

**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, 2019

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)

420 Saw Mill River Road, Ardsley, New York
(Address of principal executive offices)

13-3831168
(I.R.S. Employer
Identification No.)

10502
(Zip Code)

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock \$0.001 par value	ACOR	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 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 28, 2019, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was \$362,821,066. 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 28, 2019. Exclusion of shares held by any person should not be construed to indicate that the person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that the person is controlled by or under common control with the registrant.

As of February 20, 2020, the registrant had 47,997,023 shares of common stock, par value \$0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement for its 2020 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2019. 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.
2019 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; we may need to raise additional funds to finance our operations, repay outstanding indebtedness or satisfy other obligations, and we may not be able to do so on acceptable terms or at all; 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; 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," "Inbrija," and "ARCUS." Also, our marks "Fampyra" and "Inbrija" are registered marks 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 market Inbrija (levodopa inhalation powder), which is approved in the U.S. for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa. Inbrija is for as needed use and utilizes our 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. We also 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 (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Inbrija is marketed in the U.S. through our own specialty sales force and commercial infrastructure, and is being distributed primarily through a network of specialty pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Our Inbrija launch activities have been focused on physician awareness and market access. We are maintaining these efforts while increasing focus on patient awareness, education and training. 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. We project peak U.S. annual net revenue of Inbrija to be in the range of \$300 to \$500 million.

On September 24, 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for use in what were then the 28 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the United Kingdom left the European Union on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will end on December 31, 2020, unless it is extended. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

We have been engaged in litigation with generic drug manufacturers relating to certain Ampyra patents, which is further described below and in Part I, Item 3 of this report. In 2017, a U.S. District Court issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated other Ampyra patents that were set to expire between 2025 and 2027. In September 2018, a U.S. Court of Appeals upheld this decision, and in October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. As a result, our patent exclusivity with respect to Ampyra terminated on July 30, 2018, and we have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that have been marketed since the Court of Appeals decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

On October 23, 2019, we announced a corporate restructuring to reduce costs and focus our resources on the commercial launch of Inbrija, which was our key strategic priority for the remainder of 2019 and will remain the priority for 2020. As part of the restructuring, we reduced headcount by approximately 25% through a reduction in force. The majority of the reduction took place in the fourth quarter of 2019 immediately after the announcement, and the remainder will be completed by the first quarter of 2020. We expect to realize estimated annualized cost savings related to headcount reduction of approximately \$21.0 million, beginning in the second quarter of 2020. We are continuing our efforts to manage our cost structure, such as by identifying potential operating efficiencies and opportunities to convert fixed costs to variable costs.

On December 26, 2019, we announced the successful completion of a private exchange of \$276 million of our convertible senior notes due in 2021 in exchange for a combination of approximately \$207 million aggregate principal amount of newly-issued convertible senior secured notes due 2024 and \$55.2 million in cash. The new convertible senior

secured notes have a conversion price of approximately \$3.50 per share. As a result of the exchange, approximately \$69 million of convertible senior notes due in 2021, with a conversion price of \$42.56, remain outstanding. We are evaluating alternatives to address the remaining portion of the convertible notes due 2021, and this is a top priority in addition to our focus on the Inbrija launch. Refer to Note 10 to our Consolidated Financial Statements included in this report for more information about the terms and conditions of the 2021 and 2024 convertible notes.

As of December 31, 2019, we had cash, cash equivalents, short-term investments and restricted cash of approximately \$169 million. Restricted cash includes \$42.7 million in escrow related to the 6% semi-annual interest portion of the new convertible senior secured notes due 2024. If we elect to pay interest due in stock, the cash equivalent will be released from escrow.

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 (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Net revenue for Inbrija was \$15.3 million for the year ended December 31, 2019. We project peak U.S. annual net revenue of Inbrija to be in the range of \$300 to \$500 million.

On September 24, 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for use in what were then the 28 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the United Kingdom left the European Union on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will end on December 31, 2020, unless it is extended. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

Inbrija 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 pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our neuro-specialty sales and marketing team, built through our commercialization of Ampyra, includes our own 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 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. Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Our Inbrija launch activities have thus far been focused on physician awareness and market access. As we enter our next phase of the launch, we will be maintaining these efforts while increasing focus on patient awareness, education and training.

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 offers several support options, including: a 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 have implemented a no-cost sample program, available at physician offices, to enable patients and their physicians to assess the value of Inbrija before the patient incurs out-of-pocket co-pay or co-insurance costs. In addition, we have implemented a

free trial program, available through the Inbrija hub, for commercially insured patients who cannot access the free samples because of offices and institutions that have policies that prohibit samples.

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 of 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 for as needed use and utilizes our 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 new product exclusivity, through December 2021, as posted in the Orange book.

Information about our Inbrija clinical trials and safety profile is set forth below under *Our Products and Product Pipeline*.

Ampyra

Ampyra was approved by the FDA in January 2010 to improve walking in adults with multiple sclerosis. 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 \$163.2 million for the year ended December 31, 2019. 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 in September 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing *en banc*. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. This litigation is discussed further 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

Information about Ampyra clinical trials and safety profile is set forth below under *Our Products and Product Pipeline*.

ARCUS Product Development

We have been 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 believe there are potential opportunities with central nervous system, or CNS, as well as non-CNS, disorders.

Our ARCUS development has been focused on a program for acute treatment of migraine. Existing oral therapies for migraine can be associated with slow onset of action and gastrointestinal challenges. 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. We have been evaluating therapeutic candidates for their suitability to move forward with this program. Due to the

restructuring described above and associated cost-cutting measures, we have deferred consideration of further investment into potential new ARCUS applications in migraine pending additional progress with the Inbrija commercial launch in the U.S.

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 (funding for which has not been impacted by the restructuring) could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

Other Research and Development Programs

Our other research and development programs include rHlgM22 and cimaglermin alfa. rHlgM22 is a remyelinating antibody that is a potential therapeutic for multiple sclerosis. Data from a Phase 1 safety and tolerability trial showed that a single dose of rHlgM22 was not associated with any safety signals. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. 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. We initiated a Phase 1b clinical trial assessing three doses of cimaglermin alfa in people with heart failure, but discontinued enrollment and then received an FDA clinical hold based on the occurrence of a case of hepatotoxicity (liver injury). The FDA clinical hold was lifted after we presented additional data on the hepatotoxicity, but we have not since restarted any clinical study of cimaglermin alfa. We are considering next steps for these programs, which could include potential partnering or out-licensing, but due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of any further investment pending additional progress with the Inbrija commercial launch in the U.S.

We were previously developing SYN120 and BTT1023, but have no current plans to further invest in these programs. 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 were developing BTT1023 (timolimumab) for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. The University of Birmingham was conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, but the university informed us in January 2019 that they terminated the trial. Pending review of final data from the discontinued trial, we intend to evaluate the potential for out-licensing.

Our Strategy

Our long-term 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. For 2020, our strategic priorities include:

- **Inbrija (levodopa inhalation powder):** Driving the commercial success of Inbrija, by continuing our efforts on physician awareness and market access, and increasing our focus on patient awareness, education and training.
- **Ampyra:** Continuing to support the Ampyra franchise, including activities intended to maintain brand loyalty.
- **Financial Management:** Focusing on financial discipline and continued management of our cost structure, such as by identifying potential operating efficiencies and opportunities to convert fixed costs to variable costs.

Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Inbrija (levodopa inhalation powder)	Parkinson's disease OFF periods/episodes	FDA and EMA-approved and marketed in the U.S.	Acorda/Worldwide; seeking to out-license/partner outside of the U.S.
Ampyra (dalfampridine)	MS	FDA-approved and marketed in the U.S.	Acorda (U.S.)
Fampyra* (fampridine)	MS	Approved in a number of countries across Europe, Asia and the Americas	Biogen (outside U.S.)
Selincro** (nalmefene)	Alcohol Dependence	EMA-approved	Lundbeck
Research and Development Programs	Proposed Therapeutic Area(s)	Stage of Development	Marketing Rights
ARCUS for acute migraine	Acute migraine	Research stage; further development into potential new ARCUS applications in migraine deferred	Acorda/Worldwide
Cimaglermin alfa	Heart failure	Phase 1b clinical trial hold lifted in April 2017; further development deferred; potentially available for partnering or out-licensing	Acorda/Worldwide; seeking to out-license/partner
rHIgM22	Multiple Sclerosis	Phase 1 trial completed; further development deferred; potentially available for partnering or out-licensing	Acorda/Worldwide
SYN120	Parkinson's disease-related dementia	Phase 2 clinical trial completed; endpoints not met; no current plans for further development, available for out-licensing	Acorda (Biotie)/Worldwide
BTT1023 (timolumab)	Primary Sclerosing Cholangitis	Phase 2 proof-of-concept clinical trial terminated; no current plans for further development, available for out-licensing	Acorda (Biotie)/Worldwide;

* 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 our Biotie subsidiary 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. We are focused on developing and marketing therapeutics targeted to the conditions described below, although we have deferred investment in our research and development programs pending additional progress with the Inbrija commercial launch in the U.S. 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 disease. Current treatment strategies are focused on the management and reduction of the major symptoms of the disease and related disabilities. These therapies either aim to supplement dopamine levels in the brain, mimic the effect of dopamine in the brain by stimulating dopamine receptors or prevent the enzymatic breakdown of dopamine. The standard of care for the treatment of Parkinson's disease symptoms is oral carbidopa/levodopa. Approximately 70% of people with Parkinson's disease in the U.S. are treated with oral carbidopa/levodopa. Effective control of Parkinson's disease symptoms is referred to as an ON state.

As Parkinson's disease progresses, 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.

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 (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Net revenue for Inbrija was \$15.3 million for the year ended December 31, 2019. We project peak U.S. annual net revenue of Inbrija to be in the range of \$300 to \$500 million.

On September 24, 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for use in what were then the 28 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the United Kingdom left the European Union on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will end on December 31, 2020, unless it is extended. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

Inbrija 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 pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our neuro-specialty sales and marketing team, built through our commercialization of Ampyra, includes our own 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 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. Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Our Inbrija launch activities have thus far been focused on physician awareness and market access. As we enter our next phase of the launch, we will be maintaining these efforts while increasing focus on patient awareness, education and training.

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 offers several support options, including: a 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 have implemented a no-cost sample program, available at physician offices, to enable patients and their physicians to assess the value of Inbrija before the patient incurs out-of-pocket co-pay or co-insurance costs. In addition, we have implemented a free trial program, available through the Inbrija hub, for commercially insured patients who cannot access the free samples because of offices and institutions that have policies that prohibit samples.

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 of 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 for as needed use and utilizes our 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 new product exclusivity, through December 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 adults with multiple sclerosis. This was demonstrated by an increase in walking speed. Ampyra demonstrated efficacy in people with all four major types of multiple sclerosis (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 in September 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing *en banc*. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. This litigation is discussed further 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

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 net 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. We have filed a request to have these four patents delisted from the Orange Book. The litigation is discussed further in Part I, Item 3 of this report. The sixth Orange Book-listed patent (U.S. Patent No. 9,918,973), set to expire in 2024, was more recently issued and was not involved in the litigation. We have filed a request to have this patent delisted from the Orange Book. We note that this patent did not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that were 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 appealed the decision. In the Appeal Hearings in September 2019, the European Technical Board of Appeals upheld claims covering Fampyra in both the EP 1732548 patent and the EP 2377536 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. In June 2019, the EPO granted EP 2460521, which is a divisional of the EP 2377536 patent. In November 2019, we filed a request withdrawing our approval of the text on which EP 2460521 was granted, resulting in termination of the patent. 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 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. The data presented continue to be consistent with those reported in double-blind clinical trials, with incidence of reported seizure remaining stable over time.

The FDA's approval letter included certain post-marketing study requirements and confirmed certain commitments made by us with respect to Ampyra, all of which we have now completed. The post-marketing requirements included additional animal toxicology studies to evaluate certain impurities, in-vitro receptor binding and abuse potential studies in animals, and an evaluation of clinical adverse events related to abuse 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

We have been 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 believe there are potential opportunities with central nervous system, or CNS, as well as non-CNS, disorders.

Our ARCUS development has been focused on a program for acute treatment of migraine. Existing oral therapies for migraine can be associated with slow onset of action and gastrointestinal challenges. 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. We have been evaluating therapeutic candidates for their suitability to move forward with this program. Due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of further investment into potential new ARCUS applications in migraine pending additional progress with the Inbrija commercial launch in the U.S.

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 (funding for which has not been impacted by the restructuring) could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

Other Research and Development Programs

Our other research and development programs include rHlgM22 and cimaglermin alfa. rHlgM22 is a remyelinating antibody that is a potential therapeutic for multiple sclerosis. Data from a Phase 1 safety and tolerability trial showed that a single dose of rHlgM22 was not associated with any safety signals. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. 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. We initiated a Phase 1b clinical trial assessing three doses of cimaglermin alfa in people with heart failure, but discontinued enrollment and then received an FDA clinical hold based on the occurrence of a case of hepatotoxicity (liver injury). The FDA clinical hold was lifted after we presented additional data on the hepatotoxicity, but we have not since restarted any clinical study of cimaglermin alfa. We are considering next steps for these programs, which could include potential partnering or out-licensing, but due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of any further investment pending additional progress with the Inbrija commercial launch in the U.S.

We were previously developing SYN120 and BTT1023, but have no current plans to further invest in these programs. 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 were developing BTT1023 (timolumab) for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. The University of Birmingham was conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, but the university informed us in January 2019 that they terminated the trial. Pending review of final data from the discontinued trial, we intend to evaluate the potential for out-licensing.

Sales, Marketing and Market Access

Inbrija (levodopa inhalation powder)

Inbrija 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 pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our neuro-specialty sales and marketing team, built through our commercialization of Ampyra, includes our own 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 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. Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Our Inbrija launch activities have been focused on physician awareness and market access. We are maintaining these efforts while increasing focus on patient awareness, education and training.

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 offers several support options, including: a 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 have implemented a no-cost sample program, available at physician offices, to enable patients and their physicians to assess the value of Inbrija before the patient incurs out-of-pocket co-pay or co-insurance costs. In addition, we have implemented a free trial program, available through the Inbrija hub, for commercially insured patients who cannot access the free samples because of offices and institutions that have policies that prohibit samples.

