.S. Patent and Trademark Office. For example, in February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging two of the five Ampyra Orange Book-listed patents. Although the U.S. Patent and Trademark Office Patent Trials and Appeals Board chose not to institute inter partes review of these patents, the hedge fund has filed motions for reconsideration requesting that the denial to institute these two IPRs be reversed. In addition, in September 2015 the same hedge fund filed four additional IPR petitions challenging four of the five listed Orange Book patents, including two of the same patents that were the subject of the February 2015 IPR petitions. We opposed the requests to institute these IPRs, but in March 2016 the PTAB decided to institute the IPR proceedings on all four patents. We filed our complete Patent Owner's Response in July 2016, and the hedge fund's response was filed in September 2016. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017. A ruling on the IPR petitions is expected in March 2017. Patent litigation, IPR, and other legal proceedings involve complex legal and factual questions. We need to devote significant resources to the existing ANDA and IPR legal proceedings, and we may need to devote significant resources to other legal proceedings that arise in the future. If we are not successful, we could lose some or all of our Orange Book listed patents and our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such lawsuits and legal proceedings.

We may initiate actions to protect our intellectual property (including, for example, in connection with the filing of an ANDA as described above) and in any litigation in which our intellectual property or our licensors' intellectual property is asserted, a court may determine that the intellectual property is invalid or unenforceable. Even if the validity or enforceability of that intellectual property is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by, for example, the patent claims. In addition, effective intellectual property enforcement may be unavailable or limited in some foreign countries for a variety of legal and public policy reasons. From time to time we may receive notices from third parties alleging infringement of their intellectual property rights. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly, time consuming, and may distract management from other important tasks.

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

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, collaborators, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, collaborators, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, joint ownership may result, which could undermine the value of the intellectual property to us or disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets



become known or independently discovered by competitors, could harm us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

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

There is an increasing trend across multiple jurisdictions, including the United States and the EU, towards requiring greater transparency, particularly in the area of clinical trial results. In many jurisdictions, including the U.S. and the EU, we are required to register most of our clinical trials as well as disclose summaries of the results of those clinical trials. Further

requirements for transparency could result in the disclosure of data down to the individual patient level. In the EU, for example, the European Medicines Agency, or EMA, has instituted a new policy on transparency of clinical trial data submitted to the agency in applications for marketing authorization. These data traditionally have been regarded as confidential commercial information not subject to disclosure. Although the precise implementation of the EMA's new policy remains in flux and subject to legal challenge, it ultimately could result in the EMA's public disclosure of sponsor clinical study reports and/or patient level data in some circumstances. This could negatively impact our business in a variety of ways, including for example through disclosure of our trade secret methodologies for clinical development of our products, and/or by potentially enabling competitors to use our clinical data to gain approvals for their own products in the same or other jurisdictions. Regardless of how the EMA institutes its new policy, the trend across governments is for increased transparency, which could diminish our ability to protect our confidential commercial information.

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

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

- pay substantial damages;
- 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 CVT-301, tozadenant and SYN120 development programs. Our failure to meet any of our obligations under these license agreements could result in the loss of our rights to this intellectual property. If we lose our rights under any of these license agreements, we may be unable to commercialize, or continue commercializing, a product that uses licensed intellectual property.

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

#### Risks relating to our common stock

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

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

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

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

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

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

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater stockholders or other stockholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of February 17, 2017, we had outstanding 46,407,850 shares of voting common stock. Also, options to acquire 8,807,104 shares of common stock were outstanding as of February 17, 2017, exercisable at an average exercise price of \$31.32 per share, issued under our 2006 Employee Incentive Plan, our 2015 Omnibus Incentive Compensation Plan, or our 2016 Inducement Plan. Additional shares of common

stock are authorized for issuance pursuant to options and other stock-based awards under our 2015 Omnibus Incentive Compensation Plan and additional stock-based awards could be issued

64

---

under our 2016 Inducement 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, 2016, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 61% 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.

65

---

## 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 state-of-the-art office and laboratory space in Ardsley, New York. We relocated our headquarters to this facility to accommodate our then-current needs and to allow for future growth. We have options to extend the term of the lease for three additional five-year periods, and we have an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, we have rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. Our extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease. In 2014, we exercised our option to expand into an additional 25,405 square feet of office space, which we occupied in January 2015.

The Ardsley lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to our occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. Our base rent is currently \$4.4 million per year, which reflects an annual 2.5% escalation factor as well as our expansion, described above.

### Chelsea, Massachusetts

Through our Civitas subsidiary, we lease a manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas leases this facility from H&N Associates, LLC pursuant to a lease with a term that expires on December 31, 2025, and Civitas has two additional extension options of five years each. The base annual rent under the lease is currently \$1.0 million per year.

### Additional Facilities

In October 2016, we entered into a 10-year lease agreement commencing in January 2017 for approximately 26,000 square feet of lab and office space in Waltham, MA. We entered into this lease primarily to relocate certain personnel from our Chelsea, Massachusetts facility to enable the expansion of manufacturing operations in Chelsea.

Also, through Biotie and its U.S. subsidiary we indirectly lease office space in South San Francisco, California and Turku, Finland.

## 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. In September 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. In December 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. In January 2012, we moved to dismiss or stay Apotex's suit. In February 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. Also in February 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits,



recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed five of the six counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. In October 2014, the Court granted our motion for summary judgment against Apotex's remaining claim. Apotex has appealed both the motion to dismiss and summary judgment decisions to the Second Circuit Court of Appeals. In May 2016, the Second Circuit Court of Appeals issued an opinion affirming the decision of the lower court. Apotex did not appeal to the United States Supreme Court, and accordingly the decision of the Second Circuit Court of Appeals is final and non-appealable.

#### Ampyra ANDA Litigation

**Overview.** As further described below, our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who submitted Abbreviated New Drug Applications, or ANDAs, with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. In 2015 and 2016, we reached settlement agreements with six of the generic companies, and in February 2017, we announced that we had reached a settlement agreement with one additional generic company. As to the remaining three generic manufacturers, we are waiting for the Court's decision from a bench trial held in September 2016.

**First ANDA Filers.** In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd. and its affiliate Ascend Laboratories, LLC ("Alkem"), Apotex Inc., Aurobindo Pharma Ltd. ("Aurobindo"), Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to the filing of these ANDAs, in July 2014, we filed lawsuits against these generic pharmaceutical manufacturing companies and certain affiliates in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 5,540,938, 8,007,826, 8,354,437, 8,440,703, and 8,663,685. Requested judicial remedies include recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for these generic companies to make, use, offer for sale, sell, market, distribute, or import the proposed generic products be no earlier than the dates on which the Ampyra Orange-Book listed patents expire, or any later expiration of exclusivity to which we are or become entitled. These lawsuits with the ANDA filers have been consolidated into a single case. The U.S. District Court for the District of Delaware issued a Markman ruling in March, 2016, determining the scope and limitations of certain patent claims asserted in the litigation. A bench trial was completed in September, 2016. Post-trial briefing by the parties was completed in November, and we are waiting for the Court's decision. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving any remaining ANDAs, from parties that have not settled with Acorda, until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

In October and December 2015, we entered into settlement agreements with Actavis and Aurobindo to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreements, Actavis and Aurobindo will be permitted to market generic versions of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The Court entered an order dismissing the case against Actavis without prejudice in October 2015. As a result of the settlement agreement with Aurobindo, and upon the request of the parties, the Court entered a Consent Order, in which it

dismissed our litigation against Aurobindo in December 2015. The parties have submitted the agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. In August 2016, we entered into a settlement agreement with Alkem to resolve the patent litigation that we brought against Alkem in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Alkem will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. As a result of the settlement agreement with Alkem, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Alkem in August of 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by Federal law. In August 2016, we entered into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Limited (collectively "Accord") to resolve the patent litigation that we brought against Accord in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Accord will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain

circumstances. As a result of the settlement agreement with Alkem, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Accord in August of 2016. The parties will submit the agreement to the Federal Trade Commission and the Department of Justice, as required by state law. The settlements with Actavis, Aurobindo, Alkem and Accord do not resolve pending patent litigation that we brought against the other ANDA filers, as described in this report.

On February 8, 2017, we entered into a settlement agreement with Apotex Inc. and its subsidiary Apotex Corporation (collectively "Apotex") to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Apotex will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2025, or potentially earlier under certain circumstances. The parties will request that the Court enter a Consent Order, in which it will dismiss our litigation against Apotex referred to above. The parties will submit the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Apotex does not resolve pending patent litigation that we brought against other ANDA filers, as described in this report.

In August 2014, Mylan Pharmaceuticals, Inc. and its parent, Mylan, Inc. (collectively, "Mylan"), filed a motion challenging the jurisdiction of the U.S. District Court for the District of Delaware. In January 2015, the Court denied Mylan's motion to dismiss with respect to the ANDA filer, Mylan Pharmaceuticals, Inc. Subsequently, in January 2015, the Court granted Mylan's request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit Court of Appeals. In March 2016, the Court of Appeals denied Mylan's appeal, and the case remains in the U.S. District Court for the District of Delaware. Mylan requested the Federal Circuit Court of Appeals to reconsider its decision. However, on June 20, 2016, the Federal Circuit Court of Appeals denied Mylan's request. Mylan filed an appeal with the United States Supreme Court for review of the Federal Circuit Court of Appeals opinion. On January 9, 2017, the Supreme Court decided not to review the Federal Circuit Court of Appeals' opinion, which is now final and non-appealable. 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. In December 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. In February 2014, the District Court for the Northern District of West Virginia granted our motion to stay the proceeding in that district until the Federal Circuit Court of Appeals decides Mylan's appeal of Delaware's jurisdictional decision. The patent infringement case against Mylan, however, is still proceeding in Delaware along with the cases against the other ANDA filers.

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

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

The settlement with Par does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

#### Ampyra IPR Proceedings

In February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, or PTO, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. In August 2015, the U.S. Patent and Trademark Office Patent Trials and Appeals Board, or PTAB, ruled that it would not institute inter partes review of either of these patents. In September 2015, the hedge fund filed two motions for reconsideration to the PTAB, requesting that the denial to institute these two IPRs be reversed. However, in April 2016 the PTAB denied these motions.

In September 2015, the same hedge fund filed four new separate IPR petitions with the PTO. These later IPR petitions challenge the same two patents that were the subject of the February 2015 IPR petitions and also U.S. Patent Nos. 8,354,437 and 8,440,703. The challenged patents are four of the five Ampyra Orange-Book listed patents. We opposed the requests to institute these IPRs, but in March 2016 the PTAB decided to institute the IPR proceedings on all four patents. We filed our complete Patent Owner's Response on July 8, 2016, and the hedge fund's response was filed on September 29, 2016. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017. The PTAB's ruling on the IPR petitions is expected in March 2017. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

We will vigorously defend our intellectual property rights.

#### Item 4. Mine Safety Disclosures.

Not applicable.

## PART II

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

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

	High	Low
Fiscal Year Ended December 31, 2016		
Fourth Quarter	\$22.15	\$16.40
Third Quarter	\$27.62	\$20.51
Second Quarter	\$30.68	\$23.85
First Quarter	\$42.67	\$24.83

	High	Low
Fiscal Year Ended December 31, 2015		
Fourth Quarter	\$43.63	\$26.06
Third Quarter	\$36.28	\$25.50
Second Quarter	\$35.70	\$28.52
First Quarter	\$45.45	\$32.39

Computershare is the transfer agent and registrar for our common stock. As of February 17, 2017, we had approximately 25 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, 2011 and its relative performance is tracked through December 31, 2016.

	12/11	12/12	12/13	12/14	12/15	12/16
Acorda Therapeutics, Inc.	100.00	104.28	122.48	171.43	179.45	78.86
NASDAQ Composite	100.00	116.41	165.47	188.69	200.32	216.54
NASDAQ Biotechnology	100.00	134.68	232.37	307.67	328.76	262.08

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

#### Dividend Policy

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

#### Sales of Unregistered Securities

On January 19, 2016, we agreed to issue 2,250,900 shares of our common stock to JP Morgan Securities LLC, as initial purchaser, in a private placement transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"). The settlement of the shares with the initial purchaser occurred on January 26, 2016. The shares were issued to the initial purchaser in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act. The aggregate offering price for the sale of the shares to the initial purchaser was \$74,999,988. In connection with the private placement, we paid \$2,250,900 in aggregate discounts and commissions. We used the net proceeds from the issuance of the shares to fund, in part, the acquisition of Biotie described in this report. The shares were not registered under the Securities Act or any state securities laws and may not be offered or sold in the U.S. absent an effective registration statement or an applicable exemption from registration requirements or a transaction not subject to the registration requirements of the Securities Act or any state securities laws.

#### Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fiscal year ended December 31, 2016. 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, 2016 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,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Total net revenues	\$519,601	\$492,660	\$401,480	\$336,430	\$305,814
<b>Costs and expenses:</b>					
Cost of sales	108,109	92,297	79,981	66,009	57,007
Cost of milestone and license revenue	634	634	634	634	634
Research and development	203,437	149,209	73,470	53,877	53,881
Selling, general and administrative	235,437	205,630	201,813	185,545	168,690
Asset impairment	—	—	6,991	—	—
<b>Changes in fair value of acquired contingent consideration</b>					
	8,600	10,900	2,200	—	—
Total operating expenses	555,583	458,670	365,089	306,065	280,212
Operating (loss) income	(35,982 )	33,990	36,391	30,365	25,602
<b>Other expense:</b>					
Interest and amortization of debt discount expense	(16,527 )	(15,472 )	(9,288 )	(2,170 )	(1,880 )
Interest income	339	440	674	668	552
Other income (expense)	9,902	411	232	—	(6 )
Total other expense	(6,287 )	(14,621 )	(8,382 )	(1,502 )	(1,334 )
(Loss) income before income taxes	(42,268 )	19,369	28,009	28,863	24,268
Benefit from (provision) for income taxes	6,665	(8,311 )	(10,337 )	(12,422 )	130,690
Net loss attributable to non-controlling interest	985	—	—	—	—
<b>Net (loss) income attributable to</b>					
Acorda Therapeutics, Inc.	(34,618 )	\$11,058	\$17,672	\$16,441	\$154,958
Net (loss) income per share —basic	\$(0.76 )	\$0.26	\$0.43	\$0.41	\$3.93
Net (loss) income per share —diluted	\$(0.76 )	\$0.25	\$0.42	\$0.39	\$3.84
<b>Weighted average shares of common stock</b>					
<b>outstanding used in computing net (loss)</b>					
income per share —basic	45,259	42,230	41,150	40,208	39,459
<b>Weighted average shares of common stock</b>					
<b>outstanding used in computing net (loss)</b>					
income per share —diluted	45,259	43,621	42,544	41,682	40,332



	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents and investments	\$ 158,537	\$ 353,305	\$ 307,618	\$ 367,227	\$ 333,188
Working capital	124,756	360,725	276,335	251,376	199,101
Total assets	1,342,335	1,111,294	1,059,224	607,127	565,332
Long-term liabilities	530,223	417,675	404,586	70,131	80,540
Accumulated deficit	(243,970 )	(209,352 )	(220,410 )	(238,082)	(254,523)
Long term debt	324,030	291,527	284,042	3,228	4,244
Total stockholders' equity	664,211	603,025	540,255	440,353	385,921

On January 1, 2016, the Company adopted the provisions of Accounting Standards Updated 2015-03, "Interest – Imputation of Interest" (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. The Company adopted this guidance retrospectively and updated the classification of the total assets, long-term liabilities and long-term debt in the balance sheet for 2016 and all prior periods presented.

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

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

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

Background

We are a biopharmaceutical company focused on developing therapies that restore function and improve the lives of people with neurological disorders. We market three FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. We have a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, migraine and MS. We have three clinical-stage programs in Parkinson's disease, including CVT-301, our most advanced clinical program and our highest priority, as well as our tozadenant and SYN120 programs which we acquired with Biotie Therapeutics in 2016. We believe these three clinical development programs position Acorda as a leader in Parkinson's disease therapeutic development.

Biotie Acquisition

In 2016, we acquired Biotie Therapies Corp. pursuant to a combination agreement with Biotie for a purchase price of approximately \$376 million. On September 30, 2016, we completed the acquisition of 100% of the capital stock of Biotie. Previously, in April and May, 2016, we had acquired approximately 97% of the fully diluted capital stock of Biotie pursuant to public tender offers. On September 30, 2016, we acquired shares representing the remaining approximately 3% of Biotie's fully diluted capital stock pursuant to compulsory redemption proceedings under Finnish law that we had initiated in April 2016. Pursuant to these redemption proceedings, we were entitled to acquire these remaining Biotie shares in exchange for our provision of a cash security deposit pending a final determination and payment of the redemption price for these shares. In November 2016, the arbitration tribunal administering the redemption proceedings rendered a decision in our favor, confirming that the price for the remaining unpaid shares would be the same as the price per share set forth in the combination agreement and offered and paid to the other Biotie shareholders. We made the remaining payments in January 2017. The arbitration decision was not appealed and became final and binding in February 2017.

As a result of the acquisition, we have obtained worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. Further expanding our pipeline, we also obtained global rights to SYN120, an oral, 5-HT6/5-HT2A dual receptor antagonist in Phase 2 development with support from the Michael J. Fox Foundation for Parkinson's-related dementia. We believe these acquired Biotie clinical stage programs, together with our CVT-301 clinical development program, position Acorda as a leader in Parkinson's disease therapeutic development. Biotie is also developing BTT1023, a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease for which there is no FDA-approved treatment.

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

2016 Financing Transactions

Concurrently with the announcement of the Biotie transaction, we announced two separate financing transactions. The first was a private placement of 2,250,900 shares of our common stock in January 2016 for an aggregate purchase price of approximately \$75 million. We used the net proceeds from the private placement to fund, in part, the acquisition of Biotie described above. We also announced a commitment from JPMorgan Chase, N.A. for an asset-based credit facility for up to \$60 million, which we entered into on June 1, 2016. Availability under the facility is subject to a borrowing base, which is based on our and certain of our U.S. subsidiaries' eligible accounts receivable, inventory and equipment, after adjusting for customary factors that are subject to modification from time to time by the administrative agent under the facility at its discretion (not to be exercised unreasonably). Based on our eligible accounts receivable and inventory and other components of the borrowing base, the availability under the facility was approximately \$60 million as of December 31, 2016.

## Ampyra

### General

Ampyra was approved by the FDA in January 2010 to improve walking in people with MS. To our knowledge, Ampyra is the first and only drug approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the United States in March 2010. Net revenue for Ampyra was \$492.8 million for the year ended December 31, 2016 and \$436.9 million for the year ended December 31, 2015.

Since the March 2010 launch of Ampyra, approximately 120,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. Seven years after approval, Ampyra continues to grow, reflecting the continued unmet medical need among people with MS for a treatment to improve walking. As of December 31, 2016, 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 60-day free trial program. Our 60-day free trial program which provides eligible patients with two months of Ampyra at no cost. During 2016, on average, approximately 80% of new Ampyra patients enrolled in 60-day free trial. The program is in its sixth year, and data show that 60-day free trial participants have higher compliance and persistency rates over time compared to patients not in the program. Approximately 50% of patients who initiate therapy with the 60-day free trial free trial program convert to paid prescriptions.

