

ACORDA THERAPEUTICS INC  
Form 10-K  
February 27, 2019

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, 2018

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 001-31938

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

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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 29, 2018, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was \$1,122,560,492. For purposes of this calculation, we have excluded shares of common stock held by directors, officers and stockholders reporting ownership on Schedule 13D (or amendments thereto) that exceeds five percent of the common stock outstanding at June 29, 2018. 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.

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As of February 20, 2019, the registrant had 47,633,407 shares of common stock, par value \$0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement for its 2019 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2018. 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.

2018 FORM 10-K ANNUAL REPORT

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This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: we may not be able to successfully market Inbrija or any other products under development; risks associated with complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand; third party payers (including governmental agencies) may not reimburse for the use of Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; competition for Inbrija, Ampyra and other products we may develop and market in the future, including increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra (dalfampridine) following our loss of patent exclusivity; the ability to realize the benefits anticipated from acquisitions, 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; we may need to raise additional funds to finance our operations and may not be able to do so on acceptable terms; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; 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," and "ARCUS." Also, our mark "Fampyra" is a registered mark in the European Community Trademark Office and we have registrations or pending applications for this mark in other jurisdictions. Our trademark portfolio also includes several registered trademarks and pending trademark applications (e.g., "Inbrija") 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 are preparing for our launch of commercial sales of Inbrija (levodopa inhalation powder), which is approved for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa. Inbrija is an on-demand treatment that utilizes our innovative ARCUS pulmonary delivery system, a technology platform designed to deliver medication through inhalation that we believe has potential to be used in the development of a variety of inhaled medicines. Also, we market branded Ampyra (dalfampridine) Extended Release Tablets, 10 mg.

Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg, with no titration required. We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies. Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. We project that annual peak net revenue of Inbrija in the U.S. alone could exceed \$800 million.

We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines. After the adoption of a Committee for Medicinal Products for Human Use, or CHMP, opinion, we expect a final decision regarding the MAA from the European Commission before the end of 2019. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S.

We currently derive substantially all of our revenue from the sale of Ampyra. We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), which issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

Our strategic priorities for 2019 are as follows:

• **Inbrija (levodopa inhalation powder):** Launching the commercial sale of Inbrija in the U.S.; obtaining approval of our European MAA for Inbrija; and continuing with potential partnering discussions for commercialization outside of the U.S.

• **ARCUS Platform:** Advancing our efforts to develop additional therapeutics based on our proprietary ARCUS pulmonary drug delivery technology, looking at central nervous system, or CNS, as well as non-CNS opportunities, including our program to develop an ARCUS-based treatment for acute migraine.

Financial Management: Focusing on financial discipline to maintain a strong balance sheet, control expenses and deploy resources to maximize shareholder value.

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As of December 31, 2018, we had cash, cash equivalents short-term investments of approximately \$445 million. We have \$345 million of convertible senior notes due in 2021 with a conversion price of \$42.56.

## Company Highlights

### Inbrija (levodopa inhalation powder)/Parkinson's Disease

Inbrija (levodopa inhalation powder) is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg, with no titration required. We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies.

We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines. After the adoption of a Committee for Medicinal Products for Human Use, or CHMP, opinion, we expect a final decision regarding the MAA from the European Commission before the end of 2019. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S.

We intend to market Inbrija in the U.S. through our own specialty sales force and commercial infrastructure. We believe we have built a leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our commercial sale of Inbrija in the U.S. will benefit from the experiences and capabilities of this team. Importantly, we kept our commercial team substantially intact following a 2017 company restructuring. We currently have approximately 90 sales representatives as well as established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on our marketed products; a National Trade Account Director who works with our network of specialty pharmacies for Inbrija; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. In advance of the launch of commercial sale, we are visiting movement disorder and key neurology centers to provide education and training on Inbrija's clinical profile, the appropriate use of the Inbrija inhaler, and our Prescription Support Services hub, described below. We project that annual peak net revenue of Inbrija in the U.S. alone could exceed \$800 million.

In January 2019, we established Prescription Support Services, which we sometimes refer to as the Inbrija hub, a service provided by Acorda which is designed to help patients navigate their insurance coverage and offer reimbursement support services, when appropriate. Services fall into one of these four categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; appeals support; and assistance identifying which specialty pharmacy a patient will utilize based on their insurance coverage. For patients that may need assistance paying for their medication, Prescription Support Services will offer several support options, including: a patient assistance program, that provides no cost medication to patients who meet specific program eligibility requirements; co-pay support, which may help commercially insured (non-government funded) patients lower their out-of-pocket costs; and a bridge program, for federally-insured patients who experience a delay in coverage determination. We intend to implement a no-cost sample program to enable patients and their physicians to assess the value of Inbrija before the patient has to incur out-of-pocket co-pay or co-insurance costs.

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. The standard baseline 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 progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson's symptoms that result from low levels of dopamine between doses oral carbidopa/levodopa. OFF periods are often highly disruptive to people with Parkinson's. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods.

Inbrija is an on-demand treatment that utilizes our innovative ARCUS platform for inhaled therapeutics. ARCUS is a dry-powder pulmonary drug delivery technology that we believe has potential to be used in the development of a variety of inhaled medicines. The ARCUS platform allows systemic delivery of medication through inhalation, by transforming molecules into a light, porous dry powder. This allows delivery of substantially higher doses of medication than can be delivered via conventional dry powder technologies. We acquired the ARCUS technology platform as part of our 2014 acquisition of Civitas Therapeutics. We have worldwide rights to our ARCUS drug delivery technology, which is protected by extensive know-how and trade secrets and various U.S. and foreign patents, including patents that protect the Inbrija dry powder capsules beyond 2030. We have several patents listed in the Orange Book for Inbrija, including patents expiring between 2022 and 2032, and Inbrija is entitled to three years of regulatory exclusivity, through December 21, 2021, as posted in the Orange Book.

FDA approval of Inbrija was based on a clinical program that included approximately 900 people with Parkinson's on a carbidopa/levodopa regimen experiencing OFF periods. The Phase 3 pivotal trial for Inbrija – SPAN-PD – was a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of Inbrija in patients with mild to moderate Parkinson's experiencing OFF periods. In January 2019, we announced that The Lancet Neurology published results from the SPAN-PD clinical trial.

The SPAN-PD trial met its primary endpoint, with patients showing a statistically significant improvement in motor function at the week 12 visit, as measured by a reduction in Unified Parkinson's Disease Rating Scale (UPDRS) Part III score for Inbrija 84 mg (n=114) compared to placebo (n=112) at 30 minutes post-dose (-9.83 points and -5.91 points respectively; p=0.009). Onset of action was seen as early as 10 minutes. Maintenance of effect continued to 60 minutes post-dose, which is the longest time point assessed in the trial. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment.

The most common adverse reactions with Inbrija (at least 5% and greater than placebo) in the pivotal trial were cough (15% vs. 2%), upper respiratory tract infection (6% vs. 3%), nausea (5% vs. 3%) and discolored sputum (5% vs. 0%).

Inbrija was also studied in a Phase 3 long-term, active-controlled, randomized, open-label study (N=398) assessing safety and tolerability over one year. This study showed the average reduction in FEV1 (forced expiratory volume in 1 second) from baseline was the same (-0.1 L) for the Inbrija and observational cohorts. Patients with chronic obstructive pulmonary disease (COPD), asthma, or other chronic respiratory disease within the last five years were excluded from this study.

Inbrija is not to be used by patients who take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last two weeks.

It is not known if Inbrija is safe or effective in children.

## Ampyra

Ampyra, an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), was approved by the FDA in January 2010 to improve walking in adults with MS. To our knowledge, Ampyra is the first drug approved for this indication. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the U.S. in March 2010, and had net revenue of \$455.1 million for the year ended December 31, 2018.

We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our

four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. This litigation is discussed in further detail in Part I, Item 3 of this report. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

## ARCUS Product Development

Our strategic priorities include exploring opportunities for other proprietary products in which inhaled delivery of medicine using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients. We are looking at disorders of the central nervous system, or CNS, as well as non-CNS opportunities for ARCUS.

Our ARCUS program for acute treatment of migraine is our most advanced ARCUS development program, and one of our strategic priorities. We initiated this program studying an ARCUS-based formulation of an inhaled triptan (zolmitriptan), although as further described below, we are now looking at three different candidates for this program. 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.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of our ARCUS-based zolmitriptan formulation 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 our ARCUS-based zolmitriptan formulation had a median Tmax 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 tolerability was generally consistent with the known safety profile of zolmitriptan. In December 2016, we completed a special population study to evaluate safe inhalation of our zolmitriptan formulation in people with asthma and in smokers. Some subjects showed evidence of acute, reversible bronchoconstriction, post-inhalation. We have proceeded with additional formulation work on three different migraine candidates for this program, including reformulation of our ARCUS-based zolmitriptan, and we will be potentially moving one of these forward for further development.

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 nRDS. In collaboration with the Massachusetts Institute of Technology, we developed a formulation and delivery device based on our proprietary ARCUS drug delivery technology. nRDS is a condition affecting prematurely born infants in which their lungs are underdeveloped and thus lack a sufficient amount of lung surfactant. 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. Delivering liquid surfactant to the lungs via intubation is the standard of care. We believe that our formulation and delivery system may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. Based on recent achievement of pre-clinical proof of concept, the foundation has expanded the funding to include pre-IND development. 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.

## Other Research and Development Programs

Following is a description of our other research and development programs.

**SYN120:** SYN120 is a potential treatment for Parkinson's-related dementia, which we acquired with Biotie Therapies. Data from a Phase 2 exploratory study that we completed in 2017 showed that several of the outcome measures trended in favor of drug versus placebo, particularly with respect to neuropsychiatric symptoms. However, neither the primary nor key secondary endpoints achieved statistical significance. We are continuing to review the data.

**BTT1023:** Through Biotie Therapies, we are 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. The University of Birmingham had been conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, and data from the trial were expected in the fourth quarter of 2018, but the university recently informed us that they terminated the trial.

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•**rHIgM22:** 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. We have completed and analyzed data from a Phase 1 trial using one of two doses of rHIgM22 or placebo in 27 people with MS who experienced an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study included exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. Data from the trial showed that a single dose of rHIgM22 was not associated with any safety signals. The trial's primary objectives were safety and tolerability of a single dose following a relapse. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. We are considering next steps for the program.

•**Cimaglermin alfa:** 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. In 2013, we commenced a Phase 1b single-infusion trial in people with heart failure, which assessed the tolerability of three dose levels of cimaglermin, and also included an 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 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. The abnormal blood tests resolved within two to three weeks. We subsequently conducted additional analyses and non-clinical studies to further define the nature of the hepatotoxicity, and met with the FDA to present these data as part of our request that the program be removed from the clinical hold. The FDA lifted the clinical hold in April 2017. We are seeking to partner or out-license this program.

#### Qutenza/NP-1998 Sale

On October 30, 2018, we sold our Qutenza assets and NP-1998 development program. 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. NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were previously assessing for the treatment of neuropathic pain. Under the asset purchase agreement, the buyer made aggregate cash payments to us of approximately \$7.9 million for the assets and we are entitled to receive up to an additional \$35.0 million in cash based on achievement of specified U.S. sales milestones for Qutenza and, if it receives FDA approval, NP-1998.

#### 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. Following are our 2019 strategic priorities:

•**Inbrija (levodopa inhalation powder):** Launching the commercial sale of Inbrija in the U.S.; obtaining approval of our European Marketing Authorization Application, or MAA, for Inbrija; and continuing with potential partnering discussions for commercialization outside of the U.S.

•**ARCUS Platform:** Advancing our efforts to develop additional therapeutics based on our proprietary ARCUS pulmonary drug delivery technology, looking at central nervous system, or CNS, as well as non-CNS opportunities, including our program to develop an ARCUS-based treatment for acute migraine.

•**Financial Management:** Focusing on financial discipline to maintain a strong balance sheet, control expenses and deploy resources to maximize shareholder value.



## Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Inbrija (levodopa inhalation powder)	Parkinson's disease OFF periods/episodes	FDA-approved	Acorda/Worldwide; seeking to out-license/partner outside of the U.S.
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.)
Selincro**	Alcohol Dependence	EMA-approved	Lundbeck

## Research and

Development Programs	Proposed Therapeutic Area(s)	Stage of Development	Marketing Rights
ARCUS for acute migraine	Acute migraine	Preclinical evaluation of three potential candidate molecules	Acorda/Worldwide
SYN120	Parkinson's disease-related dementia	Phase 2 clinical trial completed; endpoints not met, data under review	Acorda (Biotie)/Worldwide
BTT1023 (timolumab)	Primary Sclerosing Cholangitis	Phase 2 proof-of-concept clinical trial terminated	Acorda (Biotie)/Worldwide;
rHIgM22	MS	Phase 1 trial completed; considering next steps	Acorda/Worldwide
Cimaglermin alfa	Heart failure	Phase 1b clinical trial hold lifted in April 2017	Acorda/Worldwide; seeking to out-license/partner

\* In November 2017, we announced a \$40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive royalties on Fampyra payable to us by Biogen, up to an agreed-upon threshold of royalties. Until this threshold is met, if ever, we will not receive Fampyra royalty revenue although we have retained the right to receive any potential future milestone payments from Biogen.

\*\* In November 2017, we announced a royalty monetization with Lundbeck pursuant to which we received a \$13 million payment from Lundbeck in exchange for an amendment to its Selincro license eliminating Lundbeck's future royalty and milestone obligations on sales of Selincro outside of the U.S. Selincro is not approved for use in the U.S. and is not under development for use in the U.S.

## 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.

#### Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. Approximately one million Americans and 1.2 million Europeans suffer from Parkinson's. There is no cure or disease-modifying treatment currently available for Parkinson's. 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, people are likely to experience OFF periods, also known as OFF episodes, which are characterized by the return of Parkinson's symptoms, which can occur despite underlying baseline therapy. 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 can increase in frequency and severity during the course of the disease, and 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 levodopa 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. In a survey of 3,000 people with Parkinson's conducted by the Michael J. Fox Foundation, 64% of respondents reporting having at least two hours of OFF time per day.

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.

### 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.

Inbrija (levodopa inhalation powder)

Inbrija (levodopa inhalation powder) is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg, with no titration required. We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies.

We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines. After the adoption of a Committee for Medicinal Products for Human Use, or CHMP, opinion, we expect a final decision regarding the MAA from the European Commission before the end of 2019. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S.

We intend to market Inbrija in the U.S. through our own specialty sales force and commercial infrastructure. We believe we have built a leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our commercial sale of Inbrija in the U.S. will benefit from the experiences and capabilities of this team. Importantly, we kept our commercial team substantially intact following a 2017 company restructuring. We currently have approximately 90 sales representatives as well as established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on our marketed products; a National Trade Account Director who works with our network of specialty pharmacies for Inbrija; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. In advance of the launch of commercial sale, we are visiting movement disorder and key neurology centers to provide education and training on Inbrija's clinical profile, the appropriate use of the Inbrija inhaler, and our Prescription Support Services hub, described below. We project that annual peak net revenue of Inbrija in the U.S. alone could exceed \$800 million.

In January 2019, we established Prescription Support Services, which we sometimes refer to as the Inbrija hub, a service provided by Acorda which is designed to help patients navigate their insurance coverage and offer reimbursement support services, when appropriate. Services fall into one of these four categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; appeals support; and assistance identifying which specialty pharmacy a patient will utilize based on their insurance coverage. For patients that may need assistance paying for their medication, Prescription Support Services will offer several support options, including: a patient assistance program, that provides no cost medication to patients who meet specific program eligibility requirements; co-pay support, which may help commercially insured (non-government funded) patients lower their out-of-pocket costs; and a bridge program, for federally-insured patients who experience a delay in coverage determination. We intend to implement a no-cost sample program to enable patients and their physicians to assess the value of Inbrija before the patient has to incur out-of-pocket co-pay or co-insurance costs.

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. The standard baseline 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 progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson's symptoms that result from low levels of dopamine between doses oral carbidopa/levodopa. OFF periods are often highly disruptive to people with Parkinson's. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods.

Inbrija is an on-demand treatment that utilizes our innovative ARCUS platform for inhaled therapeutics. ARCUS is a dry-powder pulmonary drug delivery technology that we believe has potential to be used in the development of a

variety of inhaled medicines. The ARCUS platform allows systemic delivery of medication through inhalation, by transforming molecules into a light, porous dry powder. This allows delivery of substantially higher doses of medication than can be delivered via conventional dry powder technologies. We acquired the ARCUS technology platform as part of our 2014 acquisition of Civitas Therapeutics. We have worldwide rights to our ARCUS drug delivery technology, which is protected by extensive know-how and trade secrets and various U.S. and foreign patents, including patents that protect the Inbrija dry powder capsules beyond 2030. We have several patents listed in the Orange Book for Inbrija, including patents expiring between 2022 and 2032, and Inbrija is entitled to three years of regulatory exclusivity, through December 21, 2021, as posted in the Orange Book.



## Clinical Studies and Safety Profile

FDA approval of Inbrija was based on a clinical program that included approximately 900 people with Parkinson's on a carbidopa/levodopa regimen experiencing OFF periods. The Phase 3 pivotal trial for Inbrija – SPAN-PD – was a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of Inbrija in patients with mild to moderate Parkinson's experiencing OFF periods. In January 2019, we announced that The Lancet Neurology published results from the SPAN-PD clinical trial.

The SPAN-PD trial met its primary endpoint, with patients showing a statistically significant improvement in motor function at the week 12 visit, as measured by a reduction in Unified Parkinson's Disease Rating Scale (UPDRS) Part III score for Inbrija 84 mg (n=114) compared to placebo (n=112) at 30 minutes post-dose (-9.83 points and -5.91 points respectively; p=0.009). Onset of action was seen as early as 10 minutes. Maintenance of effect continued to 60 minutes post-dose, which is the longest time point assessed in the trial. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment.

The most common adverse reactions with Inbrija (at least 5% and greater than placebo) in the pivotal trial were cough (15% vs. 2%), upper respiratory tract infection (6% vs. 3%), nausea (5% vs. 3%) and discolored sputum (5% vs. 0%).

Inbrija was also studied in a Phase 3 long-term, active-controlled, randomized, open-label study (N=398) assessing safety and tolerability over one year. This study showed the average reduction in FEV1 (forced expiratory volume in 1 second) from baseline was the same (-0.1 L) for the Inbrija and observational cohorts. Patients with chronic obstructive pulmonary disease (COPD), asthma, or other chronic respiratory disease within the last five years were excluded from this study.

Inbrija is not to be used by patients who take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last two weeks.

### Additional Important Safety Information

Before using Inbrija, patients should tell their healthcare provider about all their medical conditions, including:

- asthma, chronic obstructive pulmonary disease (COPD), or any chronic lung disease
- daytime sleepiness from a sleep disorder or if they get drowsy/sleepy without warning or take a medicine that increases sleepiness such as sleep medicines, antidepressants, or antipsychotics
- feel dizzy, nausea, sweaty, or faint when standing from sitting/lying down
- history of abnormal movement (dyskinesia)
- mental health problem such as hallucinations or psychosis
- uncontrollable urges (for example, gambling, increased sexual urges, intense urges to spend money, or binge eating)
- glaucoma
- pregnancy or plans to become pregnant. It is not known if Inbrija will harm an unborn baby.
- breastfeeding or plans to breastfeed. Levodopa (the medicine in Inbrija) can pass into breastmilk and it is unknown if it can harm the baby.

Patients should tell their healthcare provider if they take:

- MAO-B inhibitors

• dopamine D2 receptor antagonists (including phenothiazines, butyrophenones, risperidone, metoclopramide), or isoniazid

• iron salts or multivitamins that contain iron salts

No more than 1 dose (2 capsules) should be taken for any OFF period. No more than 5 doses (10 capsules) of Inbrija should be taken in a day.

Inbrija is for oral inhalation only. Inbrija capsules are not to be swallowed or opened.

Patients are not to drive, operate machinery, or do other activities until they know how Inbrija affects them. Sleepiness and falling asleep suddenly can happen as late as a year after treatment is started.

Inbrija (levodopa inhalation powder) can cause serious side effects including the following. Patients should tell their healthcare provider if they experience them:

- falling asleep during normal daily activities (such as driving, doing physical tasks, using hazardous machinery, talking, or eating) and can be without warning. If patients become drowsy while using Inbrija, they should not drive or do activities where they need to be alert. Chances of falling asleep during normal activities increases if patients take medicines that cause sleepiness.

• withdrawal-emergent hyperpyrexia and confusion (symptoms including fever, confusion, stiff muscles, and changes in breathing and heartbeat) in patients who suddenly lower or change their dose or stop using Inbrija or carbidopa/levodopa medicines.

• low blood pressure with or without dizziness, fainting, nausea, and sweating. Patients should get up slowly after sitting or lying down.

• hallucinations and other psychosis – Inbrija may cause or worsen psychotic symptoms including hallucinations (seeing/hearing things that are not real); confusion, disorientation, or disorganized thinking; trouble sleeping; dreaming a lot; being overly suspicious or feeling people want to harm them; believing things that are not real, acting aggressive, and feeling agitated/restless.

• unusual uncontrollable urges such as gambling, binge eating, shopping, and sexual urges has occurred in some people using medicines like Inbrija.

• uncontrolled, sudden body movements (dyskinesia) may be caused or worsened by Inbrija. Inbrija may need to be stopped or other Parkinson's medicines may need to be changed.

• bronchospasm – people with asthma, COPD, or other lung diseases may wheeze or have difficulty breathing after inhaling Inbrija. If patients have these symptoms, they should stop taking Inbrija and call their healthcare provider or go to the nearest hospital emergency room right away.

• increased eye pressure in patients with glaucoma. Healthcare providers should monitor this.

• changes in certain lab values including liver tests.

The most common side effects of Inbrija include cough, upper respiratory tract infection, nausea, and change in the color of saliva or spit.

It is not known if Inbrija is safe or effective in children.

## 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. 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.

We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the “District Court”) issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. This litigation is discussed in further detail in Part I, Item 3 of this report. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

#### License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen 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. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a \$25 million milestone payment from Biogen in 2011, which was triggered by Biogen’s receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters. In November 2017, we announced a \$40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. Until this threshold is met, if ever, we will not receive Fampyra royalties although we have retained the right to receive any potential future milestone payments, described above. The HCRP transaction is accounted for as a liability, as described in Note 11 to our Consolidated Financial Statements included in this report.

#### Ampyra Patent Update

Six issued Ampyra patents have been listed in the Orange Book. The five initial Orange Book-listed patents have been the subject of litigation with certain generic drug manufacturers, as described above. In connection with the litigation, our Orange Book-listed patent that expired on July 30, 2018, was upheld, but four other Ampyra patents set to expire between 2025 and 2027 were invalidated. The litigation is discussed in further detail in Part I, Item 3 of this report.

The sixth Orange Book-listed patent, not involved in the litigation, was issued more recently and was listed in the Orange Book in April 2018. The sixth Orange Book-listed patent is U.S. Patent No. 9,918,973, the claims of which relate to methods of increasing walking speed in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent will expire in 2024. We note that this patent does not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers

that are involved in the patent litigation described in 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. In February 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. The appeal hearings for both patents are scheduled for September 2019. 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.

#### 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, but the FDA may require additional studies. 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.

#### ARCUS Product Development

Our strategic priorities include exploring opportunities for other proprietary products in which inhaled delivery of medicine using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients. We are looking at disorders of the central nervous system, or CNS, as well as non-CNS opportunities for ARCUS.

Our ARCUS program for acute treatment of migraine is our most advanced ARCUS development program, and one of our strategic priorities. We initiated this program studying an ARCUS-based formulation of an inhaled triptan (zolmitriptan), although as further described below, we are now looking at three different candidates for this program. 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.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of our ARCUS-based zolmitriptan formulation 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 our ARCUS-based zolmitriptan formulation 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 tolerability was generally consistent with the known safety profile of zolmitriptan. In December 2016, we completed a special population study to evaluate safe inhalation of our zolmitriptan formulation in people with asthma and in smokers. Some subjects showed evidence of acute, reversible bronchoconstriction, post-inhalation. We have proceeded with additional formulation work on three different migraine candidates for this program, including reformulation of our ARCUS-based zolmitriptan, and we will be potentially moving one of these forward for further development.

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 nRDS. In collaboration with the Massachusetts Institute of Technology, we developed a formulation and delivery device based on our proprietary ARCUS drug delivery technology. nRDS is a condition affecting prematurely born infants in which their lungs are underdeveloped and thus lack a sufficient amount of lung surfactant. 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. Delivering liquid surfactant to the lungs via intubation is the standard of care. We believe that our formulation and delivery system may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. Based on recent achievement of pre-clinical proof of concept, the foundation has expanded the funding to include pre-IND development. 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.

#### Other Research and Development Programs

Following is a description of our other research and development programs.

**SYN120:** SYN120 is a potential treatment for Parkinson's-related dementia, which we acquired with Biotie Therapies. Data from a Phase 2 exploratory study that we completed in 2017 showed that several of the outcome measures trended in favor of drug versus placebo, particularly with respect to neuropsychiatric symptoms. However, neither the primary nor key secondary endpoints achieved statistical significance. We are continuing to review the data.

**BTT1023:** Through Biotie Therapies, we are 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. The University of Birmingham had been conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, and data from the trial were expected in the fourth quarter of 2018, but the university recently informed us that they terminated the trial.

**rHlgM22:** 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. We have completed and analyzed data from a Phase 1 trial using one of two doses of rHlgM22 or placebo in 27 people with MS who experienced an acute relapse. In addition to assessing safety and



tolerability during an acute relapse, the study included exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. Data from the trial showed that a single dose of rHIgM22 was not associated with any safety signals. The trial's primary objectives were safety and tolerability of a single dose following a relapse. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. We are considering next steps for the program.

◆Cimaglermin alfa: 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. In

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2013, we commenced a Phase 1b single-infusion trial in people with heart failure, which assessed the tolerability of three dose levels of cimaglermin, and also included an 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 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. The abnormal blood tests resolved within two to three weeks. We subsequently conducted additional analyses and non-clinical studies to further define the nature of the hepatotoxicity, and met with the FDA to present these data as part of our request that the program be removed from the clinical hold. The FDA lifted the clinical hold in April 2017. We are seeking to partner or out-license this program.

Sales, Marketing and Market Access

Inbrija (levodopa inhalation powder)

We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies.

We intend to market Inbrija in the U.S. through our own specialty sales force and commercial infrastructure. We believe we have built a leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our commercial sale of Inbrija in the U.S. will benefit from the experiences and capabilities of this team. Importantly, we kept our commercial team substantially intact following a 2017 company restructuring. We currently have approximately 90 sales representatives as well as established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on our marketed products; a National Trade Account Director who works with our network of specialty pharmacies for Inbrija; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. In advance of the launch of commercial sale, we are visiting movement disorder and key neurology centers to provide education and training on Inbrija's clinical profile, the appropriate use of the Inbrija inhaler, and our Prescription Support Services hub, described below.