Ampyra

Ampyra is marketed in the U.S. through our own specialty sales force and commercial infrastructure, which we are supplementing with contract sales representatives, and is distributed in the U.S. primarily through a network of specialty pharmacies, which deliver the medication to patients by mail. 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 multiple sclerosis, 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.

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 Investigational New Drug Applications, or 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 mid-single digit percentage royalty on net sales. For licensed products sold by a collaboration partner, Civitas will pay Alkermes the lower of either (1) a mid-single digit percentage royalty on collaboration partner net sales of licensed products in any given calendar year, or (2) 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 collaboration partner royalty paid be less than a low-single digit percentage of collaboration partner net sales of the licensed product in any given calendar year.

Civitas has the right to terminate the Alkermes agreement at any time upon giving 90 days' written notice. The Alkermes agreement may also be terminated by either party with respect to certain specified uncured breaches following notice and the expiration of a cure period.

Subject to the termination provisions described above, 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.

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). Under the Collaboration Agreement, Ampyra is marketed by Biogen as Fampyra outside the U.S. Fampyra has been approved in a number of countries across Europe, Asia and the Americas.

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., unless rights to a particular country terminate under the terms of the Collaboration Agreement, 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, spinal cord injury or other demyelinating conditions, except that we may exploit the licensed products anywhere in the world following termination of the Collaboration Agreement.

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 percentage tiered royalties on net 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 royalties 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 New Drug Application, or 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 upon 90 days’ 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 termination provisions described above, 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 a threshold level of competition in that country.

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.

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. Our manufacturing team is led by individuals who are highly experienced with manufacturing of ARCUS products and other commercial products.

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.

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. We may need 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 increased the size of the facility to approximately 95,000 square feet. The project has added a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and it has created additional warehousing space for manufactured product. Although the project was substantially completed in late 2019, it will take additional time after completion of construction to obtain the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA, Massachusetts state environmental permits, and approvals from other regulatory authorities. 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. Expanding our manufacturing capacity required substantial additional expenditures and completion of the project will require various regulatory approvals and permits. Further, if we use the expanded manufacturing capacity, 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 need the expanded capacity but are delayed in or prevented from completing the expansion and obtaining necessary regulatory approvals, 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 commercially 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 commercially 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 and other 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 single third-parties to supply critical requirements to manufacture Inbrija. This includes a third party manufacturer to make the inhaler, a supplier for levodopa, or L-dopa, the active pharmaceutical ingredient, or API, in Inbrija, as well as excipients used in the manufacture of Inbrija. Also, we rely on a single third party to package Inbrija kits after they are manufactured. Any failure or delay by a third-party manufacturer, packager or supplier may delay or impair our ability to meet demand for Inbrija and could delay, prevent or impair our commercialization of Inbrija.

Although in some cases we have contracts for these requirements, we cannot be certain that those contracts will be renewed on commercially reasonable terms, if at all. We do not have contracts with the suppliers of the API and a critical excipient used in the manufacture of Inbrija, which exposes us to the risk that they could discontinue supply at any time. Manufacturers, packagers or suppliers may choose not to conduct business with us at all, or may choose to discontinue doing business with us, for example if they determine that our particular business requirements would be unprofitable or otherwise not appropriate for their business.

We currently 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 harm our commercialization of Inbrija.

We are in the process of transitioning from our existing inhaler supplier to a new inhaler supplier. Transition to a new inhaler supplier is a lengthy and complex process. Among other things, we have to revalidate the molding and assembly process pursuant to FDA requirements and we must ensure that inhalers manufactured by the new supplier adhere to other applicable regulatory requirements. During this transition process, we are at an increased risk for an interruption in supply as we wind down our relationship with our existing supplier and wait for the new supplier to implement the needed operational changes to be capable of manufacturing the inhalers and obtain all needed regulatory approvals. If this process causes an interruption in supply, this might render us unable to meet the demand for Inbrija and our business could be adversely affected.

All other 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.

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 and Alkermes rely on a single third-party manufacturer to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra, and also on a single supplier for a critical excipient used in the manufacture of Ampyra. We also rely on a single third party to package Ampyra. If these companies experience any disruption in their operations, our supply of Ampyra could be delayed or interrupted until the problem is solved or we locate another source of supply or another packeter, which may not be available. We may not be able to enter into alternative supply or packaging arrangements on terms that are commercially reasonable, if at all. Any new supplier or packager would also be required to qualify under applicable regulatory requirements. Because of these and other factors, we could experience substantial delays before we are able to obtain qualified replacement products or services from any new supplier or packager.

Also, 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.

Intellectual Property

We have patent portfolios relating to: Ampyra/aminopyridines; Inbrija (levodopa inhalation powder); the ARCUS drug delivery technology; SYN120; BTT1023; cimaglermin alfa/neuregulins; and remyelinating antibodies/antibodies relating to nervous system disorders. These portfolios are composed 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

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. We have filed a request to have these four patents delisted from the Orange Book. The litigation is discussed further in Part I, Item 3 of this report. The sixth Orange Book-listed patent (U.S. Patent No. 9,918,973), set to expire in 2024, was more recently issued and was not involved in the litigation. We have filed a request to have this patent delisted from the Orange Book. We note that this patent did not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that were 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, Synthron 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 Synthron B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthron 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 appealed the decision. In the Appeal Hearings in September 2019, the European Technical Board of Appeals upheld claims covering Fampyra in both the EP 1732548 patent and the EP 2377536 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. In June 2019, the EPO granted EP 2460521, which is a divisional of the EP 2377536. In November 2019, we filed a request withdrawing our approval of the text on which EP 2460521 was granted, resulting in termination of the patent. 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 further 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 new product exclusivity, through December 21, 2021, as posted in the Orange Book.

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.

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.

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.

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,” “Inbrija,” and “ARCUS.” We also have trademark registrations for “Fampyra,” “Kampyra” and “Inbrija” 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

Inbrija competes against other therapies approved for intermittent, or as needed, 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 receipt of the CRL delayed but did not 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. Sunovion has resubmitted its NDA and in December 2019 announced that the NDA was accepted by the FDA and the expected action date by the FDA under the Prescription Drug User Fee Act is May 21, 2020.

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. Also, we are aware that at least one company, Impel Neuropharma, is developing intranasally delivered levodopa therapies which, if approved, might compete with Inbrija.

Ampyra/MS

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, or the Federal Circuit, which issued a ruling in September 2018 upholding the District Court’s decision (the “Appellate Decision”). In January 2019, the Federal Circuit denied our petition for rehearing en banc. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time. Our litigation with the generic drug manufacturers is described further 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

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.

FDA Regulation of Drugs and Drug Product Approval

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, 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 law requires the submission of registry and results information for most clinical trials to a publicly available database at www.clinicaltrials.gov. These requirements generally do not apply to Phase 1 clinical trials.

U.S. law requires that trials conducted to support approval for product marketing be "adequate and well controlled." This entails a number of requirements, including that there is a clear statement of 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 take 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 authorities 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, 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 can vary widely from country to country. The foreign regulatory approval process involves risks very similar to those associated with FDA approval discussed above.

Within the European Union, or EU, it is possible to obtain marketing authorizations that enable an approved product to be marketed in the entire European Economic Area, or EEA, which is composed of the EU member states plus Iceland, Lichtenstein and Norway. This can be 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 through the “mutual recognition” or “decentralized” procedure, which provides for the approval of a product by one or more member states based on an assessment of an application review performed by one or more other member states. The foreign regulatory approval process involves risks very similar to those associated with FDA approval discussed above.

On September 19, 2019, the European Commission granted a marketing authorization to Inbrija, for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson’s disease treated with a levodopa/dopa-decarboxylase inhibitor. This marketing authorization was granted through the centralized procedure and is therefore valid throughout the EEA. A new centralized marketing authorization is valid for five years and once renewed is usually valid for an unlimited period thereafter. If a product approved under the centralized procedure is not marketed in at least one EU member state within three years of the grant of the marketing authorization, the marketing authorization lapses under the EU’s sunset rules.

Products such as Inbrija that combine a drug and device co-packaged in a single presentation are regulated under the EU’s medicines rules and approved under a single marketing authorization. As part of the marketing authorization process, the applicant must demonstrate to EU regulators that the device component conforms with the essential legal requirements for medical devices under EU law and, accordingly, bears the CE-mark. Currently, the essential requirements are contained in the EU Medical Device (Directive 98/79/EC), or MDD. As of May 26, 2020, the Medical Device Directive will be repealed and replaced by the new EU Medical Device Regulation (Regulation (EU) 2017/745), or MDR, and the essential requirements for medical devices set out therein will apply from that date, subject to a transitional period. The transitional period applies to medical devices whose certificates of conformity were issued by a notified body under the MDD after May 25, 2017. The transitional period permits devices to be placed on the market under such circumstances until the sooner of (i) the date of expiry of the certificate; or (ii) a long stop date of May 27, 2024.

In the EU, innovator products, approved on the basis of a complete and independent data package are usually entitled to a total of 10 years of regulatory exclusivity from the date of first approval. This means that for a period of eight years, EU authorities may not accept marketing authorization applications that rely on the safety and efficacy data contained in the marketing authorization dossier of the innovator product. At the end of that period, generic applicants may file and authorities may review such applications. The innovator product is protected by a further two years of market exclusivity before any generic product may launch, such that the innovator product benefits from total regulatory exclusivity period of 10 years.

Inbrija received its EU marketing authorization on the basis of a complete and independent data package and therefore benefits from the 10-year regulatory exclusivity period described above (*i.e.*, eight years of data exclusivity plus two additional years of market exclusivity).

The fact that a product benefits from regulatory exclusivity does not prevent competitors from obtaining a marketing authorization based on their own independently generated data. EU regulatory authorities have stated that they consider levodopa, which is the active substance contained in Inbrija, to be a “known active substance.” In principle, this means that generic competitors could – during Inbrija’s regulatory exclusivity period -- file and receive a marketing authorization referring, for example, to data from the dossiers of older, established products containing levodopa, supplemented with other data that the competitor generates itself (*e.g.*, demonstrating the safety and efficacy of the inhaled dosage form).

As the marketing authorization holder for Inbrija in the EU, we are required to comply with a number of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal products. In particular, a marketing authorization holder's obligations include complying with the EU's pharmacovigilance or safety reporting rules. All marketing authorizations include a Risk Mitigation Plan, or RMP, describing the risk mitigation measures that a marketing authorization holder must put in place, including post-authorization obligations such as additional safety monitoring or the conduct of post-authorization safety studies. RMPs are intended to be updated throughout the lifetime of a medicine and marketing authorization holders are expected to submit updated RMPs as new information becomes available or at the request of EU regulatory authorities.

Other regulatory requirements relate, for example, to the manufacturing of products and active pharmaceutical ingredients in accordance with good manufacturing practice standards. The European Medicines Agency, or EMA, is responsible for coordinating inspections conducted by member state competent authorities to verify compliance with various aspects of the EU's medicines rules. In respect of inspecting manufacturing sites, in July 2019 the EU and U.S. implemented a mutual recognition agreement, or MRA, under which EU and U.S. regulators will now rely on each other's inspections for manufacturing sites for human medicines in their respective territories.

Non-compliance with EU requirements, particularly regarding safety monitoring or pharmacovigilance, can also result in the marketing authorization holder becoming subject to significant financial penalties. Inspections may be routine or triggered by issues arising during the assessment of the dossier or by other information, such as previous inspection experience. Inspections usually are requested during the initial review of a marketing authorization application, but could arise post-authorization. Regulatory authorities in the EU may suspend, revoke or vary a marketing authorization of a medicinal product if they consider that the product is harmful, lacks therapeutic efficacy, its risk-benefit balance is not favorable, its qualitative and quantitative composition is not as declared or for certain other reasons.

A marketing authorization holder may not delegate its ultimate legal responsibility for complying with its legal requirements nor any liability for failing to do so. However, the marketing authorization holder may delegate the performance of certain tasks to third parties, provided this is appropriately documented and managed. It is also possible to transfer a marketing authorization to a third party.

The EU's medicines rules do not require the launch of a product in a particular member state. However, once a medicinal product is launched in a member state, the marketing authorization holder is under a legal obligation to take steps to ensure it meets demand for the product in that country. The EU's medicines rules also contain so-called sunset clauses, which provide that a marketing authorization will cease to be valid if the product in question is not placed on the market in at least one jurisdiction in the EEA within three years of the grant of the marketing authorization.

As in the U.S., EU law and the regulatory systems in EU member states tightly regulate the advertising and promotion of medicinal products. Unlike in the U.S., EU law prohibits the advertising of prescription-only medicinal products (such as Inbrija) directly to patients or the general public. Advertising to healthcare professionals is permitted, provided certain conditions are met. Certain activities fall outside the scope of EU medicines advertising rules, such as the dissemination of factual, informative non-promotional announcements and reference material. All advertising for a medicine must be consistent with the product's approved Summary of Product Characteristics, or SmPC, factual, accurate, balanced and non-misleading. Advertisements to healthcare professionals must adhere to certain specific requirements. For example, the provision of inducements to healthcare professionals designed to promote the prescription, supply, sale or consumption of medicinal products is not permitted. The promotion of a medicine pre-approval is prohibited as is the promotion of off-label use and promotion that is inconsistent with the product's SmPC. While EU law provides a framework for medicines advertising rules, national laws, guidance and regulatory codes (or self-regulatory codes) can lead to differences in approach at the national level.

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 marketplace 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 discounts under a statutory program available to entities identified under Section 340B of the Public Health Service Act.

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 other aspects of the ACA may be altered or repealed by future legislation. In December 2018, a U.S. federal district court judge in Texas found the ACA's individual mandate to be unconstitutional and therefore the entire law to be invalid. In December 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the ruling regarding the individual mandate, but remanded the case to the district court for additional analysis of the question of severability and whether portions of the law remain invalid. It is likely that the case will be appealed to the U.S. Supreme Court. 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 grant of a marketing authorization in the EU does not necessarily guarantee that a product will be reimbursed in a particular member state. Rather, the approach taken varies from member state to member state and in most cases a separate reimbursement approval is required. 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 22, 2020, we had 344 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. 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 2020 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2020 Proxy Statement within 120 days after the end of our 2019 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 2020 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 became commercially available in the U.S. in the first quarter of 2019.