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

Ampyra is distributed in the U.S. exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. The specialty pharmacy providers that deliver Ampyra by mail, and Kaiser Permanente, are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar days, and some have agreed to hold a minimum of 10 business days of inventory.

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

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial formulary. Approximately 75% of insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, for Ampyra. We define limited PAs as those that require only an MS diagnosis,

documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

#### License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra available in additional markets in 2017. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales

of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a \$25 million milestone payment from Biogen in 2011, which was triggered by Biogen's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

#### Ampyra Patent Update

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

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

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers, who have submitted Abbreviated New Drug Applications with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. 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 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016 and we are waiting for the Court's decision. In February 2017, we announced that we had reached a settlement agreement with one of these four generic companies. Our Orange Book-listed patents for Ampyra are also subject to inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office (USPTO). These IPR petitions challenge four of the five Orange Book-listed patents. The USPTO held an oral argument regarding the IPR petitions on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. An adverse outcome in either of these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in further detail in Part I, Item 3 of this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both



Synthon B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

#### Zanaflex

Zanaflex Capsules and Zanaflex tablets are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many central nervous system disorders, including MS and spinal cord injury. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. The net revenue we receive from Zanaflex products has declined substantially due to generic competition.

#### Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the U.S., Canada, Latin America and certain other territories. Grunenthal GmbH (as the assignee of 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 a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, migraine and MS. We have three clinical-stage programs in Parkinson's disease, including CVT-301, our most advanced clinical program and our highest priority, as well as our tozadenant and SYN120 programs which we acquired with Biotie. We believe these three clinical development programs position Acorda as a leader in Parkinson's disease therapeutic development. These programs and the other programs in our pipeline are described below.

#### CVT-301, CVT-427 and ARCUS Technology

CVT-301 is a self-administered, inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease causes a range of symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease.

CVT-301 delivers a precise dose of dry-powder formulation of L-dopa to the lung. Oral medication can be absorbed with slow and variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain shortly thereafter, bypassing the digestive system. CVT-301 is based on our proprietary ARCUS platform, a dry-powder pulmonary drug delivery technology 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, breath-actuated proprietary inhaler. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents.

In 2016, we completed a Phase 3 efficacy and safety clinical trial of CVT-301 for the treatment of OFF periods in Parkinson's disease. On February 9, 2017, we announced efficacy and safety data from this clinical trial, showing a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. The clinical trial had three arms: CVT-301 84 mg and 60 mg doses (equivalent to 50 mg and 35 mg fine particle doses, respectively), and placebo. The trial met its primary outcome measure of improvement in motor function as measured by the Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS Part III) in people with Parkinson's disease experiencing OFF periods. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment. The primary endpoint was measured at 30 minutes post-treatment for the 84 mg dose at the 12-week visit. UPDRS Part III change was -9.83 compared to -5.91 for placebo with a p value of 0.009. The magnitude of CVT-301's benefit versus baseline was consistent with the data from the prior Phase 2b clinical trial, further described below, and represents a moderate to large clinically important

difference. The placebo-adjusted difference was lower in the Phase 3 clinical trial than the Phase 2b clinical trial but still represented a clinically important difference.

The safety profile of CVT-301 in the trial was consistent with that observed in a prior Phase 2b clinical trial. Adverse events reported in any study arm at greater than 5% were cough, upper respiratory tract infection, throat irritation, nausea and sputum discoloration. Cough was the most common adverse event, reported by approximately 15% of subjects who received CVT-301. When reported, it was typically mild and reported once per participant during the course of treatment. Three of 227 participants receiving CVT-301 discontinued the study due to cough. Reports of serious adverse events were: 3, or 2.7% in the placebo arm, 6, or 5.3% in the 60 mg arm, and 2, or 1.8% in the 84 mg arm. There was one death in the study, a suicide in the 60 mg group, judged by the investigator not to be related to drug. We are currently conducting two additional Phase 3 studies to assess the long-term safety profile of CVT-301. Up to 12-month data from these studies are expected by the end of the first quarter of 2017.

We had a pre-NDA (New Drug Application) meeting with the FDA during the third quarter of 2016 and have received the FDA's minutes of that meeting. We plan to file an NDA with the FDA in the U.S. by the end of the second quarter of 2017, pending data from the ongoing long-term safety studies. We also plan to file a Marketing Authorization Application, or MAA, in the EU by the end of 2017 pending additional data analyses. 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®. We believe the Phase 3 efficacy and safety clinical trial, combined with data from the two additional Phase 3 studies and supported by existing Phase 2b data, will be sufficient for filing an NDA. We are projecting that, if approved, annual peak net revenue of CVT-301 in the U.S. alone could exceed \$500 million. We are actively seeking to partner this program outside of the U.S., the EU and certain other countries.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF period, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured. In April 2016, data from this clinical trial were one of six platform presentations highlighted during the Movement Disorders Invited Science Session at the 68<sup>th</sup> Annual Meeting of the American Academy of Neurology. In June 2016, data from this clinical trial was also presented in three posters during the 20th International Congress of Parkinson's Disease and Movement Disorders (MDS). In October 2016, we announced that results from Phase 1, Phase 2a and preclinical studies of CVT-301 were featured in the current edition of Science Translational Medicine.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS drug delivery 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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS drug delivery technology. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in nasally delivered formulations. However, based on available data, we believe that nasally delivered triptans generally have an onset of action similar to orally administered triptans.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. In June 2016, at the 58th Annual Scientific Meeting of the American Headache Society, we presented pharmacokinetic data from the Phase 1 trial which showed increased bioavailability and faster absorption compared to oral and nasal administration of the same active ingredient in healthy adults. In particular, the data showed that CVT-427 had a median T<sub>max</sub> of about 12 minutes for all dose levels compared to 1.5 hours for the oral tablet and 3.0 hours for the nasal spray. There were no serious adverse events, dose-limiting toxicities, evidence of bronchoconstriction or discontinuations due to adverse events reported in this study. The most commonly reported treatment-emergent adverse events were cough, chest discomfort, headache, and feeling hot. Apart from cough, single dose CVT-427 tolerability was generally consistent with the known safety profile of zolmitriptan. We have also completed a special population study to evaluate safe inhalation of CVT-427 in patients with asthma and in smokers. Some subjects in this study showed evidence of

acute, reversible bronchoconstriction, post-inhalation. We plan to discuss these results with outside advisors and the FDA and, pending agreement, to advance the program into Phase 2 study by the end of 2017.

#### Biotie Programs – Tozadenant, SYN120 and BTT1023

Through Biotie we acquired worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. A2a receptor antagonists have the potential to be the first new class of drug approved in the U.S. for improvement of motor symptoms in Parkinson's disease in over 20 years. We believe that tozadenant would be complementary to our other Phase 3 product for Parkinson's disease, CVT-301, because while tozadenant is being developed as a chronic therapy for reducing overall OFF time, CVT-301 is being developed for episodic use for rapid improvement of OFF periods when they occur. Biotie is currently conducting a Phase 3 clinical trial, in which tozadenant is taken along with a person's other Parkinson's disease therapies. The trial is being conducted under a special protocol assessment, or SPA, from the FDA and is comparing two of the dose arms of tozadenant that were studied in a prior Phase 2b clinical trial versus placebo. The trial is assessing improvement of motor function and activities of daily living in people with Parkinson's disease while taking tozadenant. We believe that this trial, if successful, together with data from the prior Phase 2b clinical trial, will provide sufficient efficacy data to file an NDA with the FDA. We expect efficacy data from this trial in the first quarter of 2018. A separate open-label safety study is expected to begin enrollment in the first half of 2017.

Further expanding our pipeline, through Biotie we also obtained global rights to SYN120, an oral, 5-HT6/5-HT2A dual receptor antagonist in Phase 2 development with support from the Michael J. Fox Foundation for Parkinson's-related dementia. We expect to complete an ongoing Phase 2 exploratory study in the second half of 2017 and we expect data from this trial in the first quarter of 2018.

Biotie is also developing BTT1023 (timolumab), a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. There are no approved drug therapies for PSC and liver transplant is the only treatment. Interim data from an ongoing Phase 2 proof-of-concept clinical trial of BTT1023 for PSC are expected in the second half of 2017. We are seeking to out-license this program.

#### Remyelinating Antibodies

We are developing rHlgM22, a remyelinating antibody, 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 included several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHlgM22, found no dose-limiting toxicities at any of the five dose levels studied. In April 2015, we presented additional safety data from this trial showing that rHlgM22 was well tolerated in each of the five doses, supporting additional clinical development. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHlgM22 penetrates the central nervous system.

We are currently enrolling a Phase 1 trial using one of two doses of rHlgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the second half of 2017. We are actively seeking a partner for further development of this program after completion of this trial.

#### Cimaglermin alfa/Neuregulins

Cimaglermin alfa is our lead product candidate for our neuregulin program. We have completed a 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 report of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting FDA Drug-Induced Liver Injury Guidance (FDA 2009) stopping rules was also identified in the highest planned dose cohort, which resolved over two to three weeks. In 2015, we presented new analyses of data from this trial, which found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In 2013, we commenced a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting the FDA guidelines referenced above. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within two to three weeks, as was the case with the one case of hepatotoxicity reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial have completed the pre-planned one year of follow up. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to further define the nature of the bilirubin signal. We have met with the FDA to present analysis of the data from the cimaglermin studies, as well as data from non-clinical studies, as part of our request that the program be removed from the clinical hold. We are seeking to out-license this program.

#### 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 had 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. Grunenthal GmbH (as the assignee of Astellas Pharma Europe Ltd.) has an option to develop NP-1998 in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, we have no current plans to invest in further development of NP-1998 for neuropathic pain.

#### Ampyra/Dalfampridine Development Program

We have been studying the use of dalfampridine in patients who experience post-stroke walking difficulties, or PSWD, after experiencing an ischemic stroke. In 2016, we made the decision to stop enrollment in an ongoing Phase 3 clinical trial and conduct an unblinded analysis of the trial data. In November 2016, we announced we were discontinuing our PSWD program after reviewing the unblinded data and concluding that the results did not show sufficient efficacy to support further development. We have also been exploring a once-daily (QD) formulation of dalfampridine for use in our PSWD clinical program. A multi-dose pharmacokinetic study confirmed that we have developed a potentially viable QD formulation of dalfampridine.

#### Plumiaz

Plumiaz is a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs, or AEDs, who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures. In 2013, we submitted a New Drug Application, or NDA, for Plumiaz to



the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. In May 2015, we announced that we completed discussions with the FDA, and thereafter we continued to advance development of Plumiaz. Based on these discussions, we were conducting three clinical trials for Plumiaz. However, in May 2016 we announced that we were discontinuing the program because data from clinical trials did not demonstrate Plumiaz's bioequivalence to Diastat<sup>®</sup> rectal gel. Specifically, the data demonstrated unexpectedly lower nasal mucosa absorption of diazepam in persons with epilepsy compared to studies in healthy volunteers. Our Neuronex, Inc. subsidiary is a party to a license agreement with SK Biopharmaceuticals Co., Ltd. relating to Plumiaz.

## Outlook for 2017

### Financial Guidance for 2017

We are providing the following guidance with respect to our 2017 financial performance:

• We expect 2017 net revenue from the sale of Ampyra to range from \$535 million to \$545 million.

• Research and development (R&D) expenses in 2017 are expected to range from \$185 million to \$195 million, excluding share-based compensation charges. R&D expenses for 2017 are expected to be lower than in 2016 because of the completion of clinical trial activities that were conducted in 2016. A large portion of 2017 R&D expenses represents pre-commercialization activities, including manufacturing for CVT-301.

• Selling, general and administrative (SG&A) expenses in 2017 are expected to range from \$195 million to \$205 million, excluding share-based compensation charges.

The projected range of R&D and SG&A expenses in 2017 are provided on a non-GAAP basis, as both excluding share-based compensation charges. Due to the forward looking nature of this information, the amount of compensation charges and benefits needed to reconcile these measures to the most directly comparable GAAP financial measures is dependent on future changes in the market price of our common stock and is not available at this time. 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 these non-GAAP financial measures 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 these non-GAAP financial measures 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 2017 and beyond are as follows:

• On February 9, 2017, we announced efficacy and safety data from a completed Phase 3 clinical trial of CVT-301, showing a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. The safety profile of CVT-301 in the trial was consistent with that observed in a prior Phase 2b clinical trial. We are currently conducting two additional Phase 3 studies to assess the long-term safety profile of CVT-301. Up to 12-month data from these studies are expected by the end of the first quarter of 2017. We had a pre-NDA (New Drug Application) meeting with the FDA during the third quarter of 2016 and have received the FDA's minutes of that meeting. We plan to file an NDA with the FDA in the U.S. by the end of the second quarter of 2017, pending data from the ongoing long-term safety studies. We also plan to file a Marketing Authorization Application, or MAA, in the EU by the end of 2017 pending additional data analyses. We are actively seeking to partner this program outside of the U.S., the EU and certain other countries.

• Continue progressing Biotie's Phase 3 clinical trial of tozadenant, an oral adenosine A2a receptor antagonist being developed as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. The clinical trial, which is being conducted under a special protocol assessment, or SPA, from the FDA, is assessing improvement of motor function and activities of daily living in people with Parkinson's disease while taking tozadenant. We expect efficacy data from this trial in the first quarter of 2018. A separate open-label safety study is

expected to begin enrollment in the first half of 2017.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. We have also completed a special population study to evaluate safe inhalation of CVT-427 in patients with asthma and in smokers. Some subjects in this study showed evidence of acute, reversible bronchoconstriction, post-inhalation. We plan to discuss these results with outside advisors and the FDA and, pending agreement, to advance the program into Phase 2 study by the end of 2017.

We are currently enrolling a Phase 1 trial of rHlgM22 using one of two doses of rHlgM22 or placebo in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse,

82

---

the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in the second half of 2017. We are actively seeking a partner for further development of this program after completion of this trial.

In 2015 we announced that we had stopped enrollment in our second Phase 1 clinical trial of cimagermin based on the occurrence of a case of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting FDA Drug-Induced Liver Injury Guidance (FDA 2009) stopping rules. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to the clinical hold. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to further define the nature of the bilirubin signal. We have met with the FDA to present analysis of the data from the cimagermin studies, as well as data from non-clinical studies, as part of our request that the program be removed from clinical hold. We are seeking to out-license this program.

#### Results of Operations

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

#### Net Revenue

##### Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$492.8 million and \$436.9 million for the years ended December 31, 2016 and 2015, respectively. This net revenue reflected a 10.95% increase in our list sale price for Ampyra effective January 1, 2016. The net revenue increase comprised net volume increases of \$21.1 million and price increases and discount and allowance adjustments of \$34.8 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2016 compared to the year ended December 31, 2015 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our 60-day free trial program. As with a number of specialty pharmaceuticals, first quarter sales for Ampyra typically have been lower than the preceding fourth quarter sales due to inventory build in the fourth quarter, and the temporary effects of people changing insurance plans and entering the Medicare donut hole at the beginning of the year. We expect a similar trend in 2017. Effective January 1, 2017, we increased our list sale price to our customers by 9.5%.

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 recognized net revenue from the sale of Zanaflex products of \$3.3 million for the year ended December 31, 2016, as compared to \$24.4 million for the year ended December 31, 2015. The Company recognized a one-time increase in net revenue of \$22.2 million for the year ended December 31, 2015, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns. Net product revenues also include \$2.7 million representing the sale of our Zanaflex Capsules authorized generic product to Actavis, a subsidiary of Teva Pharmaceuticals and formerly Watson Pharma, for the year ended December 31, 2016 as compared to \$3.8 million for the year ended December 31, 2015. Prior to the third quarter of 2015, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales

price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules.

Generic competition has caused a significant decline in net revenue of Zanaflex products and is expected to cause the Company's net revenue from Zanaflex products to decline further in 2017 and beyond.

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

#### Qutenza

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$1.1 million and \$1.0 million for the years ended December 31, 2016 and 2015, 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, 2016 and 2015, respectively, related to the \$110.0 million received from Biogen in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### Royalty Revenue

We recognized \$10.6 million and \$10.5 million in royalty revenue for the years ended December 31, 2016 and 2015, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$3.9 million in royalty revenue for the year ended December 31, 2016 as compared to \$7.0 million for the year ended December 31, 2015, related to the authorized generic sale of Zanaflex Capsules.

We recognized \$2.7 million in royalty revenue for the period April 18, 2016 through December 31, 2016, related to ex- U.S. sales of Selincro by Lundbeck.

#### Cost of Sales

We recorded cost of sales of \$107.5 million for the year ended December 31, 2016 as compared to \$92.3 million for the year ended December 31, 2015. Cost of sales for the year ended December 31, 2016 consisted primarily of \$86.1 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2016 also consisted of \$11.1 million in royalty fees based on net product shipments, \$7.0 million in amortization of intangible assets, and \$0.4 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$2.7 million representing the cost of Zanaflex Capsules authorized generic product sold for the year ended December

31, 2016.

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

84

---

#### Cost of License Revenue

We recorded cost of license revenue of \$0.6 million for the years ended December 31, 2016 and 2015, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen as a result of our collaboration agreement.

#### Research and Development

Research and development expenses for the year ended December 31, 2016 were \$203.4 million as compared to \$149.2 million for the year ended December 31, 2015, an increase of \$54.2 million, or 36%. The increase was primarily due to \$30.3 million in research and development expenses related to CVT-301 and CVT-427, \$27.0 million in post-acquisition research and development expenses related to Biotie and \$2.8 million related to our life cycle management program for Ampyra. The increase was also due to an increase in overall research and development staff, compensation, and related expenses of \$8.3 million to support our various research and development initiatives. The increases in research and development expenses were partially offset by decreases of \$8.3 million related to Plumiaz, \$5.6 million related to cimaglermin alfa and \$0.8 million related to NP-1998.

#### Selling, General and Administrative

Sales and marketing expenses were \$102.7 million for the years ended December 31, 2016 and 2015.

General and administrative expenses for the year ended December 31, 2016 were \$132.7 million compared to \$102.9 million for the year ended December 31, 2015, an increase of approximately \$29.8 million, or 29%. This increase was primarily due to \$17.6 million of transaction costs incurred for the Biotie acquisition, a \$13.8 million net increase in spending for legal, finance and business development related activities, and 3.8 million in post-acquisition expenses related to Biotie. The increase in general and administrative expenses were partially offset by a decrease in staff compensation, benefits and medical affairs related expenses of \$4.9 million.

#### Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded expenses pertaining to changes in the fair-value of our acquired contingent consideration of \$8.6 million for the year ended December 31, 2016 compared to \$10.9 million for the year ended December 31, 2015, a decrease of \$2.3 million or 21%. The changes in the fair-value of the acquired contingent consideration were due to the re-calculation of discounted cash flows for the passage of time and updates to certain other estimated assumptions.