In January 2019, we established Prescription Support Services, which we sometimes refer to as the Inbrija hub, a service provided by Acorda which is designed to help patients navigate their insurance coverage and offer reimbursement support services, when appropriate. Services fall into one of these four categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; appeals support; and assistance identifying which specialty pharmacy a patient will utilize based on their insurance coverage. For patients that may need assistance paying for their medication, Prescription Support Services will offer several support options, including: a patient assistance program, that provides no cost medication to patients who meet specific program eligibility requirements; co-pay support, which may help commercially insured (non-government funded) patients lower their out-of-pocket costs; and a bridge program, for federally-insured patients who experience a delay in coverage determination. We intend to implement a no-cost sample program to enable patients and their physicians to assess the value of Inbrija before the patient has to incur out-of-pocket co-pay or co-insurance costs.

Ampyra

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 physicians. We also have

established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on Ampyra; a National Trade Account Director who works with our network of specialty pharmacies for Ampyra; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives. We have a 60-day free trial program that provides eligible patients with two months of Ampyra at no cost.

Ampyra is distributed in the U.S. primarily through a network of specialty pharmacy providers, which deliver the medication to patients by mail, 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. 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. We have relationships with six additional pharmacies through which Ampyra is available, each of which is either affiliated with an integrated health delivery network or an academic medical center. These pharmacies are not part of our specialty pharmacy network, but rather receive prescriptions for Ampyra directly from prescribers without first being routed through APSS.

We are evaluating the level of our continuing investment in certain Ampyra sales and marketing programs, including our free trial program and APSS, due to the introduction of generic competition and corresponding decline in Ampyra sales.

#### Material and Other Collaborations and License Agreements

##### Alkermes (ARCUS products)

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

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

The Alkermes agreement remains in effect until expiration of Civitas' 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.

##### 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 multiple sclerosis, or MS, (licensed products). The Collaboration Agreement includes a sublicense of our rights under an existing license agreement with Alkermes (formerly Elan). We have also entered into a related Supply Agreement pursuant to which we supply Biogen with its requirements for the licensed products through our existing supply agreement with Alkermes. Biogen Inc., the parent of Biogen, has guaranteed the performance of Biogen's obligations under the Collaboration Agreement and the Supply Agreement.

Under the Collaboration Agreement, Biogen, itself or through its affiliates, has the exclusive right to commercialize licensed products in all countries outside of the U.S., while we retain the exclusive right to commercialize licensed products in the U.S. Each party has the exclusive right to develop licensed products for its commercialization territory, although the parties may also decide to jointly carry out mutually agreed future development activities 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.

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. In November 2017, we announced a \$40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. Until this threshold is met, if ever, we will not receive Fampyra royalty revenue although we have retained the right to receive any potential future milestone payments, described above.

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 spinal cord injury, or SCI, multiple sclerosis, or 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 multiple sclerosis, or 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 (with the last milestone having been paid in 2010) and \$48.1 million in royalties under this agreement through December 31, 2018. 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. We believe the Rush license and our royalty obligations expired in 2018.

#### 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 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 multiple sclerosis, or 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 Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd. to certain patents and know-how relating to tozadenant and certain patents and know-how relating to SYN120. Tozadenant is an investigational drug we had been developing for the reduction of OFF time in Parkinson's disease patients, but we terminated this program in November 2017.

Our Biotie subsidiary has an exclusive, worldwide license from Medarex, Inc. to certain patents and know-how relating to BTT1023.

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## Manufacturing and Supply

### Inbrija (levodopa inhalation powder) and ARCUS Development Programs

#### Chelsea Manufacturing Facility

We currently manufacture all commercial supply of Inbrija at our approximately 90,000 square foot Chelsea, Massachusetts manufacturing facility that we occupy under a lease that expires in December 2025, which we may extend for up to ten years. The FDA's pre-approval inspection of this facility was successfully closed in 2018 prior to the FDA's December 21, 2018 approval of Inbrija.

We acquired the Chelsea facility with our 2014 acquisition of Civitas Therapeutics. The facility was built specifically for the commercial-scale manufacture of ARCUS products. Prior to Civitas' 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' collaborator in indications other than Parkinson's disease. Civitas subsequently took steps to recommission the facility, and prior to our Civitas acquisition it was certified by the EU regulatory authority (known as the Qualified Person, or QP, audit). The Chelsea facility produced current good manufacturing practices, or cGMP-quality human doses of Inbrija for Phase 1, Phase 2 and Phase 3 clinical trials, including our pivotal Phase 3 trial, and it is now being used for commercial manufacture.

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.

We intend to manufacture all commercial supplies of Inbrija, as well as supplies of all additional ARCUS inhaled therapeutic candidates that we may develop, in the Chelsea manufacturing facility unless and until we engage a third party for expanded manufacturing capacity. After the launch of Inbrija commercial sales, we anticipate the need for expanded manufacturing capacity at the Chelsea facility to meet demand depending on the timing and extent of sales growth. In 2018, we initiated a renovation and expansion of the Chelsea facility that will increase the size of the facility to approximately 95,000 square feet. The project will add a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and it will create additional warehousing space for manufactured product. Construction of the project is scheduled for completion in the third quarter of 2019, though we cannot be assured that the project will meet this schedule, and it will take additional time after completion of construction to obtain the FDA approval needed for use of the new production line for commercial manufacture. Our inability to expand the facility in a timely manner or unexpected demand for commercial quantities of Inbrija could cause a supply shortage that would harm our commercialization of Inbrija.

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. The expansion of our manufacturing capacity is requiring substantial additional expenditures and will require various regulatory approvals and permits. Further, we will need to hire and train additional employees and managerial personnel to staff our expanding manufacturing operations. Manufacturing scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology. Our expanded Chelsea facility will have to continue to comply with cGMP requirements, as well as other applicable environmental, safety, and other governmental permitting requirements. These challenges could delay or prevent us from successfully expanding our Chelsea manufacturing capacity. If we are delayed in or prevented from expanding our Chelsea facility, we may need to seek a third party to manufacturer additional Inbrija supply for us. As further discussed below, there

can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they could supply us with product in sufficient quantities on a timely basis to meet our needs. If we cannot increase our supply of Inbrija by expanding our capacity in Chelsea or engaging a third party manufacturer, we may not be able to meet demand for Inbrija and our ability to commercialize Inbrija could be harmed.

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 may also unexpectedly experience these types of manufacturing issues as the unintended result of the construction and other activities occurring at the facility needed for expansion. 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 Inbrija 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. Even if we do not suffer a loss of the facility or equipment within the facility, manufacturing operations can experience intermittent interruptions due to the need for routine or unexpected maintenance, inspection and repairs of the facility or the equipment, and, depending on their frequency and duration, these intermittent interruptions could also harm our business.

We do not currently have back-up manufacturing capability at another facility and there are only limited third-party manufacturers that we believe would be capable of manufacturing Inbrija or other ARCUS inhaled therapeutic products or product candidates. If the need arises to obtain supply from a third party manufacturer, there can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they could supply us in sufficient quantities on a timely basis to meet our needs. Engaging a third party manufacturer to supply ARCUS products or product candidates would likely be a lengthy process involving the transfer of a proprietary, specialized and regulated manufacturing processes and which would be subject to the FDA regulatory approval requirements described above. Also, this would require that we share proprietary trade secrets and know-how with the third party manufacturer relating to Inbrija and our ARCUS platform. When our business requires that we share that type of information, we seek to protect it, in part, with confidentiality agreements, but those agreements may not provide adequate protection or prevent the unauthorized use or disclosure of the information. The unauthorized use or disclosure of our proprietary information could harm its value by enabling others to copy or use our information for their own products, methods or technologies, and we may not have an adequate remedy for the harm caused. If we are successful in engaging a third party manufacturer, 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.

### Supply

We have relied, and we expect to continue relying, on third-party manufacturers to make the inhaler and to supply levodopa, or L-dopa, the active pharmaceutical ingredient, or API, in Inbrija, and any failure by a third-party manufacturer or supplier may delay or impair our ability to meet demand for Inbrija and could delay, prevent or impair our commercialization of Inbrija.

We source our proprietary Inbrija inhalers from a single third-party plastic molding manufacturer for the Inbrija inhalers. Our proprietary inhalers are manufactured using standard manufacturing processes and are shipped fully assembled to us. We own the molds and design history files for the inhalers. Our reliance on a single third party 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 commercialization of Inbrija. If we need to enter into alternative arrangements with a different supplier, this could delay our manufacturing, as we would have to revalidate the molding and assembly processes pursuant to FDA requirements.

We do not purchase the API for Inbrija 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.

All raw materials used for Inbrija manufacture are standard in pharmaceutical production.

#### Ampyra

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

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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' 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.

We rely on two third-party manufacturers, Regis Technologies, Inc. and CU Chemie Uetikon (GmbH), to supply 4-aminopyridine, the active pharmaceutical ingredient in Ampyra. If these companies experience any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until the problem is solved 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.

#### 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.

#### Intellectual Property

We have patent portfolios relating to: Ampyra/aminopyridines; Inbrija (levodopa inhalation powder), ARCUS-based migraine formulations; the ARCUS drug delivery technology; SYN120, BTT1023; cimaglermin alfa/neuregulins; and remyelinating antibodies/antibodies relating to nervous system disorders. 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 Ltd., formerly 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, four of which were held invalid in litigation in U.S. District Court for the District of Delaware with certain generic drug manufacturers, as further described in this report. The first 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 expired on July 30, 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). This patent was held valid by the District Court in the litigation, although in June 2017 the defendant generic drug manufacturers with whom we have not reached settlements appealed the District Court's decision upholding this patent.

The other four Orange Book-listed patents were held invalid by the District Court in the litigation with generic drug manufacturers. These patents, which had been set to expire in 2025 through 2027, consist of 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; 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; 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; and 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.

The patent litigation referenced above relates to Paragraph IV Certification Notices received from ten generic drug manufacturers in 2014 and 2015, who submitted Abbreviated New Drug Applications with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. The ANDA filers challenged the validity of our Orange Book-listed patents for Ampyra, and they 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. In February 2017, we announced that we had reached a settlement agreement with one of those four generic companies. In March 2017, the District Court rendered a decision upholding our Orange-Book listed patent for Ampyra set to expire in July 2018, but invalidating our four other Orange Book-listed patents. In May 2017, we appealed the ruling on these four patents, and as described above, in June 2017 the other non-settling parties appealed the decision on the patent set to expire in July 2018. We expect the appeals process to take approximately 12 to 18 months from the filing of the appeal in May 2017. Both the Biotechnology Innovation Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) filed amicus briefs in support of our appeal, raising important issues in conjunction with biopharmaceutical innovation.

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. The appeal hearings for both patents are scheduled for September 2019. 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.

Legal proceedings relating to our Ampyra patents are described in further detail in Part I, Item 3 of this report.

Inbrija (levodopa inhalation powder) and ARCUS Development Programs

The intellectual property portfolio that we acquired with Civitas has over 100 issued U.S. and foreign patents relating to Inbrija and the ARCUS drug delivery technology. This includes over 15 issued U.S. patents relating to Inbrija directed to compositions of the drug product, the inhaler, the capsule for the drug product, methods of delivery of L-dopa, and manufacturing processes. We have several patents listed in the Orange Book for Inbrija, including patents expiring between 2022 and 2032, and Inbrija is entitled to three years of regulatory exclusivity, through December 21, 2021, as posted in the Orange Book.

The ARCUS program for acute migraine, 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. These applications are for the original zolmitriptan formulation.

## 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 a granted U.S. and European patent set to 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, peripheral neuropathy and nerve injury.

## 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,” and “ARCUS.” We also have trademark registrations for “Fampyra” and “Kampyra” and pending trademark applications therefore, in numerous foreign jurisdictions. We have pending trademark applications for Inbrija in the U.S. and other countries. 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 Parkinson’s disease and multiple sclerosis, or MS. Many of our competitors have substantially greater financial, research and development, human and other resources than we

do. Furthermore, many of these companies have significantly more experience than we do in preclinical testing, human clinical trials, regulatory approval procedures and sales and marketing.

Inbrija (levodopa inhalation powder)/Parkinson's Disease

We expect that Inbrija will compete against other therapies approved for intermittent, or on demand use, that aim to specifically address Parkinson's disease symptoms. Apokyn, an injectable formulation of apomorphine, is approved for the

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treatment of OFF periods, also known as OFF episodes. 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 that we expect would be competitive with Inbrija if commercially launched. In January 2018, Sunovion announced positive topline results from their pivotal Phase 3 study of their product, in March 2018, they submitted a New Drug Application, or NDA, to the FDA, and in January 2019, they announced that they received a Complete Response Letter, or CRL, from the FDA. Sunovion's CRL announcement stated that the FDA determined it was unable to approve Sunovion's product in its current form, and that the FDA requested additional information and analyses but no new clinical studies. Sunovion's receipt of the CRL has delayed, but does not necessarily prevent, FDA approval of Sunovion's product and we expect it will be competitive with Inbrija if and when Sunovion receives FDA approval for and commercially launches the product.

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. Inbrija 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. Amneal Pharmaceuticals, Inc. (formerly Impax Laboratories) markets 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 Intec Pharma and Mitsubishi Tanabe Pharma Corporation. 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 Inbrija 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, among others. If approved, our product candidates may face competition in the target commercial areas for these pulmonary delivery products.

#### Ampyra/MS

Ampyra has become subject to competition from generic drug manufacturers. In 2017, in litigation with certain generic drug manufacturers, the United States District Court for the District of Delaware (the "District Court") issued a ruling upholding our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidating four other Orange Book-listed patents that were set to expire between 2025 and 2027. Under this ruling, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. The United States Court of Appeals for the Federal Circuit issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales. Our litigation with the generic drug manufacturers is described in further detail in Part I, Item 3 of this report.

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.

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 adults with MS by physicians, or because physicians may think that these products also improve walking or other neurological functions.

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. Adamas Pharmaceuticals, Inc. is developing ADS-5102 (amantadine hydrochloride) for patients with MS who have walking impairment. This potential product may compete with Ampyra in the future. Furthermore, 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 and generic versions of Ampyra are commercially available.

## 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 and our product candidates are regulated by the FDA as drugs but, as further discussed below, Inbrija is regulated as a combination product because it has both a drug and a device component. Drugs, biologics, and medical devices are regulated primarily 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 of development 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,

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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, 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 objectives 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 will likely 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 an NDA or BLA 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 for our products and product candidates 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 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, distributors, and other trading partners that govern the introduction and movement of product through the supply chain, including requirements for the exchange of transaction documentation, development of systems capable of tracking and tracing product as it moves through the distribution chain, and responding to requests from trading partners and government agencies. 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, significant price increases in recent years by certain drug manufacturers have received considerable scrutiny from U.S. Congress, in some cases forcing those companies to dramatically reduce those prices. There continues to be political pressure at both the U.S. federal and state levels related to drug pricing and drug transparency that could result in legislative or administrative actions, such as the State of California's passage of SB 17 in 2017, or at a minimum continued scrutiny. California SB 17, for example, put in place new state reporting and notification requirements for manufacturers related to drug pricing, which became effective January 1, 2018. In May 2018, the Trump presidential administration issued "American Patients First," a multi-faceted blueprint to lower drug prices. The Trump administration has taken administrative steps to implement the

blueprint, including through proposing sweeping demonstration projects aimed at putting downward pressure on drug prices. In addition, members of Congress have indicated an interest in legislative measures designed to lower drug costs. 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.

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, the 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 containing 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.

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, Inbrija relies on a device component (the inhaler) to deliver drug product to patients. In general, the FDA regulates that type of product as a “combination product.” 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, as was the case with Inbrija, 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). CDER is the lead review division for Inbrija. We anticipate that to the extent that any of our other 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. Although Inbrija includes a medical device component (the inhaler), Inbrija is a combination product that was approved by CDER via an NDA and these medical device clearance/approval requirements are not applicable to Inbrija.

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,

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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 one of our collaborators 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 & 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. 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. 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, and/or the Veterans Health Care

Act of 1992. 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 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, 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. Beginning in 2022, the Sunshine Act will also apply to payments to physician assistants and advance practice nurses. 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 markets where we or a collaborator markets or may potentially market one of our approved products, 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 certain public healthcare programs, such as Medicaid, in order for the drugs to be eligible for reimbursement under those programs. 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 and drug transparency. Several other states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising pricing and other information related to price increases. In May 2018, the Trump presidential administration issued "American Patients First," a multi-faceted blueprint to lower drug prices. The administration has taken administrative steps to implement the blueprint, including through proposing sweeping demonstration projects aimed at putting downward pressure on drug prices. In addition, members of the U.S. Congress have indicated an interest in legislative measures designed to lower drug costs.



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, as amended, requires drug manufacturers to provide a 70% 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 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.

In December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017, and the U.S. Congress and/or President Trump may seek to repeal other aspects of the ACA. In December 2018, a U.S. federal district court judge in Texas found the ACA to be unconstitutional, although the ruling was stayed while the case is appealed.

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 21, 2019, we had 474 employees.

## 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 free of

charge 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, or SEC. Also, the SEC allows us to “incorporate by reference” some information from our proxy statement for our 2019 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2019 Proxy Statement within 120 days after the end of our 2018 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 2019 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 may not be able to achieve or sustain profitability in the future; we are substantially dependent on our ability to successfully market and sell Inbrija (levodopa inhalation powder), which received FDA approval on December 21, 2018 and which we expect to be commercially available in the U.S. in the first quarter of 2019.

As of December 31, 2018, we had an accumulated deficit of approximately \$393.8 million. We had a net income of \$33.7 million for the year ended December 31, 2018 and a net loss of \$223.4 million for the year ended December 31, 2017. Since 2010, we have been highly dependent on, and have derived substantially all of our revenue from, sales of Ampyra in the U.S. However, in 2017, the United States District Court for the District of Delaware issued a ruling in litigation with certain generic drug manufacturers that invalidated our Orange Book-listed Ampyra patents, and in September 2018 the United States Court of Appeals for the Federal Circuit upheld the District Court ruling. We have experienced a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the appellate decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

Our prospects for achieving and sustaining profitability in the future will depend primarily on how successful we are in:

- successfully launching the commercial sale of Inbrija in the U.S.;
- obtaining MAA approval in the E.U. for Inbrija and commercializing Inbrija in the E.U., for which we may require a collaborator;
- continuing to advance and/or out-license or sell our earlier-stage clinical development programs; and
- 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 achieve or sustain profitability and even if we do so, 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 2019 we expect to invest a significant amount on commercialization of Inbrija.

The commercial success of Inbrija (levodopa inhalation powder) and any other 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, including Inbrija, is subject to numerous factors, some of which are not within our control, including the following:

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- the loss of intellectual property protection for our products, which would enable generic competition;
- the effectiveness of our sales, managed markets and marketing efforts;
- the acceptance of our products in the medical community, particularly with respect to whether physicians and patients view our products as safe and effective for their labeled indications, and whether they have 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 occurrence of any side effects, adverse reactions, customer complaints or misuse (or any unfavorable publicity relating thereto) stemming from the use of Inbrija or our other products or identified in ongoing or future studies of those products;
- the development of products that compete with or are an alternative to Inbrija or any future products that we may develop, the timing of market entry for 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 competing or alternative products.

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, patients and payers. 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 Inbrija or our future products that we may develop are meaningful for patients. As described below in these risk factors, FDA-approved product labeling for Inbrija includes limitations, warnings and precautions, which may harm its market acceptance. Also, if Inbrija or future products are not listed on the preferred drug lists of third-party payers, or Inbrija or other products are on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies, our sales may suffer.

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 (the “Code”), 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, 2018, we had approximately \$131.6 million of NOLs, all of which were incurred by our Biotie subsidiary during 2018 and earlier. Existing NOLs that were incurred prior to 2018 have a 20 year carryforward available (based on when they were incurred) to reduce taxable income in future years. Federal income tax losses generated in tax years ending after January 1, 2018 can generally be carried forward indefinitely, due to 2017 tax reform legislation. However, the ability to use existing NOL carryforwards, or to use NOLs we generate in 2019 and beyond, will be dependent on our ability to generate taxable income and will be subject to an annual limitation of 80% of taxable income. Furthermore, because the NOLs existing at December 31, 2018 were incurred by our Biotie subsidiary, our ability to use those NOL carryforwards will depend on the ability of that specific subsidiary to generate taxable income and we currently do not assign any value to those NOLs.

Our ability to utilize the NOL's may be further limited if we undergo an ownership change, as defined in section 382 of the Code. 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 could significantly impair any value we assign to 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, governments 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. Investigational products that rely on device components to deliver drug to patients, such as Inbrija, are regulated as combination products and require that we satisfy FDA that both the drug and device component of the 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 these products or result in these 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, current Good Manufacturing Practices (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 manufacturing processes for our products, 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 may rely on collaborators within or outside the U.S. for the manufacture, sale and/or marketing of our pharmaceutical products. The failure of these other companies to comply with laws and regulations applicable to them or the activities they perform for us could similarly harm our business.

We rely on our Chelsea manufacturing facility for the manufacture of Inbrija (levodopa inhalation powder) and other ARCUS inhaled therapeutic product candidates, and our business could be harmed if we do not maintain required regulatory approval to manufacture commercial product at that facility, if there is an interruption in operations at the facility, or if the facility does not have manufacturing capacity needed to meet product demand.

We currently manufacture all commercial supply of Inbrija 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 Inbrija, as well as supplies of all additional ARCUS inhaled therapeutic candidates that we may develop, in this manufacturing facility, unless and until we engage a third party for expanded manufacturing capacity. After launch of Inbrija commercial sales, we anticipate the need for expanded manufacturing capacity at the Chelsea facility to meet demand depending on the timing and extent of sales growth. Our inability to expand the facility in a timely manner or unexpected demand for commercial quantities of Inbrija could cause a supply shortage that would harm our commercialization of Inbrija.

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 may also unexpectedly experience these types of manufacturing issues as the unintended result of the construction and other activities occurring at the facility needed for expansion. 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 Inbrija 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. Even if we do not suffer a loss of the facility or equipment within the facility, manufacturing operations can

experience intermittent interruptions due to the need for routine

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or unexpected maintenance, inspection and repairs of the facility or the equipment, and, depending on their frequency and duration, these intermittent interruptions could also harm our business.

We do not currently have back-up manufacturing capability at another facility and there are only limited third-party manufacturers that we believe would be capable of manufacturing Inbrija or other ARCUS inhaled therapeutic products or product candidates. If the need arises to obtain supply from a third party manufacturer, there can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they could supply us in sufficient quantities on a timely basis to meet our needs. Engaging a third party manufacturer to supply ARCUS products or product candidates would likely be a lengthy process involving the transfer of a proprietary, specialized and regulated manufacturing processes and which would be subject to the FDA regulatory approval requirements described above. Also, this would require that we share proprietary trade secrets and know-how with the third party manufacturer relating to Inbrija and our ARCUS platform. When our business requires that we share that type of information, we seek to protect it, in part, with confidentiality agreements, but those agreements may not provide adequate protection or prevent the unauthorized use or disclosure of the information. The unauthorized use or disclosure of our proprietary information could harm its value by enabling others to copy or use our information for their own products, methods or technologies, and we may not have an adequate remedy for the harm caused. If we are successful in engaging a third party manufacturer, 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.

Expanding our Chelsea manufacturing capacity will be costly and involves numerous risks, and our efforts to commercialize the product could be harmed if we cannot complete expansion of the facility in a timely manner.

After the launch of Inbrija commercial sales, we anticipate the need for expanded manufacturing capacity at the Chelsea facility to meet demand depending on the timing and extent of sales growth. In 2018, we initiated a renovation and expansion of the Chelsea facility that will increase the size of the facility to approximately 95,000 square feet. The project will add a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and it will create additional warehousing space for manufactured product. Construction of the project is scheduled for completion in the third quarter of 2019, though we cannot be assured that the project will meet this schedule, and it will take additional time after completion of construction to obtain the FDA approval needed for use of the new production line for commercial manufacture.

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. Expanding our manufacturing capacity is requiring substantial additional expenditures and will require various regulatory approvals and permits. Further, we will need to hire and train additional employees and managerial personnel to staff our expanding manufacturing operations. Manufacturing scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology. Our expanded Chelsea facility will have to continue to comply with cGMP requirements, as described above in these risk factors, as well as other applicable environmental, safety, and other governmental permitting requirements.

These challenges could delay or prevent us from successfully expanding our Chelsea manufacturing capacity. If we are delayed in or prevented from expanding our Chelsea facility, we may need to seek a third party to manufacturer additional Inbrija supply for us. As described above in these risk factors, there can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they

could supply us with product in sufficient quantities on a timely basis to meet our needs. If we cannot increase our supply of Inbrija by expanding our capacity in Chelsea or engaging a third party manufacturer, we may not be able to meet demand for Inbrija and our ability to commercialize Inbrija could be harmed.

We have no manufacturing capabilities for our products or product candidates other than our Chelsea, Massachusetts facility used to manufacture Inbrija (levodopa inhalation powder) and other ARCUS inhaled therapy product candidates, and we are dependent upon third-parties to supply the materials for, and to manufacture, our products and product candidates.

We do not own or operate, and currently do not plan to own or operate, facilities for production and packaging of our products or product candidates other than our Chelsea, Massachusetts facility used to manufacture Inbrija and other ARCUS product candidates. We rely and expect to continue to rely on third parties for the production and packaging, active pharmaceutical ingredients, or APIs, inactive ingredients, and finished dosage forms of our products and product candidates, and where relevant any medical devices that are part of our products or product candidates. 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 have relied, and we expect to continue relying, on third-party manufacturers to make the inhaler and to supply the API in Inbrija, and any failure by a third-party manufacturer or supplier may delay or impair our ability to commercialize Inbrija or to complete any future clinical studies that we may need to conduct. 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 commercialization efforts. We rely on a single third party molding manufacturer for supply of the Inbrija inhalers, and if this 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 there is an interruption in supply, this might render us unable to meet the demand for this product and our business could be adversely affected. Similarly, we do not purchase the API for Inbrija 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.

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 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. We and Alkermes also rely on two third-party manufacturers, Regis Technologies, Inc. and CU Chemie Uetikon (GmbH), to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra. If these companies experience any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until the problem is solved or we locate another 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. Given the introduction of generic competition to Ampyra in the market, it may be difficult to forecast the level of supply needed to satisfy our requirements in the future.

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.

Each of our products is approved with specific indications and other conditions of use that inform our ability to promote our products. For example, Inbrija (levodopa inhalation powder) is indicated “for the intermittent treatment of OFF episodes in people with Parkinson’s disease treated with carbidopa/levodopa.” 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 Inbrija 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 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 Inbrija (levodopa inhalation powder), Ampyra or any 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 side effects from Inbrija (levodopa inhalation powder) or any other marketed drug products, or side effects from those products that are more frequent or severe than in the past, would harm our business and could lead to a significant decrease in sales or to the FDA's withdrawal of marketing approval.