As of December 31, 2019, we had an accumulated deficit of approximately \$666.8 million. We had a net loss of \$273.0 million for the year ended December 31, 2019 and a net income of \$33.7 million for the year ended December 31, 2018. 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, a U. S. District Court upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated other Ampyra patents that were set to expire between 2025 and 2027. In September 2018, a U.S. Court of Appeals upheld this decision, and in October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. As a result, our patent exclusivity with respect to Ampyra terminated on July 30, 2018, and we have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that have been marketed since the Court of Appeals decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

Our prospects for achieving and sustaining profitability in the future will depend primarily on how successful we are in successfully commercializing Inbrija, particularly in the U.S. and to a lesser extent in the EU or other countries outside of the U.S. 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.

Our restructuring may not adequately reduce our expenses, and we may encounter difficulties associated with the related organizational change.

In October 2019, we implemented a corporate restructuring to reduce costs and focus our resources on the launch of Inbrija (levodopa inhalation powder). As part of this restructuring, we reduced headcount by approximately 25%. Further restructuring activities may be required in the future, depending in particular on the rate of decline in our sales of Ampyra due to generic competition and whether we are able to sufficiently increase sales of Inbrija. Our restructuring may have other unintended consequences as well, including, for example, making it more difficult for us to attract and retain highly skilled personnel in a competitive environment. We may also experience operational disruptions from our reduction in personnel. The loss of key personnel such as in regulatory and manufacturing functions could disrupt our operations and sales force attrition could harm our ability to market and sell Inbrija and Ampyra. We have recently experienced workforce attrition in various functions across our business, and we may not be able to adjust our operations in response to prevent disruption to our business.

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, including the remainder of our convertible senior notes that mature in June 2021.

We will need to expend substantial resources for commercialization of our marketed products, including costs associated with the commercialization of Inbrija. In addition, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including our new convertible senior secured notes due 2024 and the remaining portion of our convertible senior notes that matures in June 2021, 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. Also, our research and development programs will not generate any revenues for the foreseeable future, if ever, because they are all in early stages, pharmaceutical development is subject to numerous risks including those described elsewhere in these risk factors, and generally we have discontinued funding our research and development pending additional progress with the Inbrija commercial launch in the U.S. 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, subject to the restrictions contained in the indenture governing our new convertible senior secured notes due 2024, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous and which are likely to be 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 new convertible senior secured notes due 2024, the remaining portion of our convertible senior notes due 2021, or to repurchase notes upon a fundamental change.

Holders of both our new convertible senior secured notes due 2024 and the remaining portion of our convertible senior notes due 2021 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. Our ability to settle conversions and make interest payments (including make-whole interest payments on the new 2024 notes) using shares of our common stock is subject to limitations until the time, if any, that our stockholders have approved (i) the issuance of more than 19.99% of our outstanding shares in accordance with Nasdaq listing standards and (ii) an amendment to our certificate of incorporation to increase the number of authorized shares. We intend to seek stockholder approval of these matters at our 2020 Annual Meeting of Stockholders, but if we are unable to obtain stockholder approval of these items prior to the earliest of July 31, 2020, the date stockholders approve the amendment to our certificate of incorporation and the commencement of any bankruptcy, insolvency, reorganization or similar proceeding, we will be required to make cash payments to settle conversions and make interest payments (including make-whole interest payments). This use of cash may have a material adverse effect on our liquidity. Furthermore, we may not have enough available cash or be able to obtain financing at the time we are required to make cash payments with respect to either series of notes. In addition, our ability to repurchase the notes or to pay cash upon conversion of the notes may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the applicable indenture pursuant to which the notes were issued or to make cash payments to settle conversions

or make interest payments (including make-whole interest payments on the new 2024 notes) as required by the applicable indenture, would constitute a default under the applicable indenture.

The indenture governing our new convertible senior secured notes due 2024 contains restrictions that may make it more difficult to execute our strategy or to effectively compete.

Subject to certain exceptions and qualifications, the indenture governing our new convertible senior secured notes due 2024 restricts our ability and the ability of certain of our subsidiaries to, among other things, (i) pay dividends or make other payments or distributions on capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) make certain investments, (iii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, which includes, among other items, indebtedness incurred to refinance our convertible senior notes, (iv) create liens on assets, (v) sell assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell all or substantially all assets. The indenture also requires us to make an offer to repurchase the new convertible senior secured notes due 2024 upon the occurrence of certain asset sales. These restrictions may make it difficult to successfully execute our business strategy or effectively compete with companies that are not similarly restricted.

An event of default under the indenture governing our new convertible senior secured notes due 2024 could adversely affect our liquidity and our ability to retain title to our assets, including our intellectual property.

The indenture governing our new convertible senior secured notes due 2024 provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the new convertible senior secured notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the new convertible senior secured notes in accordance with the Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the notes indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the notes indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by us to make required payments under our other indebtedness or certain subsidiaries having an outstanding principal amount of \$30.0 million or more, (vii) failure by us or certain subsidiaries to pay final judgments aggregating in excess of \$30.0 million, (viii) certain events of bankruptcy or insolvency and (ix) the commercial launch in the U.S. of a product determined by the FDA to be bioequivalent to Inbrija.

In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to us, all outstanding new convertible senior secured notes due 2024 will become due and payable immediately without further action or notice. If any other event of default occurs and is continuing, the trustee or the holders of at least 25% in aggregate principal amount of the then outstanding new convertible senior secured notes due 2024 may declare all the notes to be due and payable immediately. Such acceleration of our debt could have a material adverse effect on our liquidity if we are unable to negotiate mutually acceptable terms with the holders of the new convertible senior secured notes due 2024 or if alternate funding is not available to us. Furthermore, if we are unable to repay the new convertible senior secured notes due 2024 upon an acceleration or otherwise, we would be forced into bankruptcy or liquidation and we would lose title to substantially all of our assets, including our intellectual property.

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.

We face significant challenges in successfully commercializing our approved pharmaceutical products, including Inbrija. Generally, market acceptance of our products 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 third-party payers. Commercial success requires significant investment in sales, marketing and market access efforts, and is dependent on how well we develop and implement strategies for these efforts. Commercial success is also subject to numerous other risks, including those described below, some of which are described in further detail elsewhere in these risk factors:

- ***Market Access:*** Physicians may be discouraged from prescribing our products and/or patients may not fill or refill prescriptions for our products because of the reimbursement policies of third-party payers such as commercial insurance companies and government and government-sponsored payers such as Medicare. Our sales may suffer if Inbrija or other products are not listed on the preferred drug lists of third party payers, or if Inbrija or other products are on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies. Preconditions or other reimbursement limitations imposed by

third party payers may discourage physicians from prescribing Inbrija or other products because of the time and effort that may be needed by the prescribing physician to overcome these hurdles. Even if physicians prescribe Inbrija or another product, patients may not fill or refill the prescription if their out-of-pocket cost is too high, for example because of inadequate or lack of reimbursement from their insurance company or Medicare.

- *Safety and Efficacy:* Physicians may not prescribe our products if they do not consider our products as safe and effective for their labelled indication, 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 or, even if they do believe there is a potential benefit, they may stage or delay the use of Inbrija with patients or patient groups to evaluate patient feedback or for other reasons.
- *Side Effects:* Market acceptance of Inbrija or another product may be impeded by the occurrence of any side effects, adverse reactions, customer complaints or misuse (or any unfavorable publicity relating thereto) stemming from the use of the product or identified in ongoing or future studies. As described below in these risk factors, FDA-approved product labeling for Inbrija includes limitations, warnings and precautions, which may harm its market acceptance. For example, the Inbrija product label identifies cough as one of the most common adverse reactions observed in our clinical trials, and the risk of cough may discourage some patients from taking Inbrija, and the actual occurrence of cough may lead patients to discontinue Inbrija.
- *Competition:* The market for Inbrija may be adversely affected by 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 (and reimbursement available for) our products as compared to the pricing of (and reimbursement available for) competing or alternative products.
- *Intellectual Property:* The loss of intellectual property protection for our products would enable generic competition.

Also, in the U.S., the federal government provides 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 and could adversely affect our future prospects. 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 if 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, 2019, we had approximately \$214 million of NOLs. 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 generated 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. Of our existing NOLs, approximately \$120 million existed at December 31, 2019 and were incurred by our Biotie subsidiary. Our ability to use these Biotie NOL carryforwards will depend on the ability of that specific subsidiary to generate taxable income, and because we do not expect any taxable income from that subsidiary we currently do not assign any value to these 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 and authorities 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. Similar regulatory requirements exist for conducting clinical trials outside the U.S. For example, clinical trials conducted in the European Union, or EU, require notification to (or the authorization of) national competent authorities and a favorable opinion from a research ethics committee.

Both in the U.S. and foreign jurisdictions, 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. In the U.S., 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. In the EU, where Inbrija has received a marketing authorization, both the drug and device components are regulated under the EU's medicines rules, which, among other things, require the device component to comply with the essential legal requirements for medical devices. Failure to meet these requirements could adversely affect our ability to market Inbrija in the European Economic Area, or EEA.

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, for example in the U.S., any other requirements imposed by the applicant's NDA or BLA. All of our products and operations are subject to periodic inspections

by the FDA and other regulatory authorities. 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. In addition, in the EU, if we do not place a product (e.g., Inbrija) on the market within three years of its first marketing authorization, the EU marketing authorization would lapse under the EU's sunset rules.

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, federal and foreign laws and regulations, 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. We may need 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 both in the U.S. and foreign jurisdictions, such as in the EU where Inbrija has been granted a marketing authorization. If we or a collaborator launches Inbrija in an EU member state, such supply shortages could lead to a breach of the legal obligation to ensure continuity of supply.

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 commercially 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 and other 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.

We may not successfully complete the expansion of our Chelsea manufacturing facility.

We may need 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 increased the size of the facility to approximately 95,000 square feet. The project has added a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and has created additional warehousing space for manufactured product. Although the project was substantially completed in late 2019, it will take additional time after completion of construction to obtain the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA, Massachusetts state environmental permits, and approvals from other regulatory authorities.

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 required substantial additional expenditures and completion of the project will require various regulatory approvals and permits. Further, if we use the expanded manufacturing capacity, 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 need the expanded capacity but are delayed in or prevented from completing the expansion and obtaining necessary regulatory approvals, 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 commercially 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, including in the EU where Inbrija has received a marketing authorization. If we or a collaborator launches Inbrija in an EU member state, such an inability to meet demand could lead to a breach of the legal obligation to ensure continuity of supply.

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 expect to continue to rely on third parties for the supply of materials for research and development activities, particularly any future clinical trials we may conduct in the future. 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-parties to supply critical requirements to manufacture Inbrija. This includes a single third party manufacturer to make the inhaler, as well as single suppliers for the API and a critical excipient. Also, we rely on a single third party to package Inbrija kits. Any failure or delay by a third-party manufacturer, packager, or supplier may delay or impair our ability to commercialize Inbrija or to complete any future clinical studies that we may need to conduct. Although in some cases we have contracts for these requirements, we cannot be certain that those contracts will be renewed on commercially reasonable terms, if at all. We do not have contracts with the suppliers of the API and a critical excipient used in the manufacture of Inbrija, which exposes us to the risk that they could discontinue supply at any time. Manufacturers, packagers or suppliers may choose not to conduct business with us at all, or may choose to discontinue doing business with us, for example if they determine that our particular business requirements would be unprofitable or otherwise not appropriate for their business.

Our reliance on a 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. We currently rely on a single third party molding manufacturer for supply of the Inbrija inhalers, and are in the process of transitioning from this single supplier to a new single supplier. Transition to a new inhaler supplier is a lengthy and complex process. Among other things, we have to revalidate the molding and assembly processes pursuant to FDA requirements and we must ensure that inhalers manufactured by the new supplier adhere to other applicable regulatory requirements. During this transition process, we are at increased risk for an interruption in supply as we wind down our relationship with our existing supplier and wait for our new supplier to implement the needed operational changes to be capable of manufacturing the inhalers and obtain all needed regulatory approvals. If this process causes an interruption in supply, this might render us unable to meet the demand for Inbrija and our business could be adversely affected.

Our reliance on third party manufacturers, packagers, and suppliers subjects us to risks associated with their businesses and operations. For example, 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, packagers, and suppliers are subject to their own operational and financial risks that are outside of our control, and potentially their control also, that may cause them to suffer liquidity or operational problems and that could interfere with their business operations. For example, their operations and/or ability to source raw materials and other supplies may be interrupted by natural disasters, acts of war, terrorism, or disease outbreaks (such as the recent outbreak of COVID-19, or the novel coronavirus). 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, packagers and suppliers, must comply with cGMPs and will likely have to pass a pre-approval FDA inspection and potentially other inspections required by other regulatory authorities. Third-party manufacturers, packagers and suppliers are also subject to periodic inspections for cGMP compliance from the FDA and potentially other regulatory authorities. Failure to pass such inspections and otherwise satisfactorily complete the requisite approval regimen with respect to our products or product candidates may result in regulatory actions by the FDA and other regulatory authorities, 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, packagers or suppliers fails to perform their obligations to us or otherwise have an interruption in or discontinue supply to us, we may be forced to seek a different third party manufacturer, packager or supplier. In such event, we may experience significant delays associated with finding an alternative manufacturer, packager or supplier that is both available on commercially acceptable terms and conditions, and also properly qualified in accordance with our specifications and the requisite regulatory requirements, such as those of the FDA and other regulatory authorities. This transition may require time consuming and complex operational, testing, and regulatory approval requirements, and the process could interfere with product sales because of inadequate supply or cause interruptions of, or delays in, research and development programs. We may not be able to establish arrangements with an alternative manufacturer, packager 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, excipients 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 a single third-party manufacturer to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra, and also a single supplier for a critical excipient used in the manufacture of Ampyra. We also rely on a single third party to package Ampyra. If these companies experience any disruption in their operations, our supply of Ampyra could be delayed or interrupted until the problem is solved or we locate another source of supply or packager, which may not be available. We may not be able to enter into alternative supply or packaging arrangements on terms that are commercially reasonable, if at all. Any new supplier or packager would also be required to qualify under applicable regulatory requirements. Because of these and other factors, we could experience substantial delays before we are able to obtain qualified replacement products or services from any new supplier or packager.