#### Other Expense

Other expense was \$6.3 million for the year ended December 31, 2016 compared to \$14.6 million for the year ended December 31, 2015, a decrease of \$8.3 million, or 57%. The decrease was due primarily to a realized gain on foreign currency derivatives of \$9.9 million, partially offset by an increase of \$1.0 million in interest and debt discount amortization, principally related to the capital and R&D loans held by Biotie. Interest expense related to the convertible senior notes was \$15.0 million for the year ended December 31, 2016, of which the non-cash portion was \$9.0 million.

#### Provision for Income Taxes



We recorded a \$6.7 million benefit for income taxes for the year ended December 31, 2016 as compared to a \$8.3 million provision for income taxes for the year ended December 31, 2015. The effective income tax rates for the year ended December 31, 2016 and 2015 were 16% and 43%, respectively. The variances in the effective tax rates for the year ended December 31, 2016 and 2015 were due primarily to the valuation allowance recorded on jurisdictions with pretax losses from the acquisition of Biotie for which no tax benefit can be recognized, partially offset by a non-deductible \$8.8 million payment in July 2015 to the former equity holders of Neuronex and an increased benefit from the federal research and development tax credit. The Company's effective tax rate for this year differed from the U.S. federal statutory rate of 35% primarily due to

state taxes, foreign taxes related to the Company's Puerto Rico operations, Federal research and development tax credits, jurisdictions with pretax losses from the acquisition of Biotie for which no tax benefit can be recognized and certain other permanent tax items. The annual rate depends on the number of factors, including the jurisdiction in which operating profit is earned and the timing and nature of discrete items.

We continue to evaluate the realizability of the Company's deferred tax assets on a quarterly 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, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets and liabilities in the future would impact the Company's income taxes.

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

#### Net Revenue

##### Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$436.9 million and \$366.2 million for the years ended December 31, 2015 and 2014, respectively. This net revenue reflected a 10.95% increase in our list sale price for Ampyra effective January 2, 2015. The net revenue increase comprised net volume increases of \$30.1 million and price increases and discount and allowance adjustments of \$40.6 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2015 compared to the year ended December 31, 2014 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our 60-day free trial program. As with a number of specialty pharmaceuticals, first quarter sales for Ampyra typically have been lower than the preceding fourth quarter sales due to inventory build in fourth quarter, and the temporary effects of people changing insurance plans and entering the Medicare donut hole at the beginning of the year.

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

##### Zanaflex

We recognized net revenue from the sale of Zanaflex products of \$24.4 million for the year ended December 31, 2015, as compared to \$1.5 million for the year ended December 31, 2014. The Company recognized a one-time increase in net revenue of \$22.2 million for the year ended December 31, 2015, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns. Net product revenues also include \$3.8 million representing the sale of our Zanaflex Capsules authorized generic product to Actavis, a subsidiary of Teva Pharmaceuticals and formerly Watson Pharma, for the year ended December 31, 2015 as compared to \$4.6 million for the year ended December 31, 2014. Prior to the third quarter of 2015, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the

wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules.

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 recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$1.0 million and \$0.9 million for the years ended December 31, 2015 and 2014, respectively.

#### License Revenue

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

#### Royalty Revenue

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

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

#### Cost of Sales

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

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

#### Cost of License Revenue

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

#### Research and Development

Research and development expenses for the year ended December 31, 2015 were \$149.2 million as compared to \$73.5 million for the year ended December 31, 2014, an increase of \$75.7 million, or 103%. The increase was primarily due to \$49.3 million in research and development expenses related to CVT-301. The increase was also due to increases in expenses for various other research and development programs, including \$6.3 million related to our life cycle management program for Ampyra, \$10.8 million in expenses relating to work on Plumiaz, and \$1.9 million in expenses related to cimaglermin alfa (previously referred to as GGF2). The increase was also due to an increase in overall research and development staff, compensation, and related expenses of \$9.0 million to support our various research and development initiatives. The

increases in research and development expenses were partially offset by decreases of \$0.9 million related to AC105 and \$0.5 million related to rHIgM22.

#### Selling, General and Administrative

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

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

#### Changes in Fair Value of Acquired Contingent Consideration

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

#### Other Expense

Other expense was \$14.6 million for the year ended December 31, 2015 compared to \$8.4 million for the year ended December 31, 2014, an increase of approximately \$6.2 million, or 73.8%. The increase was due to an increase in interest expense of \$6.2 million, principally related to the cash and non-cash portions of interest expense for the convertible senior notes issued in June 2014 (the Notes). Interest expense related to the Notes was \$14.6 million for the year ended December 31, 2015, of which the non-cash portion was \$8.6 million.

#### Provision for Income Taxes

We recorded a \$8.3 million provision for income taxes for the year ended December 31, 2015 as compared to a \$10.3 million provision for income taxes for the year ended December 31, 2014. The effective income tax rates for the year ended December 31, 2015 and 2014 were 43% and 37%, respectively. The variances in the effective tax rates for the year ended December 31, 2015 and 2014 were due primarily to the non-deductible \$8.8 million payment in July 2015 to the former equity holders of Neuronex partially offset by an increased benefit from the research and development tax credit. The Company's effective tax rate for this year differed from the U.S. federal statutory rate of 35% primarily due to state taxes, foreign taxes related to the Company's Puerto Rico operations, Federal research and development tax credits and certain other permanent tax items. The annual rate depends on the number of factors, including the jurisdiction in which operating profit is earned and the timing and nature of discrete items.

We continue to evaluate the realizability of our deferred tax assets on a quarterly 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, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets and liabilities in the future would impact the Company's income taxes.

88

---

## Liquidity and Capital Resources

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

At December 31, 2016, we had \$158.5 million of cash and cash equivalents, compared to \$353.3 million at December 31, 2015. There were no investments classified as short-term or long-term at December 31, 2016. We expect that our existing cash, cash flows from operations, and availability under the asset-based credit facility which closed on June 1, 2016, will be sufficient to fund our ongoing operations over the next 12 months from the financial statement reporting date.

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

The outstanding principal balance on this promissory note was \$0.8 million as of December 31, 2016. The remaining principal and accrued interest was paid in January 2017.

### Convertible Senior Notes

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

The Notes are governed by the terms of an indenture, dated as of June 23, 2014 (the "Base Indenture") and the first supplemental indenture, dated as of June 23, 2014 (the "Supplemental Indenture", and together with the Base Indenture, the "Indenture"), each between the Company and Wilmington Trust, National Association, as trustee (the "Trustee"). The Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per \$1,000 principal amount of Notes (representing 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.

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, 2016 consisted of the following:

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

(In thousands)	December 31, 2016
Liability component:	
Principal	\$ 345,000
Less: debt discount and debt issuance costs, net	(45,605 )
Net carrying amount	\$ 299,395
Equity component	\$ 61,195

Common Stock Private Placement

Concurrently with the announcement of the Biotie acquisition, the Company entered into a transaction for the private placement of 2,250,900 shares of the Company's common stock for an aggregate purchase price of approximately \$75 million. The Company paid discounts and commissions of \$2.3 million in connection with the private placement, which

90

---

settled on January 26, 2016. The Company used the net proceeds from the private placement to fund, in part, the acquisition of Biotie.

#### Asset Based Loan

On June 1, 2016, the Company and certain of its subsidiaries entered into a Credit Agreement (the “Credit Agreement”) with JPMorgan Chase Bank, N.A., as the sole initial lender and the administrative agent for the lenders (the “Administrative Agent”).

The Credit Agreement provides the Company with a three-year senior secured revolving credit facility in the maximum amount of \$60 million. Availability under the facility is subject to a borrowing base, which is based on eligible accounts receivable, inventory and equipment of the Company and certain of its U.S. subsidiaries, after adjusting for customary factors that are subject to modification from time to time by the Administrative Agent at its discretion (not to be exercised unreasonably). Based on the Company’s eligible accounts receivable and inventory and other components of the borrowing base, the availability under the facility was approximately \$60 million as of December 31, 2016.

Amounts drawn under the facility will bear interest, at the Company’s option, at (i) an alternate base rate (the highest of (a) the prime rate, (b) the federal funds effective rate or the overnight bank funding rate plus 0.5%, and (c) the LIBOR rate (adjusted for statutory reserve requirements for eurocurrency liabilities) plus 1%) plus 1.5%, or (ii) the LIBOR rate (adjusted for statutory reserve requirements for eurocurrency liabilities) plus 2.5%. The facility is subject to an annual commitment fee of either 0.375% or 0.50%, depending on the amounts already drawn under the facility. As of December 31, 2016, there were no amounts drawn under the facility.

The Company’s obligations under the facility are guaranteed by its U.S. subsidiaries (other than its U.S. subsidiary of Biotie Therapies Oyj). The Company’s obligations under the facility and its subsidiaries’ obligations under the related guarantees are secured by first priority security interests in collateral that includes, subject to certain exceptions:

- U.S. accounts receivable, inventory and manufacturing equipment;
- Equity interests in the Company’s U.S. subsidiaries (other than its U.S. subsidiary of Biotie Therapies Oyj) and up to 65% of the voting equity interests of its directly owned foreign subsidiaries; and
- Substantially all other tangible and intangible assets, including equipment, contract rights and intellectual property (other than intellectual property related to Ampyra).

The facility contains certain covenants that, among other things, limit the Company’s ability and the ability of certain of its subsidiaries to (i) incur additional debt or issue redeemable preferred stock, (ii) pay dividends, repurchase shares or make certain other restricted payments or investments, (iii) incur liens, (iv) sell assets, (v) incur restrictions on future liens and incur restrictions on the ability of our subsidiaries to pay dividends or to make other payments to us, (vi) enter into affiliate transactions, (vii) engage in sale and leaseback transactions, and (viii) consolidate or merge. These covenants are subject to significant exceptions and qualifications. In addition, the Company will not be permitted to allow its ratio of (a) EBITDA minus Unfinanced Capital Expenditures to (b) Fixed Charges to be less than 1.10 to 1.00 on a trailing four quarter basis as of the end of any fiscal quarter during any period.

The facility has customary representations and warranties including, as a condition to borrowing, that all such representations and warranties are true and correct, in all material respects, on the date of the borrowing, including representations as to no material adverse effect on the Company’s business or financial condition since December 31, 2015. The facility also has customary defaults, including a cross-default to material indebtedness of the Company and its subsidiaries. The Administrative Agent may declare any outstanding obligations under the facility immediately due and payable upon the occurrence, and during the continuance, of an event of default. In addition, any outstanding obligations under the facility will be immediately due and payable in the event that the Company or certain of its

subsidiaries become the subject of voluntary or involuntary proceedings under any bankruptcy, insolvency or similar law.

#### Non-Convertible Capital Loans

Non-convertible capital loans (“Tekes Loans”) granted by Tekes, a Finnish Funding Agency for Technology and Innovation, with an adjusted acquisition-date fair value of \$23.3 million (€20.6 million) and a carrying value of \$22.4 million as of December 31, 2016. The Tekes Loans are composed of fourteen non-convertible loans granted by Tekes. The maturity

dates for the Tekes Loans range from eight to ten years. These loans bear interest based on the greater of 3% or the base rate set by the Finland's Ministry of Finance minus one (1) percentage point. According to certain terms and conditions of the Tekes Loans, Biotie may repay the principal amounts of these loans and the accrued and unpaid interest only if the restricted equity of Biotie, including its consolidated subsidiaries is positive (fully covered).

#### Convertible Capital Loan

Convertible capital loan issued to certain shareholders and venture capital organizations with an acquisition-date fair value of \$6 million (€5.3 million) and a carrying value of \$5.7 million as of December 31, 2016. The loan bears cash interest at a rate of 10% per annum, payable annually each year. The convertible capital loan is subject to certain terms and restrictive conditions as it relates to interest payments and repayment of the loan. The loan will yield interest from the fiscal years in which the financial statements do not present sufficient funds available for profit distribution; however, interest on the loan may be paid if Biotie, including its subsidiaries, has sufficient funds for profit distribution as of the most recently ended fiscal year. The loan may be repaid only if the restricted equity of Biotie, including its consolidated subsidiaries, for the last financial period is sufficient to repay the loan. Pursuant to the terms of the loan agreement, the loan is convertible at any time at the option of the holders into 828,000 common shares of Biotie. The conversion rates for the loan are €1.8688 per share for 540,000 of the shares and €2.3359 for the remaining 288,000 of the shares.

#### Research and Development Loans

Research and Development Loans ("R&D Loans") were granted by Tekes with an acquisition-date fair value of \$2.9 million (€2.6 million) and a carrying value of \$2.8 million as of December 31, 2016. The R&D Loans bear interest based on the greater of 1% or the base rate set by Finland's Ministry of Finance minus three (3) percentage points. The repayment of these loans will begin January 2017. The loan principal will be paid in equal annual installments over a 5 year period, ending January 2021.

#### Investment Activities

At December 31, 2016, cash and cash equivalents were approximately \$158.5 million, as compared to \$353.3 million at December 31, 2015. 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. 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, 2016, our cash and cash equivalents were \$158.5 million, as compared to \$153.2 million as of December 31, 2015. At December 31, 2016, we held no short-term investments. At December 31, 2015, we held \$200.1 million of short-term investments which consisted of U.S. Treasury bonds with original maturities greater than three months and less than one year.

#### Net Cash Provided by Operations

Net cash provided by operations was \$35.3 million and \$38.5 million for the years ended December 31, 2016 and 2015, respectively. Cash provided by operations for the year ended December 31, 2016 was primarily attributable to non-cash share-based compensation expense of \$36.4 million, an increase in accounts payable, accrued expenses and other liabilities of \$37.6 million, depreciation and amortization expense of \$21.6 million, amortization of debt discount and debt issuance costs of \$9.7 million, change in contingent consideration obligation of \$8.6 million, a decrease in prepaid expenses and other current assets of \$6.9 million and a decrease in restricted cash of \$5.7 million. Cash provided by operations was partially offset by a net loss of \$35.6 million, an increase in accounts receivable of \$20.0 million, a realized gain on foreign currency transaction of \$9.9 million, a decrease in deferred license revenue of \$9.1 million, a deferred tax benefit of \$11.2 million and an increase in inventory held by the Company of \$6.7 million.

Net Cash Used in Investing

Net cash used in investing activities for the year ended December 31, 2016 was \$73.8 million, due primarily to \$266.5 million for the acquisition of Biotie, net of cash received, purchases of investments of \$40.2 million, purchases of property and equipment of \$6.2 million, and purchases of intangible assets of \$0.9 million, partially offset by \$240 million in proceeds from maturities and sales of short-term investments.

92

---

### Net Cash Provided by Financing

Net cash provided by financing activities for the year ended December 31, 2016 was \$45.9 million, due primarily to \$75.5 million in net proceeds from the exercise of stock options partially offset by \$27.9 million for the purchase of the noncontrolling interest in Biotie and \$1.6 million in debt issuance costs.

### Contractual Obligations and Commitments

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. See Note 10 for a description of our long-term contractual obligations.

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 \$129 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, 2016, 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 and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, primarily employee compensation and contract services, which could increase our level of expenses.

### Critical Accounting Policies and Estimates

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

### Revenue Recognition

Ampyra



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

Our net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to our customers, an adjustment is recorded for estimated discounts, rebates, and chargebacks. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in 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, we have been able to make a reasonable estimate for product returns. We do not accept returns of Ampyra except for product damaged in shipping. Historically, it has been rare for us to have product damaged in shipping. We will exchange product from inventory for product damaged in shipping.

#### Zanaflex

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

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

We accept returns of Zanaflex products for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. We do not exchange product from inventory for returned product. Prior to the three months ended September 30, 2015, product returns were charged directly against deferred revenue, reducing the

amount of deferred revenue that we would recognize. In addition, we recorded a charge to cost of goods sold for the cost basis of the estimated product returns we believed would ultimately be realized at the time of product shipment to wholesalers. We recognized this charge at the date of shipment since it was probable that we would receive a level of returned product; upon the return of such product we would be unable to resell the product considering its expiration dating; and, we could reasonably estimate a range of returns. This charge represented the cost basis for the low end of the range of the Company's estimated returns. As a result of the change in revenue recognition policy, the Company recorded a charge to cost of goods sold of approximately \$0.6 million for the year ended December 31, 2015.

## Qutenza

Qutenza is distributed in the United States by Besse Medical, Inc., a specialty distributor that furnishes the medication to physician offices; and by ASD Specialty Healthcare, Inc., a specialty distributor that furnishes the medication to hospitals and clinics.

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

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

## Discounts and Allowances

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

**Government Chargebacks and Rebates:** We contract for Medicaid and other government programs such as the Federal Supply Schedule which commits us to providing favorable pricing for Ampyra, Zanaflex and Qutenza. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. We also contract with the Centers for Medicare and Medicaid Services to participate in the Coverage Gap Discount Program (the program given rise by the Affordable Care Act which closes the Medicare Part D "donut hole"). Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for chargebacks and rebates. We monitor the sales trends and adjust the chargeback and rebate percentages on a regular basis to reflect the most recent chargebacks and rebate experience. Our government chargeback and rebate accruals were \$10.4 million and \$7.1 million at December 31, 2016 and December 31, 2015, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate \$4.7 million and \$3.3 million effect on our net revenue for the years ended December 31, 2016 and December 31, 2015, 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 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 \$4.4 million and \$1.6 million at December 31, 2016 and December 31, 2015, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$2.2 million and \$0.6 million effect on our net revenue for the years ended December 31, 2016 and December 31, 2015, respectively.

**Copay Mitigation Rebates:** We offer copay mitigation to commercially insured patients who have coverage for Ampyra (in accordance with applicable law) and are responsible for a cost share regardless of financial need (income status). The copay mitigation program is intended to reduce the patient's financial responsibility for Ampyra to a specified dollar amount. Based upon our contracts and the most recent experience with respect to actual copay assistance provided, we provide an allowance for copay mitigation rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience. Our copay mitigation rebate accruals were \$0.2 million and \$0.1 million at December 31, 2016 and December 31, 2015, respectively. A 10% change in our copay mitigation rebate allowances would have had an approximate \$0.9 million and \$0.7 million effect on our net revenue for the years ended December 31, 2016 and December 31, 2015, respectively.

**Cash Discounts:** We sell Ampyra directly to our network of specialty pharmacies, Kaiser and the specialty distributor to the U.S. Department of Veterans Affairs. We sell Zanaflex directly to wholesalers and Qutenza to specialty distributors. We generally provide invoice discounts for prompt payment for Ampyra and Zanaflex. We estimate our cash discounts based on the terms offered to our customers. Discounts are accrued based on historical usage rates at the time of product shipment. We adjust accruals based on actual activity as necessary. Cash discounts are typically settled with our customers within 30 days after the end of each calendar month. Our cash discounts accruals were \$0.6 million and \$0.5 million at December 31, 2016 and December 31, 2015, respectively. A 10% change in our cash discount allowances would have had an approximate \$0.6 million and \$0.5 million effect on our net revenue for the years ended December 31, 2016 and December 31, 2015, respectively.