Based on our clinical trials, the most common adverse reactions with Inbrija (at least 5% and greater than placebo) include cough, upper respiratory tract infection, nausea and discolored sputum. Once Inbrija is commercially available for sale, we will constantly monitor adverse event reports for signals regarding potential additional adverse events. 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 Inbrija or any products perceived to be similar to Inbrija, 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 product label changes;
- healthcare practitioners, regulatory authorities, third party payers or patients may perceive or conclude that the risks associated with use of Inbrija outweigh the benefits, which could cause FDA to seek to withdraw Inbrija'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 risk evaluation and mitigation strategy, or REMS, on Inbrija 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 Inbrija, causing sales to fall below projections, and increasing our expenses.

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

Under FDA regulations, we are required to monitor the safety of Inbrija and Ampyra, and in the case of Ampyra 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. These requirements are applicable to all marketed drug products and will be applicable to Inbrija (levodopa inhalation powder) when we commence commercial sales. 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. If specialty pharmacies, 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.

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, 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 selling Inbrija will depend on the 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 Inbrija, Inbrija adverse events, or Inbrija product complaints;
- not effectively dispense or support Inbrija;

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- reduce their efforts or discontinue dispensing or supporting Inbrija;
- not devote the resources necessary to dispense Inbrija 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 existing collaborations, and may need additional collaborations, to commercialize products outside of the U.S.

We have not yet developed the capabilities to commercialize products outside of 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. For example, we may need to enter into collaborations to commercialize Inbrija (levodopa inhalation powder) outside of the U.S., if it receives marketing approval in any jurisdictions outside of the U.S., and similarly we would need to rely on collaborations for commercializing any other potential products outside of the U.S. We cannot provide any assurance that we will be able to identify suitable collaboration partners for Inbrija or other potential products, or that we will be able to enter into collaboration agreements with proposed partners on commercially reasonable terms or at all. Our inability to identify collaboration partners or enter into collaborations could harm or delay our efforts to commercialize Inbrija or other potential products outside of the U.S.

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

While we seek contractual terms and conditions intended to protect our rights and mitigate our risk relating to 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.



We do not currently receive any royalties from Biogen for sales of Fampyra, and we cannot predict whether and when we will receive additional Fampyra royalties.

Under the terms of our 2017 Fampyra royalty monetization transaction with HealthCare Royalty Partners, we will not receive royalties from the sale of Fampyra until they receive an agreed upon threshold of royalties. After this threshold is met, if ever, we will continue to receive Fampyra royalty revenue under the terms of our collaboration agreement with Biogen. We cannot predict whether and when that threshold will be met, as this will depend on Biogen's ability to commercialize Fampyra, although we expect it will take at least several years. Biogen's commercialization of Fampyra will depend on factors such as Biogen's ability to obtain and maintain regulatory approvals and to obtain adequate third-party reimbursement as described further in these risk factors. Also, we do not expect that Biogen will seek approval to market Fampyra in any new jurisdictions in the near future, if ever, which limits the potential for growth in Fampyra sales and accordingly whether and when we may receive additional Fampyra royalties.

Our collaborators will need to obtain and maintain regulatory approval in foreign jurisdictions where they seek to market or are currently marketing our products.

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 Inbrija, Fampyra or other products or product candidates in foreign markets could materially harm our business prospects. In addition, we may face adverse legal and business consequences if Biogen, our collaboration partner for Fampyra, does not comply with regulatory requirements, and if we enter into any collaborations for the marketing of Inbrija, we similarly could face adverse legal and business consequences if any Inbrija collaborator does not comply with regulatory requirements.

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 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.

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. For example, we terminated a substantial portion of our research and development workforce in connection with our 2017 reduction in force, and accordingly we may lack personnel necessary to advance some programs unless and until we can hire qualified replacements.



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. For example, in November 2017 we discontinued our clinical development program for tozadenant, an investigational drug we had been developing for the reduction of OFF time in Parkinson's disease patients. We made this decision based on new information obtained from our Phase 3 clinical trials related to agranulocytosis and associated serious adverse events. We have no current plans to restart the tozadenant clinical development program. 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 more recently we have

conducted 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

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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 drug 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. There are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, but the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for exemptions or safe harbors. Practices that involve remuneration for performing activities that we believe are legitimate in support of the distribution of our products, may be subject to scrutiny, particularly if they do not qualify for an exemption or safe harbor, and they may be found to be improperly intended to induce or facilitate the prescribing, purchasing or recommending of our products even though we believe these practices to be in compliance with applicable laws and regulations.

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. By statute, a violation of the federal anti-kickback statute may serve as the basis for a false claim under the false claims act. 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 kickbacks, such as 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.

Under the federal 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. Beginning in 2022, the Sunshine Act will also apply to payments to physician assistants and advance practice nurses. 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 submit these reports, or if the reports we submit are not accurate, we could be subject to significant penalties.

We participate in the federal Medicaid drug rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid drug rebate program, we pay a rebate to each state Medicaid program for utilization of our products that is reimbursed by those programs. Federal law requires that any company that participates in the Medicaid drug 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. The minimum basic Medicaid rebate for branded prescription drugs is 23.1% of average manufacturer price, and pharmaceutical manufacturers must pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, manufacturers must pay an additional Medicaid rebate on “line extensions” (such as extended release formulations) of solid oral dosage forms of branded products or products where the average manufacturer price has increased faster than the inflation rate.

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. 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 drug 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.

Under the Affordable Care Act (ACA), drug manufacturers are required to provide a 70% 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 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.

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

In December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017, and the U.S. Congress and/or President Trump may seek to repeal other aspects of the ACA. In December 2018, a federal district court judge in Texas found the ACA to be unconstitutional, although the ruling was stayed while the case is appealed. In May 2018, the Trump presidential administration issued "American Patients First," a multi-faceted blueprint to lower drug prices. The Trump administration has taken administrative steps to implement the blueprint, including through proposing sweeping demonstration projects aimed at putting downward pressure on drug prices. In addition, members of the U.S. Congress have indicated an interest in legislative measures designed to lower drug costs. 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 sell our products and be profitable is substantially dependent on third-party payers, such as government or government-sponsored health administrative authorities, including Medicaid and Medicare Parts B and 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, including Inbrija (levodopa inhalation powder). Third-party payers are increasingly challenging the pricing of medical products and services and their reimbursement practices may affect the price levels for Inbrija or other potential products we may develop in the future. 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 or wholesale prices. We have agreed to provide such discounts and rebates to some third-party payers in relation to Ampyra, and expect some third party payers will similarly seek such discounts and rebates for Inbrija. We expect increasing pressure to offer larger discounts and discounts 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 have implemented utilization management techniques, such as prior authorization or quantity limits for Ampyra, and third party payers could do this for Inbrija or they could refuse to provide reimbursement. 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. Both federal healthcare programs and commercial insurers are increasingly conditioning coverage, formulary placement, and/or reimbursement rates on the ability of a manufacturer to present favorable health economics and outcomes data.

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 70% 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 both the timing of when, if ever, we receive any further royalty revenue from Biogen under the terms of our Fampyra royalty monetization transaction with HealthCare Royalty Partners, and the amount of the royalty we would then 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 Inbrija (levodopa inhalation powder) receives EU marketing approval, the factors described above could prevent or harm the commercial launch of that product in the EU.

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, 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.

Inbrija (levodopa inhalation powder)/Parkinson's Disease. We expect that Inbrija will compete against other therapies approved for intermittent, or on demand, use that aim to specifically address Parkinson's disease symptoms. Apokyn, an injectable formulation of apomorphine, is approved for the treatment of OFF periods, also known as OFF episodes. 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 that we expect would be competitive with Inbrija if commercially launched. In January 2018, Sunovion announced positive topline results from their pivotal Phase 3 study of their product, in March 2018, they submitted a New Drug Application, or NDA, to the FDA, and in January 2019, they announced that they received a Complete Response Letter, or CRL, from the FDA. Sunovion's CRL announcement stated that the FDA determined it was unable to approve Sunovion's product in its current form, and that the FDA requested additional information and analyses but no new clinical studies. Sunovion's receipt

of the CRL has delayed, but does not necessarily prevent, FDA approval of Sunovion's product and we expect it will be competitive with Inbrija if and when Sunovion receives FDA approval for and commercially launches the product.

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. Inbrija 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. Amneal Pharmaceuticals, Inc. (formerly Impax Laboratories) markets 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 Intec Pharma and Mitsubishi Tanabe Pharma Corporation. 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 Inbrija 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, among others. If approved, our product candidates may face competition in the target commercial areas for these pulmonary delivery products.

Ampyra/MS. Ampyra has become subject to competition from generic drug manufacturers. In 2017, in litigation with certain generic drug manufacturers, the United States District Court for the District of Delaware (the “District Court”) issued a ruling upholding our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidating four other Orange Book-listed patents that were set to expire between 2025 and 2027. Under this ruling, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. The United States Court of Appeals for the Federal Circuit issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales. Our litigation with the generic drug manufacturers is described in further detail in Part I, Item 3 of this report.

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.

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. Adamas Pharmaceuticals, Inc. is developing ADS-5102 (amantadine hydrochloride) for patients with MS who have walking impairment. This potential product may compete with Ampyra in the future. Furthermore, 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 and generic versions of Ampyra are commercially available.

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;

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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. Acquired development programs are generally subject to all of the risks inherent in the drug development process, and our knowledge of the risks specifically relevant to acquired programs generally improves over time.

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 Inbrija or other products we currently, or may in the future, market. We cannot assure you that we would be able to make the combination of our business with that of acquired businesses or companies or in-licensed products or product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product or product candidate may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our stock, which could dilute our current shareholders' ownership interest, or securities convertible into our stock, which could dilute current shareholders' ownership interest upon conversion. Also, although we may from time to time announce that we have entered into agreements to acquire other companies or assets, we cannot assure you that these acquisitions will be completed in a timely manner or at all. These transactions are subject to an inherent risk that they may not be completed, for example because required closing conditions cannot be met at all or within specified time periods, termination rights may be exercised such as due to a breach by one of the parties, or other contingencies may arise that affect the transaction.

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

If the use or misuse of Inbrija (levodopa inhalation powder), Ampyra or any other 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.

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.

Operating our business and servicing our debt requires a significant amount of cash, and we may need to obtain additional funding in the future if we do not have sufficient cash flow from our business to continue to sufficiently fund our operations and pay our substantial debt.

We have products and product candidates in various stages of development and commercialization, and will need to expend substantial resources for research and development and commercialization of our marketed products, including costs associated with the launch and commercialization of Inbrija (levodopa inhalation powder). In addition, 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 support our operations and service our debt and make necessary capital expenditures. For example, we have experienced a rapid and significant decline in Ampyra revenue due to the marketing of generic versions of Ampyra following the September 2018 decision of the United States Court of Appeals for the Federal Circuit to uphold the United States District Court for the District of Delaware's decision to invalidate certain Ampyra patents. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales. Although we recently received FDA approval for Inbrija (levodopa inhalation powder), we have not yet commenced commercial sales, we are not yet generating any revenue from this product, and even after we commence commercial sales it may not generate sufficient cash flow. If we are unable to generate sufficient cash flow from the sale of our products, 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 fund our operations and 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 harm our business, financial condition and results of operations, as well as 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.

Our inability to attract and retain key management and other personnel, or maintain access to expert advisors, may hinder our ability to execute our business plan.

We are highly dependent on the services of Dr. on Cohen, our President and Chief Executive Officer, as well as the other principal members of our management and scientific, regulatory, manufacturing and commercial personnel. Our success depends in large part upon our ability to attract and retain highly qualified personnel with the knowledge and experience needed for these and other areas of our business. 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. In addition, the 2017 discontinuation of our tozadenant program, the 2017 United States District Court for the District of Delaware's decision to invalidate certain Ampyra patents (which was upheld by the United States Court of Appeals for the Federal Circuit in 2018), and our 2017 reduction in force may impede our ability to attract and retain highly 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, particularly our efforts to manufacture and successfully launch Inbrija. Also, we terminated a substantial portion of our research and development workforce in connection with our 2017 reduction in force, and our inability to attract qualified replacements needed for any of our research and development programs could substantially impair our ability to advance those programs.

We also have scientific, medical, clinical, marketing and other advisors who assist us in our research and development, clinical, and commercial strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Similarly, they may have arrangements with other companies to assist in the development and commercialization of products that may compete with ours.

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 research and development 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 may be the subject of litigation, which, if adversely determined, could harm our business and operating results.

From time to time, we may be subject to a variety of claims and lawsuits. The costs of defending any litigation, whether in cash expenses or in management time, could harm our business and materially and adversely affect our operating results and cash flows, even if we ultimately win the litigation. An unfavorable outcome on any litigation matter could require that we pay substantial damages, or, in connection with any intellectual property infringement claims, could require that we pay ongoing royalty payments or prohibit us from selling certain of our products. In addition, we may decide to settle any litigation, which could cause us to incur significant settlement costs. A settlement or an unfavorable outcome on any litigation matter could have a material and adverse effect on our business, operating results, financial condition and cash flows.

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

We are increasingly dependent upon information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data ) and confidential information (and personal information) with respect to our employees, customers, clinical trial patients and our business partners. In the ordinary course of our business, this type of data is also collected, stored, processed and transmitted on the networks and systems of our business partners and vendors from whom we purchase software and/or technology-based services.

The size and complexity of our and any third party information technology systems and infrastructure, and their connection to the Internet, make such systems potentially vulnerable to service interruptions, system errors leading to data loss, data theft and/or cyber attacks. These incidents could result from inadvertent or intentional actions or omissions by our employees and consultants, or those of our business partners and vendors, or from the actions of third parties with malicious or criminal intent. To date, we have not experienced any material impact to our business or operations resulting from any of these occurrences affecting our or third party information technology systems; however, there is a growing risk of harm from these types of incidents because of the rapid evolution of information technology systems, and because cyber attacks are increasing in frequency and in sophistication over time.

Data breaches or unauthorized data access or disclosure of our confidential information could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, employees and others. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. Data breaches or unauthorized data access could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Data breaches or unauthorized data access could also result in liability to others, if these incidents involve the data of others that we have agreed, or are

otherwise legally responsible, to keep confidential and protect.

Data breaches and unauthorized data access can be difficult to detect, and any delay in identifying any such incidents may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, and monitor such systems and infrastructure on an ongoing basis for any current or potential threats, there can be no assurance that these measures will prevent the type of incidents that could have a material adverse effect on our business and results of operations. Also, we rely on the security measures and monitoring activities of our business partners and vendors who may collect, store, process and transmit data on their networks and systems. In the event they experience a service issue or security incident: we may not receive timely notice from them of the issue or incident; they may not take adequate steps to remediate the issue or incident and protect against future occurrences;

we may not have any remedy against them for losses and liabilities that we suffer, or if we have a remedy it may be inadequate, even though they are or may be at fault; and we may become subject to legal claims from others whose information has been compromised regardless of whether we are at fault.

#### 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 Inbrija (levodopa inhalation powder), our ARCUS program for acute migraine, our ARCUS drug delivery technology, SYN120, BTT1023, cimaglermin alfa/neuregulins, and remyelinating antibodies/antibodies relating to nervous system disorders, 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, we have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), which issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. This litigation is discussed in further detail in Part I, Item 3 of this report. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Inventors 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 our Ampyra Orange Book-listed patents. The U.S. Patent and Trademark Office Patent Trials and Appeals Board, or PTAB, chose not to institute inter partes review of these patents. The hedge fund filed motions for reconsideration requesting that the denial to institute these two IPRs be reversed, but the motions were denied in April 2016. In addition, in September 2015 the same hedge fund filed four additional IPR petitions challenging four of our Orange Book-listed 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. In March 2017 the PTAB issued a ruling and upheld all four of the challenged patents. The ruling has become final, as the

hedge fund did not appeal the ruling before the May 2017 appeal deadline. However, the PTAB decision does not prevent parties from filing additional IPR petitions challenging our patents. Also, the PTAB's decision does not affect the District Court's decision invalidating the four patents in the District Court litigation described above.

Patent litigation, IPR proceedings, 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 since 2015 implemented a policy on transparency of clinical trial data submitted to the agency in applications for marketing authorization. These data traditionally were regarded as confidential commercial information not subject to disclosure. According to this policy, the EMA proactively publishes anonymized clinical data submitted by pharmaceutical companies to support their regulatory applications submitted after January 1, 2015 (subject to certain company redactions agreed with the EMA during the application review process). Possible redactions include commercially confidential information, identifiable information about study participants and study staff and patient level data (i.e., line listings including patient data against individual patient codes). The EMA plans to release patient level data in the future, but needs to address some data privacy concerns before doing so. The EMA may release clinical data submitted before this date on request, subject to the company having the opportunity to make similar redactions. The precise implementation of the EMA's policy remains in flux and subject to legal challenge. This could harm 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 the precise details of the EMA's 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 Inbrija (levodopa inhalation powder), Ampyra and all of our research and development programs such as our ARCUS program for acute migraine and BTT1023 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.

#### 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;

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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;

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- 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;
- government regulation of drug pricing;
- 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 recently and can in the future experience extreme price and volume fluctuations. 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 20, 2019: 47,633,407 shares of our common stock were issued and outstanding; options to acquire 8,200,829 shares of our common stock were outstanding, exercisable at an average exercise price of \$29.76 per share, issued under our 2006 Employee Incentive Plan, our 2015 Omnibus Incentive Compensation Plan, or our 2016 Inducement Plan; and restricted stock units issued under our 2015 Omnibus Incentive Compensation Plan entitling the holders to an aggregate of 49,167 shares of our common stock were outstanding. 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 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, 2018, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 79% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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

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

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

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

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

Not applicable.

#### Item 2. Properties.

Ardsey, 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 in July 2012. In 2014, we exercised our option to expand into an additional 25,405 square feet of office space, which we occupied in

January 2015. 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 right of first refusal until mid-2020 to lease up to approximately 95,000 additional square feet of space in additional buildings at the same location. Our extension, early

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termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease.

The 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 \$4.6 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 which we use to manufacture Inbrija and ARCUS product candidates. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas leases this facility from North River Everett Ave, 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 \$1.5 million per year, which reflects an annual 2.5% escalation factor as well as our 2017 lease of additional property next to the Chelsea, Massachusetts facility for parking and warehouse space.

In 2018, we initiated a renovation and expansion of the Chelsea facility that will increase the size of the facility to approximately 95,000 square feet. The project will add a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and it will create additional warehousing space for manufactured product. Pursuant to a 2018 lease amendment that enabled the renovation and expansion, upon completion of the project, annual rent under the lease will increase to \$1.7 million. Construction of the project is scheduled for completion in the third quarter of 2019, though we cannot be assured that the project will meet this schedule, and it will take additional time after completion of construction to obtain the FDA approval needed for use of the new production line for commercial manufacture.

#### 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. The base rent under the lease is currently \$1.0 million per year.

Through Biotie and its U.S. subsidiary, we previously leased office space in Turku, Finland and South San Francisco, California. We terminated the Turku, Finland lease in mid-2018, and the South San Francisco, California lease expired at the end of 2018.

### Item 3. Legal Proceedings.

#### Ampyra ANDA Litigation

**Overview.** As further described below, we have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. We filed lawsuits against these generic drug manufacturers in response to their submitting Abbreviated New Drug Applications, or ANDAs, to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. As previously reported, we settled with some, but not all, of these companies. In March 2017, the U.S. District Court for the District of Delaware (the "District Court") rendered a decision from a bench trial held in September 2016. The District Court upheld our Ampyra Orange Book-listed patent that expired in July 2018, but invalidated the four other Orange

Book-listed patents pertaining to Ampyra that are the subject of the litigation that were set to expire between 2025 and 2027. We appealed the decision on the four invalidated patents to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court.



A sixth Ampyra patent was recently issued and listed in the Orange Book. We note that this patent does not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that are involved in the patent litigation.

**First ANDA Filers.** In June and July of 2014, we received separate Paragraph IV Certification Notices from Accord Healthcare, Inc. ("Accord"), Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd. and its affiliate Ascend Laboratories, LLC ("Alkem"), Apotex Inc. ("Apotex"), Aurobindo Pharma Ltd. ("Aurobindo"), Mylan Pharmaceuticals Inc. ("Mylan"), 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 challenged the validity of the five initial Orange Book-listed patents for Ampyra, and they 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 drug manufacturers and certain affiliates in the District Court 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 included 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 were consolidated into a single case.

A bench trial was completed in September 2016, and the District Court issued a decision in March 2017. The District Court upheld U.S. Patent No. 5,540,938 (the '938 patent), which expired on July 30, 2018, but invalidated U.S. Patent Nos. 8,663,685, 8,007,826, 8,440,703, and 8,354,437. In May 2017, we appealed the ruling on these patents to the Federal Circuit. The Federal Circuit issued a decision on September 10, 2018 upholding the District Court's decision. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the decision of the Federal Circuit. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales. In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court.

As previously reported, prior to the 2017 District Court decision, we entered into settlement agreements with Accord, Actavis, Alkem, Apotex and Aurobindo (and certain affiliates). More recently, in August 2018, we reported a conditioned settlement agreement with Mylan.

**Second ANDA Filers.** In 2015 and 2017, we received Paragraph IV Certification Notices from Sun Pharmaceutical Industries Limited, Sun Pharmaceuticals Industries Inc., Par Pharmaceutical, Inc., and Micro Labs Ltd. advising that each of these companies had submitted ANDAs to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. These ANDA filers challenged the validity of four of the five initial Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and also asserted that generic versions of their products may not infringe certain claims of these patents. In response to the filing of the ANDAs, as previously reported, we filed lawsuits against these companies that were subsequently settled.

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.

Computershare is the transfer agent and registrar for our common stock. As of February 20, 2019, we had 18 registered holders of record of our common stock.

Stock Price Performance Graph

The graph below matches Acorda Therapeutics, Inc.’s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the Nasdaq Composite index and the Nasdaq Biotechnology index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from 12/31/2013 to 12/31/2018.

	12/13	12/14	12/15	12/16	12/17	12/18
Acorda Therapeutics, Inc.	100.00	139.97	146.51	64.38	73.46	53.36
Nasdaq Composite	100.00	114.62	122.81	133.19	172.11	165.84
Nasdaq Biotechnology	100.00	131.71	140.56	112.25	133.67	121.24

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

## Dividend Policy

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

## Issuer Purchases of Equity Securities

Acorda has not announced any plans or programs for the repurchase of its Common Stock. The following table provides information about our purchases of shares of Acorda stock during the three-month period ended December 31, 2018.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
October 1-31, 2018	-	-	-	-
November 1-30, 2018	6,424	\$20.28	-	-
December 1-31, 2018	2,038	\$15.68	-	-
Total	8,462	\$19.17	-	-

(1) Share repurchases reported in this column consist of shares of Acorda's common stock withheld from employees in November 2018 to cover tax liability in connection with the settlement of restricted stock units (6,424 shares) and shares of Acorda's common stock tendered by employees in December 2018 to cover taxes relating to the vesting of restricted stock awards (2,038 shares).

## Item 6. Selected Financial Data.

The following selected consolidated financial data for each of the five years in the period ended December 31, 2018 are derived from our audited consolidated financial statements. This 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, with the exception of 2014, 2015 and 2016 (balance sheet) data which are included in previously filed annual reports and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7 below.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Total net revenues	\$471,433	\$588,287	\$519,601	\$492,660	\$401,480
<b>Costs and expenses:</b>					
Cost of sales	99,310	135,080	107,475	92,297	79,981
Cost of milestone and license revenue	—	634	634	634	634
Research and development	106,383	166,105	203,437	149,209	73,470
Selling, general and administrative	172,254	181,619	235,437	205,630	201,813
Asset impairment	—	296,763	—	—	6,991
<b>Changes in fair value of acquired contingent consideration</b>					
	55,000	40,900	8,600	10,900	2,200
Total operating expenses	432,947	821,101	555,583	458,670	365,089
Operating income (loss)	38,486	(232,814)	(35,982)	33,990	36,391
<b>Other expense:</b>					
Interest and amortization of debt discount expense	(21,597)	(18,664)	(16,527)	(15,472)	(9,288)
Interest income	3,518	136	339	440	674
Other income (expense)	16	(543)	9,902	411	232
Total other expense	(18,063)	(19,071)	(6,286)	(14,621)	(8,382)
Income (loss) before income taxes	20,423	(251,885)	(42,268)	19,369	28,009
Benefit from (provision) for income taxes	13,259	28,526	6,665	(8,311)	(10,337)
Net loss attributable to non-controlling interest	—	—	985	—	—
<b>Net income (loss) attributable to</b>					
Acorda Therapeutics, Inc.	\$33,682	\$(223,359)	\$(34,618)	\$11,058	\$17,672
Net income (loss) per share —basic	\$0.72	\$(4.86)	\$(0.76)	\$0.26	\$0.43
Net income (loss) per share —diluted	\$0.71	\$(4.86)	\$(0.76)	\$0.25	\$0.42
<b>Weighted average shares of common stock</b>					
<b>outstanding used in computing net</b>					
income (loss) per share —basic	47,010	45,999	45,259	42,230	41,150
Weighted average shares of common stock	47,341	45,999	45,259	43,621	42,544
<b>outstanding used in computing net</b>					

income (loss) per share —diluted

	As of December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents and investments	\$445,553	\$307,068	\$158,537	\$353,305	\$307,618
Working capital	387,852	297,738	124,756	360,725	276,335
Total assets	1,299,666	1,197,969	1,342,335	1,111,294	1,059,224
Long-term liabilities	547,427	534,023	530,223	417,675	404,586
Accumulated deficit	(393,843 )	(455,108 )	(243,970 )	(209,352 )	(220,410 )
Long term debt	343,140	334,475	324,030	291,527	284,042
Total stockholders' equity	611,983	519,987	664,211	603,025	540,255

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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.

#### 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 are preparing for our launch of commercial sales of Inbrija (levodopa inhalation powder), which is approved for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson’s disease treated with carbidopa/levodopa. Inbrija is an on-demand treatment that utilizes our innovative ARCUS pulmonary delivery system, a technology platform designed to deliver medication through inhalation that we believe has potential to be used in the development of a variety of inhaled medicines. Also, we market branded Ampyra (dalfampridine) Extended Release Tablets, 10 mg.

Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg, with no titration required. We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies. Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. We project that annual peak net revenue of Inbrija in the U.S. alone could exceed \$800 million.

We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines. After the adoption of a Committee for Medicinal Products for Human Use, or CHMP, opinion, we expect a final decision regarding the MAA from the European Commission before the end of 2019. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S.

We currently derive substantially all of our revenue from the sale of Ampyra. We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the “District Court”) issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en

banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

Our strategic priorities for 2019 are as follows:

• **Inbrija (levodopa inhalation powder):** Launching the commercial sale of Inbrija in the U.S.; obtaining approval of our European Marketing Authorization Application, or MAA, for Inbrija; and continuing with potential partnering discussions for commercialization outside of the U.S.

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•**ARCUS Platform:** Advancing our efforts to develop additional therapeutics based on our proprietary ARCUS pulmonary drug delivery technology, looking at central nervous system, or CNS, as well as non-CNS opportunities, including our program to develop an ARCUS-based treatment for acute migraine.