Also, 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 and those in other applicable markets.

Our advertising and promotion activities are subject to stringent rules and requirements both in the U.S. and other jurisdictions, which are enforced and overseen by the FDA and other regulatory authorities in other jurisdictions. These rules and requirements vary from country to country and promotional practices and materials that are acceptable in one country may not be so in another. Importantly, unlike in the U.S., EU law prohibits the advertising of prescription-only medicinal products (such as Inbrija) directly to patients or the general public. Advertising to healthcare professionals is permitted, provided certain conditions are met.

Among other requirements, in the U.S. and EU, 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. In the U.S., 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 the relevant requirements, in the U.S. or other countries, 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, in the U.S., 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 Summary of Product Characteristics, or SmPC, in the EU marketing authorization contains a similar indication. The approved labeling in the U.S. and the EU SmPC also contain 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, third party payers or reimbursement authorities, 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.

In the U.S., EU and many other jurisdictions, we face significant risks if we promote our drugs “off-label,” i.e., for uses other than those approved by the appropriate regulatory authority in a territory (e.g., the FDA in the U.S.). 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. In the U.S., 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.” Similarly, although EU law does not in general restrict the off-label use of a product by healthcare professional, it is unlawful to promote the off-label use of a product or promotion that is inconsistent with the product’s SmPC. Accordingly, we potentially face significant risk of enforcement should we promote Inbrija (levodopa inhalation powder), Ampyra or any other products in the U.S., EU and potentially other countries for any uses that are not consistent with the products’ approved labeling in the relevant territory. 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 both in the U.S. and potentially other jurisdictions.

Notwithstanding the above-described regulatory restrictions, the FDA and other applicable regulatory authorities and EU medicines laws 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 applicable 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, in the U.S., 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 withdrawal of marketing approval in the U.S. and/or in other jurisdictions.

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. We constantly monitor Inbrija 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;

- 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 regulatory authorities such as the FDA or authorities in the EU to seek to suspend, vary or revoke Inbrija's regulatory approvals or impact the availability of adequate reimbursement by third-party payers or reimbursement authorities;
- we may be required to reformulate the product, conduct additional preclinical or clinical studies, or make changes in labeling or changes to or re-approvals of manufacturing facilities;
- regulatory authorities such as the FDA or those in the EU may take additional risk mitigation measures, such as imposing a risk evaluation and mitigation strategy (in the U.S.) or requiring an updated risk mitigation plan, detailing additional requirements to be fulfilled to manage risks (in the EU);
- 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 and EU rules and regulations, we are required to monitor the safety of Inbrija and Ampyra, as applicable, 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 and EU authorities in accordance with regulatory timelines based on their severity and expectedness. These requirements are applicable to all medicinal products marketed in the relevant territory, including Inbrija (levodopa inhalation powder) and Ampyra. Failure to make timely safety reports and to establish and maintain related records could result in the withdrawal of marketing authorization or other regulatory action, civil actions against us, or criminal or financial 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 authorities related to other regulatory requirements that apply to drugs manufactured or distributed by us.

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

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 authorities in other jurisdictions to confirm such compliance. In addition, the FDA and other relevant regulatory authorities 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. If we learn of certain reported problems with our products, we are required to submit field alert reports to the FDA and quality defect reports to the relevant EU authorities, such as the EMA, 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. Similar requirements exist under EU law, particularly pursuant to the Falsified Medicines Directive (Directive 2011/62/EU). 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 in the U.S. 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, including Parkinson's disease, which often require a high level of patient education and ongoing management. 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;
- 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;
- lose 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 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) in the EU, as well as other countries outside of the U.S. if it receives marketing approval in any other countries, 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, if 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;
- collaborators may experience financial difficulties; and
- our ability to enter into additional collaboration agreements with proposed partners may be limited by the restrictive covenants contained in the indenture that governs our new convertible senior secured notes due 2024.

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 know if Biogen will obtain 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 we or any Inbrija collaborator does not comply with regulatory requirements.

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

Future growth of our business will depend, 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 I 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. Currently, we are not making any new investments in these programs, and we have deferred consideration of further investment pending additional progress with the Inbrija launch.

Even if we do make future investments in our research and development programs, they 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. We have currently suspended work on all research and development programs, other than work funded by third-party grants, because of our limited financial resources. Also, as a result of 2017 and 2019 reductions in force, we have terminated substantially all of our research and development and clinical development workforce, and accordingly we lack personnel necessary to advance our development programs unless and until we can hire qualified replacements.

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, EU regulatory authorities 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 by the FDA and similar regulatory authorities in other countries;
- 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 regulatory authorities in other countries;
- 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 a clinical development program that we are conducting 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 regulatory authorities in other countries 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 regulatory authority in another country 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 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 in the U.S. and in foreign markets are subject to numerous regulations.

In the U.S., this includes 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, or ACA, as amended, 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.

Outside the U.S., the distribution, sale and promotion of our products is subject to a variety of rules and requirements. In the EU, these vary from country to country and we and any collaborator must comply with all applicable rules in each relevant market. For example, selling and distributing a product in the United Kingdom will be subject to complying with (among other things) the UK Bribery Act 2010, anti-inducement rules contained in the Human Medicines Regulations 2012 and with various other regulatory rules and guidelines. Failure to adhere to such rules and regulations could result in any number of possible sanctions, including fines and criminal prosecutions as well as reputational damage to us and our products.

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’s individual mandate to be unconstitutional and therefore the entire law to be invalid. In December 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the ruling regarding the individual mandate but remanded the case to the district court for additional analysis of the question of severability and whether portions of the law remain valid. It is likely that this case will ultimately be appealed to the U.S. Supreme Court. 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.

Healthcare systems outside the U.S. are varied and in the EU differ from country to country. In general, in many EU countries there is a growing pressure to lower overall expenditure on medicines and a range of government initiatives are in place or being proposed with this aim. These include measures to lower the prices of medicines, restrictions on reimbursement, and a range of substitution, procurement and prescribing initiatives. The state of healthcare legislation and regulation in the EU is also unclear and difficult to predict.

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 in the U.S. 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 in the U.S. 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 Inbrija and Ampyra, and we expect that obtaining agreements with other third-party payers to provide access to, and reimburse patients for, our products, if possible, will similarly require that we provide such discounts and rebates. 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 ACA 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 ACA 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 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 or a future collaborator for Inbrija, 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 and exert commercial pressure on pricing within a country.

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 and countries where we may seek to market Inbrija directly or through a collaborator. 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 Inbrija or Fampyra in that country.

The United Kingdom's withdrawal from the European Union, generally referred to as "Brexit," could make it more difficult for us to do business in Europe or have other adverse effects on our business.

Following negotiations on the terms of the United Kingdom's exit from the European Union, the UK Parliament, the European Council, the European Commission and the UK Prime Minister signed the Withdrawal Agreement on January 24, 2020. The Withdrawal Agreement was approved by the European Parliament and ratified by the UK January 29, 2020 and concluded by the Council of the EU on January 30, 2020. Under the Withdrawal Agreement, the UK left the EU on January 31, 2020, an event that has generally been referred to as "Brexit."

The Withdrawal Agreement provides for a transitional period until December 31, 2020, during which the will remain within the EU single market and customs union. These arrangements may be extended beyond 2020 if both the UK and the EU agree to an extension before the end of June 2020. During this transitional period, EU law and marketing authorizations will continue to apply in the UK. EU marketing authorizations granted by the EC will continue to allow products to be marketed in the UK and the operation of EU pharmaceutical supply chain will be unaffected. Medical devices will also be able to move freely between the UK and the European Economic Area, or EEA.

During this transitional period, the UK and EU will seek to negotiate and agree a mutually acceptable long-term trade agreement. Whether the UK and EU agree such a trade agreement, or an extension to the transitional period, could have a significant impact on the manner in which we may potentially do business in the UK. In particular, much will depend on whether the UK retains frictionless access to EU markets after 2020, and *vice versa*. It is possible that barrier-free access between the UK and other EU Member States or the EEA could be diminished or eliminated.

While negotiations are still underway, Brexit could significantly affect the fiscal, monetary and regulatory landscape in the UK, and could have a material impact on its economy and the future growth of its various industries, including the pharmaceutical and biotechnology industries. Further, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us. Any of the effects of Brexit could have a material adverse effect on our business, financial condition, results of operations and prospects.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

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. Inbrija competes against other therapies approved for intermittent, or as needed, 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 receipt of the CRL delayed but did not 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. Sunovion has resubmitted its NDA and in December 2019 announced that the NDA was accepted by the FDA and the expected action date by the FDA under the Prescription Drug User Fee Act is May 21, 2020.

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. Also, we are aware that at least one company, Impel Neuropharma, is developing intranasally delivered levodopa therapies which, if approved, might compete with Inbrija.

Ampyra/MS. Ampyra has become subject to competition from generic drug manufacturers. 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, or the Federal Circuit, which issued a ruling in September 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

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;
- 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;
- potential loss of our key employees or key employees of the acquired companies or businesses; and
- our ability to enter into acquisition or in-licensing agreements that do not violate the restrictive covenants contained in the indenture governing our new convertible senior secured notes due 2024.

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 stockholders' ownership interest, or securities convertible into our stock, which could dilute current stockholders' 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.

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. Ron 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 do not maintain "key man" life insurance policies on the lives of our officers, directors or employees.

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, recent developments with our business, including the adverse patent decision relating to our Orange Book-listed Ampyra patents, the termination or suspension of research and development programs, reductions in force, and the current progress of our Inbrija commercial launch, may impede our ability to attract and retain highly qualified personnel. The loss of one or more of our key employees, the loss of multiple employees in particular functions, and/or our inability to attract replacement or additional qualified personnel, could substantially impair our ability to implement our business plan, particularly our efforts to manufacture and successfully commercialize Inbrija. We have recently experienced workforce attrition in various functions across our business, which may be attributable to one or more of the factors described above, and we may not be able to adjust our operations in response to prevent disruption to our business. Also, we terminated substantially all of our research and development and clinical development workforce in connection with our 2017 and 2019 reductions in force, and our inability to attract qualified replacements needed for 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.

Biopharmaceutical 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 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 drug delivery technology, cimaglermin alfa/neuregulins, and remyelinating antibodies/antibodies relating to nervous system disorders, composed 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 Federal Circuit, which issued a ruling in September 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invents Act, specifically *inter partes* review and/or post grant review before the U.S. Patent and Trademark Office. For example, in 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed *inter partes* review (IPR) petitions with the U.S. Patent and Trademark Office, challenging some of our Ampyra Orange Book-listed patents. We successfully defended the patents in these proceedings, but this outcome did not affect the District Court's decision invalidating the same four Ampyra Orange Book-listed patents as described above. IPR petitions could be filed in the future challenging our other patents for any of our programs.

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. For example, the know-how that forms the basis of our proprietary manufacturing process for the ARCUS technology and Inbrija manufacturing is substantially dependent on trade secret protection. 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, including our proprietary ARCUS technology, 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 such as our ARCUS technology 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 for products and research and development programs, including in particular Inbrija and our ARCUS based 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;
- 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;
- dilution, or expected or potential dilution, relating to the issuance of additional shares of our common stock to satisfy conversion or make-whole payment obligations under, or interest on, our new convertible senior secured notes due 2024;
- issuance of additional shares of our common stock, and the expected dilution to our stockholders resulting therefrom, which may occur upon the refinancing of our convertible senior notes;

- 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
- Events that affect, or have the potential to affect, general economic conditions, including but not limited to political unrest, global trade wars, natural disasters, acts of war, terrorism, or disease outbreaks (such as the recent outbreak of COVID-19, or the novel coronavirus).

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, 2020, 47,997,023 shares of our common stock were issued and outstanding; options to acquire 10,057,882 shares of our common stock were outstanding, exercisable at an average exercise price of \$22.85 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 292,181 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 under our 2019 Employee Stock Purchase 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. In addition, if we elect to settle all or a portion of our conversion or make-whole payment obligations under, and/or interest payments on, our new convertible senior secured notes due 2024, our stockholders could experience significant dilution.

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, 2019, our officers, directors and current holders of 5% or more of our outstanding common stock beneficially owned approximately 72% 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 of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Ardsley, New York

In June 2011, we entered into a 15-year lease for an aggregate of approximately 138,000 square feet of 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. Our extension and early termination 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 \$4.8 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. 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 \$1.7 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 increased the size of the facility to approximately 95,000 square feet. The project has added a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and has created additional warehousing space for manufactured product. Although the project was substantially completed in late 2019, it will take additional time after completion of construction to obtain the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA, Massachusetts state environmental permits, and approvals from other regulatory authorities.

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 \$1.1 million per year.

Item 3. Legal Proceedings.

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 were 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*. On October 7, 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. This litigation has now ended as all of our appeal options have been exhausted.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

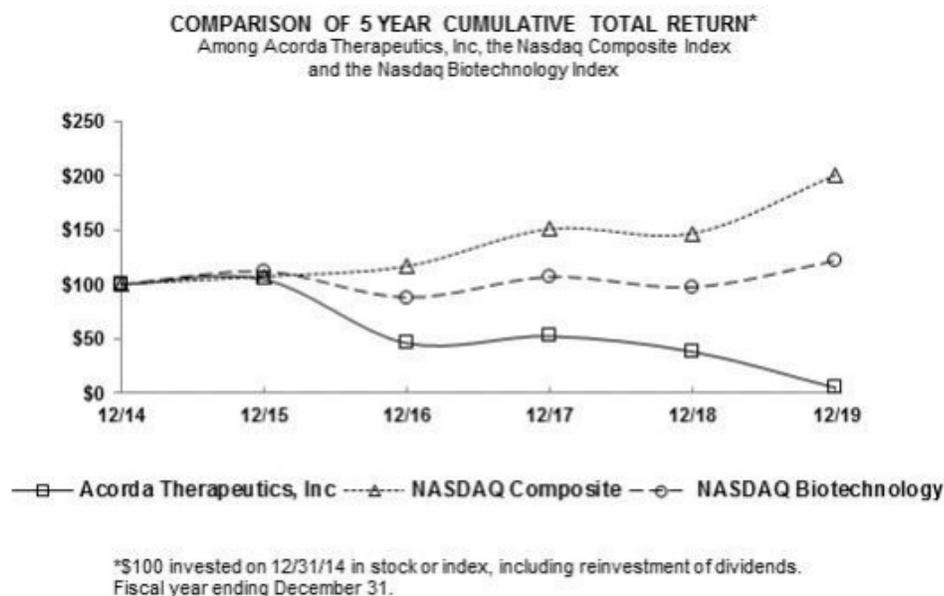
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

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, 2020, we had 17 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 12/31/2014 to 12/31/2019.