**Product Returns:** We do not accept returns of Ampyra except for product damaged in shipping. Our returns accrual for Ampyra was \$10,000 at December 31, 2016 and December 31, 2015.

We accept returns of Zanaflex products for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. Prior to the three month period ended September 30, 2015, we recorded Zanaflex product revenue based on a deferred revenue model and recognized revenue when prescriptions were filled to an end-user because once a prescription was filled the product could not be returned. Therefore, there was no returns reserve established for Zanaflex products prior to the three month period ended September 30, 2015. As of the three month period ended September 30, 2015, the Company began recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes it now has sufficient history to reasonably estimate expected returns. Our returns reserve for Zanaflex products was \$4.8 million and \$4.3 million at December 31, 2016 and December 31, 2015, respectively. A 10% change in our returns would have had an approximate \$0.6 million and \$0.7 million effect on our net revenue for the years ended December 31, 2016 and 2015, respectively.

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 accruals for Qutenza were immaterial for the years ended December 31, 2016 and December 31, 2015, respectively.

**Data Fees and Fees for Service Payable to Wholesalers:** We have contracted with the Ampyra specialty pharmacies (not including ASD Specialty Healthcare, Inc.) to obtain transactional data related to Ampyra in order to ascertain a better understanding of our selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. These contracts stipulate that the specialty pharmacies provide data directly to us, as well as indirectly through Ampyra Patient Support Services, which in turn provides data to us. We pay a data fee to the specialty pharmacies for each line of data provided and the Company provides an

allowance for these data fees. A line of data is defined as data pertaining to a single prescription. We also pay a fee for service to certain wholesalers on contractually determined rates for distribution, inventory management and data reporting services. We estimate our fee for service accruals and allowances based on sales to each wholesaler and the applicable contracted rate. Our fee for service expenses are accrued at the time of product shipment and are typically settled with the wholesalers within 60 days after the end of each respective quarter. Our data fee and fee for service accruals were \$1.4 million and \$1.1 million at December 31, 2016 and December 31, 2015, respectively.

A 10% change in our data fee and fee for service allowances would have had an approximate \$0.4 million and \$0.3 million effect on our net revenue for the years ended December 31, 2016 and 2015, 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 2016, 2015, and 2014:

(in thousands)	Managed			Cash discounts	Product returns	Data fees and fees		Total
	Government care chargebacks and rebates	Contract rebates	Copay mitigation rebates			for services payable to wholesalers	Other vendor allowances	
Balance at December 31, 2013	\$ 3,790	\$ 821	\$ 578	\$ 318	\$ 31	\$ 875	\$ —	\$ 6,413
Allowances for sales 2014	25,630	5,849	6,776	4,099	24	3,705	1,347	47,430
Allowances for prior year sales	(141 )	(53 )	—	(14 )	—	(140 )	—	(348 )
Actual credits for sales during 2014	(21,180 )	(4,688 )	(6,352 )	(3,723 )	(40 )	(2,595 )	—	(38,578)
Actual credits for prior year sales	(3,099 )	(726 )	(259 )	(288 )	—	(724 )	—	(5,096 )
Balance at December 31, 2014	\$ 5,000	\$ 1,203	\$ 743	\$ 392	\$ 15	\$ 1,121	\$ 1,347	\$ 9,821
Allowances for sales 2015	34,188	6,510	7,529	5,083	914	3,480	329	58,033
Allowances for prior year sales	(276 )	(263 )	(481 )	2	6,246	(129 )	—	5,099
Actual credits for sales during 2015	(27,179 )	(5,163 )	(7,479 )	(4,568 )	—	(2,475 )	—	(46,864)
Actual credits for prior year sales	(4,588 )	(664 )	(184 )	(395 )	(2,864)	(859 )	—	(9,554 )
Balance at December 31, 2015	\$ 7,146	\$ 1,623	\$ 127	\$ 514	\$ 4,311	\$ 1,137	\$ 1,676	\$ 16,535
Allowances for sales 2016	47,047	22,595	8,747	5,689	743	4,444	412	89,677
Allowances for prior year sales	(234 )	(256 )	—	(24 )	5,279	(39 )	—	4,726
	(36,353 )	(18,535)	(8,550 )	(5,152 )	(43 )	(3,100 )	—	(71,733)



Actual credits for sales  
during 2016

Actual credits for prior year sales	(7,201 )	(1,012 )	(151 )	(433 )	(5,530)	(1,008 )	—	(15,335)
Balance at December 31, 2016	\$ 10,405	\$ 4,415	\$ 173	\$ 594	\$ 4,760	\$ 1,434	\$ 2,088	\$ 23,870
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, we were entitled to a non-refundable upfront payment of \$110.0 million as of June 30, 2009, the date of the agreement, which was received on July 1, 2009. As a result of such payment to us, \$7.7 million became payable by us to Alkermes under our existing agreements with Alkermes. These agreements obligate us to pay an amount equal to 7% of any upfront and milestone payments that we receive from the sublicensing of rights to Ampyra or other aminopyridine products. We estimate the revenue recognition period for the upfront payment that we received from Biogen, and for any milestone payments made to us by Biogen, and for the corresponding payments that we make to Alkermes, to be approximately 12 years from the date of the receipt of payment from Biogen.

## Inventory

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

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

## Cost of Sales

### Ampyra

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

### Zanaflex

Cost of sales consists of cost of inventory, expense due to inventory reserves when necessary, royalty expense, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and

milestone obligations are set forth in the agreements entered into in connection with our Zanaflex acquisition. Any payments we made in connection with the revenue interests assignment transaction entered into in December 2005 did not constitute royalty expense or otherwise affect our cost of sales. See “—Liquidity and Capital Resources—Financing Arrangements.”

## Qutenza

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

## Research and Development

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

Research and development expense consists primarily of:

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

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

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



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

(in thousands)	Year Ended December 31,		
	2016	2015	2014
<b>Preclinical and clinical development:</b>			
Contract expenses—CVT-301	\$59,736	\$32,689	\$8,073
Contract expenses—tozadenant	19,473	—	—
Contract expenses—Ampyra LCM	18,093	15,311	8,990
Contract expenses—Diazepam Nasal Spray/Plumiaz	10,330	9,825	7,805
Contract expenses—rHIgM22	4,741	4,554	5,019
Contract expenses—CVT-427	3,412	2,678	—
Contract expenses—cimaglermin alfa (previously GGF2)	2,362	8,017	6,157
Contract expenses—SYN-120	1,609	—	—
Contract expenses—BTT-1023	599	—	—
Contract expenses—Other	527	432	60
Contract expenses—AC105	100	384	1,296
Contract expenses—NP-1998	90	908	2,015
<b>Research and development operating expenses:</b>	<b>82,310</b>	<b>65,601</b>	<b>33,980</b>
<b>Acquisitions, licenses and milestones:</b>			
Diazepam Nasal Spray/Plumiaz	—	8,750	—
AC105	—	—	20
rHIgM22	25	30	25
cimaglermin alfa (previously GGF2)	10	10	10
Other	20	20	20
<b>Total research and development</b>	<b>\$203,437</b>	<b>\$149,209</b>	<b>\$73,470</b>

With respect to previously established clinical study accruals in prior periods and for the year ended December 31, 2016 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, goodwill and intangible assets including IPR&D, developed technology, website development costs, and other assets that are determined to be impaired.

100

---

### Changes in Fair Value of Acquired Contingent Consideration

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

### Other Income (Expense)

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

### Income Taxes

Our annual effective tax rate is based on pre-tax earnings (losses) 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 quarterly 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:

Assumption	Method of estimating
Estimated expected term of	Historical term of our options based on exercise data



options	
Expected volatility	Historic volatility of our common stock
Risk-free interest rate	Yields of U.S. Treasury securities corresponding with the expected life of option grants
Forfeiture rates	Historical forfeiture data

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

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

Our financial instruments consist of cash and cash equivalents, grants receivable, convertible notes payable, senior notes and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2016, except for the fair value of the Company's convertible senior notes, which was approximately \$257.9 million as of December 31, 2016.

We have cash equivalents at December 31, 2016, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and U.S. Treasury bonds, the carrying values of our cash equivalents approximate their fair values at December 31, 2016. There were no investments classified as short-term or long-term at December 31, 2016. At December 31, 2016, we held \$158.5 million in cash and cash equivalents which had an average interest rate of approximately 0.25%.

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act"), we carried out an evaluation of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of our 2016 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, Business Operations and Principal Accounting Officer. Based on that evaluation, these officers have concluded that, as of December 31, 2016, 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, Business Operations and Principal Accounting Officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

102

---

#### 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, Business Operations and Principal Accounting Officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting as of the end of 2016 (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, 2016, 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.

In 2016, the Company completed its acquisition of Biotie Therapies Corp. which is included in the Company's 2016 consolidated financial statements and constituted \$454.0 million and \$325.3 million of total and net assets, respectively as of December 31, 2016 and \$2.7 million and \$37.5 million of revenues and net loss, respectively for the year then ended. As the acquisition occurred during 2016, management excluded the Biotie Therapies Corp. 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, 2016. This attestation report appears below.

Report of Independent Registered Public Accounting Firm

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

We have audited Acorda Therapeutics, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Acorda Therapeutics, Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

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 Biotie Therapies Corp., which is included in the 2016 consolidated financial statements of Acorda Therapeutics and Subsidiaries and constituted \$454.0 million and \$325.3 million of total and net assets, respectively, as of December 31, 2016 and \$2.7 million and \$37.5 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Acorda Therapeutics, Inc. and Subsidiaries also did not include an evaluation of the internal control over financial reporting of Biotie Therapies Corp.

In our opinion, Acorda Therapeutics, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

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

February 27, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut

February 27, 2017

Item 9B. Other Information.

None.

104

---

### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2017 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 2017 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 2017 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 2017 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 2017 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, 2016 and 2015

Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Comprehensive Income for the years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014

Notes to Financial Statements

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

(3) Exhibits

Exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately

following the signature page of this Report and incorporated herein by reference.



INDEX TO FINANCIAL STATEMENTS

	PAGE
Consolidated Financial Statements of Acorda Therapeutics, Inc. and Subsidiaries:	
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Comprehensive Income</u>	F-5
<u>Consolidated Statements of Changes in Stockholders' Equity</u>	F-6
<u>Consolidated Statements of Cash Flows</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and Subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. 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, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, 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, 2016, 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, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut

February 27, 2017

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2016	2015
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 158,537	\$ 153,204
Restricted cash	79	6,032
Short-term investments	—	200,101
Trade accounts receivable, net of allowances of \$964 and \$884, as of		
December 31, 2016 and 2015, respectively	52,239	31,466
Prepaid expenses	12,907	16,079
Finished goods inventory held by the Company	43,135	36,476
Other current assets	5,760	7,959
<b>Total current assets</b>	<b>272,657</b>	<b>451,317</b>
Property and equipment, net of accumulated depreciation	34,310	40,204
Goodwill	280,599	183,636
Deferred tax asset	4,400	2,128
Intangible assets, net of accumulated amortization	742,242	430,856
Non-current portion of deferred cost of license revenue	2,272	2,906
Other assets	5,855	247
<b>Total assets</b>	<b>\$ 1,342,335</b>	<b>\$ 1,111,294</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 26,933	\$ 14,233
Accrued expenses and other current liabilities	104,890	66,133
Current portion of deferred license revenue	9,057	9,057
Current portion of loans payable	6,256	25
Current portion of convertible notes payable	765	1,144
<b>Total current liabilities</b>	<b>147,901</b>	<b>90,592</b>
Convertible senior notes (due 2021)	299,395	290,420
Acquired contingent consideration	72,100	63,500
Non-current portion of deferred license revenue	32,456	41,513
Non-current portion of loans payable	24,635	—
Non-current portion of convertible notes payable	—	1,107
Deferred tax liability	92,807	12,146
Other non-current liabilities	8,830	8,991
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at	46	43
December 31, 2016 and 2015; issued and outstanding 45,680,042 and		

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

42,999,377 shares, including those held in treasury, as of

December 31, 2016 and 2015, respectively

Treasury stock at cost (12,420 shares at December 31, 2016 and 2015,

respectively)	(329 )	(329 )
Additional paid-in capital	921,365	812,782
Accumulated deficit	(243,970 )	(209,352 )
Accumulated other comprehensive loss	(12,901 )	(119 )
Total stockholders' equity	664,211	603,025
Total liabilities and stockholders' equity	\$1,342,335	\$1,111,294

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, 2016	Year ended December 31, 2015	Year ended December 31, 2014
<b>Revenues:</b>			
Net product revenues	\$ 493,358	\$ 466,111	\$ 373,292
Royalty revenues	17,186	17,492	19,131
License revenue	9,057	9,057	9,057
Total net revenues	519,601	492,660	401,480
<b>Costs and expenses:</b>			
Cost of sales	107,475	92,297	79,981
Cost of milestone and license revenue	634	634	634
Research and development	203,437	149,209	73,470
Selling, general and administrative	235,437	205,630	201,813
Asset impairment	—	—	6,991
Changes in fair value of acquired contingent consideration	8,600	10,900	2,200
Total operating expenses	555,583	458,670	365,089
Operating (loss) income	(35,982 )	33,990	36,391
<b>Other expense (net):</b>			
Interest and amortization of debt discount expense	(16,527 )	(15,472 )	(9,288 )
Interest income	339	440	674
Other income	9,902	411	232
Total other expense (net)	(6,286 )	(14,621 )	(8,382 )
(Loss) income before taxes	(42,268 )	19,369	28,009
Benefit from (provision for) income taxes	6,665	(8,311 )	(10,337 )
Net (loss) income	\$ (35,603 )	\$ 11,058	\$ 17,672
Net loss attributable to non-controlling interest	985	—	—
Net (loss) income attributable to Acorda Therapeutics, Inc.	\$ (34,618 )	\$ 11,058	\$ 17,672
Net (loss) income per share—basic	\$ (0.76 )	\$ 0.26	\$ 0.43
Net (loss) income per share—diluted	\$ (0.76 )	\$ 0.25	\$ 0.42
<b>Weighted average common shares outstanding used in computing net</b>			
(loss) income per share—basic	45,259	42,230	41,150
<b>Weighted average common shares outstanding used in computing net</b>			
(loss) income per share—diluted	45,259	43,621	42,544

See accompanying Notes to Consolidated Financial Statements

F-4

---

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Comprehensive (Loss) Income

(In thousands)

	Year ended December 31, 2016	Year ended December 31, 2015	Year ended December 31, 2014
Net (loss) income	\$ (35,603 )	\$ 11,058	\$ 17,672
Other comprehensive (loss) income:			
Foreign currency translation adjustment	(12,901 )	—	—
Unrealized losses on available-for-sale securities, net of tax	—	(45 )	(111 )
Reclassification of net losses to net income	119	—	—
Other comprehensive (loss) income, net of tax	\$ (12,782 )	(45 )	(111 )
Comprehensive (loss) income attributable to Acorda Therapeutics, Inc.	\$ (48,385 )	\$ 11,013	\$ 17,561
Comprehensive loss attributable to noncontrolling interests.	\$ (110 )	\$ —	\$ —

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common stock		Additional		Accumulated		Total	
	Number	Par	Treasury	paid-in	Accumulated	other	Noncontrolling	stockholders
	of	value	stock	capital	deficit	comprehensive	interest	equity
	shares					income		
						(loss)		
Balance at December 31, 2013	40,896	\$ 41	\$ (329 )	\$ 678,686	\$ (238,082 )	\$ 37	\$ —	\$ 440,353
Compensation expense for								
issuance of stock options to								
employees	—	—	—	21,910	—	—	—	21,910
Compensation expense for								
issuance of restricted stock								
to employees	242	—	—	7,527	—	—	—	7,527
Exercise of stock options	746	1	—	16,014	—	—	—	16,015
Equity component of the								
convertible notes, issuance, net	—	—	—	37,795	—	—	—	37,795
Debt issuance costs	—	—	—	(1,277 )	—	—	—	(1,277 )
Excess tax benefit from share-								
based compensation								
arrangements	—	—	—	371	—	—	—	371
	—	—	—	—	—	(111 )	—	(111 )



Other comprehensive  
loss,

net of tax								
Net income	—	—	—	—	17,672	—	—	17,672
Balance at December 31, 2014	41,884	\$ 42	\$ (329 )	\$ 761,026	\$ (220,410 )	\$ (74 )	\$ —	\$ 540,255
Compensation expense for								
issuance of stock options								
to employees	—	—	—	25,026	—	—	—	25,026
Compensation expense for								
issuance of restricted								
stock to employees	244	—	—	8,441	—	—	—	8,441
Exercise of stock options	871	1	—	18,095	—	—	—	18,096
Excess tax benefit from share-								
based compensation								
arrangements	—	—	—	194	—	—	—	194
Other comprehensive loss,								
net of tax	—	—	—	—	—	(45 )	—	(45 )
Net income	—	—	—	—	11,058	—	—	11,058
Balance at December 31, 2015	42,999	\$ 43	\$ (329 )	\$ 812,782	\$ (209,352 )	\$ (119 )	\$ —	\$ 603,025
Compensation expense for								
issuance of stock options								
to employees	—	—	—	28,090	—	—	—	28,090
Compensation expense for								
issuance of restricted								
stock to employees	236	—	—	8,296	—	—	—	8,296
Exercise of stock options	194	—	—	3,427	—	—	—	3,427
	—	—	—	(13 )	—	—	—	(13 )

Excess tax charges for share-based compensation arrangements									
Private placement, net of issuance costs	2,251	3	—	72,088	—	—	—	72,091	
Acquisition of subsidiary	—	—	—	—	—	—	25,736	25,736	
Purchase of noncontrolling interest	—	—	—	(3,305 )	—	—	(24,641 )	(27,946 )	
Other comprehensive loss, net of tax	—	—	—	—	—	(12,782 )	(110 )	(12,892 )	
Net loss	—	—	—	—	(34,618 )	—	(985 )	(35,603 )	
Balance at December 31, 2016	45,680	\$ 46	\$ (329 )	\$ 921,365	\$ (243,970 )	\$ (12,901 )	\$ —	\$ 664,211	

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(In thousands)

	Year ended	Year ended	Year ended
	December 31, 2016	December 31, 2015	December 31, 2014
Cash flows from operating activities:			
Net (loss) income	\$(35,603 )	\$11,058	\$17,672
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Recognition of deferred product revenue - Zanaflex	—	(22,186 )	—
Share-based compensation expense	36,386	33,467	29,437
Amortization of net premiums and discounts on investments	467	3,366	3,571
Amortization of debt discount and debt issuance costs	9,717	8,562	4,291
Amortization of revenue interest issuance cost	—	15	27
Depreciation and amortization expense	21,582	15,012	8,473
Intangible asset impairment	—	—	6,991
Change in contingent consideration obligation	8,600	10,900	2,200
Realized gain on foreign currency transaction	(9,856 )	—	—
Gain on put/call liability	—	—	(147 )
Deferred tax (benefit) provision	(11,190 )	3,975	6,681
Excess tax charge (benefit) from share-based compensation arrangements	15	(194 )	(371 )
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(19,965 )	744	(1,427 )
Decrease (increase) in prepaid expenses and other current assets	6,904	(998 )	(4,083 )
Increase in inventory held by the Company	(6,660 )	(10,220 )	(721 )
Decrease in inventory held by others	—	581	56
Decrease in non-current portion of deferred cost of license revenue	634	634	634
Decrease in other assets	34	34	34
Increase (decrease) in accounts payable, accrued expenses and other current liabilities			
	37,625	(825 )	13,180
(Decrease) increase in revenue interest liability interest payable	—	(374 )	108
Decrease in non-current portion of deferred license revenue	(9,057 )	(9,057 )	(9,057 )
Increase (decrease) in other non-current liabilities	16	(198 )	(301 )
Decrease in deferred product revenue—Zanaflex	—	(989 )	(2,670 )
Decrease (increase) in restricted cash	5,698	(4,826 )	71
Net cash provided by operating activities	35,347	38,481	74,649
Cash flows from investing activities:			
Purchases of property and equipment	(6,192 )	(5,921 )	(5,084 )

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Purchases of intangible assets	(893 )	(1,145 )	(2,699 )
Acquisitions, net of cash received and gain on foreign currency transaction	(266,454)	—	(476,151)
Purchases of investments	(40,215 )	(434,670)	(580,381)
Proceeds from maturities of investments	239,966	356,500	770,490
Net cash used in investing activities	(73,786 )	(85,236 )	(293,825)
Cash flows from financing activities:			
Proceeds from issuance of convertible senior notes	—	—	345,000
Debt issuance costs	(1,587 )	—	(7,516 )
Proceeds from issuance of common stock and option exercises	75,520	18,096	16,015
Purchase of non-controlling interest	(27,946 )		
Excess tax charge (benefit) from share-based compensation arrangements	(15 )	194	371
Repayments of revenue interest liability	(41 )	(501 )	(562 )
Net cash provided by financing activities	45,931	17,789	353,308
Effect of exchange rate changes on cash and cash equivalents	(2,159 )	—	—
Net increase (decrease) in cash and cash equivalents	5,333	(28,966 )	134,133
Cash and cash equivalents at beginning of period	153,204	182,170	48,037
Cash and cash equivalents at end of period	\$158,537	\$153,204	\$182,170
Supplemental disclosure:			
Cash paid for interest	\$6,059	\$7,218	\$4,522
Cash paid for taxes	4,250	4,697	4,392

See accompanying Notes to Consolidated Financial Statements.