•**Financial Management:** Focusing on financial discipline to maintain a strong balance sheet, control expenses and deploy resources to maximize shareholder value.

As of December 31, 2018, we had cash, cash equivalents and short-term investments of approximately \$445 million. We have \$345 million of convertible senior notes due in 2021 with a conversion price of \$42.56.

#### Inbrija (levodopa inhalation powder)/Parkinson's Disease

Inbrija (levodopa inhalation powder) is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg, with no titration required. We expect Inbrija to be commercially available in the first quarter of 2019 and to be distributed through a network of specialty pharmacies.

We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines. After the adoption of a Committee for Medicinal Products for Human Use, or CHMP, opinion, we expect a final decision regarding the MAA from the European Commission before the end of 2019. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S.

We intend to market Inbrija in the U.S. through our own specialty sales force and commercial infrastructure. We believe we have built a leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our commercial sale of Inbrija in the U.S. will benefit from the experiences and capabilities of this team. Importantly, we kept our commercial team substantially intact following a 2017 company restructuring. We currently have approximately 90 sales representatives as well as established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on our marketed products; a National Trade Account Director who works with our network of specialty pharmacies for Inbrija; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Our preparations for the commercial sale of Inbrija continue, including sales force training and education, managed care discussions, market research and social media initiatives. In advance of the launch of commercial sale, we are visiting movement disorder and key neurology centers to provide education and training on Inbrija's clinical profile, the appropriate use of the Inbrija inhaler, and our Prescription Support Services hub, described below. We project that annual peak net revenue of Inbrija in the U.S. alone could exceed \$800 million.

In January 2019, we established Prescription Support Services, which we sometimes refer to as the Inbrija hub, a service provided by Acorda which is designed to help patients navigate their insurance coverage and offer reimbursement support services, when appropriate. Services fall into one of these four categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; appeals support; and assistance identifying which specialty pharmacy a patient will utilize based on their insurance coverage. For patients that may need assistance paying for their medication, Prescription Support Services will offer several support options, including: a patient assistance program, that provides no cost medication to patients who meet specific program eligibility requirements; co-pay support, which may help commercially insured (non-government funded) patients lower their out-of-pocket costs; and a bridge

program, for federally-insured patients who experience a delay in coverage determination. We intend to implement a no-cost sample program to enable patients and their physicians to assess the value of Inbrija before the patient has to incur out-of-pocket co-pay or co-insurance costs.

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. The standard baseline 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 progresses, people are likely

to experience OFF periods, which are characterized by the return of Parkinson's symptoms that result from low levels of dopamine between doses oral carbidopa/levodopa. OFF periods are often highly disruptive to people with Parkinson's. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods.

Inbrija is an on-demand treatment that utilizes our innovative ARCUS platform for inhaled therapeutics. ARCUS is a dry-powder pulmonary drug delivery technology that we believe has potential to be used in the development of a variety of inhaled medicines. The ARCUS platform allows systemic delivery of medication through inhalation, by transforming molecules into a light, porous dry powder. This allows delivery of substantially higher doses of medication than can be delivered via conventional dry powder technologies. We acquired the ARCUS technology platform as part of our 2014 acquisition of Civitas Therapeutics. We have worldwide rights to our ARCUS drug delivery technology, which is protected by extensive know-how and trade secrets and various U.S. and foreign patents, including patents that protect the Inbrija dry powder capsules beyond 2030. We have several patents listed in the Orange Book for Inbrija, including patents expiring between 2022 and 2032, and Inbrija is entitled to three years of data exclusivity, through December 2021, as posted in the Orange book.

FDA approval of Inbrija was based on a clinical program that included approximately 900 people with Parkinson's on a carbidopa/levodopa regimen experiencing OFF periods. The Phase 3 pivotal trial for Inbrija – SPAN-PD – was a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of Inbrija in patients with mild to moderate Parkinson's experiencing OFF periods. In January 2019, we announced that The Lancet Neurology published results from the SPAN-PD clinical trial.

The SPAN-PD trial met its primary endpoint, with patients showing a statistically significant improvement in motor function at the week 12 visit, as measured by a reduction in Unified Parkinson's Disease Rating Scale (UPDRS) Part III score for Inbrija 84 mg (n=114) compared to placebo (n=112) at 30 minutes post-dose (-9.83 points and -5.91 points respectively; p=0.009). Onset of action was seen as early as 10 minutes. Maintenance of effect continued to 60 minutes post-dose, which is the longest time point assessed in the trial. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment.

The most common adverse reactions with Inbrija (at least 5% and greater than placebo) in the pivotal trial were cough (15% vs. 2%), upper respiratory tract infection (6% vs. 3%), nausea (5% vs. 3%) and discolored sputum (5% vs. 0%).

Inbrija was also studied in a Phase 3 long-term, active-controlled, randomized, open-label study (N=398) assessing safety and tolerability over one year. This study showed the average reduction in FEV1 (forced expiratory volume in 1 second) from baseline was the same (-0.1 L) for the Inbrija and observational cohorts. Patients with chronic obstructive pulmonary disease (COPD), asthma, or other chronic respiratory disease within the last five years were excluded from this study.

Inbrija is not to be used by patients who take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last two weeks.

It is not known if Inbrija is safe or effective in children.

Ampyra

General

Ampyra was approved by the FDA in January 2010 to improve walking in adults with MS. To our knowledge, Ampyra is the first 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). Net revenue for Ampyra was \$455.1 million for the year ended December 31, 2018 and \$543.3 million for the year ended December 31, 2017.

Ampyra is marketed in the U.S. through our own specialty sales force and commercial infrastructure, and is distributed in the U.S. primarily through a network of specialty pharmacy providers, which deliver the medication to patients by mail, 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. We have relationships with six additional pharmacies through which Ampyra is available, each of which is either affiliated with

an integrated health delivery network or an academic medical center. These pharmacies are not part of our specialty pharmacy network, but rather receive prescriptions for Ampyra directly from prescribers without first being routed through APSS. 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. We have a 60-day free trial program that provides eligible patients with two months of Ampyra at no cost. We are evaluating the level of our continuing investment in certain Ampyra sales and marketing programs, including our free trial program and APSS, due to the introduction of generic competition and corresponding decline in Ampyra sales.

We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the “District Court”) issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. We intend to file a petition for certiorari appealing the case to the U.S. Supreme Court. This litigation is discussed in further detail in Part I, Item 3 of this report. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in our Ampyra sales.

#### License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen 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. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a \$25 million milestone payment from Biogen in 2011, which was triggered by Biogen’s receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters. In November 2017, we announced a \$40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. Until this threshold is met, if ever, we will not receive Fampyra royalties although we have retained the right to receive any potential future milestone payments, described above. The HCRP transaction is accounted for as a liability, as described in Note 11 to our Consolidated Financial Statements included in this report.

#### Ampyra Patent Update

Six issued Ampyra patents have been listed in the Orange Book. The five initial Orange Book-listed patents have been the subject of litigation with certain generic drug manufacturers, as described above. In connection with the litigation, our Orange Book-listed patent that expired on July 30, 2018, was upheld, but four other Ampyra patents set to expire between 2025 and 2027 were invalidated. The litigation is discussed in further detail in Part I, Item 3 of this report.

The sixth Orange Book-listed patent, not involved in the litigation, was issued more recently and was listed in the Orange Book in April 2018. The sixth Orange Book-listed patent is U.S. Patent No. 9,918,973, the claims of which relate to methods of increasing walking speed in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent will expire in 2024. We note that this patent does not entitle

us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that are involved in the patent litigation described in 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. In February 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. The appeal hearings for both patents are scheduled for September 2019. 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.

#### ARCUS Product Development

Our strategic priorities include exploring opportunities for other proprietary products in which inhaled delivery of medicine using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients. We are looking at disorders of the central nervous system, or CNS, as well as non-CNS opportunities for ARCUS.

Our ARCUS program for acute treatment of migraine is our most advanced ARCUS development program, and one of our strategic priorities. We initiated this program studying an ARCUS-based formulation of an inhaled triptan (zolmitriptan), although as further described below, we are now looking at three different candidates for this program. 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.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of our ARCUS-based zolmitriptan formulation 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 our ARCUS-based zolmitriptan formulation had a median Tmax 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 tolerability was generally consistent with the known safety profile of zolmitriptan. In December 2016, we completed a special population study to evaluate safe inhalation of our zolmitriptan formulation in people with asthma and in smokers. Some subjects showed evidence of acute, reversible bronchoconstriction, post-inhalation. We have proceeded with additional formulation work on three different migraine candidates for this program, including reformulation of our ARCUS-based zolmitriptan, and we will be potentially moving one of these forward for further development.

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 nRDS. In collaboration with the Massachusetts Institute of Technology, we developed a formulation and delivery device based on our proprietary ARCUS drug delivery technology. nRDS is a condition affecting prematurely born infants in which their lungs are underdeveloped and thus lack a sufficient amount of lung surfactant. 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. Delivering liquid surfactant to the lungs via intubation is the standard of care. We believe that our formulation and delivery system may present a more practical alternative for use in developing areas of the world,

where intubation poses numerous problems. Based on recent achievement of pre-clinical proof of concept, the foundation has expanded the funding to include pre-IND development. 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.

#### Other Research and Development Programs

Following is a description of our other research and development programs.

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**SYN120:** SYN120 is a potential treatment for Parkinson's-related dementia, which we acquired with Biotie Therapies. Data from a Phase 2 exploratory study that we completed in 2017 showed that several of the outcome measures trended in favor of drug versus placebo, particularly with respect to neuropsychiatric symptoms. However, neither the primary nor key secondary endpoints achieved statistical significance. We are continuing to review the data.

**BTT1023:** Through Biotie Therapies, we are 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. The University of Birmingham had been conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, and data from the trial were expected in the fourth quarter of 2018, but the university recently informed us that they terminated the trial.

**rHIgM22:** 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. We have completed and analyzed data from a Phase 1 trial using one of two doses of rHIgM22 or placebo in 27 people with MS who experienced an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study included exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. Data from the trial showed that a single dose of rHIgM22 was not associated with any safety signals. The trial's primary objectives were safety and tolerability of a single dose following a relapse. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. We are considering next steps for the program.

**Cimaglermin alfa:** 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. In 2013, we commenced a Phase 1b single-infusion trial in people with heart failure, which assessed the tolerability of three dose levels of cimaglermin, and also included an 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 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. The abnormal blood tests resolved within two to three weeks. We subsequently conducted additional analyses and non-clinical studies to further define the nature of the hepatotoxicity, and met with the FDA to present these data as part of our request that the program be removed from the clinical hold. The FDA lifted the clinical hold in April 2017. We are seeking to partner or out-license this program.

#### Qutenza/NP-1998 Sale

On October 30, 2018, we sold our Qutenza assets and NP-1998 development program. 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. NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were previously assessing for the treatment of neuropathic pain. Under the asset purchase agreement, the buyer made aggregate cash payments to us of approximately \$7.9 million for the assets and we are entitled to receive up to an additional \$35.0 million in cash based on achievement of specified U.S. sales milestones for Qutenza and, if it receives FDA approval, NP-1998.

#### Financial Guidance for 2019

We are providing the following guidance with respect to our 2019 financial performance:

**Research and development (R&D) expenses in 2019 are expected to range from \$70 million to \$80 million, excluding share-based compensation charges.**

Selling, general and administrative (SG&A) expenses in 2019 are expected to range from \$200 million to \$210 million, excluding share-based compensation charges.

The projected ranges of R&D and SG&A expenses in 2019 are provided on a non-GAAP basis, as both exclude 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.

## Results of Operations

### Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

#### Net Revenue

##### Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$455.1 million and \$543.3 million for the years ended December 31, 2018 and 2017, respectively. This net revenue reflected a 9.5% increase in our list sale price for Ampyra effective January 1, 2018 and July 1, 2018. The net revenue decrease is comprised of net volume decrease of \$361.6 million partially offset by price increases and discount and allowance adjustments of \$273.3 million. Net revenue from sales of Ampyra decreased for the year ended December 31, 2018 compared to the year ended December 31, 2017 due to the entry of generic versions of Ampyra as a result of the invalidation of our Ampyra patents in 2017 offset by our list sale price increases.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates and discounts. Discounts and allowances are recorded following shipment of Ampyra tablets to our customers. 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 increased in 2018 due to the entry of generic versions of Ampyra as a result of invalidation of our Ampyra patents in 2017 and they may further 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 \$1.5 million for the year ended December 31, 2018, as compared to \$2.7 million for the year ended December 31, 2017. Net product revenues also included \$3.0 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, 2017. We also recognized product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules.

In November 2017, the Company entered into an asset purchase agreement to sell its rights and interests related to its Zanaflex assets for a purchase price of \$4.0 million. We recognized a gain on the sale of approximately \$3.5 million

for the year ended December 31, 2017, which is reflected as a reduction to selling, general and administrative expenses in the statements of operations.

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.

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### Qutenza

We recognized product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$0.5 million and \$0.7 million for the years ended December 31, 2018 and 2017, respectively.

In May 2018, the Company entered into an asset purchase agreement to sell its rights and interests related to its Qutenza assets for a purchase price of \$7.9 million. We recognized a gain on the sale of approximately \$7.8 million for the year ended December 31, 2018, which is reflected as a reduction to selling, general and administrative expenses in the statements of operations.

### License Revenue

We recognized \$9.1 million in amortized license revenue for the year ended December 31, 2017, related to the \$110.0 million received from Biogen in 2009 as part of our collaboration agreement. As of January 1, 2018, we adopted ASC 606 "Revenue from Contracts with Customers" ("ASC 606). Under ASC 606, revenue related to the upfront payment is recognized at a point in time rather than over time. As a result of adopting ASC 606, we recognized the remaining deferred revenue as of January 1, 2018 as a cumulative effect adjustment to the accumulated deficit on the consolidated balance sheet.

### Royalty Revenue

We recognized \$11.7 million and \$11.6 million in royalty revenue for the years ended December 31, 2018 and 2017, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$2.6 million in royalty revenue for the year ended December 31, 2017 related to the authorized generic sale of Zanaflex Capsules.

We recognized \$2.3 million in royalty revenue for the year ended December 31, 2017, related to ex-US sales of Selincro by Lundbeck. We recognized an additional \$13.0 million in royalty revenue for the year ended December 31, 2017, related to the agreement which was effective as of October 1, 2017, to provide a fully paid up royalty free license on ex-US sales of Selincro to Lundbeck. We sold Zanaflex and monetized Selincro in fiscal 2017.

### Cost of Sales

We recorded cost of sales of \$99.3 million for the year ended December 31, 2018 as compared to \$135.1 million for the year ended December 31, 2017. Cost of sales for the year ended December 31, 2018 consisted primarily of \$80.8 million in inventory costs related to recognized revenues, \$8.4 million in inventory costs related to the reserve for excess inventory, \$7.7 million in royalty fees based on net product shipments, \$1.7 million in amortization of intangible assets, \$0.2 million in period costs related to freight, stability testing, and packaging and \$0.5 million for costs related to sales of the authorized generic version of Ampyra.

Cost of sales for the year ended December 31, 2017 consisted primarily of \$95.8 million in inventory costs related to recognized revenues, \$12.3 million in royalty fees based on net product shipments, \$23.7 million in amortization of intangible assets, \$0.3 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$3.0 million representing the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2017.

### Cost of License Revenue

We recorded cost of license revenue of \$0.6 million for the year ended December 31, 2017. 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. As of January 1, 2018, we adopted ASC 606 “Revenue from Contracts with Customers” (“ASC 606). As a result of adopting ASC 606, we recognized the remaining deferred cost of license revenue as of January 1, 2018 as a cumulative effect adjustment to the accumulated deficit on the consolidated balance sheet.

## Research and Development

Research and development expenses for the year ended December 31, 2018 were \$106.4 million as compared to \$166.1 million for the year ended December 31, 2017, a decrease of \$59.7 million, or 35.9%. The decrease was primarily due to reductions of \$36.6 million in research and development expenses related to Biotie, due to termination of the tozadenant program, \$4.5 million related to our life cycle management program for Ampyra, \$10.2 million in overall research and development, staff, compensation and related expenses, \$4.3 million in restructuring expenses, \$2.9 million related to other programs and \$0.6 million in research and development expenses related to Inbrija and our ARCUS program for acute migraine.

## Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2018 were \$96.0 million compared to \$93.2 million for the year ended December 31, 2017, an increase of approximately \$2.8 million, or 3.0%. This increase was due primarily to an increase in cost related to pre-launch activities for Inbrija of \$8.5 million and an increase in overall salaries and benefits of \$3.1 million, partially offset by a decrease in marketing related spending of \$8.8 million.

General and administrative expenses for the year ended December 31, 2018 were \$76.2 million compared to \$88.4 million for the year ended December 31, 2017, a decrease of approximately \$12.2 million, or 13.8%. This decrease was primarily due to reductions of \$6.0 million in staff compensation, benefits and medical affairs related expenses, gain on the sale of Qutenza of \$7.8 million which was recorded as an offset to general and administrative expense and a decrease of \$2.0 million related to restructuring expense. This was partially offset by an absence of the gain on sale of Zanaflex of \$3.5 in 2018 compared to 2017.

## Asset Impairment

We recognized asset impairment expenses of approximately \$296.7 million for the year ended December 31, 2017. The asset impairment expenses included \$233.5 million related to tozadenant due to the termination of the clinical trials based on the receipt of additional Phase 3 data related to previously disclosed agranulocytosis and associated serious adverse events, \$39.4 million related to Selincro due to a downward revision to the projected cash flows we expected to receive on royalties for sales of Selincro outside of the U.S., and \$23.8 million related to SYN120 due to the receipt of Phase 2 study data which indicated that neither the primary nor key secondary endpoints achieved statistical significance.

## Changes in Fair Value of Acquired Contingent Consideration

As a result of the original spin out of Civitas from 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 \$55.0 million for the year ended December 31, 2018 compared to \$40.9 million for the year ended December 31, 2017, an increase of \$14.1 million or 34%. The changes in the fair-value of the acquired contingent consideration were primarily due to the FDA approval of Inbrija in 2018 which increased the probability of success and partly 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 \$18.1 million for the year ended December 31, 2018 compared to \$19.1 million for the year ended December 31, 2017, a decrease of \$1.0 million, or 5%. The decrease was due primarily to an increase in interest

income of approximately \$3.4 million and an annual decrease in realized losses on foreign currency exchange of approximately \$0.5 million partially offset by an increase in interest and amortization of debt discount expense of \$2.9 million primarily related to the convertible senior notes.

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## Benefit from Income Taxes

On December 22, 2017, the U.S. enacted Public Law No. 115-97 ("Act"), originally introduced as the Tax Cuts and Jobs Act, which significantly modified the Internal Revenue Code. The Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%, created a territorial-type tax system with an exemption for foreign dividends, and imposed a one-time deemed repatriation tax on a U.S. company's historical undistributed earnings and profits of foreign affiliates. Among other provisions, the Act also increased expensing for certain business assets, created new taxes on certain foreign sourced earnings, adopted limitations on business interest expense deductions, repealed deductions for income attributable to domestic production activities, and added other anti-base erosion rules. The effective dates for the provisions set forth in the Act vary as to when the provisions will apply to the company.

In response to the Act, the U.S. Securities and Exchange Commission ("SEC") provided guidance by issuing Staff Accounting Bulletin No. 118 ("SAB 118"), which has since been codified by the release of ASU No. 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. ASU 2018-05 allows companies to record provisional amounts during a measurement period with respect to the impacts of the Act for which the accounting requirements under ASC Topic 740 are not complete, but a reasonable estimate has been determined. The measurement period under ASU 2018-05 ends when a company has obtained, prepared, and analyzed the information that was needed in order to complete the accounting requirements under ASC Topic 740, but cannot exceed one year.

As of December 31, 2018, the Company has completed the accounting for the effects of the Act. The company has included the impact of the Act on its annual effective tax rate and has recorded a total tax benefit of \$14.8 million for the remeasurement of deferred tax assets and liabilities of which \$1.5 million of the benefit was booked in the fourth quarter of 2018.

We recorded a \$13.3 million benefit from income taxes for the year ended December 31, 2018 as compared to a \$28.5 million benefit from income taxes for the year ended December 31, 2017. The effective income tax rates for the year ended December 31, 2018 and 2017 were (65%) and 11%, respectively.

The variances in the effective tax rates for the year ended December 31, 2018 and 2017 were due primarily to the release of the valuation allowance, the impairment of indefinite lived intangible assets in the prior year, state taxes, the decrease in the benefit of the research and development and orphan drug credit, and due to a one-time, non-cash income tax benefit recorded in the prior period as a result of the enactment of the Act.

The Company's overall effective tax rate differed from the U.S. federal statutory rate of 21% primarily due to the release of most of the U.S. valuation allowance, Biotie U.S. and foreign losses for which no benefit has been recognized and the related foreign tax rate differential, state taxes, federal return to provision adjustments including the related tax reform impact and stock compensation. 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. U.S. income taxes are not provided for unremitted earnings of international subsidiaries and affiliates where our intention is to reinvest these earnings permanently.

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, 2017 Compared to Year Ended December 31, 2016

Net Revenue

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the

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sale of Ampyra to these customers of \$543.3 million and \$492.8 million for the years ended December 31, 2017 and 2016, respectively. This net revenue reflected 9.5% and 4.0% increases in our list sale price for Ampyra effective January 1, 2017 and July 1, 2017, respectively. The net revenue increase comprised net volume increases of \$9.8 million and price increases and discount and allowance adjustments of \$40.7 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2017 compared to the year ended December 31, 2016 due to our price increases and greater demand we believe due to, in part, the success of certain marketing programs such as our 60-day free trial program.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates and discounts. Discounts and allowances are recorded following shipment of Ampyra tablets to our customers. 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.

#### Zanaflex

We recognized net revenue from the sale of Zanaflex products of \$2.7 million for the year ended December 31, 2017, as compared to \$3.3 million for the year ended December 31, 2016. Net product revenues also include \$3.0 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, 2017 as compared to \$2.7 million for the year ended December 31, 2016. We also recognized product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules.

In November 2017, the Company entered into an asset purchase agreement to sell its rights and interests related to its Zanaflex assets for a purchase price of \$4.0 million. We recognized a gain on the sale of approximately \$3.5 million, which is reflected as a reduction to selling, general and administrative expenses in the statements of operations.

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

Prior to sale of Qutenza assets in October 2018, Qutenza was 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.

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$0.7 million and \$1.1 million for the years ended December 31, 2017 and 2016, respectively.

#### License Revenue

We recognized \$9.1 million in amortized license revenue for the years ended December 31, 2017 and 2016, related to the \$110.0 million received from Biogen in 2009 as part of our collaboration agreement.

#### Royalty Revenue

We recognized \$11.6 million and \$10.6 million in royalty revenue for the years ended December 31, 2017 and 2016, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$2.6 million in royalty revenue for the year ended December 31, 2017 as compared to \$3.9 million for the year ended December 31, 2016, related to the authorized generic sale of Zanaflex Capsules.

We recognized \$2.3 million in royalty revenue for the year ended December 31, 2017, related to ex-US sales of Selincro by Lundbeck. We recognized an additional \$13.0 million in royalty revenue for the year ended December 31, 2017,

related to the agreement which was effective as of October 1, 2017, to provide a fully paid up royalty free license on ex-US sales of Selincro to Lundbeck. 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. We sold Zanaflex in fiscal 2017.

#### Cost of Sales

We recorded cost of sales of \$135.1 million for the year ended December 31, 2017 as compared to \$107.5 million for the year ended December 31, 2016. Cost of sales for the year ended December 31, 2017 consisted primarily of \$95.8 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2017 also consisted of \$12.3 million in royalty fees based on net product shipments, \$23.7 million in amortization of intangible assets, and \$0.3 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$3.0 million representing the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2017.

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 License Revenue

We recorded cost of license revenue of \$0.6 million for the years ended December 31, 2017 and 2016, 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, 2017 were \$166.1 million as compared to \$203.4 million for the year ended December 31, 2016, a decrease of \$37.3 million, or 18%. The decrease was primarily due to reductions of \$21.8 million in research and development expenses related to Inbrija and our ARCUS program for acute migraine, \$13.6 million related to our life cycle management program for Ampyra, \$13.1 million in overall research and development, staff, compensation and related expenses, \$9.9 million related to Plumiaz and \$4.3 million related to other programs, partially offset by increases of \$20.0 million in post-acquisition research and development expenses related to Biotie and \$5.6 million in restructuring expenses.

#### Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2017 were \$93.2 million compared to \$102.7 million for the year ended December 31, 2016, a decrease of approximately \$9.5 million, or 9.3%. This decrease was due primarily to a decrease in marketing, trade and sales related spending of \$6.1 million, a decrease in overall salaries and benefits of \$3.7 million, partially offset by an increase in other selling related expenses of \$0.3 million.

General and administrative expenses for the year ended December 31, 2017 were \$88.4 million compared to \$132.7 million for the year ended December 31, 2016, a decrease of approximately \$44.3 million, or 33%. This decrease was primarily due to reductions of \$29.0 million in spending for legal and business development related activities, \$6.3 million in post-acquisition expenses related to Biotie, \$7.2 million in staff compensation, benefits and medical affairs related expenses, \$3.5 million related to the gain on the sale of Zanaflex which was recorded as an offset to general and administrative expense, partially offset by an increase of \$2.5 million related to restructuring expense.



## Asset Impairment

We recognized asset impairment expenses of approximately \$296.7 million for the year ended December 31, 2017. The asset impairment expenses included \$233.5 million related to tozadenant due to the termination of the clinical trials based on the receipt of additional Phase 3 data related to previously disclosed agranulocytosis and associated serious adverse events, \$39.4 million related to Selincro due to a downward revision to the projected cash flows we expected to receive on royalties for sales of Selincro outside of the U.S., and \$23.8 million related to SYN120 due to the receipt of Phase 2 study data which indicated that neither the primary nor key secondary endpoints achieved statistical significance.

## Changes in Fair Value of Acquired Contingent Consideration

As a result of the original spin out of Civitas from 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 \$40.9 million for the year ended December 31, 2017 compared to \$8.6 million for the year ended December 31, 2016, an increase of \$32.3 million or 376%. 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 \$19.1 million for the year ended December 31, 2017 compared to \$6.3 million for the year ended December 31, 2016, an increase of \$12.8 million, or 203%. The increase was due primarily to a realized gain on foreign currency derivatives of \$9.9 million in 2016 compared to no gain in 2017, the write-off of debt issuance costs pertaining to the termination of the asset based loan in 2017 of \$1.1 million, interest expense pertaining to the Fampyra royalty monetization transaction of \$0.7 million and an annual increase in realized losses on foreign currency transactions of \$0.4 million. Interest expense related to the convertible senior notes was \$15.4 million for the year ended December 31, 2017, of which the non-cash portion was \$9.4 million.

## Benefit from Income Taxes

We recorded a \$28.5 million benefit from income taxes for the year ended December 31, 2017 as compared to a \$6.7 million benefit from income taxes for the year ended December 31, 2016. The effective income tax rates for the year ended December 31, 2017 and 2016 were 11% and 16%, respectively.