	12/14	12/15	12/16	12/17	12/18	12/19
Acorda Therapeutics, Inc.	100.00	104.67	46.00	52.48	38.12	4.99
Nasdaq Composite	100.00	106.96	116.45	150.96	146.67	200.49
Nasdaq Biotechnology	100.00	111.77	87.91	106.92	97.45	121.92

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

Dividend Policy

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

Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fourth quarter of 2019. Acorda has not announced any plans or programs for the repurchase of its Common Stock.

Item 6. Selected Financial Data.

The following selected consolidated financial data for each of the five years in the period ended December 31, 2019 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 2015, 2016 and 2017 (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,				
	2019	2018	2017	2016	2015
	(in thousands, except per share data)				
Statement of Operations Data:					
Total net revenues	\$ 192,408	\$ 471,433	\$ 588,287	\$ 519,601	\$ 492,660
Costs and expenses:					
Cost of sales	34,849	97,640	111,322	100,442	91,709
Cost of milestone and license revenue	—	—	634	634	634
Research and development	60,083	106,383	166,105	203,437	149,209
Selling, general and administrative	192,846	172,254	181,619	235,437	205,630
Goodwill and intangible asset impairments	277,561	—	296,763	—	—
Amortization of intangible assets	25,636	1,670	23,758	7,033	588
Changes in fair value of acquired contingent consideration	(86,935)	55,000	40,900	8,600	10,900
Total operating expenses	504,040	432,947	821,101	555,583	458,670
Operating (loss) income	(311,632)	38,486	(232,814)	(35,982)	33,990
Other income (expense), net:					
Interest and amortization of debt discount expense	(21,872)	(21,597)	(18,664)	(16,527)	(15,472)
Interest income	4,170	3,518	136	339	440
Other income (expense)	13	16	(543)	9,902	411
Gain on debt extinguishment	55,073	—	—	—	—
Total other income (expense), net	37,384	(18,063)	(19,071)	(6,286)	(14,621)
(Loss) income before income taxes	(274,248)	20,423	(251,885)	(42,268)	19,369
Benefit from (provision for) income taxes	1,282	13,259	28,526	6,665	(8,311)
Net loss attributable to non-controlling interest	—	—	—	985	—
Net (loss) income attributable to					
Acorda Therapeutics, Inc.	\$ (272,966)	\$ 33,682	\$ (223,359)	\$ (34,618)	\$ 11,058
Net (loss) income per share —basic	\$ (5.75)	\$ 0.72	\$ (4.86)	\$ (0.76)	\$ 0.26
Net (loss) income per share —diluted	\$ (5.75)	\$ 0.71	\$ (4.86)	\$ (0.76)	\$ 0.25
Weighted average shares of common stock outstanding used in computing net (loss) income per share —basic	47,512	47,010	45,999	45,259	42,230
Weighted average shares of common stock outstanding used in computing net (loss) income per share —diluted	47,512	47,341	45,999	45,259	43,621

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and investments	\$ 125,839	\$ 445,553	\$ 307,068	\$ 158,537	\$ 353,305
Working capital	114,728	387,852	297,738	124,756	360,725
Total assets	799,718	1,299,666	1,197,969	1,342,335	1,111,294
Long-term liabilities	402,513	547,427	534,023	530,223	417,675
Accumulated deficit	(666,809)	(393,843)	(455,108)	(243,970)	(209,352)
Long term debt	218,269	343,140	334,475	324,030	291,527
Total stockholders' equity	310,820	611,983	519,987	664,211	603,025

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 market Inbrija (levodopa inhalation powder), which is approved in the U.S. for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa. Inbrija is for as needed use and utilizes our 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. We also 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 (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Inbrija is marketed in the U.S. through our own specialty sales force and commercial infrastructure, and is being distributed primarily through a network of specialty pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Our Inbrija launch activities have been focused on physician awareness and market access. We are maintaining these efforts while increasing focus on patient awareness, education and training. 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. We project peak U.S. annual net revenue of Inbrija to be in the range of \$300 to \$500 million.

On September 24, 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for use in what were then the 28 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the United Kingdom left the European Union on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will

end on December 31, 2020, unless it is extended. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

We have been engaged in litigation with generic drug manufacturers relating to certain Ampyra patents, which is further described below and in Part I, Item 3 of this report. In 2017, a U.S. District Court issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated other Ampyra patents that were set to expire between 2025 and 2027. In September 2018, a U.S. Court of Appeals upheld this decision, and in October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. As a result, our patent exclusivity with respect to Ampyra terminated on July 30, 2018, and we have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that have been marketed since the Court of Appeals decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

On October 23, 2019, we announced a corporate restructuring to reduce costs and focus our resources on the commercial launch of Inbrija, which was our key strategic priority for the remainder of 2019 and will remain the priority for 2020. As part of the restructuring, we reduced headcount by approximately 25% through a reduction in force. The majority of the reduction took place in the fourth quarter of 2019 immediately after the announcement, and the remainder will be completed by the first quarter of 2020. We expect to realize estimated annualized cost savings related to headcount reduction of approximately \$21.0 million, beginning in the second quarter of 2020. We are continuing our efforts to manage our cost structure, such as by identifying potential operating efficiencies and opportunities to convert fixed costs to variable costs.

On December 26, 2019, we announced the successful completion of a private exchange of \$276 million of our convertible senior notes due in 2021 in exchange for a combination of approximately \$207 million aggregate principal amount of newly-issued convertible senior secured notes due 2024 and \$55.2 million in cash. The new convertible senior secured notes have a conversion price of approximately \$3.50 per share. As a result of the exchange, approximately \$69 million of convertible senior notes due in 2021, with a conversion price of \$42.56, remain outstanding. We are evaluating alternatives to address the remaining portion of the convertible notes due 2021, and this is a top priority in addition to our focus on the Inbrija launch. Refer to Note 10 to our Consolidated Financial Statements included in this report for more information about the terms and conditions of the 2021 and 2024 convertible notes.

As of December 31, 2019, we had cash, cash equivalents, short-term investments and restricted cash of approximately \$169 million. Restricted cash includes \$42.7 million in escrow related to the 6% semi-annual interest portion of the new convertible senior secured notes due 2024. If we elect to pay interest due in stock, the cash equivalent will be released from escrow.

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 (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 72% of commercial and 25% of Medicare plan lives. Net revenue for Inbrija was \$15.3 million for the year ended December 31, 2019. We project peak U.S. annual net revenue of Inbrija to be in the range of \$300 to \$500 million.

On September 24, 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for use in what were then the 28 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the United Kingdom left the European Union on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will end on December 31, 2020, unless it is extended. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

Inbrija 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 pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). Our neuro-specialty sales and marketing team, built through our

commercialization of Ampyra, includes our own 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 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. Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 10,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Our Inbrija launch activities have thus far been focused on physician awareness and market access. As we enter our next phase of the launch, we will be maintaining these efforts while increasing focus on patient awareness, education and training.

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 offers several support options, including: a 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 have implemented a no-cost sample program, available at physician offices, to enable patients and their physicians to assess the value of Inbrija before the patient incurs out-of-pocket co-pay or co-insurance costs. In addition, we have implemented a free trial program, available through the Inbrija hub, for commercially insured patients who cannot access the free samples because of offices and institutions that have policies that prohibit samples.

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 of 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 for as needed use and utilizes our 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 new product exclusivity, through December 2021, as posted in the Orange book.

Ampyra

Ampyra was approved by the FDA in January 2010 to improve walking in adults with multiple sclerosis. 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 \$163.2 million for the year ended December 31, 2019. 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 in September 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing *en banc*. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. This litigation is discussed further 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. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

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 net 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. We have filed a request to have these four patents delisted from the Orange Book. The litigation is discussed further in Part I, Item 3 of this report. The sixth Orange Book-listed patent (U.S. Patent No. 9,918,973), set to expire in 2024, was more recently issued and was not involved in the litigation. We have filed a request to have this patent delisted from the Orange Book. We note that this patent did not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that were 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 appealed the decision. In the Appeal Hearings in September 2019, the European Technical Board of Appeals upheld claims covering Fampyra in both the EP 1732548 patent and the EP 2377536 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. In June 2019, the EPO granted EP 2460521, which is a divisional of the EP 2377536 patent. In November 2019, we filed a request withdrawing our approval of the text on which EP 2460521 was granted, resulting in termination of the patent. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

ARCUS Product Development

We have been 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 believe there are potential opportunities with central nervous system, or CNS, as well as non-CNS, disorders.

Our ARCUS development has been focused on a program for acute treatment of migraine. Existing oral therapies for migraine can be associated with slow onset of action and gastrointestinal challenges. 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.

We have been evaluating therapeutic candidates for their suitability to move forward with this program. Due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of further investment into potential new ARCUS applications in migraine pending additional progress with the Inbrija commercial launch in the U.S.

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 (funding for which has not been impacted by the restructuring) could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

Other Research and Development Programs

Our other research and development programs include rHIgM22 and cimaglermin alfa. rHIgM22 is a remyelinating antibody that is a potential therapeutic for multiple sclerosis. Data from a Phase 1 safety and tolerability trial showed that a single dose of rHIgM22 was not associated with any safety signals. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. 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. We initiated a Phase 1b clinical trial assessing three doses of cimaglermin alfa in people with heart failure, but discontinued enrollment and then received an FDA clinical hold based on the occurrence of a case of hepatotoxicity (liver injury). The FDA clinical hold was lifted after we presented additional data on the hepatotoxicity, but we have not since restarted any clinical study of cimaglermin alfa. We are considering next steps for these programs, which could include potential partnering or out-licensing, but due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of any further investment pending additional progress with the Inbrija commercial launch in the U.S.

We were previously developing SYN120 and BTT1023, but have no current plans to further invest in these programs. 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 were developing BTT1023 (timolumab) for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. The University of Birmingham was conducting a Phase 2 proof-of-concept clinical trial of BTT1023 for PSC, but the university informed us in January 2019 that they terminated the trial. Pending review of final data from the discontinued trial, we intend to evaluate the potential for out-licensing.

Financial Guidance for 2020

We are providing the following guidance with respect to our 2020 financial performance:

- Net revenue from the sale of Ampyra in 2020 is expected to range from \$85 million to \$110 million.
- Net revenue from the sale of Inbrija in 2020 is expected to range from \$35 million to \$40 million.
- Operating expenses in 2020 are expected to range from \$170 million to \$180 million. This is a non-GAAP projection that excludes restructuring costs and share-based compensation charges, as more fully described below.

The projected ranges of operating expenses in 2020 specified above were not prepared in accordance with accounting principles generally accepted in the United States (GAAP) because this guidance excludes restructuring costs and share-based compensation charges. Due to the forward looking nature of this information, the amount of compensation charges and benefits needed to reconcile this measure to the most directly comparable GAAP financial measure 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 this non-GAAP financial measure, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our ongoing and projected operating performance because it excludes (i) expenses that pertain to non-routine restructuring events, and (ii) non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe this non-GAAP financial measure helps indicate underlying trends in our business, and is important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses this non-GAAP financial measure to establish budgets and operational goals, and to manage our business and to evaluate its performance.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Net Revenue

Net Product Revenues

Inbrija

We recognize product sales of Inbrija following receipt of product by companies in our distribution network, which for Inbrija primarily includes specialty pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). We recognized net revenue from the sale of Inbrija of \$15.3 million for the year ended December 31, 2019.

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which for Ampyra primarily includes specialty pharmacies, which deliver the medication to patients by mail. We recognized net revenue from the sale of Ampyra to these customers of \$163.2 million and \$455.1 million for the years ended December 31, 2019 and 2018, respectively. The net revenue decrease comprised decreased net volume of \$327.9 million partially offset by price increase and discount and allowance adjustments of \$36.0 million. Net revenue from sales of Ampyra decreased for the year ended December 31, 2019 compared to the year ended December 31, 2018 due to the entry of generic versions of Ampyra as a result of the invalidation of our Ampyra patents in 2017.

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. Discounts and allowances are recorded following shipment of our products 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 may increase as a percentage of sales as we enter into managed care contracts in the future.

Other Product Revenues

We recognized net revenue from the sale of other products of \$2.3 million for the year ended December 31, 2019 as compared to \$4.6 million for the year ended December 31, 2018.

Royalty Revenue

We recognized \$11.7 million in royalty revenue for both the years ended December 31, 2019 and 2018, related to ex-U.S. sales of Fampyra by Biogen.

Cost of Sales

We recorded cost of sales of \$34.8 million for the year ended December 31, 2019 as compared to \$97.6 million for the year ended December 31, 2018. Cost of sales for the year ended December 31, 2019 consisted primarily of \$32.2 million in inventory costs related to recognized revenues, \$0.9 million in royalty fees based on net product shipments, idle capacity costs of \$0.7 million, \$0.5 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 of \$1.8 million for inventory manufactured pre-launch for Inbrija was not recorded for the year ended December 31, 2019, since the inventory manufactured prior to the FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses in 2018. Production costs related to idle capacity are not included in the cost of inventory but are charged directly to cost of sales in the period incurred.

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, \$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.

Amortization of Intangibles

We commenced amortization of the intangible asset upon launch in February 2019 and recorded amortization of \$25.6 million for the year ended December 31, 2019 as compared to \$1.7 million related to Ampyra for the year ended December 31, 2018.