F-7

## 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 focused on developing therapies that restore function and improve the lives of people with neurological disorders.

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

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

##### Principles of Consolidation

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

##### Use of Estimates

The preparation of the consolidated financial statements requires management to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include share based compensation accounting, which are largely dependent on the fair value of the Company's equity securities, measurement of changes in the fair value of acquired contingent consideration which is based on a probability weighted discounted cash flow valuation methodology and valuation allowances on deferred tax assets which are based on an assessment of recoverability of the deferred tax assets against future taxable income. Actual results could differ from those estimates.

##### Risks and Uncertainties

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of intellectual property rights.

##### Cash and Cash Equivalents

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

#### Restricted Cash

Restricted cash represents a bank account with funds to cover the Company's self-funded employee health insurance. At December 31, 2016, the Company also held \$0.3 million of restricted cash related to cash collateralized standby letters of credit in connection with obligations under facility leases, which is included with other assets in the consolidated balance sheet due to the long-term nature of the letters of credit. (see Note 8).

F-8

---

## Investments

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

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

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

## Other Comprehensive (Loss) Income

The Company's other comprehensive (loss) income is comprised of unrealized gains and losses on available-for-sale securities and adjustments for foreign currency translation and is recorded and presented net of income tax. There was no income tax allocated to the foreign currency translation adjustment in Other Comprehensive (Loss) Income for the period ended December 31, 2016. The cumulative foreign currency translation adjustment reported in Other Comprehensive (Loss) Income was \$12.9 million for the period ended December 31, 2016. There was no foreign currency translation adjustment reported in Other Comprehensive (Loss) Income for the period ended December 31, 2015.

## Inventory

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

## Ampyra

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

## Property and Equipment

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

charged to expense as incurred.

#### Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. See Note 4 for a discussion of goodwill.

F-9

---



### Intangible Assets

The Company has finite lived intangible assets related to Selincro, 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, tozadenant, SYN120 and BTT1023. 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 4 for discussion on intangible assets.

### Contingent Consideration

The Company may record contingent consideration as part of the cost of business acquisitions. Contingent consideration is recognized at fair value as of the date of acquisition and recorded as a liability on the consolidated balance sheet. The contingent consideration is re-valued on a quarterly basis using a probability weighted discounted cash-flow approach until fulfillment or expiration of the contingency. Changes in the fair value of the contingent consideration are recognized in the statement of operations. See Note 12 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

F-10

---

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 that are determined to have had a drop in their fair value are adjusted downward and an expense is recognized in the statement of operations. These assets are tested at least annually or sooner when a triggering event occurs that could indicate a potential impairment.

#### Accounting for Income Taxes

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

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

#### Revenue Recognition

##### Ampyra

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

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies, Kaiser Permanente and ASD Specialty Healthcare, Inc., an adjustment is recorded for estimated discounts, rebates, and chargebacks. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for discounts, rebates, and

chargebacks are established based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales. The Company does not accept returns of Ampyra with the exception of product damages that occur during shipping.

#### Zanaflex

The Company applies the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex tablet and capsule (Zanaflex products) shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the

F-11

---

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

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

#### Qutenza

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

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

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

F-12

---

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. The Company leases a manufacturing facility in Chelsea, Massachusetts which produces CVT-301 for clinical trials and eventually will produce commercial supply, if approved.

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

The Company's principal direct customers as of December 31, 2016 were a network of specialty pharmacies, Kaiser Permanente, and ASD Specialty Healthcare, Inc. for Ampyra, wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets, and two specialty distributors for Qutenza. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. Three customers individually accounted for more than 10% of the Company's revenue in 2016 and 2015 and four customers individually accounted for more than 10% of the Company's revenue in 2014. Three customers individually accounted for more than 10% of the Company's accounts receivable as of December 31, 2016 and 2015, respectively. The Company's net product revenues are generated in the U.S.

#### Allowance for Cash Discounts

An allowance for cash discounts is accrued based on historical usage rates at the time of product shipment. The Company adjusts accruals based on actual activity as necessary. Cash discounts are typically settled with customers within 30 days after the end of each calendar month. The Company had cash discount allowances of \$5.7 million and \$5.1 million for the years ended December 31, 2016 and 2015, respectively. The Company's accruals for cash discount allowances were \$0.6 million and \$0.5 million as of December 31, 2016 and 2015, respectively.

#### Allowance for Doubtful Accounts

A portion of the Company's accounts receivable may not be collected due principally to customer disputes. The Company provides reserves for these situations based on the evaluation of the aging of its trade receivable portfolio and an analysis of high-risk customers. The Company has not historically experienced material losses related to credit risk. The Company has recognized an allowance related to one customer of approximately \$0.4 million as of December 31, 2016 and December 31, 2015. For the year ended December 31, 2016 and 2015, the Company recorded no provision and did not record any write-offs.

#### Contingencies

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

#### Fair Value of Financial Instruments

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

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

- (a) Cash equivalents, grants receivable, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these instruments;
- (b) Available-for-sale securities are recorded based primarily on quoted market prices;

F-13

---



- (c) Acquired contingent consideration related to the Civitas acquisition is measured at fair value using a probability weighted, discounted cash flow approach;
- (d) 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; and
- (e) Capital and R&D loans were measured at fair value based on a discounted cash flow approach.

#### Earnings per Share

Basic net income (loss) per share and diluted 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 14 for discussion on earnings (loss) 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.

#### Foreign Currency Translation

The functional currency of operations outside the United States of America is deemed to be the currency of the local country, unless otherwise determined that the United States dollar would serve as a more appropriate functional currency given the economic operations of the entity. Accordingly, the assets and liabilities of the Company's foreign subsidiary, Biotie, are translated into United States dollars using the period-end exchange rate; and income and expense items are translated using the average exchange rate during the period; and equity transactions are translated at historical rates. Cumulative translation adjustments are reflected as a separate component of equity. Foreign currency transaction gains and losses are charged to operations.

#### Segment and Geographic Information

The Company is managed and operated as one business which is focused on developing therapies that restore function and 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 to allocate resources to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment. Net product revenues reported to date are derived from the sales of Ampyra, Zanaflex and Qutenza in the U.S.

Accumulated Other Comprehensive (Loss)

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

F-14

---

## Recent Accounting Pronouncements - Adopted

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 Company adopted this guidance effective December 31, 2016. The adoption of this guidance did not have a significant impact on the Company’s consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update 2015-03, “Interest – Imputation of Interest” (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. ASU-2015-03 is effective for fiscal years and interim periods therein beginning after December 15, 2015, with early adoption permitted. The Company adopted this guidance retrospectively effective in the three-month period ended March 31, 2016. The impact of the adoption of this guidance on the Company’s consolidated balance sheet as of December 31, 2015 was a reclassification of approximately \$5.0 million representing the unamortized balance of debt issuance costs as of December 31, 2015 from Other Assets to the Convertible Senior Notes liability.

(In thousands)	Balance at December 31, 2015	
	Revised Reporting	As Previously Reported
Other assets	\$247	\$5,296
Convertible notes payable – due 2021	\$(290,420)	\$(295,469)

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

In September 2015, the FASB issued Accounting Standards update 2015-16, “Business Combinations” (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (ASU 2015-16), which requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the period in which the adjustment amount is determined. The acquirer is required to also record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. In addition the acquirer is required to present separately on the face of the income statement or disclose in the notes to the financial statements the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. This guidance is effective for fiscal years and interim periods therein beginning after December 15, 2015 with early adoption permitted, and requires prospective application. The Company adopted this guidance

effective December 31, 2015. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

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

In December 2016, the FASB issued Accounting Standards Update 2016-19, "Technical Corrections and Improvements". With regard to fair value measurement disclosures, ASU 2016-19 clarifies the difference between a valuation approach and a valuation technique and also requires disclosure about when there has been a change in either or both a valuation approach and/or a valuation technique. This change was effective immediately upon issuance of ASU 2016-

09. The adoption of this guidance did not have a significant effect on the Company's consolidated financial statements or related disclosures.

#### Recent Accounting Pronouncements – Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (Topic 606) (ASU 2014-09). This new standard will replace all current U.S. GAAP guidance on this topic and eliminate all industry-specific guidance. In July 2015, the FASB deferred the effective date of the new revenue standard for interim and annual periods beginning after December 15, 2017 (previously December 15, 2016). The Company expects to adopt this guidance when effective. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. The Company is evaluating the transition method that will be elected and the potential effects of adopting the provisions of ASU No. 2014-09.

The new guidance requires the application of a five-step model to determine the amount and timing of revenue to be recognized. The underlying principle is that revenue is to be recognized for the transfer of goods or services to customers that reflects the amount of consideration that the Company expects to be entitled to in exchange for those goods or services.

The Company is continuing to assess the impact of the new guidance on its accounting policies and procedures and is evaluating the new requirements as applied to existing revenue contracts. Although the Company is continuing to assess the impact of the new guidance, the Company believes the most significant impact will relate to the recognition of license revenues associated with its Biogen contract at a point in time rather than over a period of time. The Company is reviewing its revenue contracts and working on its plan for implementation of the new guidance which it expects to adopt beginning in the first quarter of 2018.

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

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

In February 2016, the FASB issued Accounting Standards Update 2016-02, “Leases” (Topic 842). The main objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating whether it will adopt this guidance early and the impact it may have on its consolidated financial statements is not currently estimable.

In March 2016, the FASB issued Accounting Standards Update 2016-06, “Derivatives and Hedging” (Topic 815): Contingent Put and Call Options in Derivative Contracts (ASU 2016-06), which clarifies the requirements for assessing whether contingent options that can accelerate the payment of principal on debt instruments are clearly and

closely related to their debt hosts. This ASU is effective for fiscal years beginning after December 15, 2016 and interim periods therein, with early adoption permitted. The Company is currently evaluating whether it will adopt this guidance early and the impact it may have on its financial statements.

In March 2016, the FASB issued Accounting Standards Update 2016-09, "Compensation – Stock Compensation" (Topic 718). The main objective of this update is to simplify the accounting, and reporting classifications for certain aspects of share-based payment transactions. This ASU is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company expects to adopt this guidance when effective and the impact it will have on its consolidated financial statements is not currently estimable.

F-16

---

In August 2016, the FASB issued Accounting Standards Update ASU 2016-15 “Statement of Cash Flows” (Topic 230): Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15), which specifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU requires retrospective application to all periods presented and is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the new guidance to determine the impact it may have on its consolidated financial statements.

In November 2016, the FASB issued Accounting Standards Update ASU 2016-18 “Statement of Cash Flows” (Topic 230), Restricted Cash (ASU 2016-18), which defines new requirements for the presentation of restricted cash and restricted cash equivalents in the statement of cash flows. The amendments in this ASU require retrospective application to each period presented and are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating whether it will adopt this guidance early and the impact it may have on its consolidated financial statements.

In January 2017, the FASB issued Accounting Standards Update 2017-01, “Business Combinations” (Topic 805): Clarifying the Definition of a Business (ASU 2017-01), which provides additional clarification to aid in determining when a set of assets and activities is not a business. The amendments in this update require prospective applications and are effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating whether it will adopt this guidance early and the impact it may have on its consolidated financial statements.

#### Subsequent Events

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

On February 8, 2017, we entered into a settlement agreement with Apotex Inc. and its subsidiary Apotex Corporation (collectively “Apotex”) to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Apotex will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2025, or potentially earlier under certain circumstances. The parties will request that the Court enter a Consent Order, in which it will dismiss our litigation against Apotex referred to above. The parties will submit the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Apotex does not resolve pending patent litigation that we brought against other ANDA filers, as described in this report. The settlement is reflected in our results of operations for the period ending December 31, 2016.

#### (3) Acquisitions

Biotie Therapies Corp.

On April 18, 2016, the Company acquired a controlling interest in Biotie Therapies Corp. (“Biotie”) pursuant to a combination agreement entered into in January 2016. The acquisition of Biotie positions the Company as a leader in Parkinson’s disease therapeutic development, with three clinical-stage compounds that have the potential to improve the lives of people with Parkinson’s disease. In accordance with the combination agreement, the Company closed a public tender offer for all of Biotie’s capital stock, pursuant to which the Company acquired approximately 93% of the fully diluted capital stock of Biotie for a cash purchase price of approximately \$350 million. On May 4, 2016, the Company acquired an additional approximately 4% of Biotie’s fully diluted capital stock pursuant to a subsequent public offer to Biotie stockholders that did not tender their shares in the initial tender offer. The purchase consideration for the subsequent tender offer was approximately \$14.5 million. The acquisition of the additional 4% of Biotie’s fully diluted capital stock resulted in the Company owning approximately 97% of the fully diluted capital stock of Biotie (the “Acquisition”) as of June 30, 2016.

On September 30, 2016, the Company acquired the remaining approximately 3% of Biotie’s fully diluted capital stock in exchange for the payment of a cash security deposit of approximately \$13.5 million, as determined by the arbitral tribunal administering the redemption proceedings. Accordingly, the Company owned 100% of the fully diluted capital stock of Biotie as of September 30, 2016.

F-17

---



The Company estimated the preliminary fair value of the assets acquired and liabilities assumed as of the date of acquisition based on the information available at that time. The Company recorded measurement-period adjustments to its preliminary purchase price allocation to increase current liabilities and to decrease other current assets and other long-term liabilities from the acquisition date through December 31, 2016. The total net impact of these adjustments was an increase to goodwill of \$1.2 million, which reduced current assets and long-term liabilities and increased current liabilities and the deferred tax liability with a corresponding decrease to goodwill. These changes had an immaterial effect on any related amortizations for the period April 18, 2016 through December 31, 2016. The valuation of the assets and liabilities is subject to further analysis however, the Company believes that finalization of the valuation of the long-term debt and accounting for deferred taxes are the key remaining outstanding items. As the Company finalizes the fair values of the assets acquired and liabilities assumed, additional purchase price adjustments may be recorded during the measurement period and such adjustments could be material. The Company will reflect measurement period adjustments, if any, in the period in which the adjustments are recognized.

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 of April 18, 2016, as adjusted through the period ended December 31, 2016:

	Preliminary Allocation as of the acquisition date	Measurement Period Adjustments	Preliminary Allocation, as adjusted through December 31, 2016
(In thousands)			
Cash and cash equivalents	\$ 73,854	\$ —	\$ 73,854
Other current assets	2,208	(330 )	1,878
Other long-term assets	4,962	—	4,962
Intangible assets (indefinite-lived)	260,500	—	260,500
Intangible assets (definite-lived)	65,000	—	65,000
Current liabilities	(17,547 )	(1,025 )	(18,572 )
Deferred taxes	(89,038 )	(870 )	(89,908 )
Other long-term liabilities	(26,715 )	1,025	(25,690 )
Fair value of assets and liabilities acquired	273,224	(1,200 )	272,024
Goodwill	102,676	1,200	103,876
Total purchase price	375,900	—	375,900
Less: Noncontrolling interests	(25,736 )	—	(25,736 )
Purchase consideration on date of acquisition	\$ 350,164	\$ —	\$ 350,164

The Company accounted for the Acquisition as a business combination using the acquisition method of accounting. Under the acquisition method of accounting, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of the date of acquisition. The Company incurred approximately \$18.1 million in acquisition related expenses to date. For the year ended December 31, 2016, the Company incurred approximately \$17.6 million in acquisition related expenses, which were included in selling, general and administrative expenses in the consolidated statement of operations. The results of Biotie's operations have been included in the consolidated statements of operations from the acquisition date of April 18, 2016.

The definite-lived intangible asset will be amortized on a straight line basis over the period in which the Company expects to receive economic benefit and will be reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable.

The fair value of the IPR&D will be capitalized as of the acquisition date and subsequently accounted for as indefinite-lived intangible assets until disposition of the assets or completion or abandonment of the associated research and development efforts. Accordingly, during the development period after the completion of the acquisition, these assets will not be amortized into earnings; rather, these assets will be subject to periodic impairment testing. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined and the assets will be considered definite-lived intangible assets and amortized over their expected useful lives.

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

F-18

---

The revenue of Biotie included in the consolidated statements of operations for the period April 18, 2016 through December 31, 2016 was \$2.7 million. The net loss of Biotie included in the consolidated statement of operations for the period April 18, 2016 through December 31, 2016 was \$37.5 million.