The variances in the effective tax rates for the year ended December 31, 2017 and 2016 were due primarily to the changes in valuation allowance due the determination that it was more likely than not that certain deferred assets would not be recoverable, the impairment of indefinite lived intangible assets, the decrease in the benefit of the research and development and orphan drug credit, and due to a one-time, non-cash income tax benefit recorded in the current period as a result of the enactment of the Tax Cuts and Jobs Act (“Act”) on December 22, 2017. The Act significantly revised the U.S. federal corporate income tax by, among other things, lowering the corporate income tax rate to 21% beginning in 2018 and imposing a mandatory repatriation tax on accumulated foreign earnings. U.S. GAAP accounting for income taxes requires that Acorda record the impacts of any tax law change on our deferred income taxes in the quarter that the tax law change is enacted. Due to the complexities involved in accounting for the enactment of the Act, SEC Staff Accounting Bulletin (SAB) 118 allowed companies to provide a provisional estimate of the impacts of the legislation. Acorda had provisionally estimated, based on then available information, that the enactment of the Act will result in a one-time reduction in net deferred income tax liabilities of approximately \$13.2 million, primarily due to the re-measurement of U.S. deferred tax liabilities at the lower 21% U.S. federal corporate

income tax rate, and no impact from the repatriation tax.

The Company's effective tax rate for this year differed from the U.S. federal statutory rate of 35% primarily due to Biotie US and foreign losses for which no benefit has been recognized and the related foreign tax rate differential offset by the reversal of deferred tax liabilities related to indefinite lived intangibles, the generation of fewer research and development credits, state taxes, and as the result of the enactment of the Act, a one-time reduction in net deferred income tax liabilities due to the re-measurement of U.S. deferred tax liabilities at the lower 21% U.S. federal corporate income tax rate. The annual rate depends on a number of factors, including the jurisdiction in which operating profit is earned and the timing and nature of discrete items.

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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.

### 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, royalty monetizations, and our revenue interest financing arrangement.

At December 31, 2018, we had \$445.6 million of cash, cash equivalents and short-term investments, compared to \$307.1 million at December 31, 2017. There were no investments classified as short-term or long-term at December 31, 2017. We expect that our existing cash and cash flows from operations 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 Inbrija and Ampyra, the continued progress of and expenditures on 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

#### 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 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, 2018 consisted of the following:

(In thousands)	December 31, 2018
Liability component:	
Principal	\$ 345,000
Less: debt discount and debt issuance costs, net	(26,330 )
Net carrying amount	\$ 318,670
Equity component	\$ 61,195

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### Non-Convertible Capital Loans

Non-convertible capital loans granted by Business Finland (formerly Tekes), with an adjusted acquisition-date fair value of \$20.5 million (€18.2 million) and a carrying value of \$23.2 million as of December 31, 2018. The loans are composed of fourteen non-convertible loans. The 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. The maturity dates for these loans range from eight to ten years from the date of issuance, however, according to certain terms and conditions of the loans, the Company may repay the principal and accrued and unpaid interest of the loans only when the consolidated retained earnings of Biotie is sufficient to fully repay the loans.

### Research and Development Loans

Research and Development Loans (“R&D Loans”) were granted by Business Finland with an acquisition-date fair value of \$2.9 million (€2.6 million) and a carrying value of \$1.8 million as of December 31, 2018. 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 began in January 2017. The loan principal will be paid in equal annual installments over a 5 year period, ending January 2021.

### Fampyra Royalty Monetization

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP (“Royalty Agreement”). In exchange for the payment of \$40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the Collaboration and Licensing Agreement between the Company and Biogen, up to an agreed upon threshold of royalties. When this threshold is met, if ever, the Fampyra royalty revenue will revert back to the Company and the Company will continue to receive the Fampyra royalty revenue from Biogen until the revenue stream ends.

The Company maintained the rights under the license and collaboration agreement with Biogen, therefore, the Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. The Company recorded the receipt of the \$40 million payment from HCRP and established a corresponding liability in the amount of \$40 million, net of transaction costs of approximately \$2.2 million.

The following table shows the activity within the liability account from the inception of the royalty agreement to December 31, 2018:

	December 31,	Inception Date through December
(In thousands)	2018	31, 2017
Liability related to sale of future royalties - beginning balance	\$ 35,788	\$ —
Proceeds from sale of future royalties	—	40,000
Deferred transaction costs	784	(2,115 )
Non-cash royalty revenue payable to HCRP	(10,291 )	(2,705 )
Non-cash interest expense recognized	4,435	608

Liability related to sale of future royalties - ending balance	\$ 30,716	\$ 35,788
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Investment Activities

At December 31, 2018, cash and cash equivalents and short-term investments were approximately \$445.6 million, as compared to \$307.1 million at December 31, 2017. 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 money market funds. Our short-term investments consist of high-grade corporate debt securities and commercial paper with original maturities of twelve months or less at date of purchase. 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. At December 31, 2017, we held no investments.

### Net Cash Provided by Operations

Net cash provided by operations was \$150.8 million and \$96.5 million for the years ended December 31, 2018 and 2017, respectively. Cash provided by operations for the year ended December 31, 2018 was primarily attributable to the net income of \$33.7 million, a change in the contingent consideration obligation of \$55.0 million, share-based compensation expense of \$21.3 million, depreciation and amortization expense of \$11.5 million, amortization of debt discount and debt issuance costs of \$15.8 million, a decrease in accounts receivable of \$58.0 million, a decrease in inventory of \$8.4 million and an increase in other non-current liabilities of \$0.1 million.

Cash provided by operations was partially offset by a deferred tax benefit of \$14.5 million, royalty revenues of \$10.3 million, an increase in prepaid expenses and other current assets of \$15.4 million, a gain on sale of Qutenza assets of \$7.8 million, a decrease in accounts payable, accrued expenses and other current liabilities of \$3.5 million and amortization of net premiums and discounts on investments of \$1.2 million.

### Net Cash Used in Investing

Net cash used in investing activities for the year ended December 31, 2018 was \$176.9 million, which was due primarily to purchases of short-term investments and property and equipment of \$249.1 million and \$33.3 million, respectively. This was partially offset by proceeds from maturities of investments of \$98.3 million and proceeds from sale of Qutenza assets of \$7.9 million.

### Net Cash Provided by Financing

Net cash provided by financing activities for the year ended December 31, 2018 was \$12.8 million, due primarily to net proceeds of \$15.2 million from the exercise of stock options, partially offset by the repurchase of treasury stock of \$1.7 million and repayment of loans payable of \$0.7 million.

### 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 14 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 research and development 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 research and development activities and in the commercialization of products. We have committed to make potential future milestone payments to third parties of up to approximately \$51.6 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, 2018, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

### Effects of Inflation

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

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## 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

On January 1, 2018, we adopted the new accounting standard ASC 606, "Revenue from Contracts with Customers" (Topic 606) ("ASC 606") and the related amendments to all contracts with customers that were not completed as of the date of adoption using the modified retrospective method. ASC 606 supersedes prior revenue guidance under ASC 605, "Revenue Recognition" ("ASC 605") and requires entities to recognize revenue to depict the transfer of promised goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company completed its assessment of the new guidance and evaluated the new requirements as applied to its existing revenue contracts not completed as of the date of initial application. As a result of the assessment, with the exception of the changes to our recognition of license revenue as further described in Note 2, the Company determined that adoption of the new standard did not have a significant impact on its revenue recognition methodology. In accordance with ASC 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the good or service.

ASC 606 outlines a five-step process for recognizing revenue from contracts with customers: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon receipt of the product by the customer.

ASC 606 requires entities to record a contract asset when a performance obligation has been satisfied or partially satisfied, but the amount of consideration has not yet been received because the receipt of the consideration is conditioned on something other than the passage of time. ASC 606 also requires an entity to present a revenue contract as a contract liability in instances when a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (e.g. receivable), before the entity transfers a good or service to the customer. We currently do not have any contract assets or contract liabilities.

### Product Revenue, Net

Net revenue from product sales is recognized at the transaction price when the customer obtains control of the Company's products, which occurs at a point in time, typically upon receipt of the product by the customer. The Company's products are sold primarily to a network of specialty providers which are contractually obligated to hold no more than an agreed upon number of days of inventory. The Company's payment terms are between 30 to 35 days.

The Company's net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. These adjustments represent variable consideration under ASC 606 and are recorded for the Company's estimate of cash consideration expected to be given by the Company to a customer that is presumed to be a reduction of the transaction price of the Company's products and, therefore, are characterized as a reduction of revenue. These adjustments 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. Adjustments for variable consideration are determined 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.

#### Discounts and Allowances

Revenue from product sales are recorded at the transaction price, which includes estimates for discounts and allowances for which reserves are established and includes cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. Actual discounts and allowances are recorded following shipment of product and the appropriate reserves are credited. These reserves are classified as reductions of accounts receivable (if the amount is payable to the Customer and right of offset exists) or a current liability (if the amount is payable to a party other than a Customer). These allowances are established by management as its best estimate based on 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. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. 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 U.S. Federal government programs to allow for our products to remain eligible for reimbursement under these programs. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. 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. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. Our government chargeback and rebate accruals were \$7.9 million and \$16.2 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate \$5.6 million and \$5.9 million effect on our net revenue for the years ended December 31, 2018 and December 31, 2017, respectively.

**Managed Care Contract Rebates:** We contract with various managed care organizations including health insurance companies and pharmacy benefit managers. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided our product 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 monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. Our managed care contract rebate accruals were \$13.7 million and \$11.8 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$7.5 million and \$4.3 million effect on our net revenue for the years ended December 31, 2018 and December 31, 2017, respectively.

**Copay Mitigation Rebates:** We offer copay mitigation to commercially insured patients who have coverage for our products (in accordance with applicable law) and are responsible for a cost share. 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 \$0.8 million and \$0.2 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our copay mitigation rebate allowances would have had an approximate \$1.1 million effect on our net revenue for the years ended December 31, 2018 and December 31, 2017.

**Cash Discounts:** We sell directly to companies in our distribution network, which primarily includes specialty pharmacies and ASD Specialty Healthcare, Inc. We generally provide invoice discounts for prompt payment for our products. We estimate our cash discounts based on the terms offered to our customers. Discounts are estimated based on rates that are explicitly stated in the Company's contracts as it is expected they will take the discount and are recorded as a reduction of revenue at the time of product shipment when product revenue is recognized. We adjust estimates based on actual activity as necessary. Our cash discount allowances were \$0.4 million and \$0.8 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our cash discount allowances would have had an approximate \$0.6 million and \$0.7 million effect on our net revenue for the years ended December 31, 2018 and December 31, 2017, respectively.

**Product Returns:** We either offer customers no return except for products damaged in shipping or consistent with industry practice, a limited right of return based on the product's expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The company currently estimates product return liabilities using historical sales information and inventory remaining in the distribution channel.

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.

Prior to sale of Zanaflex assets in 2017, we accepted returns of Zanaflex products for six months prior to and twelve months after their expiration date. We provided 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. Our returns reserve for Zanaflex products were \$1.6 million and \$3.9 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our returns would have had an approximate \$(0.2) million and \$0.0 million effect on our net revenue for the years ended December 31, 2018 and 2017, 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, 2018, December 31, 2017 and December 31, 2016, respectively.

**Data Fees and Fees for Services Payable to Specialty Pharmacies:** We have contracted with certain specialty pharmacies to obtain transactional data related to our products in order to develop 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. We pay a variable fee to the specialty pharmacies to provide us the data. We also pay the specialty pharmacies a fee in exchange for providing distribution and inventory management services, including the provision of inventory management data to the Company. We estimate our fee for service accruals and allowances based on sales to each specialty pharmacy and the applicable contracted rate. Our fee for service expenses are accrued at the time of product shipment and are typically settled with the specialty pharmacies within 60 days after the end of each respective quarter. Our data fee and fee for service accruals were \$1.4 million and \$1.8 million at December 31, 2018 and December 31, 2017, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate \$0.5 million and \$0.6 million effect on our net revenue for the years ended December 31, 2018 and 2017, respectively.

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

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The following table provides a summary of activity with respect to the Company's sales discounts and allowances during 2018, 2017, and 2016:

(in thousands)	Managed			Cash discounts	Product returns	Data fees	Other vendor allowances	Total
	Government care chargebacks and rebates	contract rebates	Copay mitigation rebates			and fees for services payable to wholesalers		
Balance at December 31, 2015	\$ 7,146	\$ 1,623	\$ 127	\$ 514	\$ 4,311	\$ 1,137	\$ 1,676	\$ 16,535
Allowances for sales	46,813	22,339	8,747	5,665	6,022	4,405	412	94,403
Actual credits for sales during 2016	(36,353 )	(18,535 )	(8,550 )	(5,152 )	(43 )	(3,100 )	—	(71,733 )
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
Allowances for sales	58,753	43,128	10,942	6,898	(152 )	5,605	(177 )	124,997
Actual credits for sales during 2017	(42,988 )	(31,378 )	(10,697 )	(6,056 )	(52 )	(3,974 )	—	(95,145 )
Actual credits for prior year sales	(9,966 )	(4,343 )	(234 )	(592 )	(678 )	(1,280 )	(584 )	(17,677 )
Balance at December 31, 2017	\$ 16,204	\$ 11,822	\$ 184	\$ 844	\$ 3,878	\$ 1,785	\$ 1,327	\$ 36,045
Allowances for sales	56,089	75,376	10,801	6,371	(1,530 )	5,363	—	152,470
Actual credits for sales during 2018	(52,744 )	(63,976 )	(9,945 )	(5,993 )	(44 )	(4,115 )	—	(136,817 )
Actual credits for prior year sales	(11,624 )	(9,538 )	(243 )	(827 )	(644 )	(1,634 )	—	(24,510 )
Balance at December 31, 2018	\$ 7,925	\$ 13,684	\$ 797	\$ 395	\$ 1,660	\$ 1,399	\$ 1,327	\$ 27,188

Royalty revenue recorded by the Company relates exclusively to the Company's License and Collaboration agreement with Biogen which provides for ongoing royalties based on sales of Fampyra outside of the U.S. The Company recognizes revenue for royalties under ASC 606, which provides revenue recognition constraints by requiring the recognition of revenue at the later of the following: 1) sale or usage of the products or 2) satisfaction of the performance obligations. The Company has satisfied its performance obligations and therefore recognizes royalty revenue when the sales to which the royalties relate are completed.

#### License Revenue

License revenue relates to the License and Collaboration agreement with Biogen which provides for milestone payments for the achievement of certain regulatory and sales milestones during the term of the agreement. Regulatory milestones are contingent upon the approval of Fampyra for new indications outside of the U.S. Sales milestones are contingent upon the achievement of certain net sales targets for Fampyra sales outside of the U.S. The Company recognizes license revenue under ASC 606, which provides constraints for entities to recognize license revenue which is deemed to be variable by requiring the Company to estimate the amount of consideration to which it is entitled in exchange for transferring the promised goods or services to a customer. The Company recognizes an estimate of revenue to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the milestone is achieved. For regulatory milestones, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. For sales-based milestones, the Company recognizes revenue upon the achievement of the specific sale milestones.



## 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. The Company records a reserve for excess and obsolete inventory based on the historic and forecasted sales pattern and specifically identified obsolete inventory based on the expiration dates of its products. The Company periodically reviews inventory for slow moving or obsolete amounts based on expected sales. The Company reviews projected market share as well as current buying patterns from its customers. The Company analyzes its ability to sell the inventory on hand and committed to customers prior to the expiration period of the respective inventory. As a result, significant judgment is employed in determining the appropriateness of the Company's ability to sell inventory on hand and commitments based on the sales projections. If annual and expected volumes are less than expected, the Company may be required to make additional allowances for excess or obsolete inventory in the future. For the year ended December 31, 2018, upon review of expected future product sales volumes and the projected expiration of Ampyra inventory, we recorded an \$8.4 million charge for potential obsolete and excess inventory primarily due to the loss of patents related to Ampyra in 2018. For the year ended December 31, 2017, we recorded a \$0.7 million charge for potential inventory obsolescence.

## 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.

Qutenza

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.

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## Selincro

Cost of sales consists of amortization of the intangible asset through September 30, 2017 based on the initial useful life and the subsequent accelerated amortization associated with the amendment to the licensing agreement with Lundbeck. See Note 4 – for further information about intangible assets.

## 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,		
	2018	2017	2016
<b>Preclinical and clinical development:</b>			
Contract expenses—Inbrija	\$ 18,195	\$ 31,307	\$ 59,736
Contract expenses—tozadenant	10,747	39,405	19,473
Contract expenses—BTT-1023	996	951	599
Contract expenses—rHlgM22	219	3,130	4,741
Contract expenses—SYN-120	162	2,594	1,609
Contract expenses—cimaglermin alfa (previously GGF2)	96	163	2,362
Contract expenses—ARCUS program for acute migraine	52	902	3,412
Contract expenses—Ampyra LCM	44	4,528	18,093
Contract expenses—NP-1998	43	70	90
Contract expenses—Diazepam Nasal Spray/Plumiaz	38	453	10,330
Contract expenses—Other	7	12	527
Contract expenses—AC105	—	—	100
<b>Research and development operating expenses:</b>	<b>75,738</b>	<b>82,544</b>	<b>82,310</b>
<b>Acquisitions, licenses and milestones:</b>			
rHlgM22	26	26	25
cimaglermin alfa (previously GGF2)	—	—	10
Other	20	20	20
<b>Total research and development</b>	<b>\$ 106,383</b>	<b>\$ 166,105</b>	<b>\$ 203,438</b>

With respect to previously established clinical study accruals in prior periods and for the year ended December 31, 2018 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

### 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 project will be further developed or have an alternative future use; otherwise it is expensed. The estimated fair value of IPR&D projects acquired in a business combination is capitalized. Several methods may be used to determine the estimated fair value of the IPR&D assets acquired in a business combination. The Company utilizes the "income method" which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, estimated 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 impaired, as appropriate. These assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to us or our competitors, the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug which could have a negative effect on cash flows and which could result in an impairment. If impairment indicators are present or changes in circumstance suggest that an impairment may exist, we perform an impairment analysis by comparing the sum of the estimated discounted future cash flows, or fair value, of each intangible asset to its carrying value on the consolidated balance sheet. We will recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

#### Finite-Lived Intangible Assets

Intangible assets with finite lives 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 impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss in the statement of operations if the carrying value of the intangible asset exceeds its fair value. Fair value is generally estimated based on either appraised value or other valuation techniques. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to us or our competitors, new or better products entering the market, changes in market share or market pricing, changes in the economic lives of the assets, changes in the legal framework covering patents, rights or licenses, and other market changes which could have a negative effect on cash flows and which could result in an impairment.

#### Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired in a business combination 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. We perform our impairment testing at the reporting level where we have determined that we have a single reporting unit and operating segment. We test goodwill for impairment using a quantitative method (primarily based on market capitalization). The impairment test for goodwill uses a two-step approach. Step one compares the estimated fair value of the reporting unit including goodwill to its carrying value. If the carrying value of the reporting unit exceeds the estimated fair value of the reporting unit, step two must be performed. Step two compares the carrying value of the reporting unit to the fair value of all of the assets and liabilities of the reporting unit as if the reporting unit was acquired in a business combination. If the carrying value of the reporting unit's goodwill exceeds the implied fair value of its goodwill calculated in this manner, an impairment loss is recognized in an amount equal to the excess of the carrying value over the implied fair value.

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

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



### Other Income (Expense)

Interest income consists of income earned on our cash, cash equivalents and short-term investments. Interest expense consists of cash and non-cash interest expense for the convertible senior notes issued in June 2014, our capital and R&D loans and non-cash interest expense pertaining to the Fampyra royalty monetization.

### 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.

As of December 31, 2018, the Company has completed its accounting for the tax effects of the enactment of the 2017 Tax Cuts and Jobs Act as described in Note 17 – Income Taxes.

### Share-Based Compensation

We account for stock options, restricted stock and restricted stock units 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 options	Historical term of our options based on exercise data
Expected volatility	Historic volatility of our common stock

Risk-free interest rate	Yields of U.S. Treasury securities corresponding with the expected life of option grants
Forfeiture rates	Historical forfeiture data

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

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

Our financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, convertible notes payable, senior notes, liability related to the sale of future royalties and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2018, except for the fair value of the Company's convertible senior notes, which was approximately \$289.4 million as of December 31, 2018.

We have cash equivalents and short-term investments at December 31, 2018, 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, high-grade corporate bonds and commercial paper, the carrying values of our cash equivalents and short-term investments approximate their fair values at December 31, 2018. At December 31, 2018, we held \$445.6 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 2.0%.

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 2018 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, 2018, 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, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on the effectiveness of controls

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

#### Management's Report on Internal Control Over Financial Reporting

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

Under the supervision of and with the participation of our Chief Executive Officer and our Chief, 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 2018 (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, 2018, our internal control over financial reporting was effective. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions.

Ernst & Young LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2018. This attestation report appears below.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Acorda Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Acorda Therapeutics, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2018, 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). In our opinion, Acorda Therapeutics, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 27, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control over Financial Reporting

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.

/s/ Ernst & Young LLP

Hartford, Connecticut

February 27, 2019

Item 9B. Other Information.

None.

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### PART III

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

The information required by this item will be contained in our 2019 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 “Investors” 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 2019 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 2019 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 2019 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 2019 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 Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2018 and 2017

Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016

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

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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
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<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

To the Shareholders and the Board of Directors of Acorda Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, 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, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue from contracts with customers in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, "Revenue from Contracts with Customers (Topic 606)", and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.

Hartford, Connecticut

February 27, 2019

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$293,564	\$307,068
Restricted cash	532	410
Short term investments	151,989	—
Trade accounts receivable, net of allowances of \$2,681 and \$845, as of December 31, 2018 and 2017, respectively	23,430	81,403
Prepaid expenses	19,384	13,333
Inventory, net	29,014	37,501
Other current assets	10,194	1,983
Total current assets	528,107	441,698
Property and equipment, net of accumulated depreciation	60,519	36,669
Goodwill	282,059	286,611
Intangible assets, net of accumulated amortization	428,570	430,603
Non-current portion of deferred cost of license revenue	—	1,638
Other assets	411	750
Total assets	\$1,299,666	\$1,197,969
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$48,859	\$27,367
Accrued expenses and other current liabilities	76,882	99,850
Current portion of deferred license revenue	—	9,057
Current portion of loans payable	616	645
Current portion of liability related to sale of future royalties	8,985	6,763
Current portion of acquired contingent consideration	4,914	278
Total current liabilities	140,256	143,960
Convertible senior notes (due 2021)	318,670	308,805
Non-current portion of acquired contingent consideration	163,086	112,722
Non-current portion of deferred license revenue	—	23,398
Non-current portion of loans payable	24,470	25,670
Deferred tax liability	7,483	22,459
Non-current portion of liability related to sale of future royalties	21,731	29,025
Other non-current liabilities	11,987	11,943
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value. Authorized 1,000,000 shares at December 31, 2018 and December 31, 2017; no shares issued as of December 31, 2018 and December 31, 2017	—	—
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Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2018 and 2017; issued 47,508,505 and 46,441,428 shares, including those held in treasury, as of December 31, 2018 and 2017, respectively

Treasury stock at cost (87,737 and 16,151 shares at December 31, 2018 and 2017,

respectively)	(2,133 )	(389 )
Additional paid-in capital	1,005,105	968,580
Accumulated deficit	(393,843 )	(455,108 )
Accumulated other comprehensive income	2,806	6,858
Total stockholders' equity	611,983	519,987
Total liabilities and stockholders' equity	\$1,299,666	\$1,197,969

See accompanying Notes to Consolidated Financial Statements

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(In thousands, except per share data)

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
<b>Revenues:</b>			
Net product revenues	\$ 459,739	\$ 549,749	\$ 493,358
Royalty revenues	11,694	29,481	17,186
License revenue	—	9,057	9,057
Total net revenues	471,433	588,287	519,601
<b>Costs and expenses:</b>			
Cost of sales	99,310	135,080	107,475
Cost of milestone and license revenue	—	634	634
Research and development	106,383	166,105	203,437
Selling, general and administrative	172,254	181,619	235,437
Asset impairment	—	296,763	—
Changes in fair value of acquired contingent consideration	55,000	40,900	8,600
Total operating expenses	432,947	821,101	555,583
Operating income (loss)	38,486	(232,814 )	(35,982 )
<b>Other expense (net):</b>			
Interest and amortization of debt discount expense	(21,597 )	(18,664 )	(16,527 )
Interest income	3,518	136	339
Other income (expense)	16	(543 )	9,902
Total other expense (net)	(18,063 )	(19,071 )	(6,286 )
Income (loss) before taxes	20,423	(251,885 )	(42,268 )
Benefit from income taxes	13,259	28,526	6,665
Net income (loss)	\$ 33,682	\$ (223,359 )	\$ (35,603 )
Net (loss) attributable to non-controlling interest	—	—	985
Net income (loss) attributable to Acorda Therapeutics, Inc.	\$ 33,682	\$ (223,359 )	\$ (34,618 )
Net income (loss) per share—basic	\$ 0.72	\$ (4.86 )	\$ (0.76 )
Net income (loss) per share—diluted	\$ 0.71	\$ (4.86 )	\$ (0.76 )
<b>Weighted average common shares outstanding used in computing net</b>			
income (loss) per share—basic	47,010	45,999	45,259
<b>Weighted average common shares outstanding used in computing net</b>			
income (loss) per share—diluted	47,341	45,999	45,259

See accompanying Notes to Consolidated Financial Statements



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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Net income (loss)	\$ 33,682	\$ (223,359 )	\$ (35,603 )
Other comprehensive income (loss):			
Foreign currency translation adjustment	(3,927 )	19,759	(12,901 )
Unrealized losses on available-for-sale securities, net of tax	(125 )	—	—
Reclassification of net losses to net income	—	—	119
Other comprehensive (loss) income, net of tax	\$ (4,052 )	\$ 19,759	(12,782 )
Comprehensive income (loss) attributable to Acorda Therapeutics, Inc.	\$ 29,630	\$ (203,600 )	\$ (48,385 )
Comprehensive (loss) attributable to noncontrolling interests.	\$ —	\$ —	\$ (1,095 )

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common stock		Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)		Noncontrolling interest	Total stockholders equity
	Number of shares	Par value				income	(loss)		
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	
Excess tax charges for share-based compensation arrangements	—	—	—	(13 )	—	—	—	(13 )	
Private placement, net of									
issuance costs	2,251	3	—	72,088	—	—	—	72,091	
Acquisition of subsidiary	—	—	—	—	—	—	25,736	25,736	
Purchase of noncontrolling	—	—	—	(3,305 )	—	—	(24,641 )	(27,946 )	