Research and Development

Research and development expenses for the year ended December 31, 2019 were \$60.1 million as compared to \$106.4 million for the year ended December 31, 2018, a decrease of \$46.3 million, or 44%. The decrease was primarily due to reductions in spending of \$26.0 million due to the commercialization of Inbrija, reductions of \$10.7 million in research and development expenses related to Biotie, due to termination of the tozadenant program and reductions of \$9.6 million due to restructuring and decrease in several programs to shift focus on Inbrija launch.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2019 were \$109.5 million compared to \$96.0 million for the year ended December 31, 2018, an increase of approximately \$13.5 million, or 14%. The increase was attributable primarily to an increase in marketing related spending of \$26.0 million due to launch activities for Inbrija, partially offset by a decrease in overall salaries and benefits of \$7.4 million and a decrease in spending related to marketing for Ampyra of \$5.1 million.

General and administrative expenses for the year ended December 31, 2019 were \$83.3 million compared to \$76.2 million for the year ended December 31, 2018, an increase of approximately \$7.1 million, or 9%. This increase was primarily due to an increase in spending related to launch activities of \$7.2 million, absence of gain on the sale of Qutenza of \$7.8 million which was recorded as an offset to general and administrative expense in 2018 and restructuring expenses of \$3.0 million in 2019. This increase was partially offset by reductions of \$6.8 million in staff compensation, benefits and medical affairs related expenses, business development costs of \$1.9 million and legal costs and certain other costs of \$2.2 million.

Goodwill Impairment

We recognized a goodwill impairment charge of \$277.6 million for the year ended December 31, 2019. During the third quarter of 2019, we experienced a significant decline in our stock price that reduced the market capitalization below the carrying value of the Company. We performed a quantitative assessment and after completing the assessment during the third quarter of 2019, we concluded that the carrying value of the Company exceeded its estimated fair value and therefore, the goodwill was fully impaired. We did not recognize any goodwill impairment charge in the year ended December 31, 2018.

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 income pertaining to changes in the fair value of our acquired contingent consideration of \$86.9 million for the year ended December 31, 2019 compared to expense of \$55.0 million for the year ended December 31, 2018, a decrease of \$141.9 million or 258%. The changes in the fair-value of the acquired contingent consideration were primarily due to the updates to certain estimated assumptions and partly due to the re-calculation of discounted cash flows for the passage of time.

Other Income (Expense), Net

Other income, net was \$37.4 million for the year ended December 31, 2019 compared to other expense, net of \$18.1 million for the year ended December 31, 2018, a decrease in expense of \$55.4 million, or 307%. The decrease was due primarily to the gain recorded on debt extinguishment of \$55.1 million and an increase in interest income of approximately \$0.7 million, partially offset by increase in interest and debt discount expense of \$0.3 million.

Benefit from Income Taxes

We recorded a \$1.3 million benefit from income taxes for the year ended December 31, 2019 as compared to a \$13.3 million benefit from income taxes for the year ended December 31, 2018. The effective income tax rates for the year ended December 31, 2019 and 2018 were 0.5% and (65%), respectively.

The variances in the effective tax rates for the year ended December 31, 2019 and 2018 were due primarily to changes in the valuation allowance in 2019 and 2018, goodwill impairment, state taxes, equity based compensation and return to provision variances (primarily capital loss carryforwards).

The Company's overall effective tax rate differed from the U.S. federal statutory rate of 21% primarily due to the impairment of non-deductible goodwill and the federal return to provision difference primarily related to a capital loss deduction which is fully offset by a valuation allowance.

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, 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 for Ampyra primarily includes specialty pharmacies which deliver the medication to patients by mail. 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 comprised decreased net volume of \$361.6 million partially offset by price increase 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.

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, 2017, 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 \$97.6 million for the year ended December 31, 2018 as compared to \$111.3 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, \$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, \$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 million 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.

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 completed the accounting for the effects of the Act. The company 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.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily from: private placements and public offerings of our capital stock; borrowing money through loans and the issuance of debt instruments; payments received under our collaboration and licensing agreements; revenue from sales of Ampyra, Fampyra, and Inbrija, as well as our former products, Zanaflex and Qutenza; royalty monetizations and our revenue interest financing arrangement; and, to a lesser extent, funding from government grants.

At December 31, 2019, we had \$125.8 million of cash, cash equivalents and short-term investments, compared to \$445.6 million at December 31, 2018. We expect that our existing cash and cash flows from operations will be sufficient to fund our ongoing operations over the 12 months from the issuance of the financial statements contained in this report. Our December 31, 2019 cash, cash equivalents and short-term investments balance does not include restricted cash, currently held in escrow under the terms of our new convertible senior secured notes due 2024, further described below under *Financing Arrangements*, which may potentially be released from escrow if we pay interest on those notes using shares of our common stock.

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. Our future capital requirements will depend on a number of factors, including:

- the amount of revenue generated from sales of Inbrija and Ampyra;
- our ability to manage operating expenses;
- the amount and timing of purchase price, milestone or other payments that we may owe or have a right to receive under collaboration, license, asset sale, acquisition, or other agreements or transactions; and the extent to which the terms and conditions of our new convertible senior secured notes due 2024 restrict or direct our use of proceeds from such transactions;
- our ability to make required payments relating to our new convertible senior secured notes due 2024 using shares of our common stock rather than cash;
- the extent to which we can refinance our remaining convertible senior notes due 2021 with later-maturing debt, the terms and conditions of any new debt that we issue, and the extent to which we make any cash payments in connection with such a transaction;
- 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.

Financing Arrangements

New Convertible Senior Secured Notes Due 2024

On December 24, 2019, the Company completed the private exchange of \$276.0 million aggregate principal amount of its outstanding 1.75% Convertible Senior Notes due 2021 (the “2021 Notes”) for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the “New Notes”) and cash. For each \$1,000 principal amount of exchanged 2021 Notes, the Company issued \$750 principal amount of the New Notes and made a cash payment of \$200 (the “Exchange”). In the aggregate, the Company issued approximately \$207.0 million aggregate principal amount of the New Notes and paid approximate \$55.2 million in cash to participating holders. The Exchange was conducted with a limited number of institutional holders of the 2021 Notes pursuant to Exchange Agreements dated as of December 20, 2019 (each, an “Exchange Agreement”).

The New Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among the Company, its wholly owned subsidiary, Civitas Therapeutics, Inc. (along with any domestic subsidiaries acquired or formed after the date of issuance, the “Guarantors”), and Wilmington Trust, National Association, as trustee and collateral agent (the “Indenture”). The New Notes are senior obligations of the Company and the Guarantors, secured by a first priority security interest in substantially all of the assets of the Company and the Guarantors, subject to certain exceptions described in the Security Agreement, dated as of December 23, 2019, between the grantors party thereto and Wilmington Trust, National Association, as collateral agent (the “Security Agreement”).

The New Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms prior to such date. Interest on the New Notes will be payable semi-annually in arrears at a rate of 6.00% per annum on each June 1 and December 1, beginning on June 1, 2020. The Company may elect to pay interest in cash or shares of the Company’s common stock, subject to the satisfaction of certain conditions. If the Company elects to pay interest in shares of common stock, such common stock will have a per share value equal to 95% of the daily volume-weighted average price for the 10 trading days ending on and including the trading day immediately preceding the relevant interest payment date.

The New Notes will be convertible at the option of the holder into shares of common stock of the Company at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion rate for the New Notes is 285.7142 shares of the Company’s common stock per \$1,000 principal amount of New Notes, representing an initial conversion price of approximately \$3.50 per share of common stock. The conversion rate is subject to adjustment in certain circumstances as described in the Indenture.

The Company may elect to settle conversions of the New Notes in cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock. Holders who convert their New Notes prior to June 1, 2023 (other than in connection with a make-whole fundamental change) will also be entitled to an interest make-whole payment equal to the sum of all regularly scheduled stated interest payments, if any, due on such New Notes on each interest payment date occurring after the conversion date for such conversion and on or before June 1, 2023. In addition, the Company will have the right to cause all New Notes then outstanding to be converted automatically if the volume-weighted average price per share of the Company’s common stock equals or exceeds 130% of the conversion price for a specified period of time and certain other conditions are satisfied.

Holders of the New Notes will have the right, at their option, to require the Company to purchase their New Notes if a fundamental change (as defined in the Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the New Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

Notwithstanding the foregoing, the Company’s ability to settle conversions and make interest payments using shares of its common stock is subject to certain limitations set forth in the Indenture until the time, if any, that the Company’s stockholders have approved (i) the issuance of more than 19.99% of the Company’s outstanding shares in accordance with Nasdaq listing standards and (ii) an amendment to the Company’s certificate of incorporation to increase the number of authorized shares. The Company intends to seek stockholder approval of these matters at its 2020 Annual Meeting of Stockholders.

Subject to a number of exceptions and qualifications, the Indenture restricts the ability of the Company and certain of its subsidiaries to, among other things, (i) pay dividends or make other payments or distributions on their capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) make certain investments, (iii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, which includes, among other items, indebtedness incurred to refinance the 2021 Notes, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell of all or substantially all of their assets. The Indenture also requires the Company to make an offer to repurchase the New Notes upon the occurrence of certain asset sales.

The Indenture provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the New Notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the New Notes in accordance with the Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the Indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by the Company to make required payments under other indebtedness of the Company or certain subsidiaries having an outstanding principal amount of \$30.0 million or more, (vii) failure by the Company or certain subsidiaries to pay final judgments aggregating in excess of \$30.0 million, (viii) certain events of bankruptcy or insolvency and (ix) the commercial launch in the United States of a product determined by the U.S. FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to the Company, all outstanding New Notes will become due and payable immediately without further action or notice. If any other event of default occurs and is continuing, the trustee or the holders of at least 25% in aggregate principal amount of the then outstanding New Notes may declare all the notes to be due and payable immediately.

The 2021 Notes received by the Company in the Exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, \$69.0 million of the 2021 Notes remained outstanding.

The Company assessed all terms and features of the New Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the New Notes, including the conversion, put and call features. Per the terms of the Indenture, the Company's ability to settle conversions and make interest payments using shares of its common stock is limited until such time as the Company's stockholders have approved a waiver of a share limit imposed under Nasdaq rules and a necessary increase in the number of authorized shares of common stock. The Company has until July 31, 2020 to obtain the necessary stockholder approvals and, prior to the earlier of July 31, 2020 and the date such approvals are received, the Company is entitled to settle conversions and make interest whole payments using shares of common stock, and is not required to make cash payments with respect to shares of common stock that are not delivered due to the applicable share limits. In consideration of these provisions, the Company concluded the conversion feature required bifurcation as a derivative. The fair value of the conversion feature derivative was determined based on the difference between the fair value of the New Notes with the conversion option and the fair value of the New Notes without the conversion option. The Company determined that the fair value of the derivative upon issuance of the New Notes was \$59.4 million and recorded this amount as a derivative liability and the offsetting amount as a debt discount as a reduction to the carrying value of the Notes on the closing date, or December 24, 2019. The conversion feature will be measured at fair value on a quarterly basis and the change in the fair value of the conversion feature for the period will be recorded on the consolidated statements of operations.

The outstanding New Note balance as of December 31, 2019 consisted of the following:

(In thousands)	December 31, 2019
Liability component:	
Principal	\$ 207,000
Less: debt discount and debt issuance costs, net	(80,028)
Net carrying amount	126,972
Derivative liability-conversion Option	\$ 59,409

Convertible Senior Notes Due 2021

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 "2021 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. On December 24, 2019, the Company completed the private exchange of \$276.0 million aggregate principal amount of its outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the “New Notes”) and cash. The 2021 Notes received by the Company in the exchange have been cancelled in accordance with their terms. As a result, upon completion of the exchange, \$69.0 million of the 2021 Notes remained outstanding.

The 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 Notes.

The 2021 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 2021 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 2021 Notes, the Company separated the 2021 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 2021 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 2021 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 New Note balances as of December 31, 2019 consisted of the following:

(In thousands)	December 31, 2019
Liability component:	
Principal	\$ 69,000
Less: debt discount and debt issuance costs, net	(3,198)
Net carrying amount	<u>\$ 65,802</u>
Equity component	<u>\$ 22,791</u>

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 \$24.9 million as of December 31, 2019. 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 \$1.2 million as of December 31, 2019. 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 for the years ended December 31, 2019 and 2018:

(In thousands)	December 31, 2019		December 31, 2018	
Liability related to sale of future royalties - beginning balance	\$	30,716	\$	35,788
Deferred transaction costs amortized		639		784
Non-cash royalty revenue payable to HCRP		(10,271)		(10,291)
Non-cash interest expense recognized		3,316		4,435
Liability related to sale of future royalties - ending balance	\$	24,400	\$	30,716

Investment Activities

At December 31, 2019, cash and cash equivalents and short-term investments were approximately \$125.8 million, as compared to \$445.6 million at December 31, 2018. 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.

Net Cash Used in Operations

Net cash used in operations was \$128.1 million compared to net cash provided of \$150.8 million for the years ended December 31, 2019 and 2018, respectively. Cash used in operations for the year ended December 31, 2019 was primarily attributable to the net loss of \$273.0 million, a decrease in accounts payable, accrued expenses and other current liabilities of \$60.6 million, a change in the contingent consideration obligation of \$86.9 million, a deferred tax benefit of \$2.0 million, royalty revenues of \$10.3 million, gain on extinguishment of debt of \$55.1 million, amortization of net premiums and discounts on investments of \$1.5 million and decrease in other non-current liabilities of \$0.4 million.

Cash used in operations was partially offset by goodwill impairment charge of \$277.6 million, a decrease in prepaid expenses and other current assets of \$14.4 million, share-based compensation expense of \$14.3 million, depreciation and amortization expense of \$34.6 million, amortization of debt discount and debt issuance costs of \$15.7 million, a decrease in accounts receivable of \$1.3 million, and a decrease in inventory of \$3.8 million.

Net Cash Used in Investing

Net cash used in investing activities for the year ended December 31, 2019 was \$0.5 million, which was due primarily to purchases of short-term investments and property and equipment of \$226.6 million and \$90.4 million, respectively. This was partially offset by proceeds from maturities of investments of \$316.5 million.