#### Noncontrolling Interests

The fair value of the noncontrolling interest comprised the fair value of Biotie's equity interests not acquired by the Company. The fair value of the noncontrolling interest was determined by quoted market price, which is considered to be a Level 1 input under the fair value measurements and disclosure guidance. The noncontrolling interest in Biotie was presented as permanent equity in the Company's consolidated balance sheet. Noncontrolling interests are generally adjusted for the net income or loss and other comprehensive income or loss attributable to the noncontrolling shareholders and any additional acquisition of noncontrolling interests. On May 4, 2016, the Company acquired an additional approximately 4% of Biotie's fully diluted capital stock. On September 30, 2016, the Company acquired shares representing the remaining approximately 3% of Biotie's fully diluted capital stock, which eliminated the noncontrolling interest as of September 30, 2016.

#### Financial Instruments

The Company does not enter into hedging transactions in the normal course of business. However, as a result of the Biotie acquisition which was completed in Euros, the Company was exposed to fluctuations in exchange rates between the U.S. dollar and the Euro until the completion of the transaction. To mitigate this risk, the Company entered into foreign currency options to limit its exposure to fluctuations in exchange rates between the U.S. dollar and the Euro until the transaction was completed. The foreign currency options were settled as of May 2, 2016. There were no foreign currency options outstanding as of December 31, 2016.

The Company had a realized gain on the foreign currency options of approximately \$9.9 million, which is included in other income in the consolidated statements of operations for the year ended December 31, 2016.

#### Pro-Forma Financial Information Associated with the Biotie Acquisition (Unaudited)

The following table summarizes certain supplemental pro forma financial information for the years ended December 31, 2016 and 2015 as if the acquisition of Biotie had occurred as of January 1, 2015. The unaudited pro forma financial information for the year ended December 31, 2016 reflects (i) the net impact to amortization expense based on the fair value adjustments to the intangible assets acquired from Biotie; (ii) the impact to operations resulting from the reversal of transaction costs related to the Acquisition; (iii) the impact to operations resulting from the reversal of the unrealized and realized gains on the foreign currency option; (iv) the impact to interest expense based on the fair value adjustments to the debt acquired from Biotie; (v) the tax effects of those adjustments; and (vi) the net loss attributable to the noncontrolling interests resulting from the acquisition.

The unaudited pro forma financial information for the year ended December 31, 2015 reflects (i) the net impact to amortization expense based on the fair value adjustments to the intangible assets acquired from Biotie; (ii) the impact to interest expense based on the fair value adjustments to the debt acquired from Biotie; (iii) the net loss attributable to the noncontrolling interests resulting from the acquisition; and (iv) 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

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

(In thousands)	Year ended December 31, 2016		Year ended December 31, 2015	
	Reported	Pro Forma	Reported	Pro Forma
Net revenues	\$519,601	\$520,658	\$492,660	\$496,688
Net (loss) income from continuing operations				
attributable to Acorda	\$(34,618 )	\$(57,925 )	\$11,058	\$(28,684 )

F-19

---

#### (4) Intangible Assets and Goodwill

##### Intangible Assets

##### Tozadenant, SYN120, BTT1023 and Selincro IPR&D

In connection with the acquisition of Biotie (Note 3), the Company acquired global rights to tozadenant, SYN120, and BTT1023. Tozadenant is an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF periods. SYN120 is an oral, dual antagonist with the potential to facilitate pro-cognitive and antipsychotic activities for patients with neurodegenerative diseases, such as Parkinson's disease and Alzheimer's disease. BTT1023 is a fully human monoclonal antibody that targets vascular adhesion for the potential treatment of inflammatory/fibrotic disease, such as rheumatoid arthritis and psoriasis. The Company also acquired rights to Selincro, an orally administered drug used for the treatment of alcohol dependence. Selincro received European Medicines Agency approval in 2013 and is currently marketed across Europe by Biotie's partner H. Lundbeck A/S, a Danish pharmaceutical company.

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, based upon the estimated fair values of those assets and liabilities at the date of acquisition. The Company classified the fair value of the acquired IPR&D as indefinite lived intangible assets until the successful completion or abandonment of the associated research and development efforts. The Company classified the fair value of Selincro as a definite lived intangible asset. The value allocated to Selincro was \$65 million, which will be amortized over the estimated remaining useful life of approximately 6 years. The value allocated to the indefinite lived intangible assets was \$260.5 million.

##### CVT-301 and ARCUS Technology IPR&D

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

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

##### Ampyra

In January 2010, the Company received marketing approval from the FDA for Ampyra triggering two milestone payments of \$2.5 million to Alkermes and \$0.8 million to Rush-Presbyterian St. Luke's Medical Center (Rush) and an additional \$2.5 million payable to Alkermes two years from date of approval. The Company made the milestone payments totaling \$5.75 million, which were recorded as intangible assets in the consolidated financial statements.

The Company had a License Agreement with the Canadian Spinal Research Organization (CSRO) that granted the Company an exclusive and worldwide license under certain patent assets and know-how of CSRO. The agreement required the Company to pay royalties to CSRO 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 2010, the Company purchased CSRO's rights to all royalty payments under the agreement for \$3.0 million. This payment was recorded as an intangible asset in the consolidated financial statements.

#### 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 carrying value of the intangible assets may be impaired or that the estimated remaining useful lives of these assets may warrant

F-20

---

revision. As of December 31, 2016, the Company determined that the intangible assets were not impaired and that there are no facts or circumstances that would indicate a need for changing the estimated remaining useful lives of these assets.

Intangible assets consisted of the following:

	December 31, 2016				December 31, 2015			
	Estimated Remaining Useful Lives (Years)	Cost	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Cost	Accumulated Amortization	Net Carrying Amount
(Dollars In thousands)								
In-process research & development <sup>(1)</sup>	Indefinite-lived	\$683,500	\$ —	\$ (1,794 )	\$681,706	\$423,000	\$ —	\$423,000
Selincro	6	65,000	(6,445 )	(4,061 )	54,494	—	—	—
Ampyra milestones	10	5,750	(2,677 )	—	3,073	5,750	(2,380 )	3,370
Ampyra CSRO royalty buyout	3	3,000	(2,108 )	—	892	3,000	(1,817 )	1,183
Website development costs	3	13,459	(11,485 )	—	1,974	12,504	(9,467 )	3,037
Website development costs—in process	n/a	103	—	—	103	266	—	266
		\$770,812	\$ (22,715 )	\$ (5,855 )	\$742,242	\$444,520	\$ (13,664 )	\$430,856

(1)Includes the fair values of: CVT-301: \$423.0 million; tozadenant: \$232.0 million; SYN120: \$24.2 million and BTT-1023: \$4.3 million

The Company recorded \$9.1 million and \$3.1 million in amortization expense related to these intangible assets for the years ended December 31, 2016 and 2015, respectively.

Estimated future amortization expense for intangible assets subsequent to December 31, 2016 is as follows:

(In thousands)  
2017 \$11,119

2018	10,423
2019	10,055
2020	9,602
2021	9,583
Thereafter	13,712
	\$64,494

## Goodwill

The following table presents the goodwill balances at December 31, 2016 and 2015 and the associated changes in goodwill through December 31, 2016.

(In thousands)	
Balance at December 31, 2015	\$183,636
Goodwill associated with the acquisition of Biotie Therapies Corp.	102,676
Increase to goodwill due to measurement period adjustments	1,200
Foreign currency translation adjustment	(6,913 )
Balance at December 31, 2016	\$280,599



## (5) Investments

The Company has determined that all of its investments were 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:

		Gross	Gross	Estimated
	Amortized	unrealized	unrealized	fair
(In thousands)	Cost	gains	losses	value
December 31, 2016				
US Treasury bonds	\$ —	\$ —	\$ —	\$ —
December 31, 2015				
US Treasury bonds	\$ 200,244	\$ —	\$ (143 )	\$ 200,101

The Company held no available-for-sale securities as of December 31, 2016. These securities were sold during 2016 to effect the Biotie acquisition. The Company had a realized gain on the sale of these investments of \$0.03 million, which is reflected in earnings for the year ended December 31, 2016. The Company's available-for-sale securities were classified as short-term investments and consisted of U.S. Treasury bonds as of December 31, 2015.

Short-term investments with maturities of three months or less from date of purchase have been classified as cash and cash equivalents, and amounted to \$18.5 million and \$83.5 million as of December 31, 2016 and 2015, 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, 2016 and 2015.

The Company holds available-for-sale investment securities which are reported at fair value on the Company's balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive (loss) income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the net unrealized holding losses on available-for-sale investments during the years ended December 31, 2016 and 2015 were as follows (in thousands):

	Net Unrealized
	Gains (Losses) on
	Marketable
(In thousands)	Securities
Balance at December 31, 2014	\$ (74 )
Other comprehensive loss before reclassifications:	(45 )
Amounts reclassified from accumulated other	—

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

comprehensive loss		
Net current period other comprehensive loss	(119	)
Balance at December 31, 2015	(119	)
Other comprehensive loss before reclassifications:		
Amounts reclassified from accumulated other		
comprehensive loss	119	
Net current period other comprehensive income	119	
Balance at December 31, 2016	\$	—

F-22

---

## (6) Property and Equipment

Property and equipment consisted of the following:

	December 31,	December 31,	Estimated
(In thousands)	2016	2015	useful lives used
Machinery and equipment	\$ 21,964	\$ 21,026	2-7 years Lesser of useful life or
Leasehold improvements	19,406	19,135	remaining lease term
Computer equipment	18,700	15,776	1-3 years
Laboratory equipment	7,522	6,514	2-5 years
Furniture and fixtures	2,890	2,064	4-7 years
Capital in progress	3,629	1,318	
	74,111	65,833	
Less accumulated depreciation	(39,801 )	(25,629 )	
	\$ 34,310	\$ 40,204	

Depreciation and amortization expense on property and equipment was \$12.3 million and \$11.9 million for the years ended December 31, 2016 and 2015, respectively.

## (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, 2016, the Company had granted an aggregate of 2,384,345 shares as restricted stock of stock options under the 1999 Plan, of which there were no remaining shares subject to outstanding options.

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

The 2006 Plan was administered by the Compensation Committee of the Board of Directors, which selected the individuals to be granted options and restricted stock, determined the time or times at which options and restricted stock were to be granted, determined the number of shares to be granted subject to any option or restricted stock and

the duration of each option and restricted stock, and made any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. The number of shares of common stock authorized for issuance under the 2006 Plan as of December 31, 2016 was 14,912,048 shares. The total number of shares of common stock available for issuance under the 2006 Plan, including shares of common stock subject to the then outstanding awards, automatically increased on January 1 of each year during the term of the 2006 Plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board approved the automatic increases of 4% for 2015, 2014, and 2013. As of December 31, 2016, the Company had granted an aggregate of 12,620,331 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 7,150,883 shares remained subject to outstanding options.

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

F-23

---

The 2015 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and restricted stock, determines the time or times at which options and restricted stock are to be granted, determines the number of shares to be granted subject to any option or restricted stock and the duration of each option and restricted stock, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2015 Plan. Under the 2015 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Since inception, the number of shares of common stock authorized for issuance under the 2015 Plan as of December 31, 2016 is 5,100,000 shares. Upon the exercise of options in the future, the Company intends to issue new shares. As of December 31, 2016, the Company had granted an aggregate of 2,392,521 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 4,818,858 shares remained subject to outstanding options.

On April 14, 2016 the Compensation Committee of the Company's Board of Directors (the "Compensation Committee") approved the Acorda Therapeutics, Inc. 2016 Inducement Plan (the "2016 Plan") to provide equity compensation to certain individuals or directors of the Company (or its subsidiaries) in order to induce such individuals to enter into employment with the Company or its subsidiaries. These equity awards were issued to individuals employed by Biotie Therapies Corp. and its subsidiary Biotie Therapies, Inc. (collectively, "Biotie") in connection with our acquisition of Biotie. The number of shares of common stock authorized for issuance under the 2016 Plan is 366,950 shares. As of December 31, 2016, the Company had granted an aggregate of 331,950 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2016 Plan, of which 234,750 shares remained subject to outstanding options. Our Board of Directors could but has not as of the date, authorized the issuance of any additional equity awards under this Plan.

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,		
	2016	2015	2014
Employees and directors:			
Estimated volatility%	44.63 %	46.68 %	51.26 %
Expected life in years	5.99	5.88	5.84
Risk free interest rate%	1.46 %	1.74 %	1.79 %
Dividend yield	—	—	—

The Company estimated volatility for purposes of computing compensation expense on its employee and director options using the historic volatility of the Company's stock price. The expected life used to estimate the fair value of employee and director options 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, 2016, 2015 and 2014 amounted to approximately \$13.26, \$15.85, and \$17.61, respectively. No options were granted to non-employees for the years ended December 31, 2016, 2015 and 2014.

During the year ended December 31, 2016, the Company granted 2,641,683 stock options and restricted stock awards to employees and directors under all plans. The stock options were issued with a weighted average exercise price of \$30.85 per share. As a result of these grants, the total compensation charge to be recognized over the service period is \$36.7 million, of which \$10.8 million was recognized during the year ended December 31, 2016.

F-24

---

Compensation costs for options and restricted stock granted to employees and directors amounted to \$36.4 million, \$33.5 million, and \$29.4 million, for the years ended December 31, 2016, 2015 and 2014, respectively. There were no compensation costs capitalized in inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, and selling, general and administrative expense based on employee job function. The following table summarizes share-based compensation expense included within the Company's consolidated statements of operations:

(In thousands)	Year ended December 31,		
	2016	2015	2014
Research and development	\$10,610	\$8,474	\$5,939
Selling, general and administrative	25,777	24,992	23,498
Total	\$36,387	\$33,466	\$29,437

A summary of share based compensation activity for the year ended December 31, 2016 is presented below:

#### Stock Option Activity

	Number	Weighted Average Intrinsic		
	of Shares	Weighted Average	Remaining	Value
	(In thousands)	Exercise Price	Contractual Term	(In thousands)
Balance at December 31, 2013	6,486	\$ 25.61		
Granted	2,352	36.56		
Forfeited and expired	(306 )	32.40		
Exercised	(746 )	21.46		
Balance at December 31, 2014	7,786	\$ 29.05		
Granted	1,651	35.45		
Forfeited and expired	(343 )	34.85		
Exercised	(871 )	20.77		
Balance at December 31, 2015	8,223	\$ 30.97		
Granted	1,766	31.55		
Forfeited and expired	(723 )	34.21		
Exercised	(194 )	17.69		
Balance at December 31, 2016	9,072	\$ 31.11	6.3	\$ 70,680
Vested and expected to vest at December 31, 2016	8,994	\$ 31.10	6.3	\$ 70,032
Vested and exercisable at December 31, 2016	6,152	\$ 30.00	5.2	\$ 59,612

Range of exercise price	Options Outstanding		Options Exercisable	
	Outstanding	Weighted-average	Exercisable	Weighted-average
	as of	average	as of	average

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

	December 31, 2016	remaining contractual life	exercise price	December 31, 2016	exercise price
	(In thousands)			(In thousands)	
\$15.91 - \$26.35	2,335	4.0	\$ 22.97	2,102	\$ 22.82
\$26.38 - \$30.46	1,879	7.0	29.27	1,200	29.64
\$30.49 - \$35.53	2,395	6.9	33.83	1,459	33.23
\$35.58 - \$39.38	2,278	7.3	37.28	1,318	37.54
\$39.67 - \$44.50	185	8.1	41.37	73	41.62
	9,072	6.3	\$ 31.11	6,152	\$ 30.00

F-25

---



## Restricted Stock Activity

	Number of Shares
Restricted Stock	(In thousands)
Nonvested at December 31, 2013	421
Granted	387
Vested	(241 )
Forfeited	(48 )
Nonvested at December 31, 2014	519
Granted	205
Vested	(244 )
Forfeited	(39 )
Nonvested at December 31, 2015	441
Granted	664
Vested	(236 )
Forfeited	(244 )
Nonvested at December 31, 2016	625

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2016 totaled \$52.5 million and is expected to be recognized over a weighted average period of approximately 2.3 years.

## (8) Debt

## Convertible Senior Notes

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

The Notes are 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, under certain circumstances as outlined in the indenture, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per \$1,000 principal amount of Notes (representing an initial conversion price of approximately \$42.56 per share).

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, under certain circumstances as outlined in the indenture.

The Company pays 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 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 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 equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The outstanding note balance as of December 31, 2016 and 2015 consisted of the following:

(In thousands)	December 31, 2016	December 31, 2015
<b>Liability component:</b>		
Principal	\$ 345,000	\$ 345,000
Less: debt discount and debt issuance costs, net	(45,605)	(54,580)
Net carrying amount	299,395	\$ 290,420
<b>Equity component</b>	<b>\$ 61,195</b>	<b>\$ 61,195</b>

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 a reduction in the carrying amount of the debt liability on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the Notes using the effective interest method.

The Company determined the expected life of the debt was equal to the seven year term on the Notes. The fair value of the Company's convertible senior notes was approximately \$257.9 million as of December 31, 2016.

As of December 31, 2016, the remaining contractual life of the Notes is approximately 3.5 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through December 31, 2016. The following table sets forth total interest expense recognized related to the Notes for the years ended December 31, 2016 and 2015:

(In thousands)	Year ended December 31, 2016	Year ended December 31, 2015
Contractual interest expense	\$ 6,038	\$ 6,038
Amortization of debt issuance costs	830	792
Amortization of debt discount	8,145	7,770
Total interest expense	\$ 15,013	\$ 14,600

### 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 which were subsequently transferred to funds affiliated with Saints Capital. One promissory note remains outstanding in the amount of \$0.8 million and bears interest at a rate of 3%. This note was paid in full in January 2017. (See Note 12).

### Asset Based Loan

On June 1, 2016, the Company and certain of its subsidiaries entered into a Credit Agreement (the “Credit Agreement”) with JPMorgan Chase Bank, N.A., as the sole initial lender and the administrative agent for the lenders (the “Administrative Agent”).

The Credit Agreement provides the Company with a three-year senior secured revolving credit facility in the maximum amount of \$60 million. Availability under the facility is subject to a borrowing base, which is based on eligible accounts receivable, inventory and equipment of the Company and certain of its U.S. subsidiaries, after adjusting for customary factors that are subject to modification from time to time by the Administrative Agent at its discretion (not to be exercised

F-27

---

unreasonably). Based on the Company's eligible accounts receivable and inventory and other components of the borrowing base, the availability under the facility was approximately \$60 million as of December 31, 2016.

Amounts drawn under the facility will bear interest, at the Company's option, at (i) an alternate base rate (the highest of (a) the prime rate, (b) the federal funds effective rate or the overnight bank funding rate plus 0.5%, and (c) the LIBOR rate (adjusted for statutory reserve requirements for eurocurrency liabilities) plus 1%) plus 1.5%, or (ii) the LIBOR rate (adjusted for statutory reserve requirements for eurocurrency liabilities) plus 2.5%. The facility is subject to an annual commitment fee of either 0.375% or 0.50%, depending on the amounts already drawn under the facility. As of December 31, 2016, there were no amounts drawn under the facility.