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interest								
Other comprehensive loss,								
net of tax	—	—	—	—	—	(12,782 )	(110 )	(12,893 )
Net loss	—	—	—	—	(34,618 )	—	(985 )	(35,603 )
Balance at December 31, 2016	45,680	\$ 46	\$(329 )	\$921,365	\$(243,970 )	\$(12,901 )	\$(0 )	\$664,211
Adjustment to accumulated deficit								
(pursuant to adoption of								
ASU 2016-09)	—	—	—	—	12,221	—	—	12,221
Compensation expense for								
issuance of stock options								
to employees	—	—	—	24,910	—	—	—	24,910
Compensation expense for								
issuance of restricted								
stock to employees	263	—	—	7,904	—	—	—	7,904
Exercise of stock options	498	—	—	10,479	—	—	—	10,479
Restructuring Cost pursuant to								
equity modification	—	—	—	967	—	—	—	967
Purchase of Treasury Stock	—	—	(60 )	—	—	—	—	(60 )
Purchase of noncontrolling								
interest	—	—	—	2,955	—	—	—	2,955
Other comprehensive income	—	—	—	—	—	19,759	—	19,759
Net loss	—	—	—	—	(223,359 )	—	—	(223,359 )
Balance at December 31, 2017	46,441	\$ 46	\$(389 )	\$968,580	\$(455,108 )	\$ 6,858	\$ —	\$519,987
Adjustment to accumulated deficit	—	—	—	—	27,583	—	—	27,583
(pursuant to adoption of								

ASU 2014-09)								
Compensation expense for								
issuance of stock options								
to employees	—	—	—	15,182	—	—	—	15,182
Compensation expense for								
issuance of restricted								
stock to employees	306	—	—	6,147	—	—	—	6,147
Exercise of stock options	689	2	—	15,196	—	—	—	15,198
Purchase of Treasury Stock	72	—	(1,744)	—	—	—	—	(1,744 )
Other comprehensive loss	—	—	—	—	—	(4,052	)	(4,052 )
Net income	—	—	—	—	33,682	—	—	33,682
Balance at December 31, 2018	47,508	\$ 48	\$(2,133 )	\$1,005,105	\$(393,843 )	\$ 2,806	\$ —	\$ 611,983

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, 2018	December 31, 2017	December 31, 2016
Cash flows from operating activities:			
Net income (loss)	\$33,682	\$(223,359)	\$(35,603)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Share-based compensation expense	21,252	32,814	36,386
Amortization of net premiums and discounts on investments	(1,417)	—	467
Amortization of debt discount and debt issuance costs	15,822	12,153	9,717
Depreciation and amortization expense	11,479	23,234	21,582
Intangible asset impairment	—	296,763	—
Change in contingent consideration obligation	55,000	40,622	8,600
Gain on sale of Zanaflex franchise	—	(3,534)	—
Gain on sale of Qutenza assets	(7,837)	—	—
Realized gain on foreign currency transaction	—	247	(9,856)
Non-cash royalty revenue	(10,291)	(2,705)	—
Deferred tax benefit	(14,505)	(54,044)	(11,190)
Excess tax charge (benefit) from share-based compensation arrangements	—	—	15
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	57,972	(29,112)	(19,965)
(Increase) decrease in prepaid expenses and other current assets	(15,402)	3,445	6,904
Decrease (increase) in inventory	8,440	5,505	(6,660)
Decrease in non-current portion of deferred cost of license revenue	—	634	634
Decrease in other assets	34	4,138	34
(Decrease) Increase in accounts payable, accrued expenses and other current liabilities	(3,488)	(2,099)	37,625
Decrease in non-current portion of deferred license revenue	—	(9,057)	(9,057)
Increase in other non-current liabilities	52	1,491	17
Net cash provided by operating activities	150,793	97,136	29,649
Cash flows from investing activities:			
Purchases of property and equipment	(33,328)	(13,688)	(6,192)
Purchases of intangible assets	(587)	(688)	(893)
Acquisitions, net of cash received and gain on foreign currency transaction	—	—	(266,454)
Net proceeds from sale of Qutenza assets	7,884	—	—
Net proceeds from sale of Zanaflex franchise	—	3,663	—

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Purchases of investments	(249,107)	—	(40,215 )
Proceeds from maturities of investments	98,273	—	239,968
Net cash used in investing activities	(176,865)	(10,713 )	(73,786 )
Cash flows from financing activities:			
Debt issuance costs	—	—	(1,587 )
Proceeds from issuance of common stock and option exercises	15,198	10,479	75,520
Repayment/(purchase) of non-controlling interest	—	2,722	(27,946 )
Purchase of treasury stock	(1,744 )	(60 )	—
Net proceeds from royalty monetizations	—	50,787	—
Repayment of loans payable	(657 )	(2,409 )	—
Excess tax (benefit) charge from share-based compensation arrangements	—	—	(15 )
Repayments of revenue interest liability	—	—	(41 )
Net cash provided by financing activities	12,797	61,519	45,931
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(412 )	1,225	(2,159 )
Net (decrease) increase in cash and cash equivalents and restricted cash	(13,687 )	149,167	(364 )
Cash, cash equivalents and restricted cash at beginning of period	308,038	158,871	159,235
Cash, cash equivalents and restricted cash at end of period	\$294,351	\$308,038	\$158,871
Supplemental disclosure:			
Cash paid for interest	\$6,064	\$6,066	\$6,059
Cash paid for taxes	20,709	14,929	4,250

See accompanying Notes to Consolidated Financial Statements.

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements

#### (1) Organization and Business Activities

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a biopharmaceutical company 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.

#### (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, estimated deductions to determine net revenue such as allowances for customer credits, including estimated discounts, rebates, and chargebacks, which are estimated based on available information that will be adjusted to reflect known changes in the factors that impact such allowances, estimates of reserves for obsolete and excess inventory, and estimates of unrecognized tax benefits 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 which is 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, 2018, 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 10).

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## Investments

Short-term investments consist primarily of high-grade commercial paper and corporate 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 all its 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 Income (Loss)

The Company's other comprehensive income (loss) 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 Income (Loss) for the period ended December 31, 2018 and 2017. The cumulative foreign currency translation adjustment reported in Other Comprehensive Income (Loss) was \$(3.9) million and \$19.8 million for the period ended December 31, 2018 and 2017, respectively.

## Inventory

Inventory is stated at the lower of cost or 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's inventory primarily consisted of finished goods as of December 31, 2018 and 2017. The Company establishes reserves as necessary for obsolescence and excess inventory. The Company records a reserve for excess and obsolete inventory based on the expected future product sales volumes and the projected expiration of inventory and specifically identified obsolete inventory. The Company recorded a charge for excess and obsolete inventory of \$8.4 million and \$0.7 million for the years ended December 31, 2018 and 2017, respectively.

## 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, except for assets acquired in a business combination, which are recorded at fair value as of the acquisition date. 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.

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## Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired in a business combination 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. We perform our impairment testing at the reporting unit level where we have determined that we have a single reporting unit and operating segment. We test goodwill for impairment using a quantitative method (primarily based on market capitalization). The impairment test for goodwill uses a two-step approach. Step one compares the estimated fair value of the reporting unit including goodwill to its carrying value. If the carrying value of the reporting unit exceeds the estimated fair value of the reporting unit, step two must be performed. Step two compares the carrying value of the reporting unit to the fair value of all of the assets and liabilities of the reporting unit as if the reporting unit was acquired in a business combination. If the carrying value of the reporting unit's goodwill exceeds the implied fair value of its goodwill calculated in this manner, an impairment loss is recognized in an amount equal to the excess of the carrying value over the implied fair value. See Note 4 for a discussion of goodwill.

## Intangible Assets

### In Process Research and Development

The Company has indefinite lived intangible assets for the value of acquired 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 project will be further developed or have an alternative future use; otherwise it is expensed. The estimated fair value of IPR&D projects acquired in a business combination is capitalized. Several methods may be used to determine the estimated fair value of the IPR&D assets acquired in a business combination. The Company utilizes the "income method" which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, estimated 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 impaired, as appropriate. These assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to us or our competitors, the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug which could have a negative effect on cash flows and which could result in an impairment. If impairment indicators are present or changes in circumstance suggest that an impairment may exist, we perform an impairment analysis by comparing the sum of the estimated discounted future cash flows, or fair value, of each intangible asset to its carrying value on the consolidated balance sheet. We will recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

### Finite-Lived Intangible Assets

The Company has finite lived intangible assets that 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 impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a

recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss in the statement of operations if the carrying value of the intangible asset exceeds its fair value. Fair value is generally estimated based on either appraised value or other valuation techniques. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to us or our competitors, new or better products entering the market, changes in market share or market pricing, changes in the economic lives of the assets, changes in the legal framework covering patents, rights or licenses, and other market changes which could have a negative effect on cash flows and which could result in an impairment.

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### 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 16 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.

### Non-Cash Interest Expense on Liability Related to Sale of Future Royalties

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP (“Royalty Agreement”). In exchange for the payment of \$40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the Collaboration and Licensing Agreement between the Company and Biogen, up to an agreed upon threshold of royalties. When this threshold is met, if ever, the Fampyra royalty revenue will revert back to the Company and the Company will continue to receive the Fampyra royalty revenue from Biogen until the revenue stream ends. The transaction does not include potential future milestones to be paid by Biogen to Acorda.

The Company maintained the rights under the license and collaboration agreement with Biogen, therefore, the Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. In order to determine the amortization of the liability, the Company is required to estimate the total amount of future net royalty payments to be made to HCRP over the term of the agreement up to the agreed upon threshold of royalties. The total threshold of net royalties to be paid, less the net proceeds received will be recorded as interest expense over the life of the liability. The Company imputes interest on the unamortized portion of the liability using the effective interest method and records interest expense based on the timing of the payments received over the term of the royalty agreement. The Company’s estimate of the interest rate under the arrangement is based on forecasted net royalty payments expected to be made to HCRP over the life of the royalty agreement. The Company estimated an effective annual interest rate of approximately 15%. Over the course of the Royalty Agreement, the actual interest rate will be affected by the amount and timing of net royalty revenue recognized and changes in forecasted revenue. On a quarterly basis, the Company will reassess the effective interest rate and adjust the rate prospectively as required. Non-cash royalty revenue is reflected as royalty revenue and non-cash interest expense is reflected as interest and amortization of debt discount expense in the Statement of Operations.

### 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

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pass through costs. As actual costs become known to the Company, it adjusts the accrual; such changes in estimate may be a material change in its clinical study accrual, which could also materially affect its results of operations. All research and development costs are expensed as incurred except when accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. These payments are capitalized at the time of payment and expensed ratably over the period the research and development activity is performed.

#### Accounting for Income Taxes

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

On January 1, 2018, the Company adopted the new accounting standard ASC 606, "Revenue from Contracts with Customers" (Topic 606) ("ASC 606") and the related amendments to all contracts with customers that were not completed as of the date of adoption using the modified retrospective method. ASC 606 supersedes prior revenue guidance under ASC 605 "Revenue Recognition" ("ASC 605") and requires entities to recognize revenue to depict the transfer of promised goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company completed its assessment of the new guidance and evaluated the new requirements as applied to its existing revenue contracts not completed as of the date of initial application. As a result of the assessment, with the exception of the changes to our recognition of license revenue as further described below, the Company determined that adoption of the new standard did not have a significant impact on its revenue recognition methodology. In accordance with ASC 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the good or service.

The Company determined that the revenue recognition methodology for the deferred license revenue changed as a result of the adoption of ASC 606. License revenue recorded by the Company prior to January 1, 2018 related exclusively to the recognition of the upfront payment received from Biogen upon the execution of the License and Collaboration agreement that granted Biogen an exclusive non sub-licensable license to sell Fampyra outside of the U.S. License revenue recorded prior to January 1, 2018 was recognized under ASC 605 on a pro rata basis as the Company's obligations were satisfied throughout the duration of the license and collaboration agreement. As of January 1, 2018, the Company adopted ASC 606 which changed the Company's determination of its distinct performance obligations resulting in an acceleration of the recognition of the revenue in the arrangement. The material performance obligations were completed prior to January 1, 2018, and as a result, the Company recognized its previously deferred license revenue and the associated deferred costs as a cumulative effect adjustment of \$27.6 million within the accumulated deficit on the consolidated balance sheet as of January 1, 2018.



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The cumulative effect of applying ASC 606 to the company's consolidated balance sheet was as follows:

(In thousands)	Balance as of December 31, 2017	Net Adjustments	Balance as of January 1, 2018
<b>Assets</b>			
Other current assets	\$1,983	\$ (634 )	\$1,349
Non-current portion of deferred cost of license revenue	1,638	(1,638 )	—
<b>Total Assets</b>	<b>\$1,197,969</b>	<b>\$ (2,272 )</b>	<b>\$1,195,697</b>
<b>Liabilities and Stockholders' Equity</b>			
Current portion of deferred license revenue	\$9,057	\$ (9,057 )	\$—
Non-current portion of deferred license revenue	23,398	(23,398 )	—
Deferred tax liability	22,459	2,600	25,059
Accumulated deficit	(455,108 )	27,583	(427,525 )
<b>Total liabilities and stockholders' equity</b>	<b>\$1,197,969</b>	<b>\$ (2,272 )</b>	<b>\$1,195,697</b>

The impact of the adoption of ASC 606 on the Company's consolidated balance sheet as of December 31, 2018 was as follows:

(In thousands)	Balance as of December 31, 2018	Prior to Adoption of ASC 606	Net Adjustments	Balance as of December 31, 2018 as Reported Under ASC 606
<b>Assets</b>				
Other current assets	\$10,828	\$ (634 )	\$ (634 )	\$10,194
Non-current portion of deferred cost of license revenue	1,004	(1,004 )	(1,004 )	—
<b>Total Assets</b>	<b>\$1,301,304</b>	<b>\$ (1,638 )</b>	<b>\$ (1,638 )</b>	<b>\$1,299,666</b>
<b>Liabilities and Stockholders' Equity</b>				
Current portion of deferred license revenue	\$9,057	\$ (9,057 )	\$ (9,057 )	\$—
Non-current portion of deferred license revenue	14,341	(14,341 )	(14,341 )	—
Deferred tax liability	6,988	495	495	7,483
Accumulated deficit	(415,108 )	21,265	21,265	(393,843 )
<b>Total liabilities and stockholders' equity</b>	<b>\$1,301,304</b>	<b>\$ (1,638 )</b>	<b>\$ (1,638 )</b>	<b>\$1,299,666</b>

The impact of the adoption of ASC 606 on the Company's consolidated statement of operations for the year ended December 31, 2018 was as follows:

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	Year Ended December 31, 2018		Year Ended December 31, 2018
	Balance Prior to		Balance as Reported
(In thousands)	Adoption of ASC 606	Effect of Change	Under ASC 606
License revenue	\$ 9,057	\$(9,057 )	\$ —
Cost of license revenue	634	(634 )	—
Operating income (loss)	\$ 46,909	\$(8,423 )	\$ 38,486
(Benefit from) provision for income taxes	(15,364 )	2,105	(13,259 )
Net income (loss)	\$ 40,000	\$(6,318 )	\$ 33,682
Net income (loss) per share—basic	\$ 0.85	\$(0.13 )	\$ 0.72
Net income (loss) per share—diluted	\$ 0.84	\$(0.13 )	\$ 0.71

ASC 606 did not have an aggregate impact on the Company's net cash provided by operating activities.

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ASC 606 outlines a five-step process for recognizing revenue from contracts with customers: i) identify the contract with the customer, ii) identify the performance obligations in the contract, (iii) determine the transaction price, iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon receipt of the product by the customer.

ASC 606 requires entities to record a contract asset when a performance obligation has been satisfied or partially satisfied, but the amount of consideration has not yet been received because the receipt of the consideration is conditioned on something other than the passage of time. ASC 606 also requires an entity to present a revenue contract as a contract liability in instances when a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (e.g. receivable), before the entity transfers a good or service to the customer. We did not have any contract assets or liabilities as of December 31, 2018.

#### Product Revenue, Net

##### Ampyra

Ampyra is available primarily through a network of specialty pharmacy providers that provide the medication to patients by mail 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.

##### Qutenza

Prior to the sale of Qutenza assets, Qutenza was 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.

Net revenue from product sales is recognized at the transaction price when the customer obtains control of the Company's products, which occurs at a point in time, typically upon receipt of the product by the customer. The Company's products are sold primarily to a network of specialty providers which are contractually obligated to hold no more than an agreed upon number of days of inventory. The Company's payment terms are between 30 to 35 days.

The Company's net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. These adjustments represent variable consideration under ASC 606 and are recorded for the Company's estimate of cash consideration expected to be given by the Company to a customer that is presumed to be a reduction of the transaction price of the Company's products and, therefore, are characterized as a reduction of revenue. These adjustments 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. Adjustments for variable consideration are determined 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.

#### Discounts and Allowances

Revenue from product sales are recorded at the transaction price, which includes estimates for discounts and allowances for which reserves are established and includes cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. Actual discounts and allowances are recorded following shipment of product and the appropriate reserves are credited. These reserves are classified as reductions of accounts receivable (if the amount is payable to the Customer and right of offset exists) or a current liability (if the amount is payable to a party other than a Customer). These

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allowances are established by management as its best estimate based on 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. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. 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 U.S. Federal government programs to allow for our products to remain eligible for reimbursement under these programs. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. 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. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

**Managed Care Contract Rebates:** We contract with various managed care organizations including health insurance companies and pharmacy benefit managers. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided our product 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 monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

**Copay Mitigation Rebates:** We offer copay mitigation to commercially insured patients who have coverage for our products (in accordance with applicable law) and are responsible for a cost share. 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.

**Cash Discounts:** We sell directly to companies in our distribution network, which primarily includes specialty pharmacies and ASD Specialty Healthcare, Inc. We generally provide invoice discounts for prompt payment for our products. We estimate our cash discounts based on the terms offered to our customers. Discounts are estimated based on rates that are explicitly stated in the Company's contracts as it is expected they will take the discount and are recorded as a reduction of revenue at the time of product shipment when product revenue is recognized. We adjust estimates based on actual activity as necessary.

**Product Returns:** We offer no right of return except for products damaged in shipping to Ampyra customers or a limited right of return based on the product's expiration date to previous Zanaflex customers. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The company currently estimates product return liabilities using historical sales information and inventory remaining in the distribution channel.

Data Fees and Fees for Services Payable to Specialty Pharmacies: We have contracted with certain specialty pharmacies to obtain transactional data related to our products in order to develop 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. We pay a variable fee to the specialty pharmacies to provide us the data. We also pay the specialty pharmacies a fee in exchange for providing distribution and inventory management services, including the provision of inventory management data to the Company. We estimate our fee for service accruals and allowances based on sales to each specialty pharmacy and the applicable contracted rate.

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## Royalty Revenue

Royalty revenue recorded by the Company relates exclusively to the Company's License and Collaboration agreement with Biogen which provides for ongoing royalties based on sales of Fampyra outside of the U.S. The Company recognizes revenue for royalties under ASC 606, which provides revenue recognition constraints by requiring the recognition of revenue at the later of the following: 1) sale or usage of the products or 2) satisfaction of the performance obligations. The Company has satisfied its performance obligations and therefore recognizes royalty revenue when the sales to which the royalties relate are completed.

## License Revenue

License revenue relates to the License and Collaboration agreement with Biogen which provides for milestone payments for the achievement of certain regulatory and sales milestones during the term of the agreement. Regulatory milestones are contingent upon the approval of Fampyra for new indications outside of the U.S. Sales milestones are contingent upon the achievement of certain net sales targets for Fampyra sales outside of the U.S. The Company recognizes license revenue under ASC 606, which provides constraints for entities to recognize license revenue which is deemed to be variable by requiring the Company to estimate the amount of consideration to which it is entitled in exchange for transferring the promised goods or services to a customer. The Company recognizes an estimate of revenue to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the milestone is achieved. For regulatory milestones, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. For sales-based milestones, the Company recognizes revenue upon the achievement of the specific sale milestones. The Company did not recognize any license revenue related to milestones for the years ended December 31, 2018, 2017 or 2016.

The following table disaggregates our revenue by major source (in thousands):

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Revenues:			
Net product revenues	\$ 459,739	\$ 549,749	\$ 493,358
Royalty revenues	\$ 11,694	29,481	\$ 17,186
License revenue	\$ —	9,057	\$ 9,057
Total net revenues	\$ 471,433	\$ 588,287	\$ 519,601

## 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 does not require any collateral for its accounts receivable. The Company maintains cash, cash equivalents and



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

The Company does not own or operate, and currently does not plan to own or operate, facilities for production and packaging of Ampyra or its other commercial product 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 Inbrija. The Company leases a manufacturing facility in Chelsea, Massachusetts which produces Inbrija for clinical trials and commercial supply.

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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, 2018 were a network of specialty pharmacies and ASD Specialty Healthcare, Inc. for Ampyra. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. Four customers individually accounted for more than 10% of the Company's revenue or approximately 81% of total revenue in 2018. Four and Three customers individually accounted for more than 10% of the Company's revenue in 2017 and 2016, respectively. Five customers individually accounted for more than 10% of the Company's accounts receivable or approximately 88% of total accounts receivable as of December 31, 2018. Four customers individually accounted for more than 10% of the Company's accounts receivable or approximately 69% of total accounts receivable as of December 31, 2017. 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 34 days after the end of each calendar month. The Company provided cash discount allowances of \$6.4 million and \$6.9 million for the years ended December 31, 2018 and 2017, respectively. The Company's reserve for cash discount allowances were \$0.4 million and \$0.8 million as of December 31, 2018 and 2017, respectively.

	Cash
(in thousands)	discounts
Balance at December 31, 2016	\$ 594
Allowances for sales	6,898
Actual credits	(6,648 )
Balance at December 31, 2017	\$ 844
Allowances for sales	6,371
Actual credits	(6,820 )
Balance at December 31, 2018	\$ 395

#### Allowance for Doubtful Accounts

A portion of the Company's accounts receivable may not be collected. The Company provides reserves based on an 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 had no recognized allowance for doubtful accounts as of December 31, 2018 or December 31, 2017. There were no provisions and write-offs for the years ended December 31, 2018 and 2017.

#### Allowance for Chargebacks

Based upon the Company's contracts and the most recent experience with respect to sales with the US government, the Company provides an allowance for chargebacks. The Company monitors the sales trends and adjusts the chargebacks on a regular basis to reflect the most recent chargebacks experience. The Company recorded a charge of \$18.9 million for the year ended December 31, 2018 for allowance related to chargebacks. The Company did not record any allowance for chargebacks for the year ended December 31, 2017. The Company made a payment of \$16.7 million related to the chargebacks allowances for the year ended December 31, 2018. The Company's reserve for chargebacks allowance was \$2.2 million as of December 31, 2018.

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## 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, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these instruments;
- (b) Short-term investments are recorded based primarily on quoted market prices;
- (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 the debt securities; 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 18 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 10.

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 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.

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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 Amypra and Qutenza in the U.S. for the year ended December 31, 2018 and Ampyra, Zanaflex and Qutenza in the U.S. for the years ended December 31, 2017 and 2016.

### Accumulated Other Comprehensive Income

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

### Recent Accounting Pronouncements - Adopted

As noted above, in May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers" (Topic 606). This new standard replaced all previous U.S. GAAP guidance on this topic and eliminated all industry-specific guidance. The new standard 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 adopted the new standard effective January 1, 2018 using the modified retrospective transition method. See discussion of the adoption above in Revenue Recognition.

In November 2016, the FASB issued 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. The Company adopted this guidance effective January 1, 2018 retrospectively. This ASU requires entities to present the statement of cash flows in a manner such that it reconciles beginning and ending totals of cash, cash equivalents, restricted cash or restricted cash equivalents. Also, when cash, cash equivalents, restricted cash or restricted cash equivalents are presented in more than one line item within the statement of financial position, an entity should, for each period that a statement of financial position is presented, present on the face of the statement of cash flows or disclose in the notes to the financial statements, the line items and amounts of cash, cash equivalents, and restricted cash or restricted cash equivalents reported within the statement of financial position. The amounts, disaggregated by the line item in which they appear within the statement of financial position, shall sum to the total amount of cash, cash equivalents, and restricted cash or restricted cash equivalents at the end of the corresponding period shown in the statement of cash flows.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the statement of financial position that sum to the total of the same amounts shown in the statement of cash flows:

	December 31, 2018	December 31, 2017	December 31, 2016
(In thousands)			

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	Beginning of period	End of period	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	\$307,068	\$293,564	\$158,537	\$307,068	\$153,204	\$158,537
Restricted cash	410	532	79	410	6,031	79
Restricted cash included in Other assets	560	255	255	560	—	255
Total Cash, cash equivalents and restricted cash per statement of cash flows	\$308,038	\$294,351	\$158,871	\$308,038	\$159,235	\$158,871

Amounts included in restricted cash represent those amounts required to be set aside to cover the Company's self-funded employee health insurance. Restricted cash included in other assets on the statement of financial position relates to

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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.

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. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

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. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s 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. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued Accounting Standards Update 2017-09, “Compensation – Stock Compensation” (Topic 718): Scope of Modification Accounting (ASU 2017-09). This new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-09 allows for prospective application and is effective for fiscal years beginning after December 15, 2017, and interim periods therein with early adoption permitted for interim or annual periods. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. Previously, share-based payment arrangements with employees were accounted for under ASC 718, while nonemployee share-based payments issued for goods and services were accounted for under ASC 505-50. ASC 505-50, before the amendments, differed significantly from ASC 718. However, FASB concluded that awards granted to employees are economically similar to awards granted to nonemployees and therefore two different accounting models were not justified. This ASU is effective for fiscal years beginning after December 15, 2018, and interim periods therein with early adoption permitted. The Company early adopted this guidance beginning April 1, 2018. The adoption of this guidance did not have an impact on its consolidated financial statements.

In March 2018, the FASB issued ASU 2018-05, “Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin (SAB) No. 118”. The ASU adds seven paragraphs to ASC 740, Income Taxes, that contain SEC guidance related to SAB 118 (codified as SEC SAB Topic 5.EE, “Income Tax Accounting Implications of the Tax Cuts and Jobs Act”), which provides guidance for companies that are not able to complete their accounting for the income tax effects of the Tax Cuts and Jobs Act in the period of enactment which is the period that includes December 22, 2017. The measurement period should not extend beyond one year from the enactment date. The Company completed its accounting for the income tax effects for the year ended December 31, 2018. See note 17 for a discussion of the impact of the guidance on the Company’s consolidated financial statements.



Recent Accounting Pronouncements – Not Yet Adopted

In February 2016, the FASB issued ASU 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. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; ASU No. 2018-11, Targeted Improvements and ASU No. 2018-20, Narrow-Scope Improvements for Lessors. The new standard establishes a right-of-use model (“ROU”) that requires a lessee to recognize an ROU asset and lease

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liability on the balance sheet for all leases with a term longer than 12 months. For lessees, leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

This ASU is effective for the Company on January 1, 2019. We expect to adopt the new standard on its effective date. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We expect to adopt the new standard on January 1, 2019 and use the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The new standard provides a number of optional practical expedients in transition. We expect to elect the ‘package of practical expedients’, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

While we continue to assess all of the effects of adoption, we currently believe the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on our balance sheet for our real estate operating leases and (2) providing significant new disclosures for our leasing activities.