Net Cash Used in Financing

Net cash used in financing activities for the year ended December 31, 2019 was \$60.6 million, which was due primarily to payment on convertible senior notes exchange of \$55.2 million, debt issuance costs related to the exchange of the convertible senior notes of \$4.7 million, repayment of loans payable of \$0.6 million and the repurchase of treasury stock of \$0.1 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 to our Consolidated Financial Statements included in this report 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 \$41.6 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, 2019, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

Effects of Inflation

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

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, 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 \$5.6 million and \$7.9 million at December 31, 2019 and December 31, 2018, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate \$2.2 million and \$5.6 million effect on our net revenue for the years ended December 31, 2019 and December 31, 2018, 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 \$8.5 million and \$13.7 million at December 31, 2019 and December 31, 2018, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$3.2 million and \$7.5 million effect on our net revenue for the years ended December 31, 2019 and December 31, 2018, 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 \$0.3 million and \$0.8 million at December 31, 2019 and December 31, 2018, respectively. A 10% change in our copay mitigation rebate allowances would have had an approximate \$0.7 million and \$1.1 million effect on our net revenue for the years ended December 31, 2019 and December 31, 2018, respectively.

Cash Discounts: We sell directly to companies in our distribution network, which primarily includes specialty pharmacies and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). 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 at December 31, 2019 and December 31, 2018. A 10% change in our cash discount allowances would have had an approximate \$0.3 million and \$0.6 million effect on our net revenue for the years ended December 31, 2019 and December 31, 2018, 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 \$0.6 million and \$1.6 million at December 31, 2019 and December 31, 2018, respectively. A 10% change in our returns would have had an approximate \$(0.1) million and \$(0.2) million effect on our net revenue for the years ended December 31, 2019 and 2018, 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, 2019 and December 31, 2018.

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 \$1.5 million and \$1.4 million at December 31, 2019 and December 31, 2018, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate \$0.5 million effect on our net revenue for the years ended December 31, 2019 and 2018.

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 make adjustments when we believe actual experience may differ from its estimates. The allowances included in the table below reflect these adjustments.

The following table provides a summary of activity with respect to the Company's sales discounts and allowances during 2019, 2018, and 2017:

(in thousands)	Government chargebacks and rebates	Managed care contract rebates	Copay mitigation rebates	Cash discounts	Product returns	Data fees and fees for services payable to wholesalers	Other vendor allowances	Total
Balance at December 31, 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
Allowances for sales	22,105	32,047	7,228	2,722	(516)	5,364	—	68,950
Actual credits for sales during 2019	(20,391)	(27,237)	(6,927)	(2,368)	(2)	(4,051)	—	(60,976)
Actual credits for prior year sales	(4,085)	(10,020)	(797)	(337)	(536)	(1,172)	—	(16,947)
Balance at December 31, 2019	\$ 5,554	\$ 8,474	\$ 301	\$ 412	\$ 606	\$ 1,540	\$ 1,327	\$ 18,215

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.

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.

Cost of Sales

Inbrija

Cost of sales includes the cost of inventory, expense due to inventory reserves when necessary, royalty expense, packaging costs, freight and required inventory stability testing costs. Cost of sales include those costs directly associated with the production of revenues, such as raw material consumed, factory overhead and other direct production costs. In periods of idle plant capacity, costs are charged directly to cost of sales in the period incurred.

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.

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 to our Consolidated Financial Statements included in this report 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 preclinical and clinical 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,		
	2019	2018	2017
Preclinical and clinical development:			
Contract expenses—Inbrija	\$ 5,021	\$ 18,195	\$ 31,307
Contract expenses—tozadenant	(171)	10,747	39,405
Contract expenses—BTT-1023	36	996	951
Contract expenses—rHlgM22	93	219	3,130
Contract expenses—SYN-120	25	162	2,594
Contract expenses—cimaglermin alfa (previously GGF2)	105	96	163
Contract expenses—ARCUS program for acute migraine	494	52	902
Contract expenses—Ampyra LCM	35	44	4,528
Contract expenses—NP-1998	7	43	70
Contract expenses—Diazepam Nasal Spray/Plumiaz	18	38	453
Contract expenses—Other	260	7	12
Research and development operating expenses:	54,160	75,738	82,544
Acquisitions, licenses and milestones:			
rHlgM22	—	26	26
Other	—	20	20
Total research and development	\$ 60,083	\$ 106,383	\$ 166,105

With respect to previously established clinical study accruals in prior periods and for the year ended December 31, 2019 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. The impairment test for goodwill uses an approach which 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, an impairment loss is recognized in an amount equal to the excess of the carrying value over the estimated fair value. The Company recorded an impairment charge of \$277.6 million for the year ended December 31, 2019 in the statement of operations. See note 4 to our Consolidated Financial Statements included in this report for a discussion of goodwill.

Derivative Liability – Conversion Option

During 2019, a derivative liability was initially recorded as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024 (see Note 10 to our Consolidated Financial Statements included in this report). The Company initially determined the fair value of the liability upon issuance. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) share price as of the valuation date, (2) assumed timing of conversion of the Notes, (3) historical volatility of share price and (4) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement. The fair value of the derivative liability was determined using a Monte Carlo simulation approach by calculating the fair value of the Notes with the conversion feature as compared to the fair value of the Notes without the conversion feature, with the difference representing the value of the conversion feature, or the derivative liability. The conversion feature will be measured at fair value on a quarterly basis and the change in the fair value of the conversion feature for the period will be recorded in the consolidated statements of operations.

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 new convertible senior secured notes due 2024 issued in December 2019, convertible senior notes due 2021 issued in June 2014, our capital and R&D loans and non-cash interest expense pertaining to the Fampyra royalty monetization.

Income Taxes

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

We will continue to evaluate the realizability of our deferred tax assets and liabilities on a quarterly basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities and the progress of ongoing tax audits, if any. We consider all

available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods.

Share-Based Compensation

We account for stock options, 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:

<u>Assumption</u>	<u>Method of estimating</u>
<ul style="list-style-type: none"> ● Estimated expected term of options ● Expected volatility ● Risk-free interest rate 	<ul style="list-style-type: none"> ● Historical term of our options based on exercise data ● Historic volatility of our common stock ● Yields of U.S. Treasury securities corresponding with the expected life of option grants
<ul style="list-style-type: none"> ● Forfeiture rates 	<ul style="list-style-type: none"> ● 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, 2019, except for the fair value of the Company's convertible senior notes due 2021, which was approximately \$52.1 million, and the Company's new convertible senior secured notes due 2024, which was approximately \$210.6 million as of December 31, 2019.

We have cash equivalents and short-term investments at December 31, 2019, 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, 2019. At December 31, 2019, we held \$125.8 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 2.3%.

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 2019 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, 2019, 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, 2019 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 2019 (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, 2019, 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, 2019. 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated February 28, 2020 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 28, 2020

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2020 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 in the corporate governance section of “Investors” of our website, www.acorda.com.

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

Item 11. Executive Compensation.

The information required by this item will be contained in our 2020 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 2020 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 2020 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 2020 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, 2019 and 2018

Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017

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.

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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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 28, 2020 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 28, 2020

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,085	\$ 293,564
Restricted cash	12,836	532
Short term investments	63,754	151,989
Trade accounts receivable, net of allowances of \$682 and \$2,681, as of December 31, 2019 and 2018, respectively	22,083	23,430
Prepaid expenses	11,574	19,384
Inventory, net	25,221	29,014
Other current assets	3,560	10,194
Total current assets	201,113	528,107
Property and equipment, net of accumulated depreciation	142,527	60,519
Goodwill	—	282,059
Intangible assets, net of accumulated amortization	402,329	428,570
Right of use asset, net of accumulated amortization	23,450	—
Restricted cash	30,270	255
Other assets	29	156
Total assets	\$ 799,718	\$ 1,299,666
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 26,257	\$ 48,859
Accrued expenses and other current liabilities	39,077	76,882
Current portion of loans payable	603	616
Current portion of liability related to sale of future royalties	10,836	8,985
Current portion of lease liability	7,746	—
Current portion of acquired contingent consideration	1,866	4,914
Total current liabilities	86,385	140,256
Convertible senior notes	192,774	318,670
Derivative liability	59,409	—
Non-current portion of acquired contingent consideration	78,434	163,086
Non-current portion of loans payable	25,495	24,470
Deferred tax liability	9,581	7,483
Non-current portion of liability related to sale of future royalties	13,565	21,731
Non-current portion of lease liability	22,996	—
Other non-current liabilities	259	11,987
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value. Authorized 1,000,000 shares at December 31, 2019 and December 31, 2018; no shares issued as of December 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2019 and 2018; issued 47,730,396 and 47,508,505 shares, including those held in treasury, as of December 31, 2019 and 2018, respectively	48	48
Treasury stock at cost (29,304 and 87,737 shares at December 31, 2019 and 2018, respectively)	(638)	(2,133)
Additional paid-in capital	979,388	1,005,105
Accumulated deficit	(666,809)	(393,843)
Accumulated other comprehensive (loss) income	(1,169)	2,806
Total stockholders' equity	310,820	611,983
Total liabilities and stockholders' equity	\$ 799,718	\$ 1,299,666

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(In thousands, except per share data)

	<u>Year ended December 31, 2019</u>	<u>Year ended December 31, 2018</u>	<u>Year ended December 31, 2017</u>
Revenues:			
Net product revenues	\$ 180,736	\$ 459,739	\$ 549,749
Royalty revenues	11,672	11,694	29,481
License revenue	—	—	9,057
Total net revenues	192,408	471,433	588,287
Costs and expenses:			
Cost of sales	34,849	97,640	111,322
Cost of milestone and license revenue	—	—	634
Research and development	60,083	106,383	166,105
Selling, general and administrative	192,846	172,254	181,619
Goodwill and intangible asset impairments	277,561	—	296,763
Amortization of intangible assets	25,636	1,670	23,758
Changes in fair value of acquired contingent consideration	(86,935)	55,000	40,900
Total operating expenses	504,040	432,947	821,101
Operating (loss) income	(311,632)	38,486	(232,814)
Other (income) expense, net:			
Interest and amortization of debt discount expense	(21,872)	(21,597)	(18,664)
Interest income	4,170	3,518	136
Other income (expense)	13	16	(543)
Gain on debt extinguishment	55,073	—	—
Total other (income) expense, net	37,384	(18,063)	(19,071)
(Loss) income before taxes	(274,248)	20,423	(251,885)
Benefit from income taxes	1,282	13,259	28,526
Net (loss) income	\$ (272,966)	\$ 33,682	\$ (223,359)
Net (loss) income per share—basic	\$ (5.75)	\$ 0.72	\$ (4.86)
Net (loss) income per share—diluted	\$ (5.75)	\$ 0.71	\$ (4.86)
Weighted average common shares outstanding used in computing net (loss) income per share—basic	47,512	47,010	45,999
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	47,512	47,341	45,999

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**Consolidated Statements of Comprehensive Income (Loss)****(In thousands)**

	<u>Year ended December 31, 2019</u>	<u>Year ended December 31, 2018</u>	<u>Year ended December 31, 2017</u>
Net (loss) income	\$ (272,966)	\$ 33,682	\$ (223,359)
Other comprehensive (loss) income:			
Foreign currency translation adjustment	(4,118)	(3,927)	19,759
Unrealized gains (losses) on available-for-sale securities, net of tax	143	(125)	—
Other comprehensive (loss) income, net of tax	\$ (3,975)	\$ (4,052)	19,759
Comprehensive (loss) income	<u>\$ (276,941)</u>	<u>\$ 29,630</u>	<u>\$ (203,600)</u>

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)	Total stockholders equity
	Number of shares	Par value					
Balance at December 31, 2016	45,680	46	(329)	921,365	(243,970)	(12,901)	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 (pursuant to adoption of ASU 2014-09)	—	—	—	—	27,583	—	27,583
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	\$ 611,984
Compensation expense for issuance of stock options to employees	—	—	—	9,923	—	—	9,923
Compensation expense for issuance of restricted stock to employees	278	—	—	4,327	—	—	4,327
Exercise of stock options	2	—	—	24	—	—	24
Purchase of Treasury Stock	(58)	—	1,495	(1,587)	—	—	(93)
Equity component of convertible notes exchange	—	—	—	(38,404)	—	—	(38,404)
Other comprehensive loss	—	—	—	—	—	(3,975)	(3,975)
Net loss	—	—	—	—	(272,966)	—	(272,966)
Balance at December 31, 2019	47,730	\$ 48	\$ (638)	\$ 979,388	\$ (666,809)	\$ (1,169)	\$ 310,820

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In thousands)

	<u>Year ended December 31, 2019</u>	<u>Year ended December 31, 2018</u>	<u>Year ended December 31, 2017</u>
Cash flows from operating activities:			
Net (loss) income	(272,966)	\$ 33,682	\$ (223,359)
Adjustments to reconcile net (loss) income to net cash (used) provided by operating activities:			
Share-based compensation expense	14,250	21,252	32,814
Amortization of net premiums and discounts on investments	(1,647)	(1,417)	—
Amortization of debt discount and debt issuance costs	15,724	15,822	12,153
Depreciation and amortization expense	34,573	11,479	23,234
Gain on debt extinguishment	(55,073)	—	—
Goodwill and intangible asset impairments	277,561	—	296,763
Change in contingent consideration obligation	(86,935)	55,000	40,622
Gain on sale of Zanaflex franchise	—	—	(3,534)
Gain on sale of Qutenza assets	—	(7,837)	—
Realized gain on foreign currency transaction	—	—	247
Non-cash royalty revenue	(10,271)	(10,291)	(2,705)
Deferred tax benefit	(1,978)	(14,505)	(54,044)
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	1,347	57,972	(29,112)
Decrease (increase) in prepaid expenses and other current assets	14,439	(15,402)	3,445
Decrease in inventory	3,793	8,440	5,505
Decrease in non-current portion of deferred cost of license revenue	—	—	634
Decrease in other assets	11	34	4,138
Decrease in accounts payable, accrued expenses and other current liabilities	(60,564)	(3,488)	(2,099)
Decrease in non-current portion of deferred license revenue	—	—	(9,057)
(Decrease) increase in other non-current liabilities	(431)	52	1,491
Net cash (used) provided by operating activities	<u>(128,167)</u>	<u>150,793</u>	<u>97,136</u>
Cash flows from investing activities:			
Purchases of property and equipment	(90,426)	(33,328)	(13,688)
Purchases of intangible assets	—	(587)	(688)
Net proceeds from sale of Qutenza assets	—	7,884	—
Net proceeds from sale of Zanaflex franchise	—	—	3,663
Purchases of investments	(226,587)	(249,107)	—
Proceeds from maturities of investments	316,508	98,273	—
Net cash used in investing activities	<u>(505)</u>	<u>(176,865)</u>	<u>(10,713)</u>
Cash flows from financing activities:			
Payments on convertible senior notes exchange	(55,199)	—	—
Debt issuance costs	(4,670)	—	—
Proceeds from issuance of common stock and option exercises	24	15,198	10,479
Repayment of non-controlling interest	—	—	2,722
Purchase of treasury stock	(91)	(1,744)	(60)
Net proceeds from royalty monetizations	—	—	50,787
Repayment of loans payable	(614)	(657)	(2,409)
Net cash (used) provided by financing activities	<u>(60,550)</u>	<u>12,797</u>	<u>61,519</u>
Effect of exchange rate changes on cash and cash equivalents and restricted cash	62	(412)	1,225
Net (decrease) increase in cash and cash equivalents and restricted cash	<u>(189,160)</u>	<u>(13,687)</u>	<u>149,167</u>
Cash, cash equivalents and restricted cash at beginning of period	294,351	308,038	158,871
Cash, cash equivalents and restricted cash at end of period	<u>\$ 105,191</u>	<u>\$ 294,351</u>	<u>\$ 308,038</u>
Supplemental disclosure:			
Non-cash debt issuance cost	\$ 490	\$ —	\$ —
Cash paid for interest	6,056	6,064	6,066
Cash paid for taxes	2,791	20,709	14,929

See accompanying Notes to Consolidated Financial Statements.