The Company's obligations under the facility are guaranteed by its U.S. subsidiaries (other than its U.S. subsidiary of Biotie Therapies Oyj). The Company's obligations under the facility and its subsidiaries' obligations under the related guarantees are secured by first priority security interests in collateral that includes, subject to certain exceptions:

- U.S. accounts receivable, inventory and manufacturing equipment;
- Equity interests in the Company's U.S. subsidiaries (other than its U.S. subsidiary of Biotie Therapies Oyj) and up to 65% of the voting equity interests of its directly owned foreign subsidiaries; and
- Substantially all other tangible and intangible assets, including equipment, contract rights and intellectual property (other than intellectual property related to Ampyra).

The facility contains certain covenants that, among other things, limit the Company's ability and the ability of certain of its subsidiaries to (i) incur additional debt or issue redeemable preferred stock, (ii) pay dividends, repurchase shares or make certain other restricted payments or investments, (iii) incur liens, (iv) sell assets, (v) incur restrictions on future liens and incur restrictions on the ability of our subsidiaries to pay dividends or to make other payments to us, (vi) enter into affiliate transactions, (vii) engage in sale and leaseback transactions, and (viii) consolidate or merge. These covenants are subject to significant exceptions and qualifications. In addition, the Company will not be permitted to allow its ratio of (a) EBITDA minus Unfinanced Capital Expenditures to (b) Fixed Charges to be less than 1.10 to 1.00 on a trailing four quarter basis as of the end of any fiscal quarter during any period.

The facility has customary representations and warranties including, as a condition to borrowing, that all such representations and warranties are true and correct, in all material respects, on the date of the borrowing, including representations as to no material adverse effect on the Company's business or financial condition since December 31, 2015. The facility also has customary defaults, including a cross-default to material indebtedness of the Company and its subsidiaries. The Administrative Agent may declare any outstanding obligations under the facility immediately due and payable upon the occurrence, and during the continuance, of an event of default. In addition, any outstanding obligations under the facility will be immediately due and payable in the event that the Company or certain of its subsidiaries become the subject of voluntary or involuntary proceedings under any bankruptcy, insolvency or similar law.

#### Non-convertible Capital Loans

Prior to and subsequent to the acquisition of Biotie on April 18, 2016, Biotie held non-convertible capital loans ("Tekes Loans") granted by Tekes, a Finnish Funding Agency for Technology and Innovation. The non-convertible capital loans had an adjusted acquisition-date fair value of \$23.3 million (€20.6 million) and a carrying value of \$22.4 million as of December 31, 2016. The Tekes Loans are comprised of fourteen non-convertible loans granted by Tekes. The maturity dates for the Tekes Loans range from eight to ten years. These loans bear interest based on the greater of 3% or the base rate set by Finland's Ministry of Finance minus one (1) percentage point. According to certain terms and conditions of the Tekes Loans, Biotie may repay the principal amounts of these loans and the accrued and unpaid interest only if the restricted equity of Biotie, including its consolidated subsidiaries, is positive (fully covered).

### Convertible Capital Loan

Prior to and subsequent to the acquisition of Biotie on April 18, 2016, Biotie held a convertible capital loan that was issued to certain shareholders and venture capital organizations. The convertible capital loan had an acquisition-date fair value of \$6.0 million (€5.3 million) and a carrying value of \$5.7 million as of December 31, 2016. The loan is included as a current liability in the consolidated balance sheet as the Company intends to repay this loan within 12 months from the balance sheet date. The loan bears cash interest at a rate of 10% per annum, payable annually each year. The convertible capital loan is subject to certain terms and restrictive conditions as it relates to interest payments and repayment of the loan.

F-28

---

The loan will yield interest from the fiscal years in which the financial statements do not present sufficient funds available for profit distribution; however, interest on the loan may be paid if Biotie, including its subsidiaries, has sufficient funds for profit distribution as of the most recently ended fiscal year. The loan may be repaid only if the restricted equity of Biotie, including its consolidated subsidiaries, for the last financial period is sufficient to repay the loan. Pursuant to the terms of the loan agreement, the loan is convertible at any time at the option of the holders into 828,000 common shares of Biotie. The conversion rates for the loan are €1.8688 per share for 540,000 of the shares and €2.3359 for the remaining 288,000 of the shares.

#### Research and Development Loans

Prior to and subsequent to the acquisition of Biotie on April 18, 2016, Biotie held research and development loans (“R&D Loans”) granted by Tekes. The R&D loans had an acquisition-date fair value of \$2.9 million (€2.6 million) and a carrying value of \$2.8 million as of December 31, 2016. The R&D Loans bear interest based on the greater of 1% or the base rate set by Finland’s Ministry of Finance minus three (3) percentage points. The repayment of these loans will begin January 2017. The loan principal will be paid in equal annual installments over a 5 year period, ending January 2021.

#### Revenue Interests Assignment

In December 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 had assigned PRF revenue interest in Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products, which was subsequently sold to Valeant Pharmaceuticals International, Inc. in November 2014. The agreement covered all Zanaflex net revenues (as defined in the agreement) generated from October 1, 2005 through and including December 31, 2015.

The Company recorded approximately \$0.9 million and \$1.7 million in interest expense related to this agreement in 2015 and 2014, respectively.

#### Letters of Credit

As of December 31, 2016, the Company has \$0.3 million of cash collateralized standby letters of credit outstanding (see Note 2).

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

Accrued expenses and other current liabilities consisted of the following:

	December 31,	December 31,
(In thousands)	2016	2015
Product allowance accruals	\$26,995	\$ 18,325
Research and development expense accruals	21,151	10,447

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Bonus payable	15,962	12,324
Accrued inventory	14,629	6,497
Royalties payable	2,977	2,838
Vacation accrual	2,825	2,270
Commercial and marketing expense accruals	2,040	3,054
Sales force commissions and incentive payments payable	1,933	1,978
Administrative expenses	1,805	1,133
Medical affairs expenses	1,004	1,498
Other accrued expenses	13,569	5,769
Total	\$ 104,890	\$ 66,133

(10) Commitments and Contingencies

The Company's 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, the Company is required to make payments for the manufacture and supply of its clinical and approved products. The Company's major outstanding contractual obligations are for payments related to its convertible notes, capital loans,

F-29

---



operating leases and commitments to purchase inventory. The following table summarizes the contractual obligations at December 31, 2016 and the effect such obligations are expected to have on the Company's liquidity and cash flow in future periods:

(In thousands)	Payments due by period (1)(8)			
	Total	Less than 1 year	1-3 years	4-5 years
Convertible Senior Notes (2)	\$371,557	\$6,038	\$12,075	\$353,444
Convertible notes payable (3)	767	767	—	—
Capital loans (4)	28,056	5,689	—	22,367
Research and development loans (5)	2,835	567	1,134	1,134
Operating leases (6)	35,904	7,268	14,297	14,339
Inventory purchase commitments (7)	30,791	30,791	—	—
<b>Total</b>	<b>\$469,910</b>	<b>\$51,120</b>	<b>\$27,506</b>	<b>\$391,284</b>

- (1) Excludes a liability for uncertain tax positions totaling \$6.9 million. This liability has been excluded because the Company 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 principal and interest payment on the convertible note.
- (4) Represents payments for the convertible and non-convertible capital loans. The convertible capital loan and the non-convertible capital loans have a stated maturity of less than one year. However, the repayment of the non-convertible capital loans and payment of accrued interest thereon are governed by a restrictive condition, according to which the loan principal may only be repaid if Biotie's consolidated restricted equity is fully covered. Accrued interest may only be paid if Biotie, including its subsidiaries, has sufficient funds for profit distribution as of the most recently ended fiscal year. Interest accrues in the interim.
- (5) Represents the future principal payments on the R&D loans acquired from Biotie.
- (6) Represents payments for the operating leases of the Company's Ardsley, NY headquarters, the Company's manufacturing facility in Chelsea, MA, and lab and office space in Waltham, MA, Biotie's office/clinical operations in South San Francisco, CA and the office in Turku Finland.
- (7) Represents Ampyra, Zanaflex, and Qutenza inventory commitments. The Ampyra inventory commitment is an estimate as the price paid for Ampyra inventory is based on a percentage of the net product sales during the quarter Alkermes ships inventory to us. Under our supply agreement with Alkermes, we provide Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for our supply requirements of Ampyra and two-year forecasts for our supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra following the submission of our written 18-month forecast we are obligated to purchase the quantity specified in the forecast, even if our actual requirements are greater or less. We have agreed to purchase at least 75% of our annual requirements of Ampyra from Alkermes, unless Alkermes is unable or unwilling to meet its requirements, for a percentage of net product sales and the quantity of product shipped by Alkermes to us.
- (8) Pursuant to the UCB Termination and Transition Agreement, Biotie is required to pay up to \$4.1 million (€ 3.9 million) to UCB. The amount that will be paid will be determined based on a percentage of future consideration Biotie will receive from tozadenant. The liability is excluded as the Company cannot currently estimate the period in which the liability will be payable, if ever.

## 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. 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

F-30

---

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 lease term. These payments consist of base rent, which takes into account the costs of the facility improvements funded by the facility owner prior to the Company's occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent is currently \$4.4 million per year, which reflects an annual 2.5% escalation factor as well as the expansion, described above.

Chelsea, Massachusetts

Through our Civitas subsidiary, we lease a manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas leases this facility from H&N Associates, LLC pursuant to a lease with a term that expires on December 31, 2025, and Civitas has two additional extension options of five years each. The base rent under the lease is currently \$1.0 million per year.

#### Additional Facilities

In October 2016, we entered into a 10-year lease agreement with a term commencing January 1, 2017, for approximately 26,000 square feet of lab and office space in Waltham, MA. The lease provides for monthly rental payments over the lease term. The base rent under the lease is currently \$1.0 million per year.

Also, through Biotie and its U.S. subsidiary, we indirectly lease office space in South San Francisco, California and Turku, Finland. The base rent under the South San Francisco, CA lease is currently \$0.6 million per year.

The lease in Turku, Finland was scheduled to expire in November 2016 but was extended through May 2017. The remaining rent under the extended lease is approximately \$0.1 million.

Future minimum commitments under all non-cancelable operating leases subsequent to December 31, 2016 are as follows:

(In thousands)	
2017	\$7,268
2018	7,396
2019	6,901
2020	7,078
2021	7,261
Later years	18,342
	\$54,246

Rent expense under these operating leases during the years ended December 31, 2016, 2015 and 2014 was approximately \$6.0 million, \$4.8 million, and \$3.5 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 \$129 million over the life of the contracts. Further milestone amounts are payable in connection with additional indications.

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

F-31

---

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 annual written five-year forecasts for its supply requirements of Ampyra and two-year forecasts for its supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra following the submission of its written 18-month forecast, the Company is obligated to purchase the quantity specified in the forecast, even if its actual requirements are greater or less. Inventory purchase commitments were \$30.8 million as of December 31, 2016.

#### Employment Agreements

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

#### Other

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. While losses, if any, are possible the Company is not able to estimate any ranges of losses as of December 31, 2016. Litigation expenses are expensed as incurred.

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

#### (11) 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.

F-32

---

## 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, 2016 and December 31, 2015, 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>2016</b>			
Assets Carried at Fair Value:			
Cash equivalents	\$18,514	\$—	\$—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	72,100
<b>2015</b>			
Assets Carried at Fair Value:			
Cash equivalents	\$70,504	\$13,009	\$—
Short-term investments	—	200,101	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	63,500

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	Year ended
	December 31,	December 31,
	2016	2015
Acquired contingent consideration:		
Balance, beginning of period	\$ 63,500	\$ 52,600
Fair value change to contingent consideration (unrealized)		
included in the statement of operations	8,600	10,900
Balance, end of period	\$ 72,100	\$ 63,500

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach based on estimated future sales expected from CVT-301, a phase 3 candidate for the treatment of OFF periods of Parkinson's disease and CVT-427, a Phase 1 candidate. CVT-427 is an inhaled triptan intended for acute treatment of migraine using the ARCUS drug delivery technology. 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 revenue forecasts for CVT-301 and CVT-427, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of revenue milestones ranged from 43.9% to 70% with milestone payment outcomes ranging from \$0 to \$54 million in the aggregate for CVT-301 and CVT-427. The valuation is performed quarterly. Gains and losses representing changes in the fair value of the contingent consideration are included in the statement of operations. For the year ended December 31, 2016 and 2015, changes in the fair value of the acquired contingent consideration were due to the recalculation of cash flows for the passage of time and updates to certain other estimated assumptions. Refer to Note 12 for more information about the Alkermes ARCUS agreement.

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



(12) License, Research and Collaboration Agreements

Alkermes plc

The Company is a party to a 2003 amended and restated license agreement and a 2003 supply agreement with Alkermes for Ampyra (“Agreement”). 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 Alkermes patent to expire 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 100% of the products, it is entitled to a compensating payment for the quantities of product provided by the alternative manufacturer.

Convertible Note

Under the Agreement, Alkermes loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes, the first promissory note in the amount of \$5 million and the second promissory note in the amount of \$2.5 million, both of which were subsequently transferred to funds affiliated with Saints Capital. The first promissory note in the amount of \$5.0 million bears interest at a rate of 3%. The outstanding balance of \$0.8 million on the first promissory note was paid in full in January 2017. The second promissory note was converted into shares of common stock in December 2006 and is no longer outstanding.

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

The Company 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.

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

As of December 31, 2016, 2015 and 2014, the Company made or accrued royalty payments totaling \$48.1 million, \$37.4 million and \$27.8 million, respectively.

F-34

---

Biogen Inc.

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

Under the Collaboration Agreement, the Company received an upfront payment of \$110.0 million in July 2009, and a \$25 million milestone payment in August 2011 upon approval of the product in the European Union. The Company is also entitled to receive additional payments based on the successful achievement of future regulatory and sales milestones. Biogen is also required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. Also under the terms of the Collaboration Agreement, the Company will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the U.S. Acorda will continue to develop and commercialize Ampyra independently in the U.S.

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

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

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized \$9.1 million in amortized license revenue, a portion of the \$110.0 million received from Biogen, and \$0.6 million in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during each of the years ended December 31, 2016, 2015 and, 2014.

Actavis/Watson

The Company has an agreement with Actavis, a subsidiary of Teva Pharmaceuticals and formerly Watson Pharma, to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, which was launched in February 2012. In accordance with the agreement, the Company receives a royalty based on Allergan's gross margin, as defined by the agreement, of the authorized generic product. During the years ended December 31, 2016 and 2015, the Company recognized royalty revenue of \$3.9 million and \$7.0 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the years ended December 31, 2016 and 2015, the Company also recognized revenue and a corresponding cost of sales of \$2.7 million and \$3.8 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Allergan, which is recorded in net product revenues and cost of sales.

F-35

---

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 leased the facility where the Alkermes operations were previously 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 11 – Fair Value Measurements for more information on the contingent consideration liability.

Roche (Tozadenant and SYN120)

Our Biotie subsidiary is a party to an amended and restated license agreement with Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd. (the "Roche Entities"), pursuant to which Biotie obtained exclusive, royalty-bearing, worldwide licenses under the Roche Entities' patent rights and know-how to develop, manufacture and commercialize products incorporating specified Roche Entities compounds, including tozadenant and SYN120 (classified into tiered programs). Under the license agreement, tozadenant is a Tier 2 compound and SYN120 is a Tier 1 compound. Biotie's license with respect to products containing Tier 2 compounds, or Tier 2 products, extends to the field of any and all uses to treat or prevent human diseases and disorders. Biotie's license with respect to products containing Tier 1 compounds, or Tier 1 products, is limited to the field of any and all uses to treat or prevent central nervous system diseases and disorders. Under the terms of the Roche license agreement, following the completion of certain studies, the Roche Entities had the right to opt-in to obtain an exclusive right to develop and commercialize the Tier 1 products and terminate the license granted to Biotie with respect to such Tier 1 products. In June 2012, following Biotie's completion of the specified studies, the Roche Entities notified Biotie of their decision not to exercise their opt-in right for SYN120. Following the Roche Entities' decision not to exercise their opt-in right, Biotie retains its licensed global development and commercialization rights to SYN120 under the Roche license agreement.

Pursuant to the Roche license agreement, Biotie is obligated to make certain milestone payments to the Roche Entities on the achievement of specified regulatory and commercial milestones, totaling up to \$37 million for Tier 1 products, including SYN120 and \$29 million for Tier 2 products, including tozadenant. Biotie is also obligated to pay the Roche Entities tiered single-digit royalties, starting in the low single digits and increasing to the high single digits, on net sales of licensed products. Biotie's obligation to pay royalties to the Roche Entities will expire on a product-by-product

and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the licensed Roche Entities patents, Biotie's patent rights or patent rights jointly owned with the Roche Entities that cover the composition, use or manufacture of the applicable product in such country or 10 years from the first commercial sale of such product in such country. Biotie is required to exercise commercially reasonable efforts to perform the activities set forth in an agreed upon development plan for SYN120 and must use commercially reasonable efforts to develop and commercialize, either directly or through affiliates or sublicensees, SYN120 and tozadenant in the U.S. and Europe and in such other markets as Biotie deems commercially reasonable.

The term of the Roche license agreement will expire on the date of the expiration of all payment obligations of both parties under the agreement. Upon expiration of the Roche license agreement, all licenses granted to each party that were in effect immediately prior to such expiration will be retained on a nonexclusive, fully paid, royalty-free basis. The Roche Entities may terminate the Roche license agreement either on a program-by-program basis for certain programs or in its

F-36

---

entirety, for any reason or no reason upon 90 days' written notice. In the event of the Roche Entities' unilateral termination of the Roche license agreement without cause, all licenses and other rights granted by the Roche Entities to Biotie will remain in full force and effect in accordance with their respective terms. Biotie may also terminate the Roche license agreement either on a program-by-program basis for certain of the programs or in its entirety, for any reason or no reason upon 90 days' written notice. In the event of Biotie's unilateral termination without cause, all licenses granted to Biotie with respect to the compounds and products in the terminated program (or, in the case of termination of the entire agreement, all compounds and products) will terminate. Either party may terminate the Roche license agreement for cause in the event of a breach by the other party of any material provision of the agreement if such breach has continued for 60 days after notice was provided (or a reasonably longer time if a party is diligently pursuing cure of a breach that was not susceptible of cure within the 60 day notice period). In the case of agreement disputes, specified officers must attempt resolution, and if no resolution is achieved, the matter may be referred to binding arbitration for final settlement as the exclusive forum for dispute resolution except for certain matters relating to patents and other intellectual property rights.

#### Neuronex

Our Neuronex, Inc. subsidiary is a party to a license agreement with SK Biopharmaceuticals Co., Ltd., relating to Plumiaz, a proprietary nasal spray formulation of diazepam that we were developing as a treatment for certain epilepsy patients. In 2016 we announced that we were discontinuing our Plumiaz development program.