The new standard also provides practical expedients and certain exemptions for an entity’s ongoing accounting. We currently expect to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also currently expect to elect the practical expedient to not separate lease and non-lease components for all of our leases. We have determined the completeness of our lease population as of January 1, 2019. We expect to complete our assessment of the full financial impact of ASC 842 during the first quarter of 2019, and will include all required presentation and disclosures under ASC 842 in our Form 10-Q for the three months ending March 31, 2019.

In January 2017, the FASB issued ASU 2017-04, “Intangibles – Goodwill and Other” (Topic 350): Simplifying the Test for Goodwill Impairment (ASU 2017-04). This new standard simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. ASU 2017-04 allows for prospective application and is effective for fiscal years beginning after December 15, 2019, and interim periods therein with early adoption permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating whether it will adopt this guidance early. The Company does not expect the adoption of this guidance to have a significant impact on its consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, ‘Income Statement—Reporting Comprehensive Income’ (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (ASU 2018-02). This new standard provides entities with an option to reclassify stranded tax effects within AOCI to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or portion thereof) is recorded. ASC 740-10-35-4 requires that deferred tax assets and liabilities should be adjusted to account for any changes in tax laws or rates within the period that the enactment of these changes occurs and any adjustments to flow through income from continuing operations. Since the adjustments due to the Tax Cuts and Jobs Act are required to flow through income from continuing operations, the tax effects of items within accumulated other comprehensive income known now as “stranded tax effects,” do not reflect the appropriate tax rate. As such, FASB issued ASU 2018-02, in order to address these stranded income tax effects. The new standard requires entities to disclose the following:

- A description of the accounting policy for releasing income tax effects from AOCI;
- Whether they elect to reclassify the stranded income tax effects from the Tax Cuts and Jobs Act, and
- Information about the other income tax effects that are reclassified.

The ASU is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact it may have on its consolidated financial statements.

In July 2018, the FASB issued ASU 2018-09, "Codification Improvements." The ASU's amendments clarify, correct errors in, or make minor improvements to a variety of ASC topics. The changes in ASU 2018-09 are not expected to have a significant effect on current accounting practices. Some of the amendments in this update do not require transition guidance

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and will be effective upon issuance of this update. However, many of the amendments in this update do have transition guidance with effective dates for annual periods beginning after December 15, 2018, for public business entities. The Company does not expect this ASU to have a significant impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 “Fair Value Measurement (Topic 820): “Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.” The amendments in this ASU eliminate, add and modify certain disclosure requirements for fair value measurements as part of its disclosure framework project. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public business entities will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact it may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.” The ASU clarifies certain aspects of ASU 2015-05, “Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement,” which was issued in April 2015. Specifically, the ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license).” The ASU is effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact it may have on its consolidated financial statements.

In August 2018, the Securities Exchange Commission (“SEC”) adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders’ equity as required under the new SEC guidance will be included in its Form 10-Q for the three-month period ended March 31, 2019.

In November 2018, the FASB issued ASU 2018-18, Collaborative arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606. ASU 2018-18 clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The ASU is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating 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 there were no subsequent events that required disclosure in our financial statements.

(3) Acquisitions

Biotie Therapies Ltd.

On April 18, 2016, the Company acquired a controlling interest in Biotie Therapies Ltd., formerly Biotie Therapies Corp. (“Biotie”), pursuant to a combination agreement entered into in January 2016. 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

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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.

During the year ended December 31, 2017, the Company received a refund of the cash security deposit of approximately \$2.7 million following the final determination and payment of the redemption price for the shares subject to the redemption proceedings. During the year ended December 31, 2017, the Company recorded final measurement period adjustments of approximately \$6.4 million to its purchase price allocation with a corresponding offset to goodwill. The final measurement period adjustments included a reduction to current liabilities of approximately \$3.8 million related to the convertible capital loans as the Company was able to determine the fair market value of these loans, a reduction to other long-term liabilities of approximately \$2.7 million due to the finalization of the valuation of the non-convertible capital loans and an increase to deferred tax liabilities of approximately \$0.2 million due to the finalization of the provisional amounts recorded for deferred tax liabilities.

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

(In thousands)	Preliminary Allocation, as adjusted through December 31, 2016	Measurement Period Adjustments	Final Allocation, as of April 18, 2017
Cash and cash equivalents	\$ 73,854	\$ —	\$ 73,854
Other current assets	1,878	—	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	(18,572 )	3,837	(14,735 )
Deferred taxes	(89,908 )	(156 )	(90,064 )
Other long-term liabilities	(25,690 )	2,740	(22,950 )
Fair value of assets and liabilities acquired	272,024	6,421	278,445
Goodwill	103,876	(6,421 )	97,455
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 \$18.6 million in total acquisition related expenses, all of which were expensed and included in selling, general and administrative expenses in the consolidated statements of

operations. For the year ended December 31, 2017 and 2016, the Company incurred approximately \$0.6 million and \$17.6 million, respectively, 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 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.

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## 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, 2017.

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 year ended December 31, 2016 as if the acquisition of Biotie had occurred as of January 1, 2016. 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 was prepared for comparative purposes only and is not necessarily indicative of what would have occurred had the acquisitions been made at those times or of results which may occur in the future

(In thousands)	Year ended December 31, 2016	
	Reported	Pro Forma
Net revenues	\$519,601	\$520,658
Net loss from continuing operations attributable to Acorda	\$(34,618 )	\$(57,925 )



(4) Intangible Assets and Goodwill

Intangible Assets

Inbrija (levodopa inhalation powder) and ARCUS Technology IPR&D

In connection with the acquisition of Civitas in October 2014, the Company acquired global rights to Inbrija, a Phase 3 treatment candidate for Parkinson's disease OFF periods, also known as OFF episodes. The acquisition of Civitas also included rights to Civitas' proprietary ARCUS drug delivery technology, which the Company believes has potential to be

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used in the development of a variety of inhaled medicines. In December 2018, the FDA approved Inbrija for intermittent treatment of OFF episodes in people with Parkinson's disease treated with carbidopa/levodopa.

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 of the associated research and development efforts. The value allocated to the indefinite lived intangible asset was \$423 million. In December 2018, the Company received FDA approval for Inbrija and accordingly reclassified the indefinite lived intangible asset to a definite lived intangible asset with amortization scheduled to begin upon launch in 2019.

#### 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.

On March 31, 2017, the United States District Court for the District of Delaware upheld U.S. Patent No. 5,540,938 (the '938 patent), which was set to expire in July 2018. The claims of the '938 patent 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. The District Court invalidated U.S. Patent Nos. 8,663,685, 8,007,826, 8,440,703, and 8,354,437, which pertain to Ampyra. In May 2017, the Company appealed the ruling on these patents. As a result of the District Court's ruling, the Company performed an interim impairment test for the intangible assets related to Ampyra in connection with the preparation of the unaudited interim condensed consolidated financial statements for the first quarter of 2017. Based on the impairment test performed, the Company determined that these intangible assets were not impaired.

As a result of the invalidation of the patents, the estimated remaining useful lives of the Ampyra intangible assets were reviewed to determine if there was a change in the estimated useful lives of these assets. Based on the review, the Company determined that there was a change in the estimated useful lives of these assets that would require an acceleration of the amortization expense. The Company determined that the estimated useful lives of these intangible assets will coincide with the expiration of the '938 patent, unless the appeal is resolved favorably. The Company accounted for this change prospectively as a change in an accounting estimate beginning in the three-month period ended June 30, 2017. The acceleration of the amortization associated with the change in the estimated remaining useful lives of these intangible assets, did not have a material impact on the Company's statement of operations for the year ended December 31, 2018 or December 31, 2017.

#### 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 (timolumab). Tozadenant was a potential treatment for Parkinson's disease patients to reduce off periods.

SYN120 is a potential treatment for Parkinson's-related dementia. BTT1023 is a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. 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 marketed across Europe by 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

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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 was being amortized over the estimated remaining useful life of approximately 6 years. The value allocated to the indefinite lived intangible assets was \$260.5 million.

In November 2017, the Company announced that it was discontinuing its clinical development program for tozadenant, including immediately discontinuing dosing of all participants that were already enrolled in tozadenant studies. The Company made this decision based on additional data obtained from the Phase 3 clinical trial related to previously disclosed agranulocytosis and associated serious adverse events. Based on the analysis of the additional data, the Company determined that tozadenant was fully impaired. The Company recorded a non-cash impairment charge in the amount of approximately \$233.5 million to write-off the asset for the year ended December 31, 2017.

In December 2017, the Company received and reviewed the data read-out from the Phase II proof-of-concept study for SYN120. The data from the Phase II study showed that neither the primary nor key secondary endpoints achieved statistical significance. Based on the data from the study indicating a lack of statistical significance for the key endpoints in the study, management determined that SYN120 was fully impaired. The Company recorded a non-cash impairment charge in the amount of approximately \$23.8 million to write-off the asset for the year ended December 31, 2017.

In the three-month period ended September 30, 2017, the Company determined the carrying value of Selincro was greater than the estimated fair market value. The Company recorded a non-cash impairment charge of \$39.4 million representing the amount by which the carrying value exceeded the fair market value for the year ended December 31, 2017.

In November 2017, the Company executed an Amendment to its existing License and Commercialization Agreement with Lundbeck for the Company to provide to Lundbeck, a fully paid up royalty free license under the licensed IP for sales of Selincro outside of the U.S. in exchange for a payment of approximately \$13.0 million (or approximately €11.0 million). Selincro is not approved for use in the U.S. The Company recorded the receipt of the payment from Lundbeck as royalty income for the year ended December 31, 2017 and accelerated the amortization of the remaining carrying value to account for the asset monetization. The Company recorded amortization expense related to Selincro of approximately \$14.7 million (or approximately €12.4 million) in the three-month period ended December 31, 2017. As of December 31, 2017, the net book value of Selincro was \$0.

#### 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 revision. As of December 31, 2018, 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:

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		December 31, 2018					December 31, 2017					
Estimated												
Remaining							Foreign Net					
Useful Lives		Accumulated		Reclass to	Currency		Accumulated		Currency			
(Years)		Cost	Amortization	Definite-lived	Translation	Carrying	Cost	Amortization	Impairment	Translation	Carrying	
Thousands)						Amount					Amount	
process research & development		Indefinite-lived	\$427,500	\$—	\$(423,000)	\$(200)	\$4,300	\$683,500	\$—	\$(257,317)	\$1,317	\$427,500
trija <sup>(2)</sup>	14	—	—	423,000	—	423,000	—	—	—	—	—	—
incro	n/a	—	—	—	—	—	65,000	(27,932)	(39,446)	2,378	—	—
pyra	n/a	5,750	(5,750)	—	—	—	5,750	(4,438)	—	—	—	1,312
stones	n/a	3,000	(3,000)	—	—	—	3,000	(2,642)	—	—	—	358
pyra	n/a	13,857	(13,289)	—	—	568	13,983	(12,816)	—	—	—	1,167
RO	n/a	702	—	—	—	702	266	—	—	—	—	266
ty	n/a	—	—	—	—	—	—	—	—	—	—	—
ayout	n/a	—	—	—	—	—	—	—	—	—	—	—
bsite	n/a	—	—	—	—	—	—	—	—	—	—	—
velopment	n/a	—	—	—	—	—	—	—	—	—	—	—
sts	3	13,857	(13,289)	—	—	568	13,983	(12,816)	—	—	—	1,167
bsite	n/a	702	—	—	—	702	266	—	—	—	—	266
velopment	n/a	—	—	—	—	—	—	—	—	—	—	—
sts-in	n/a	702	—	—	—	702	266	—	—	—	—	266
cess	n/a	702	—	—	—	702	266	—	—	—	—	266
		\$450,809	\$(22,039)	\$—	—	\$(200)	\$428,570	\$771,499	\$(47,828)	\$(296,763)	\$3,695	\$430,600

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- (1) Includes the fair values of Inbrija: \$423.0 million and BTT1023: \$4.5 million as of December 31, 2017.  
 (2) In December 2018, the Company received FDA approval for Inbrija and accordingly reclassified the indefinite lived intangible assets to definite lived intangible assets with amortization scheduled to begin upon launch in 2019.

The Company recorded \$2.4 million and \$25.1 million in amortization expense related to these intangible assets for the years ended December 31, 2018 and 2017, respectively.

Estimated future amortization expense for intangible assets subsequent to December 31, 2018 is as follows:

(In thousands)	
2019	\$ 30,796
2020	30,533
2021	30,424
2022	30,395
2023	30,395
Thereafter	271,024
	\$423,567

The weighted-average remaining useful lives of all amortizable assets is approximately 17.0 years.

#### Goodwill

The following table presents the goodwill balances at December 31, 2018 and 2017 and the associated changes in goodwill through December 31, 2018.

(In thousands)	
Balance at December 31, 2017	\$286,611
Foreign currency translation adjustment	(4,552 )
Balance at December 31, 2018	\$282,059

#### (5) Qutenza and Zanaflex Asset Sales

On May 22, 2018, the Company entered into an Asset Purchase Agreement (the “Agreement”) to sell to its rights and interests related to Qutenza assets for a purchase price of \$7.9 million. The Company recognized a gain on the sale of approximately \$7.8 million for the year ended December 31, 2018 after reflecting the net book value of the inventory transferred to the buyer. The Company is entitled to receive up to an additional \$35.0 million in cash based on achievement of specified U.S. sales milestones for Qutenza. The gain on the sale is recognized in the Statement of Operations as a reduction to the selling, general and administrative expenses.

On November 13, 2017, the Company entered into an asset purchase agreement (“Agreement”) to sell its rights and interests related to its Zanaflex assets for a purchase price of \$4.0 million. The Company recognized a gain on the sale

of approximately \$3.5 million for the year ended December 31, 2017 after reflecting the direct costs to complete the transaction and the net book value of the inventory transferred to the buyer. The gain on the sale is recognized in the Statement of Operations as a reduction to the selling, general and administrative expenses.

(6) Investments

The Company has determined that all of its investments are classified as available-for-sale. Available-for-sale debt securities are carried at fair value with interest on these investments included in interest income and are recorded based on quoted market prices. Available-for-sale investments consisted of the following at December 31, 2018:

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Type	Amortized	Gross unrealized gains	Gross unrealized losses	Estimated fair value
(In thousands)	Cost	gains	losses	value
Commercial Paper	\$ 47,149	\$ —	\$ (41 )	\$ 47,108
Corporate Bonds	104,965	6	(90 )	104,881
Total Short-term Investments	\$ 152,114	\$ 6	\$ (131 )	\$ 151,989

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately \$9.6 million as of December 31, 2018. Short-term investments have original maturities of greater than 3 months but less than 1 year and amounted to approximately \$152.0 million as of December 31, 2018. The aggregate fair value of short-term investments in an unrealized loss position amounted to approximately \$139.6 million as of December 31, 2018. The Company held no short-term investments at December 31, 2017. Short-term investments at December 31, 2018 primarily consisted of high-grade commercial paper and corporate bonds. Long-term investments have original maturities of greater than 1 year. There were no investments classified as long-term at December 31, 2018 or December 31, 2017. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of December 31, 2018 as the Company does not intend to sell its investments and it is not more likely than not that the Company will be required to sell its investments prior to the recovery of its amortized cost basis.

Unrealized holding gains and losses, which relate to debt instruments, are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding losses on available-for-sale investments during the year ended December 31, 2018, were as follows (in thousands):

	Net Unrealized Gains (Losses) on Short-term Investments
(In thousands)	
Balance at December 31, 2017	\$ —
Other comprehensive loss before reclassifications:	(125 )
Amounts reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive loss	(125 )
Balance at December 31, 2018	(125 )

#### (7) Property and Equipment

Property and equipment consisted of the following:



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			Estimated
(In thousands)	December 31, 2018	December 31, 2017	useful lives used
Machinery and equipment	\$ 24,798	\$ 24,956	2-7 years
			Lesser of useful life or
			remaining
Leasehold improvements	25,047	23,978	lease term
Computer equipment	21,472	21,560	1-3 years
Laboratory equipment	9,021	8,542	2-5 years
Furniture and fixtures	2,599	2,635	4-7 years
Construction in progress	34,489	4,995	
	117,426	86,666	
Less accumulated depreciation	(56,907 )	(49,997 )	
	\$ 60,519	\$ 36,669	

Depreciation and amortization expense on property and equipment was \$9.0 million and \$11.0 million for the years ended December 31, 2018 and 2017, respectively.

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## (8) Preferred Stock

### Stockholder Rights Plan

On August 31, 2017, the Board of Directors of the Company adopted a stockholder rights plan (Rights Plan) to preserve the ability of the Board to protect the interests of stockholders in transactions that may result in an acquisition of control of the Company, including tender offers and open market purchases of the Company's securities. In general terms, the Rights Plan works by significantly diluting the stock ownership of any person or group that acquires 15% or more of the outstanding common stock of the Company without the approval of the Board (such person, an Acquiring Person). The rights plan exempts any person or group owning 15% or more of the Company's outstanding common stock when we announced the rights plan, however the exemption does not apply to additional shares acquired after the announcement.

Under the Rights Plan, on August 31, 2017, the Board authorized and declared a dividend of one preferred share purchase right (Right) for each outstanding share of common stock, par value \$0.001 per share, of the Company. The dividend was payable to the stockholders of record on September 11, 2017 (Record Date). Each Right, when it becomes exercisable, entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share, of the Company at a price of \$110 per one one-thousandth of a Preferred Share, subject to adjustment. As of December 31, 2018 and 2017, there were 1,000,000 preferred shares authorized and no such shares issued and outstanding. In addition, one Right will automatically attach to each Common Share that becomes outstanding between the Record Date and the earliest of the Distribution Date, the redemption of the Rights or the expiration of the Rights. The Distribution Date is the close of business on the tenth day after the first date of public announcement that any person has become an Acquiring Person or such earlier date as a majority of the Board becomes aware of the existence of an Acquiring Person. Until a Right is exercised, the holder thereof, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends. The Rights were not exercisable until the Distribution Date. The Rights expired at the close of business on August 31, 2018. There were no rights exercised prior to the expiration.

## (9) Common Stock Options and Restricted Stock

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, 2018 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. As of December 31, 2018, the Company had granted an aggregate of 11,398,450 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 5,037,630 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 or stock grants 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.

The 2015 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options, restricted stock, and restricted stock units, determines the time or times at which options, restricted stock, and restricted stock units are to be granted, determines the number of shares to be granted subject to any option,

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restricted stock or restricted stock unit and the duration of each option, restricted stock, and restricted stock unit, 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, 2018 is 8,100,000 shares. As of December 31, 2018, the Company had granted an aggregate of 4,595,489 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 3,116,439 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 of the Company (or its subsidiaries) in order to induce such individuals to enter into employment with the Company or its subsidiaries. The only equity awards issued under this plan were issued to individuals employed by Biotie Therapies Ltd., formerly 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 for these awards is 366,950 shares. As of December 31, 2018, the Company had granted an aggregate of 147,850 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2016 Plan, of which 40,000 shares remained subject to outstanding options.

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

	Year ended December 31,		
	2018	2017	2016
Employees and directors:			
Estimated volatility%	52.29%	48.02%	44.63%
Expected life in years	6.16	6.15	5.99
Risk free interest rate%	2.76 %	2.08 %	1.46 %
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, 2018, 2017 and 2016 amounted to approximately \$12.71, \$10.70, and \$13.26, respectively. No options were granted to non-employees for the years ended December 31, 2018, 2017 and 2016.

During the year ended December 31, 2018, the Company granted 781,135 stock options to employees and directors under all plans. The stock options were issued with a weighted average exercise price of \$24.81 per share. As a result of these grants, the total compensation charge to be recognized over the service period is \$9.2 million, of which \$2.9 million was recognized during the year ended December 31, 2018.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$21.3 million, \$32.8 million, and \$36.4 million, for the years ended December 31, 2018, 2017 and 2016, 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,		
	2018	2017	2016
Research and development	\$5,560	\$9,683	\$10,610
Selling, general and administrative	15,692	23,131	25,777
Total	\$21,252	\$32,814	\$36,387

A summary of share based compensation activity for the year ended December 31, 2018 is presented below:

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## 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, 2017	8,929	\$ 29.46		
Granted	781	24.81		
Forfeited and expired	(784 )	29.26		
Exercised	(733 )	20.74		
Balance at December 31, 2018	8,193	\$ 29.81	5.5	\$ 162,119
Vested and expected to vest at December 31, 2018	8,168	\$ 29.83	5.5	\$ 162,050
Vested and exercisable at December 31, 2018	6,842	\$ 30.40	5.0	\$ 160,597

Range of exercise price	Options Outstanding		Options Exercisable	
	Outstanding	Outstanding	Exercisable	Exercisable
	as of	Weighted-	as of	Weighted-
	December	December	December	December
	31,	31,	31,	31,
	2018	2018	2018	2018
	average	average	average	average
	remaining	remaining	remaining	remaining
	exercise price	exercise price	exercise price	exercise price
	(In thousands)	(In thousands)	(In thousands)	(In thousands)
	actual life	actual life	actual life	actual life
\$13.80 - \$24.35	1,857	6.4	1,281	19.74
\$24.45 - \$28.15	1,682	5.9	1,216	26.79
\$28.30 - \$32.55	1,642	4.4	1,587	30.84
\$32.56 - \$35.74	1,952	5.4	1,722	35.18
\$35.84 - \$44.50	1,061	5.2	1,036	39.21
	8,194	5.5	6,842	30.40

## Restricted Stock Activity

	Number of Shares
	(In thousands)
Restricted Stock	
Nonvested at December 31, 2017	698
Granted	—
Vested	(334 )
Forfeited	(132 )

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2018 totaled \$19.3 million and is expected to be recognized over a weighted average period of approximately 1.7 years.

(10) 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 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.

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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, 2018 and 2017 consisted of the following:

(In thousands)	December 31, 2018	December 31, 2017
<b>Liability component:</b>		
Principal	\$ 345,000	\$ 345,000
Less: debt discount and debt issuance costs, net	(26,330)	(36,195)
Net carrying amount	318,670	\$ 308,805
<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 \$289.4 million as of December 31, 2018.

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As of December 31, 2018, the remaining contractual life of the Notes is approximately 2.5 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through December 31, 2018.

The following table sets forth total interest expense recognized related to the Notes for the years ended December 31, 2018 and 2017:

(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017
Contractual interest expense	\$ 6,038	\$ 6,038
Amortization of debt issuance costs	913	871
Amortization of debt discount	8,952	8,539
Total interest expense	\$ 15,903	\$ 15,448

#### Non-Convertible Capital Loan

Prior to and subsequent to the acquisition of Biotie on April 18, 2016, Biotie held non-convertible capital loans granted by Business Finland (formerly Tekes). The non-convertible capital loans had an adjusted acquisition-date fair value of \$20.5 million (€18.2 million) and a carrying value of \$23.2 million as of December 31, 2018. The loans are comprised of fourteen non-convertible loans. The 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. The maturity dates of the loans range from eight to ten years from the date of issuance, however, according to certain terms and conditions of the loans, the Company may repay the principal and accrued and unpaid interest of the loans only when the consolidated retained earnings of Biotie is sufficient to fully repay the loans.

#### Research and Development Loans

Research and Development Loans ("R&D Loans") were granted by Business Finland with an acquisition-date fair value of \$2.9 million (€2.6 million) and a carrying value of \$1.8 million as of December 31, 2018. 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 began in January 2017. The loan principal will be paid in equal annual installments over a 5 year period, ending January 2021.

#### Letters of Credit

As of December 31, 2018, the Company has \$0.3 million of cash collateralized standby letters of credit outstanding (see Note 2).

#### (11) Liability Related to Sale of Future Royalties

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP ("Royalty Agreement"). In exchange for the payment of \$40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the License and Collaboration Agreement between the Company and Biogen, up to an agreed upon threshold of royalties. When this threshold is met, if ever, the Fampyra royalty revenue will revert back to the Company and the Company will continue to receive the Fampyra royalty revenue from Biogen until the revenue stream ends. The transaction does not include potential future milestones to be paid.

The Company maintained the rights under the license and collaboration agreement with Biogen, therefore, the Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. The Company recorded the receipt of the \$40 million payment from HCRP and established a corresponding liability in the amount of \$40 million, net of transaction costs of approximately \$2.2 million. The net liability is classified between the current and non-current portion of liability related to sale of future royalties in the consolidated balance sheets based on the recognition of the interest and principal payments to be received by HCRP in the next 12 months from the financial statement reporting date. The total net royalties to be paid, less the net proceeds received will be recorded to interest expense using the effective interest method over the life of the royalty agreement. The Company will estimate the payments to be made to HCRP over the term of the Agreement based on forecasted royalties and will calculate the interest rate required to discount such payments back to the liability balance. Over

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the course of the Royalty Agreement, the actual interest rate will be affected by the amount and timing of net royalty revenue recognized and changes in forecasted revenue. On a quarterly basis, the Company will reassess the effective interest rate and adjust the rate prospectively as necessary.

The following table shows the activity within the liability account from the inception of the royalty agreement in November 2017 to December 31, 2017 and December 2018.

(In thousands)	December 31, 2018	Inception Date through December 31, 2017
Liability related to sale of future royalties - beginning balance	\$ 35,788	\$ —
Proceeds from sale of future royalties	—	40,000
Deferred transaction costs amortized	784	(2,115 )
Non-cash royalty revenue payable to HCRP	(10,291 )	(2,705 )
Non-cash interest expense recognized	4,435	608
Liability related to sale of future royalties - ending balance	\$ 30,716	\$ 35,788

The interest and debt discount amortization expense is reflected as interest and amortization of debt discount expense in the Statement of Operations.

#### (12) Corporate Restructuring

On April 5, 2017, the Company announced a corporate restructuring to reduce its cost structure and focus its resources on its then late-stage program, Inbrija.

The adoption of this restructuring plan followed the previously announced decision by the United States District Court for the District of Delaware invalidating certain patents pertaining to Ampyra.

As part of this restructuring, the Company reduced headcount by approximately 20%. For the years ended December 31, 2018 and December 31, 2017, the Company incurred pre-tax severance and employee separation related expenses of approximately \$1.3 million and \$7.6 million associated with the restructuring. The pre-tax charges incurred include a cash component of approximately \$1.1 million and \$6.6 million representing employee charges for severance payments and benefits and a non-cash component of approximately \$0.2 million and \$1.0 million representing stock compensation charges for the years ended December 31, 2018 and December 31, 2017, respectively. Of the pre-tax severance and employee separation related expenses incurred, \$1.2 million and \$5.5 million were recorded in research and development expenses and \$0.1 million and \$2.1 million were recorded in selling, general and administrative expenses for the years ended December 31, 2018 and December 31, 2017, respectively.

A summary of the restructuring costs for the years ended December 31, 2018 and 2017 is as follows:

(In thousands)	Restructuring Costs
Restructuring Liability as of December 31, 2016	\$ —
2017 Restructuring costs	7,646
2017 Payments	(7,142 )

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Restructuring Liability as of December 31, 2017	\$ 504
2018 Restructuring costs	1,316
2018 Payments	(1,820 )
Restructuring Liability as of December 31, 2018	\$ —

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## (13) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2018	December 31, 2017
Product allowances accruals	\$ 26,931	\$ 37,604
Bonus payable	18,381	10,730
Accrued inventory	14,254	15,324
Sales force commissions and incentive payments payable	3,453	1,654
Administrative expenses	2,651	2,276
Vacation accrual	2,395	2,449
Research and development expense accruals	2,374	9,092
Commercial and Marketing expense accruals	1,933	1,643
Royalties payable	509	3,707
Other accrued expenses	4,001	15,371
<b>Total</b>	<b>\$ 76,882</b>	<b>\$ 99,850</b>

## (14) 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, operating leases and commitments to purchase inventory. The following table summarizes the contractual obligations at December 31, 2018 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) (3) (7)			
	Total	Less than 1 year	1-3 years	4-5 years
Convertible Senior Notes (2)	\$359,214	\$6,038	\$353,176	\$—
Research and development loans (4)	1,848	616	1,232	—
Operating leases (5)	36,090	7,382	15,538	13,170
Inventory purchase commitments (6)	2,281	2,281	—	—
<b>Total</b>	<b>\$399,433</b>	<b>\$16,317</b>	<b>\$369,946</b>	<b>\$13,170</b>

(1) Excludes a liability for uncertain tax positions totaling \$7.7 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. The Notes will mature and will be payable on June 15, 2021. See Note 10.

- (3) Excludes a liability for the non-convertible capital loans totaling \$23.2 million. 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. 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.
- (4) Represents the future principal payments on the R&D loans acquired with Biotie. The repayment is made in equal annual installment with last payment due in January 2021. See Note 10.
- (5) 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, and excludes field auto leases which are for a one year term.

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- (6) Represents Ampyra inventory commitments. The Ampyra inventory commitment is an estimate as the price paid for Ampyra inventory is based on a percentage of the net product sales during the quarter Alkermes ships inventory to us. Under our supply agreement with Alkermes, we provide Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for our supply requirements of Ampyra. 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. 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.
- (7) 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

##### Ardsey, New York

In June 2011, the Company entered into a 15-year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. In 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 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 a right of first refusal until mid-2020 to lease up to approximately 95,000 additional square feet of space in additional buildings at the same location. The Company's extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that the Company not be in default under the lease.

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 \$4.6 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 North River Everett Ave, 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 \$1.5 million per year, which reflects an annual escalation factor of 2.5% as well as an amendment to the lease to add additional property at the Chelsea, Massachusetts site as further described below.

In 2017, the Company's Civitas subsidiary amended its existing Chelsea, Massachusetts lease. The amendment added expansion property located in Chelsea, Massachusetts next to the existing facility. The additional property includes land being used for parking and a free-standing warehouse building on the same site. The base rent for the additional property under the lease included in the rent number above, is currently \$0.5 million per year with an annual escalation factor of 3.0%.

In 2018, the Company initiated a renovation and expansion of the Chelsea facility that will increase the size of the facility to approximately 95,000 square feet. The project will add a new manufacturing production line for Inbrija and



other ARCUS products that has greater capacity than the existing manufacturing line, and it will create additional warehousing space for manufactured product. Pursuant to a 2018 lease amendment that enabled the renovation and expansion, upon completion of the project, annual rent under the lease will increase to \$1.7 million. Construction of the project is scheduled for completion in the third quarter of 2019, though we cannot be assured that the project will meet this schedule, and it will take additional time after completion of construction to obtain the FDA approval needed for use of the new production line for commercial manufacture.

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### 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.

Through Biotie and its U.S. subsidiary, we previously indirectly leased office space in Turku, Finland and South San Francisco, California. We terminated the Turku, Finland lease in mid-2017, and the South San Francisco, California lease expired at the end of 2018.

Future minimum commitments under all non-cancelable operating leases subsequent to December 31, 2018 are as follows:

(In thousands)	
2019	\$7,382
2020	7,669
2021	7,869
2022	10,071
2023	3,100
Later years	7,769
	\$43,860

Rent expense under these operating leases during the years ended December 31, 2018, 2017 and 2016 was approximately \$8.2 million, \$8.1 million, and \$6.0 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. 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.

Under the Company's license agreement with Rush-Presbyterian-St. Luke's Medical Center, it was obligated to make royalty payments as a low single digit percentage of net Ampyra and Fampyra sales in the United States and in countries other than the United States. The Company believes this license agreement and the royalty obligations expired in 2018.

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. In each of the 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 \$2.3 million as of December 31, 2018.

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 \$51.6 million over the life of the contracts.

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.

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## 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, 2018. 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 could potentially have a material adverse effect on its consolidated financial position or liquidity and could potentially be material to the Company's consolidated results of operations in any one accounting period.

## (15) Fair Value Measurements

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

The Company utilizes a fair value hierarchy which requires it to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company primarily applies the market approach for recurring fair value measurements. There were no changes in valuation techniques during the year ended December 31, 2018. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

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## Recurring

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and December 31, 2017, 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>2018</b>			
Assets Carried at Fair Value:			
Money market funds	\$9,586	\$—	\$—
Commercial paper	—	47,108	—
Corporate bonds	—	104,881	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	168,000
<b>2017</b>			
Assets Carried at Fair Value:			
Money market funds	\$9,163	\$—	\$—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	113,000

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

## Acquired contingent consideration

(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017
Acquired contingent consideration:		
Balance, beginning of period	\$ 113,000	\$ 72,100
Fair value change to contingent consideration (unrealized)		
included in the statement of operations	55,000	40,900
Balance, end of period	\$ 168,000	\$ 113,000

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 Inbrija (levodopa inhalation powder), an FDA approved drug for the treatment of OFF periods of Parkinson's disease and our ARCUS program for acute migraine. Using this approach, expected future cash flows are calculated over the expected life of the agreement and discounted to estimate the current value of the liability at the period end date. Some of the more significant assumptions made in the valuation include (i) the estimated revenue forecasts for Inbrija and our ARCUS program for acute migraine, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of

revenue milestones ranged from 26.3% to 100.0% with milestone payment outcomes ranging from \$0 to \$70 million in the aggregate for Inbrija and our ARCUS program for acute migraine. 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, 2018, changes in the fair value of the acquired contingent consideration were primarily due to an increase in the probability of success reflecting the FDA approval of Inbrija, recalculation of cash flows for the passage of time and updates to certain other estimated assumptions. Refer to Note 16 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 Inbrija and our ARCUS program for acute migraine and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value determined.

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(16) 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’ 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.

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. The Company did not make any compensatory payment in 2018.

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, the Company was obligated to make royalty payments as a low single digit percentage of net Ampyra and Fampyra sales in the United States and in countries other than the United States. The Company believes the license and the royalty obligations expired in 2018.

As of December 31, 2018, 2017 and 2016, the Company made or accrued royalty payments totaling \$66.6 million, \$59.9 million and \$48.1 million, respectively.

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.

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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 recognized 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, 2017 and 2016. On January 1, 2018, we adopted the new accounting standard ASC 606, "Revenue from Contracts with Customers" (Topic 606) ("ASC 606") and the related amendments to all contracts with customers that were not completed as of the date of adoption using the modified retrospective method. As a result of the adoption of ASC 606, the Company determined that the revenue recognition methodology for the deferred license revenue changed under the new guidance. License revenue recorded by the Company prior to January 1, 2018 related exclusively to the recognition of the upfront payment received from Biogen upon the execution of the License and Collaboration agreement that granted Biogen an exclusive non sub-licensable license to sell Fampyra outside of the U.S. License revenue recorded prior to January 1, 2018 was recognized under ASC 605 on a pro rata basis as the Company's obligations were satisfied throughout the duration of the license and collaboration agreement. As of January 1, 2018, the Company adopted ASC 606 which changed the Company's determination of its distinct performance obligations resulting in an acceleration of the recognition of the revenue in the arrangement. The material performance obligations were completed prior to January 1, 2018, and as a result, the Company recognized its

previously deferred revenue as a cumulative effect adjustment of \$27.6 million within the beginning accumulated deficit balance on the consolidated balance sheet as of January 1, 2018 (See Note 2).

Actavis/Watson

Prior to the Company's sale of its Zanaflex assets, the Company had 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 received a royalty based on Actavis' gross margin, as defined by the agreement, of the authorized generic product. During the years ended December 31, 2017 and 2016, the Company recognized royalty revenue of \$2.6 million and \$3.9 million, respectively,

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related to the gross margin of the Zanaflex Capsule authorized generic. During the years ended December 31, 2017 and 2016, the Company also recognized revenue and a corresponding cost of sales of \$3.0 million and \$2.7 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Actavis, which is recorded in net product revenues and cost of sales.

#### Alkermes (ARCUS products)

In December 2010, Civitas, the Company's wholly-owned subsidiary, entered into the Asset Purchase and License Agreement ("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 15 – Fair Value Measurements for more information about the contingent consideration liability.

#### Roche (Tozadenant and SYN120)

Our Biotie subsidiary has an exclusive, worldwide license from Roche Palo Alto, LLC, Hoffman-La Roche, Inc. and F. Hoffman-La Roche, Ltd. to certain patents and know-how relating to tozadenant and certain patents and know-how relating to SYN120.

#### (17) Income Taxes

On December 22, 2017, the U.S. enacted Public Law No. 115-97 ("Act"), originally introduced as the Tax Cuts and Jobs Act, which significantly modified the Internal Revenue Code. The Act reduced the U.S. federal corporate tax rate from 35.0% to 21.0%, created a territorial-type tax system with an exemption for foreign dividends, and imposed a one-time deemed repatriation tax on a U.S. company's historical undistributed earnings and profits of foreign affiliates. Among other provisions, the Act also increased expensing for certain business assets, created new taxes on certain foreign sourced earnings, adopted limitations on business interest expense deductions, repealed deductions for income attributable to domestic production activities, and added other anti-base erosion rules. The effective dates for the provisions set forth in the Act vary as to when the provisions will apply to the Company.

In response to the Act, the U.S. Securities and Exchange Commission ("SEC") provided guidance by issuing Staff Accounting Bulletin No. 118 ("SAB 118"), which has since been codified by the release of ASU No. 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. ASU 2018-05 allows companies to record provisional amounts during a measurement period with respect to the impacts of the Act for which the accounting requirements under ASC Topic 740 are not complete, but a reasonable estimate has been determined. The measurement period under ASU 2018-05 ends when a company has obtained, prepared, and analyzed the information that was needed in order to complete the accounting requirements under ASC Topic 740, but cannot exceed one year.

As of December 31, 2018, the Company has completed the accounting for the effects of the Act. The Company has included the impact of the Act on its annual effective tax rate and has recorded a total tax benefit of \$14.8 million for the

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remeasurement of deferred tax assets and liabilities, of which \$1.6 million of the benefit was recorded in the fourth quarter of 2018.

The domestic and foreign components of (loss) income before income taxes were as follows:

(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Domestic	\$ 19,211	\$ (172,560)	) \$ (36,454)
Foreign	1,211	(79,325)	) (5,814)
Total	\$ 20,422	\$ (251,885)	) \$ (42,268)

The benefit from (provision for) income taxes in 2018, 2017 and 2016 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
<b>Current:</b>			
Federal	\$ 2,991	\$ (11,948)	) \$ (852)
State	(4,143)	) (12,653)	) (4,517)
Foreign	(93)	) (91)	) 781
	(1,245)	) (24,692)	) (4,588)
<b>Deferred:</b>			
Federal	13,790	42,322	9,465
State	714	5,377	1,788
Foreign	—	5,519	—
	14,504	53,218	11,253
<b>Total benefit from (provision for) income taxes</b>	<b>\$ 13,259</b>	<b>\$ 28,526</b>	<b>\$ 6,665</b>

As of December 31, 2018, Acorda's U.S. consolidated Tax Group had utilized all of its available Federal net operating loss (NOL) carryforwards to offset its consolidated U.S. federal taxable income. The NOL carryforward of approximately \$131.6 million as of December 31, 2018 represents the NOL's of Biotie US, which files a separate company federal income tax return. These NOLs are offset entirely by a valuation allowance and are expected to begin to expire in 2026. Based on a recently completed IRC Section 382 analysis, the Company has determined that there were additional NOL's that will be expiring of approximately \$16.0 million.

The Company's research and development and orphan drug credit carry-forwards of \$17.1 million and \$34.5 million as of December 31, 2018 and 2017, respectively, begin to expire in 2031. 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 and 2015. The alternative minimum tax credit carryforwards of \$4.8 million at December 31, 2017 and 2016 can be used to offset future regular income tax liability.

As of December 31, 2018, the Company is expected to utilize approximately \$4.5 million and the remaining \$0.3 million of unused credits under the Act, will become refundable over the next four years.

The Company had available state NOL carryforwards of approximately \$170.1 million, \$167.9 million and \$170.9 million as of December 31, 2018, 2017 and 2016, respectively. The state losses are expected to begin to expire in 2027, 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 2015 however, such net operating losses utilized by the Company in years subsequent to 2002 is subject to review. The Internal Revenue Service completed its examination of the Company's U.S. income tax return for 2015 in the third quarter of 2018 that resulted in an immaterial adjustment.

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The Internal Revenue Service commenced its examination of the Company's wholly-owned subsidiary, Biotie Therapies, Inc.'s, U.S. income tax return for the short period ended December 31, 2016 in the third quarter of 2018. There have been no proposed adjustments at this stage of the examination.

The New York State Department of Tax commenced an examination of the Company's income tax returns for the years 2014 through 2016 in the third quarter of 2018. There have been no proposed adjustments at this stage of the examination.

The Internal Revenue Code 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. These provisions were unchanged by the Act. 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 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 Acorda and the Neuronex, Inc. and Civitas Therapeutics, Inc. acquisitions. Based on a recently completed IRC Section 382 analysis by the Company, the limitation triggered by the acquisition of Biotie Therapies, Inc. will result in an estimated \$31.5 million of unused federal net operating loss carryforwards and \$5.1 million of unused federal credit carryforwards expiring before they can be utilized. Future ownership changes may further limit the use of these carryforwards. Under the Act, U.S. net operating losses generated after December 31, 2017 can be carried forward indefinitely.

The Company has \$67.6 million of net operating loss carryforwards outside of the U.S. as of December 31, 2018, that begin to expire in 2019 all of which are fully reserved with a valuation allowance.

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 any portion of 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. The Company continued to maintain a full valuation allowance against its net U.S. and net foreign deferred tax assets of Biotie and recorded a benefit of \$3.8 million and \$0.7 million in each jurisdiction respectively. The \$3.8 million benefit was primarily due to the completion of the 382 study which determined that additional NOLs would expire. Additionally, the Company had a net release of \$23.1 million of valuation allowance against certain U.S. federal and state deferred taxes.

The reconciliation of the statutory U.S. federal income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31, 2018		Year ended December 31, 2017		Year ended December 31, 2016	
U.S. federal statutory tax rate	21.0	%	35.0	%	35.0	%
State and local income taxes	8.7	%	(0.1)	)%	(3.8)	)%
Foreign income tax	—		—		1.2	%
Stock option compensation	0.7	%	(0.5)	)%	(3.8)	)%
Stock option shortfall	12.6	%	(1.5)	)%	(6.5)	)%

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Research and development and orphan drug credits	5.6	%	1.2	%	28.9	%
Uncertain Tax Positions	(0.7	)%	(0.3	)%	(4.8	)%
Other nondeductible and permanent differences	(5.0	)%	(0.4	)%	(1.1	)%
Valuation allowance, net of foreign tax rate differential	(107.9	)%	(19.8	)%	(31.6	)%
Transaction cost	—		—		(5.9	)%
Gain or loss on hedging	—		—		8.2	%
NOL Write-off	16.6	%	—		—	
Federal return to provision differences	(16.6	)%	—		—	
Tax reform	—		(2.3	)%	—	
Effective income tax rate	(65.0	)%	11.3	%	15.8	%

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The Company's overall effective tax rate is affected primarily by the release of the U.S valuation allowance, Biotie U.S. and foreign losses for which no benefit has been recognized and the related foreign tax rate differential, state taxes, federal return to provision adjustments including the related tax reform impact and stock compensation. 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. U.S. income taxes are not provided for unremitted earnings of international subsidiaries and affiliates where our intention is to reinvest these earnings permanently.

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

(In thousands)	December 31, 2018	December 31, 2017
<b>Deferred tax assets:</b>		
Net operating loss and other carryforwards	\$ 51,543	\$ 53,632
Tax credits	19,401	31,699
Deferred revenue	—	5,597
Stock based compensation	22,733	24,531
Contingent consideration	38,594	26,041
Employee compensation	3,677	3,212
Legal reserve	—	—
Rebate and returns reserve	5,798	8,215
Capitalized R&D	10,791	11,295
Other	13,881	12,368
Total deferred tax assets	\$ 166,418	\$ 176,590
Valuation allowance	\$ (71,570 )	\$ (98,609 )
Total deferred tax assets net of valuation allowance	\$ 94,848	\$ 77,981
<b>Deferred tax liabilities:</b>		
Intangible assets	(94,771 )	(91,991 )
Convertible debt	(5,971 )	(8,449 )
Depreciation	(1,256 )	—
Other	(333 )	—
Total deferred tax liabilities	\$ (102,331 )	\$ (100,440 )
Net deferred tax liability	\$ (7,483 )	\$ (22,459 )

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:

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(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Beginning of period balance	\$ 7,397	\$ 6,856	\$ 4,835
Increases for tax positions taken during a prior period	55	687	570
Decreases for tax positions taken during a prior period	(194 )	(146 )	—
Increases for tax positions taken during the current period	—	—	1,451
	\$ 7,258	\$ 7,397	\$ 6,856

Due to the amount of the Company's 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

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consolidated balance sheet and recorded as a component of income tax expense. All of its unrecognized tax benefits, if recognized, would impact the effective tax rate.

The Company is subject to taxation in the United States and various state and foreign jurisdictions. The Company has operations in the United States and Puerto Rico, as well as filing obligations in Finland, Switzerland and Germany. Typically, the period for the statute of limitations ranges from 3 to 5 years, however, this 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.

The beginning and ending amounts of valuation allowances reconcile as follows:

(In thousands)	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Valuation allowance for deferred tax assets:				
Year ended December 31, 2016	\$ 5,277	57,948	—	\$ 63,225
Year ended December 31, 2017	\$ 63,225	39,007	(3,623 )	\$ 98,609
Year ended December 31, 2018	\$ 98,609	5,465	(32,504 )	\$ 71,570

#### (18) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2018, 2017 and 2016:

(In thousands, except per share data)	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Basic and diluted			
Net income (loss)	\$ 33,682	\$ (223,359 )	\$ (34,618 )
Weighted average common shares outstanding used in			
computing net income (loss) per share—basic	47,010	45,999	45,259
Plus: net effect of dilutive stock options and unvested			
restricted common shares	331	—	—
Weighted average common shares outstanding used in			
computing net income (loss) per share—diluted	47,341	45,999	45,259
Net income (loss) per share—basic	\$ 0.72	\$ (4.86 )	\$ (0.76 )
Net income (loss) per share—diluted	\$ 0.71	\$ (4.86 )	\$ (0.76 )

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

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

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

(In thousands)	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Denominator			
Stock options and restricted common shares	7,370	8,804	7,749
Convertible note	—	—	10

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, 2018, 2017 and 2016.

#### (19) Employee Benefit Plan

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The plan includes an employer match contribution to employee deferrals. For each dollar an employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was \$2.4 million, \$2.4 million and \$2.6 million for the years ended December 31, 2018, 2017, and 2016, respectively.

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

(In thousands, except per share amounts)	2018			
	March 31	June 30	September 30	December 31
Total net revenues	\$ 106,165	\$ 153,302	\$ 142,814	\$ 69,152
Gross profit	84,815	122,208	117,423	47,678
Net (loss) income (1)	(8,199 )	46,197	(13,911 )	9,595
Net (loss) income per share—basic	\$(0.18 )	\$0.99	\$(0.29 )	\$ 0.20
Net (loss) income per share—diluted	\$(0.18 )	\$0.98	\$(0.29 )	\$ 0.20
	2017			
	March 31	June 30	September 30	December 31
Total net revenues	\$ 119,386	\$ 139,438	\$ 141,065	\$ 188,398
Gross profit	94,044	109,614	110,914	137,999
Net loss (2) (3)	(18,904 )	(8,196 )	(25,195 )	(171,064 )
Net loss attributable to Acorda Therapeutics, Inc.				
—basic and diluted	(18,904 )	(8,196 )	(25,195 )	(171,064 )
Net loss per share—basic and diluted	\$(0.41 )	\$(0.18 )	\$(0.55 )	\$(3.70 )

(1) In the fourth quarter of 2018, the Company recognized a gain of approximately \$7.8 million on the sale of Qutenza assets. See Note 5 for a discussion of the gain on the sale. In the fourth quarter of 2018, the Company recognized a charge of approximately \$8.4 million related to inventory obsolescence reserve. See Note 2 for a discussion of the inventory reserve charges.

(2) In the third quarter of 2017, the Company recognized an asset impairment charge of \$39.4 million. See Note 4 for a discussion of the impairment charges.

(3) In the fourth quarter of 2017, the Company recognized an asset impairment charge of \$257.3 million. See Note 4 for a discussion of the impairment charges.

(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 former and current SEC File Numbers 000-50513 and 001-31938, respectively.

Exhibit Description  
No.

- |     |   |
|-----|---|
| 1.1 | <u>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.</u>                         |
| 3.1 | <u>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.</u>                       |
| 3.2 | <u>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.</u>  |
| 3.3 | <u>Certificate of Designations of Series A Junior Participating Preferred Stock of Acorda Therapeutics, Inc. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 1, 2017.</u>           |
| 4.1 | <u>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.</u>                                |
| 4.2 | <u>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.</u>                    |
| 4.3 | <u>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.</u> |
| 4.4 | <u>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.</u>   |

- 4.5 Rights Agreement, dated as of August 31, 2017, between the Registrant and Computershare Trust Company, N.A., as Rights Agent, which includes the Form of Certificate of Designations, the Form of Right Certificate, and the Summary of Rights to Purchase Preferred Shares attached thereto as Exhibits A,B, and C respectively. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on September 1, 2017.
- 10.1\*\* 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.
- 10.2\*\* 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.
- 10.3\*\* Forms of Equity Award Documents. Incorporated herein by reference to Exhibit 10.58 to Registrant's Annual Report on Form 10-K filed on March 1, 2011.
- 10.4\*\* 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.



Exhibit No.	Description
10.5**	<u>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.</u>
10.6**	<u>Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan as amended June 27, 2018. Incorporated herein by reference to Appendix A to the Registrant's 2018 Proxy Statement filed as Schedule 14A on April 27, 2018.</u>
10.7**	<u>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.</u>
10.8**	<u>Revised forms of equity award documents for certain awards under the Acorda Therapeutics 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 August 8, 2017.</u>
10.9**	<u>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.</u>
10.10**	<u>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.</u>
10.11**	<u>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.</u>
10.12**	<u>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.</u>
10.13**	<u>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.</u>
10.14**	

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.

10.15\*\* Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

10.16\*\* Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

10.17\*\* Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.68 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.

Exhibit No.	Description
10.18**	<u>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.</u>
10.19**	<u>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.</u>
10.20**	<u>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.</u>
10.21**	<u>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.</u>
10.22**	<u>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.</u>
10.23**	<u>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.</u>
10.24**	<u>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.</u>
10.25**	<u>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.</u>
10.26**	<u>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.</u>
10.27**	

Employment Agreement, dated September 1, 2017, by and between the Registrant and Richard Batycky. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K filed on March 1, 2018.

10.28\*\* 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.

10.29\*\* 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.

10.30 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.

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Exhibit Description  
No.

- 10.31 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.
- 10.32 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.
- 10.33 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.
- 10.34 Amendment A, 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.
- 10.35 Amendment B, 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.
- 10.36 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.
- 10.37 Letter agreement dated March 25, 2015, between Civitas Therapeutics, Inc. and Alkermes, Inc. regarding extension of the Sublease dated December 27, 2010, by and between Civitas Therapeutics, Inc. and Alkermes, Inc. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2015.
- 10.38 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.
- 10.39 Amendment C, dated October 11, 2017, by and between North River Everett Ave, LLC (as successor to H&N Associates, LLC) and Civitas Therapeutics, Inc. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2017.

- 10.40 Amendment D, dated March 29, 2018, by and between North River Everett Ave, LLC (as successor to H&N Associates, LLC) and Civitas Therapeutics, Inc. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2018.
- 10.41 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.
- 10.42\* 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.
- 10.43 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.

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Exhibit Description  
No.

10.44\* 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.

10.45\* 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.

10.46 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.

10.47\* 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.

10.48 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.

10.49\* 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.

10.50\* 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.

10.51 Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

10.52 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.

10.53

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.

10.54 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.

10.55\* 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.

10.56\* 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.

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Exhibit Description  
No.

- 10.57\* 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.
- 10.58\* 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.
- 10.59\* 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.
- 10.60\* 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.
- 10.61 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.
- 10.62\* 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.
- 10.63\* 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.
- 10.64\* 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.
- 10.65\* 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.
- 10.66\*

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.

10.67 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.

10.68\* 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
10.69*	<u>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.</u>
10.70*	<u>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.</u>
10.71*	<u>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.</u>
10.72	<u>Cooperation Agreement dated February 27, 2018, by and between the Registrant and Scopia Capital Management LP. Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed February 28, 2018.</u>
21	<u>List of Subsidiaries of the Registrant.</u>
23	<u>Consent of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm.</u>
31.1	<u>Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.</u>
31.2	<u>Certification by the Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.</u>
32.1	<u>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.</u>
32.2	<u>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.</u>

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.

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Item 16. Form 10-K Summary.

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 27<sup>th</sup> day of February, 2019.

Acorda Therapeutics, Inc.

By: /s/ Ron Cohen, M.D.  
Ron Cohen, M.D.

President and Chief Executive Officer

Signature	Title	Date
/s/ Ron Cohen, M.D. Ron Cohen, M.D.	President, Chief Executive Officer and Director	February 27, 2019
/s/ David Lawrence, M.B.A. David Lawrence, M.B.A.	Chief, Business Operations and Principal Accounting Officer	February 27, 2019
/s/ Barry Greene Barry Greene	Director	February 27, 2019
/s/ Peder K. Jensen, M.D. Peder K. Jensen, M.D.	Director	February 27, 2019
/s/ John P. Kelley John P. Kelley	Director	February 27, 2019
/s/ Sandra Panem, Ph.D. Sandra Panem, Ph.D.	Director	February 27, 2019
/s/ Lorin J. Randall Lorin J. Randall	Director	February 27, 2019
/s/ Steven M. Rauscher, M.B.A. Steven M. Rauscher, M.B.A.	Director	February 27, 2019
/s/ Catherine D. Strader, Ph.D. Catherine D. Strader, Ph.D.	Director	February 27, 2019