#### (13) Income Taxes

The domestic and foreign components of (loss) income before income taxes were as follows:

	Year ended	Year ended	Year ended
	December 31,	December 31,	December 31,
(In thousands)	2016	2015	2014
Domestic	\$ (36,454 )	\$ 16,284	\$ 25,679
Foreign	(5,814 )	3,085	2,330
Total	\$ (42,268 )	\$ 19,369	\$ 28,009

The benefit from (provision for) income taxes in 2016, 2015 and 2014 consists of current and deferred federal, state and foreign taxes as follows:

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

	Year ended	Year ended	Year ended
	December 31,	December 31,	December 31,
(In thousands)	2016	2015	2014
<b>Current:</b>			
Federal	\$ (852 )	\$ (603 )	\$ (1,105 )
State	(4,517 )	(2,773 )	(1,819 )
Foreign	781	(960 )	(732 )
	(4,588 )	(4,336 )	(3,656 )
<b>Deferred:</b>			
Federal	9,465	(2,960 )	(6,085 )
State	1,788	(1,015 )	(596 )
Foreign	—	—	—
	11,253	(3,975 )	(6,681 )
<b>Total benefit from (provision for) income taxes</b>	<b>\$ 6,665</b>	<b>\$ (8,311 )</b>	<b>\$ (10,337 )</b>

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 U.S. states and Puerto Rico where it has operations and NOL carryforwards are not available or are limited. The Company was subject to the alternative minimum tax during 2016, 2015 and 2014 and expects it will continue to be subject to such tax in the near term. The payment of alternative minimum tax generates a credit that may be carried forward indefinitely and can be used to offset its future regular income tax liability.



The Company had available federal NOL carryforwards of approximately \$252.6 million and \$195.0 million and state NOL carryforwards of approximately \$170.9 million and \$97.1 million as of December 31, 2016 and 2015, respectively. The net operating loss carryforwards include approximately \$34.6 million of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected above. The deferred tax asset of \$12.1 million associated with the exercise of these stock options will be recorded as an adjustment to the beginning retained earnings balance in the first quarter of 2017 in accordance with the adoption of Accounting Standards Update 2016-09, "Compensation – Stock Compensation." The federal losses are expected to begin to expire in 2027, while the state losses are expected to expire during similar periods, although not all states conform to the federal carryforward period and occasionally limit the use of net operating losses for a period of time. The Company is no longer subject to federal income tax audits for tax years prior to 2012 however, such net operating losses utilized by the Company in years subsequent to 2002 is subject to review. In 2013 the Company completed an IRS exam for tax years 2009 through 2011.

The Company also has research and development and orphan drug credit carry-forwards of \$33.3 million and \$20.3 million as of December 31, 2016 and 2015, respectively, that begin to expire in 2017. The Company also has Alternative Minimum Tax credit carry-forwards of \$4.7 million and \$3.8 million as of December 31, 2016 and 2015, 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, Inc. and Neuronex, Inc., its wholly owned subsidiary. An additional limitation was triggered in 2014 for Civitas Therapeutics Inc. and a current limitation was triggered in 2016 for Biotie Therapies, Inc., both wholly owned subsidiaries of Acorda Therapeutics, Inc. The Company believes that such limitations are not expected to result in the expiration or loss of any of its federal net operating loss carryforwards and income tax credit carryforwards for the Neuronex, Inc. and Civitas Therapeutics, Inc. acquisitions. However, the limitation triggered by the acquisition of Biotie Therapeutics, Inc. resulted in \$15.6 million of unused federal net operating loss carryforwards and \$5.1 million of unused federal credit carryforwards expiring. As a result of the expiration of these carryforwards, the Company wrote off these attributes and reversed the valuation allowance previously recorded. Future ownership changes may further limit the use of these carryforwards.

The Company has \$63.7 million of net operating loss carryforwards outside of the U.S. as of December 31, 2016, that begin to expire in 2017.

The temporary differences between the book and tax treatment of income and expenses results in deferred tax assets and liabilities, which are included within the consolidated balance sheet. The Company must assess the likelihood that any recorded deferred tax assets will be recovered against future taxable income. To the extent the Company believes it is more likely than not that the deferred tax asset will not be recoverable, a valuation allowance must be established. To the extent the Company establishes a valuation allowance or changes the allowance in a future period, income tax expense will be impacted. In calendar year 2016, the Company recorded a \$57.9 million valuation allowance primarily on federal and foreign deferred tax assets acquired through the acquisition of Biotie Therapies, Inc., of which \$48.1 million was recorded through the purchase accounting.

The reconciliation of the statutory U.S. federal income tax rate to the Company's effective income tax rate is as follows:

	Year ended		Year ended		Year ended	
	December 31,		December 31,		December 31,	
	2016		2015		2014	
U.S. federal statutory tax rate	35.0	%	35.0	%	35.0	%
State and local income taxes	(3.8)	)%	13.3	%	3.7	%
Non-deductible payment to prior shareholders	—		15.8	%	—	
Foreign income tax	1.2	%	3.2	%	1.8	%
Stock option compensation	(3.8)	)%	10.4	%	4.8	%
Stock option shortfall	(6.5)	)%	—		—	
Research and development and orphan drug credits	28.9	%	(42.9)	)%	(15.5)	)%
Increase to Uncertain Tax Positions	(4.8)	)%	7.1	%	2.3	%
Other nondeductible and permanent differences	(1.1)	)%	1.9	%	2.6	%
Valuation allowance	(31.6)	)%	(0.9)	)%	2.2	%
Transaction Cost	(5.9)	)%	—		—	
Gain or Loss on Hedging	8.2	%	—		—	
Effective income tax rate	15.8	%	42.9	%	36.9	%

The effective tax rate related to state taxes is primarily driven by Acorda's state tax return filings as a stand-alone entity, without the benefit of Civitas and Biotie's losses. The state taxes reflect 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:

	December 31,	December 31,
(In thousands)	2016	2015
<b>Deferred tax assets:</b>		
Net operating loss and other carryforwards	\$97,391	\$60,889
Tax credits	35,489	20,778
Deferred revenue	11,672	13,949
Stock based compensation	34,700	27,142
Contingent consideration	26,543	23,298
Employee compensation	6,116	5,603
Legal reserve	2,707	—
Rebate and returns reserve	7,582	4,994
Capitalized R&D	10,025	—
Other	4,096	3,126
Total deferred tax assets	\$236,321	\$159,779
Valuation allowance	\$(63,225 )	\$(5,277 )
Total deferred tax assets net of valuation allowance	\$173,096	\$154,502
<b>Deferred tax liabilities:</b>		
Intangible assets	(245,500)	(145,433)
Convertible debt	(16,003 )	(19,087 )
Total deferred tax liabilities	\$(261,503)	\$(164,520)
Net deferred tax liability	\$(88,407 )	\$(10,018 )

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:

	Year ended	Year ended	Year ended
(In thousands)	December 31,	December 31,	December 31,
	2016	2015	2014
Beginning of period balance	\$ 4,835	\$ 3,295	\$ 2,244
Increases for tax positions taken during a prior period	570	308	451

Decreases for tax positions taken during a prior period	—	—	(200 )
Increases for tax positions taken during the current period	1,451	1,232	800
Reduction as a result of a lapse of statute of limitations	—	—	—
	\$ 6,856	\$ 4,835	\$ 3,295

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 is subject to taxation in the United States, various state and foreign jurisdictions. The Company has operations in the United States, Puerto Rico, Finland, Switzerland and Germany. The U.S. and Puerto Rico have statute of limitations ranging from 3 to 5 years and all other foreign jurisdictions have statute of limitation ranging from 4 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 limitations 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.

## (14) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2016, 2015 and 2014:

	Year ended	Year ended	Year ended
	December 31,	December 31,	December 31,
(In thousands, except per share data)	2016	2015	2014
<b>Basic and diluted</b>			
Net (loss) income	\$ (34,618 )	\$ 11,058	\$ 17,672
<b>Weighted average common shares outstanding used in</b>			
computing net (loss) income per share—basic	45,259	42,230	41,150
Plus: net effect of dilutive stock options and unvested			
restricted common shares	—	1,391	1,394
<b>Weighted average common shares outstanding used in</b>			
computing net (loss) income per share—diluted	45,259	43,621	42,544
Net (loss) income per share—basic	\$ (0.76 )	\$ 0.26	\$ 0.43
Net (loss) income per share—diluted	\$ (0.76 )	\$ 0.25	\$ 0.42

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	Year ended	Year ended
	December 31,	December 31,	December 31,

	2016	2015	2014
Denominator			
Stock options and restricted common shares	7,749	4,179	4,078
Convertible note	10	19	29

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net income per diluted share for the years ended December 31, 2016, 2015 and 2014.

#### (15) Employee Benefit Plan

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The plan includes an employer match contribution to employee deferrals. For each dollar an employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was \$2.6 million, \$2.4 million and \$1.9 million for the years ended December 31, 2016, 2015, and 2014, respectively.

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

(In thousands, except per share amounts)	2016			
	March 31	June 30	September 30	December 31
Total net revenues	\$115,904	\$127,458	\$135,613	\$140,627
Gross profit	92,559	100,864	107,810	110,258
Net loss—basic and diluted	(520 )	(18,957 )	(13,032 )	(3,094 )
Net loss attributable to Acorda Therapeutics, Inc.				
—basic and diluted	(520 )	(18,279 )	(12,725 )	(3,094 )
Net loss per share—basic	\$(0.01 )	\$(0.40 )	\$(0.28 )	\$(0.07 )
Net loss per share—diluted	(0.01 )	(0.40 )	(0.28 )	(0.07 )

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

- (1) In the third quarter of 2015, the Company recognized a one-time increase in net revenue of \$22.2 million, representing previously deferred product sales for Zanaflex products due to the Company's conversion from the deferred revenue recognition model (sell-through) to the traditional revenue recognition model (sell-in).
- (2) In the third quarter of 2015, the Company made a payment of \$8.75 million to the former shareholders of Neuronex in exchange for certain modifications to the Company's future contingent payment obligations pertaining to Plumiaz. This payment was reflected as R&D expense.

(b) Exhibits.

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

Exhibit Description  
No.

- |     |  |
|-----|--|
| 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 | Combination Agreement, dated as of January 19, 2016, by and among the Registrant and Biotie Therapies Corp. Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 19, 2016.                 |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006.                       |
| 3.2 | Bylaws of the Registrant, as amended on December 15, 2011. Incorporated herein by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.  |
| 4.1 | Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.                                |
| 4.2 | Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2014.                    |
| 4.3 | First Supplemental Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 23, 2014. |
| 4.4 | Form of 1.75% Convertible Senior Note due 2021 (included in exhibit 4.3). Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed June 23, 2014.   |



Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

- 10.1\*\* Acorda Therapeutics 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
- 10.2\*\* Amendment to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
- 10.3\*\* Amendment No. 2 to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
- 10.4\*\* Acorda Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
- 10.5\*\* Acorda Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2006. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.
- 10.6\*\* Forms of Equity Award Documents. Incorporated herein by reference to Exhibit 10.58 to Registrant's Annual Report on Form 10-K filed on March 1, 2011.
-

Exhibit No.	Description
10.7**	Acorda Therapeutics 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Appendix A to the Registrant's 2015 Proxy Statement filed as Schedule 14A on April 30, 2015.
10.8**	Acorda Therapeutics 2015 Omnibus Incentive Compensation Plan as amended June 8, 2016. Incorporated herein by reference to Appendix A to the Registrant's 2016 Proxy Statement filed as Schedule 14A on April 29, 2016.
10.9**	Forms of equity award documents for awards under the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.10**	Form of Performance Unit Agreement for awards under the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2016.
10.11**	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.
10.12**	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.
10.13**	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.
10.14**	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.
10.15**	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.
10.16**	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

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Form S-1/A, No. 333-128827, filed on January 5, 2006.

- 10.17\*\* 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.
- 10.18\*\* 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.
- 10.19\*\* 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.
- 10.20\*\* 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.
-

Exhibit No.	Description
10.21**	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.
10.22**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.23**	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.
10.24**	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.
10.25**	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.
10.26**	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.
10.27**	Employment Agreement, dated as of June 8, 2015, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.28**	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.
10.29**	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.
10.30**	

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

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.

10.31\*\* 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.

10.32\*\* Non-Statutory Stock Option Certificate under the 2006 Employee Stock Option Plan, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.

10.33\*\* Restricted Stock Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.

10.34\*\* Employment Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2015.

---

Exhibit No.	Description
10.35**	Executive Employment Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (formerly Corregidor Therapeutics, Inc.) and Rick Batycky. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.36**	First Amendment to Executive Employment Agreement, dated as of June 27, 2013, between Civitas Therapeutics, Inc. and Rick Batycky. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.37**	Second Amendment to Executive Employment Agreement, dated as of June 30, 2014, between Civitas Therapeutics, Inc. and Rick Batycky. Incorporated herein by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.38**	Employment offer letter, dated December 5, 2014, by and between the Registrant and Richard Batycky. Incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.39**	Employment offer letter, dated June 9, 2016, by and between the Registrant and Burkhard Blank, M.D. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2016.
10.40**	Employment Agreement, dated as of July 1, 2016, by and between the Registrant and Burkhard Blank, M.D. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2016.
10.41	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.
10.42	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.
10.43	First Amendment to Lease, dated as of May 21, 2015, by and between BMR-Ardsley Park LLC and the Registrant. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.44	

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Lease Agreement, dated as of December 6, 2000, by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.

- 10.45 First Amendment, dated August 22, 2002, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
- 10.46 Second Amendment, dated December 4, 2006, to Lease Agreement by and between H&N Associates, LLC and Advanced Inhalation Research, Inc. Incorporated herein by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
- 10.47 Sublease Agreement, dated December 27, 2010, by and between Alkermes, Inc. and Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.). Incorporated herein by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
- 10.48 Letter agreement dated March 25, 2015, between Civitas Therapeutics, Inc. and Alkermes, Inc. regarding extension of the Sublease dated December 27, 2010, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2015.
-

Exhibit Description  
No.

- 10.49 Assignment and Amendment of Lease dated November 30, 2015, among H&N Associates, LLC, Civitas Therapeutics, Inc., and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.51 to the Registrant's Annual Report on Form 10-K filed on February 29, 2016.
- 10.50 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.
- 10.51 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.
- 10.52 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.
- 10.53\* 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.
- 10.54 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.
- 10.55\* 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.
- 10.56\* 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.
- 10.57 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.
- 10.58\*



Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

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.

- 10.59 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.
- 10.60\* 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.
- 10.61\* 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.
- 10.62 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.
-

Exhibit Description  
No.

- 10.63 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.
- 10.64 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.
- 10.65 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.
- 10.66\* 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.
- 10.67\* 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.
- 10.68\* 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.
- 10.69\* Addendum Number 3 to Collaboration and License Agreement and to Supply Agreement between the Registrant and Biogen Idec International GmbH dated February 14, 2013. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013.
- 10.70\* Amended and Restated Addendum #2 effective June 6, 2016 to the Supply Agreement between the Registrant and Biogen Idec International GmbH dated June 30, 2009, as Amended. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2016.
- 10.71\* 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.

10.72

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

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.

- 10.73\* 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.
- 10.74\* 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.
- 10.75 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.
- 10.76 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.
-

Exhibit Description  
No.

- 10.77 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.
- 10.78 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.
- 10.79 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.
- 10.80 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.
- 10.81\* 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.
- 10.82\* 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.
- 10.83\* Asset Purchase and License Agreement, dated as of December 27, 2010, between Civitas Therapeutics, Inc. (f/k/a Corregidor Therapeutics, Inc.) and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.75 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
- 10.84\* Amendment to Asset Purchase and License Agreement, dated as of December 9, 2011, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.76 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.
- 10.85\* Second Amendment to Asset Purchase and License Agreement, dated as of December 19, 2014, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.77 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015.

- 10.86\* Termination and Transition Agreement among Biotie Therapies, Inc. Biotie Therapies AG and UCB Biopharma S.P.R.L., dated August 22, 2014. Incorporated herein by reference to Exhibit 10.12 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
- 10.87\* Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Synosia Therapeutics, Inc. and Synosia Therapeutics AG, dated December 10, 2008. Incorporated herein by reference to Exhibit 10.13 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
- 10.88 First Letter Agreement to the Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Synosia Therapeutics, Inc. and Synosia Therapeutics AG, dated January 14, 2009. Incorporated herein by reference to Exhibit 10.14 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
- 10.89\* Second Letter Agreement to the Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Synosia Therapeutics, Inc. and Synosia Therapeutics AG, dated October 20, 2009. Incorporated herein by reference to Exhibit 10.15 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
-

Exhibit No.	Description
10.90*	Third Letter Agreement to the Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Synosia Therapeutics, Inc. and Synosia Therapeutics AG, dated May 7, 2010. Incorporated herein by reference to Exhibit 10.16 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
10.91*	Fourth Letter Agreement to the Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Synosia Therapeutics, Inc. and Synosia Therapeutics AG, dated September 11, 2012. Incorporated herein by reference to Exhibit 10.17 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
10.92*	Letter Exercising the Tier 2 and 3 Field Expansion Option under the Amended and Restated License Agreement among Roche Palo Alto LLC, Hoffman-La Roche Inc., F.Hoffman-La Roche Ltd, Biotie Therapies, Inc. and Biotie Therapies AG, dated February 28, 2013. Incorporated herein by reference to Exhibit 10.18 to Biotie Therapies Corp.'s Registration Statement on Form F-1 (File Number 001-37423) filed on May 14, 2015.
10.93	Credit Agreement dated June 1, 2016 among the Registrant and certain of its subsidiaries as the Borrowers thereunder and JPMorgan Chase Bank, N.A. as Administrative Agent thereunder. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2016.
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 Principal 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 Principal 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

\*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.

---

## 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, 2017.

Acorda Therapeutics, Inc.

By: /s/ Ron Cohen, M.D.  
Ron Cohen, M.D.

President and Chief Executive Officer

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

Signature	Title	Date
/s/ Ron Cohen, M.D. Ron Cohen, M.D.	President, Chief Executive Officer and Director	February 27, 2017
/s/ David Lawrence, M.B.A. David Lawrence, M.B.A.	Chief, Business Operations and Principal Accounting Officer	February 27, 2017
/s/ Barry Greene Barry Greene	Director	February 27, 2017
/s/ Peder K. Jensen, M.D. Peder K. Jensen, M.D.	Director	February 27, 2017
/s/ John P. Kelley John P. Kelley	Director	February 27, 2017
/s/ Sandra Panem, Ph.D. Sandra Panem, Ph.D.	Director	February 27, 2017
/s/ Lorin J. Randall Lorin J. Randall	Director	February 27, 2017
/s/ Steven M. Rauscher, M.B.A. Steven M. Rauscher, M.B.A.	Director	February 27, 2017



/s/ Ian Smith  
Ian Smith

Director

February 27, 2017

Catherine D. Strader, Ph.D.

Director

February \_\_, 2017

---

EXHIBIT INDEX

Exhibit No. Description

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 Principal 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 Principal  
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