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

(1) Organization and Business Activities

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a biopharmaceutical company 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 derivative liability associated with the exchange of the new convertible senior secured notes due 2024, which is marked to market each quarter based on a Monte Carlo model approach, 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 an escrow account with funds to maintain the interest payments for an amount equal to all remaining scheduled interest payments on the outstanding new convertible senior secured notes due 2024 through the interest

payment date of June 1, 2023; and a bank account with funds to cover the Company's self-funded employee health insurance. At December 31, 2019, 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 and \$30.0 million related to the escrow account for interest payments included in restricted cash – non current in the consolidated balance sheet due to the long-term nature of the letters of credit and interest payments. (see Note 10).

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:

(In thousands)	December 31, 2019		December 31, 2018		December 31, 2017	
	Beginning of period	End of period	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	\$ 293,564	\$ 62,085	\$ 307,068	\$ 293,564	\$ 158,537	\$ 307,068
Restricted cash	532	12,836	410	532	79	410
Restricted cash-non current	255	30,270	560	255	255	560
Total Cash, cash equivalents and restricted cash per statement of cash flows	<u>\$ 294,351</u>	<u>\$ 105,191</u>	<u>\$ 308,038</u>	<u>\$ 294,351</u>	<u>\$ 158,871</u>	<u>\$ 308,038</u>

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) consisted 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, 2019 and 2018. The cumulative foreign currency translation adjustment reported in Other Comprehensive Income (Loss) was \$(4.1) million and \$(3.9) million for the period ended December 31, 2019 and 2018, 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 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 \$0.0 million and \$8.4 million for the years ended December 31, 2019 and 2018, respectively. Production costs related to idle capacity are not included in the cost of inventory but are charged directly to cost of sales in the period incurred. We recorded an idle

capacity charge to cost of goods sold of \$0.7 million and \$0.0 million for the years ended December 31, 2019 and 2018, respectively.

The following table provides the major classes of inventory:

(In thousands)	December 31, 2019		December 31, 2018	
Raw materials	\$	1,753	\$	—
Work-in-progress		13,509		—
Finished goods		9,959		29,014
Total	\$	25,221	\$	29,014

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. The Company capitalizes interest costs for assets under construction.

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. The impairment test for goodwill uses an approach which 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, an impairment loss is recognized in an amount equal to the excess of the carrying value over the estimated fair value. The Company recorded an impairment charge of \$277.6 million for the year ended December 31, 2019 in the statement of operations. 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.

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, including identifiable intangible assets subject to amortization and property plant and equipment, 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. Factors the Company considers important that could trigger an impairment review include significant changes in the use of any assets, changes in historical trends in operating performance, changes in projected operating performance, stock price, loss of a major customer and significant negative economic trends. The decline in the trading price of the Company's common stock during the quarter ended September 30, 2019, and related decrease in the Company's market capitalization, was determined to be a triggering event in connection with the Company's review of the recoverability of its long-lived assets for the year ended December 31, 2019. The Company performed a recoverability test during the third quarter of fiscal 2019 using the undiscounted cash flows, which are the sum of the future undiscounted cash flows expected to be derived from the direct use of the long-lived assets to the carrying value of the long-lived assets. Estimates of future cash flows were based on the Company's own assumptions about its own use of the long-lived assets. The cash flow estimation period was based on the long-lived assets' estimated remaining useful life to the Company. After performing the recoverability test, the Company determined that the undiscounted cash flows exceeded the carrying value and the long-lived assets were not impaired. Changes in these assumptions and resulting valuations could result in future long-lived asset impairment charges. Management will continue to monitor any changes in circumstances for indicators of impairment. 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 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.

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
Assets			
Other current assets	\$ 1,983	\$ (634)	\$ 1,349
Non-current portion of deferred cost of license revenue	1,638	(1,638)	—
Total Assets	\$ 1,197,969	\$ (2,272)	\$ 1,195,697
Liabilities and Stockholders’ Equity			
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)
Total liabilities and stockholders' equity	\$ 1,197,969	\$ (2,272)	\$ 1,195,697

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
Assets			
Other current assets	\$ 10,828	\$ (634)	\$ 10,194
Non-current portion of deferred cost of license revenue	1,004	(1,004)	—
Total Assets	\$ 1,301,304	\$ (1,638)	\$ 1,299,666
Liabilities and Stockholders' Equity			
Current portion of deferred license revenue	\$ 9,057	\$ (9,057)	\$ —
Non-current portion of deferred license revenue	14,341	(14,341)	—
Deferred tax liability	6,988	495	7,483
Accumulated deficit	(415,108)	21,265	(393,843)
Total liabilities and stockholders' equity	\$ 1,301,304	\$ (1,638)	\$ 1,299,666

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:

(In thousands)	Year Ended December 31, 2018 Balance Prior to Adoption of ASC 606	Effect of Change	Year Ended December 31, 2018 Balance as Reported 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.

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, 2019 and December 31, 2018.

Product Revenue, Net

Inbrija

Inbrija is available primarily through a network of specialty pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate).

Ampyra

Ampyra is distributed primarily through a network of specialty pharmacies, which deliver the medication to patients by mail.

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.

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, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSourceBergen affiliate). 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 upon receipt to Ampyra and Inbrija customers or a limited right of return based on the product's expiration date to previous Zanaflex and Qutenza 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.

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, 2019, 2018 or 2017.

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

(In thousands)	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Revenues:			
Net product revenues:			
Ampyra	\$ 163,162	\$ 455,096	\$ 543,343
Inbrija	15,303	—	—
Other	2,271	4,643	6,406
Total net product revenues	<u>180,736</u>	<u>459,739</u>	<u>549,749</u>
Royalty revenues	11,672	11,694	29,481
License revenue	—	—	9,057
Total net revenues	<u>\$ 192,408</u>	<u>\$ 471,433</u>	<u>\$ 588,287</u>

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 its product Ampyra. 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.

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, 2019 were a network of specialty pharmacies and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate) for Inbrija and a network of specialty pharmacies 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 83% of total revenue in 2019. Four customers individually accounted for more than 10% of the Company's revenue in 2018 and 2017. Four customers individually accounted for more than 10% of the Company's accounts receivable or approximately 91% of total accounts receivable as of December 31, 2019. 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. 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 \$2.7 million and \$6.4 million for the years ended December 31, 2019 and 2018, respectively. The Company's reserve for cash discount allowances was \$0.4 million as of December 31, 2019 and 2018,

(in thousands)	Cash discounts	
Balance at December 31, 2017	\$	844
Allowances for sales		6,371
Actual credits		(6,820)
Balance at December 31, 2018	\$	395
Allowances for sales		2,722
Actual credits		(2,705)
Balance at December 31, 2019	\$	412

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, 2019 or December 31, 2018. There were no provisions and write-offs for the years ended December 31, 2019 and 2018.

Allowance for Chargebacks

Based upon the Company's contracts and the most recent experience with respect to sales with the U.S. 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 \$6.5 million and \$18.9 million for the years ended December 31, 2019 and December 31, 2018, respectively. The Company made a payment of \$8.5 million and \$16.7 million related to the chargebacks allowances for the years ended December 31, 2019 and December 31, 2018, respectively. The Company's reserve for chargebacks allowance was \$0.2 million and \$2.2 million as of December 31, 2019 and December 31, 2018, respectively.

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;
- (e) Capital and R&D loans were measured at fair value based on a discounted cash flow approach;
- (f) New convertible senior secured notes due 2024 were measured at fair value based on market quoted prices of the debt securities; and
- (g) Derivate liability related to conversion option of the new convertible senior secured notes due 2024 is measured at fair value using a Monte Carlo simulation 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. Cumulative translation adjustments are reflected as a separate component of equity. Foreign currency transaction gains and losses are charged to operation and reported in other income (expense) in consolidated statements of operations.

Segment and Geographic Information

The Company is managed and operated as one business which is focused on developing therapies that restore function and improve the lives of people with neurological disorders. The entire business is managed by a single management team

that reports to the Chief Executive Officer. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare discrete financial information to allocate resources to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment. Net product revenues reported to date are derived from the sales of Ampyra and Inbrija in the U.S. for the year ended December 31, 2019 and Ampyra and Qutenza in the U.S. for the year ended December 31, 2018 and Ampyra, Zanaflex and Qutenza in the U.S. for the year ended December 31, 2017.

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

In February 2016, the FASB issued ASU 2016-02, "Leases" Topic 842, which amends the guidance in former ASC Topic 840, *Leases*. The new standard increases transparency and comparability most significantly by requiring the recognition by lessees of right-of-use ("ROU") assets and lease liabilities on the balance sheet for all leases longer than 12 months. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. For lessees, leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

The Company adopted the new lease guidance effective January 1, 2019 using the modified retrospective transition approach, applying the new standard to all of its leases existing at the date of initial application which is the effective date of adoption. 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. We elected the package of practical expedients which permits us to not reassess (1) whether any expired or existing contracts are or contain leases, (2) the lease classification for any expired or existing leases, and (3) any initial direct costs for any existing leases as of the effective date. We did not elect the hindsight practical expedient which permits entities to use hindsight in determining the lease term and assessing impairment. The adoption of the lease standard did not change our previously reported consolidated statements of operations and did not result in a cumulative catch-up adjustment to opening equity. See Note 3 for further information.

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 adopted the rule in the three-month period ended March 31, 2019 and included its first presentation of changes in stockholders' equity in its Form 10-Q for the three-month period ended March 31, 2019.

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. The reclassification is the difference between the amount previously recorded in other comprehensive income at the historical U.S. federal tax rate that remains in accumulated other comprehensive loss at the time the Act was effective and the amount that would have been recorded using the newly enacted rate. This guidance became effective in Q1 2019; however, the Company did not elect to make the optional reclassification.

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 and are 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 ASU became effective in Q1 2019. The ASU did not have a significant impact on its consolidated financial statements.

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 adopted this guidance on April 1, 2019. The ASU did not have an impact upon adoption on its consolidated financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This ASU provides guidance for recognizing credit losses on financial instruments based on an estimate of current expected credit losses model. This new standard amends the current guidance on the impairment of financial instruments and adds an impairment model known as current expected credit loss (CECL) model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. The FASB subsequently issued ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments and ASU 2019-11, Codification Improvements to Topic 326, Financial Instruments - Credit Losses to clarify and address certain items related to the amendments in ASU 2016-13. ASU 2019-05, Financial Instruments - Credit Losses (Topic 326): Targeted Transition Relief, was issued to provide entities that have certain instruments within the scope of ASC 326 with an option to irrevocably elect the fair value option under ASC 825-10, Financial Instruments - Overall, applied on an instrument-by-instrument basis for eligible instruments. ASC 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those fiscal years with early adoption permitted. The Company does not anticipate a significant impact on its consolidated financial statements based on the available for sale debt instruments currently held and its historical trend of bad debt expense relating to trade accounts receivable.

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 amendment 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 the adoption of this guidance may have on its disclosure requirements in 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 to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license).” The ASU is effective 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 the adoption of this guidance may have on its consolidated financial statements.

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 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 the adoption of this guidance may have on its consolidated financial statements

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes. The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This ASU is effective for fiscal years beginning after December 15,

2020, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance 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) Leases

In February 2016, the FASB issued ASU 2016-02, "Leases" Topic 842, which amends the guidance in former ASC Topic 840, *Leases*. The new standard increases transparency and comparability most significantly by requiring the recognition by lessees of right-of-use ("ROU") assets and lease liabilities on the balance sheet for all leases longer than 12 months. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. For lessees, leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

The Company adopted the new lease guidance effective January 1, 2019 using the modified retrospective transition approach, applying the new standard to all of its leases existing at the date of initial application which is the effective date of adoption. 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. We elected the package of practical expedients which permits us to not reassess (1) whether any expired or existing contracts are or contain leases, (2) the lease classification for any expired or existing leases, and (3) any initial direct costs for any existing leases as of the effective date. We did not elect the hindsight practical expedient which permits entities to use hindsight in determining the lease term and assessing impairment. The adoption of the lease standard did not change our previously reported consolidated statements of operations and did not result in a cumulative catch-up adjustment to opening equity. The adoption of the new guidance resulted in the recognition of ROU assets of \$28.0 million and lease liabilities of \$35.1 million at January 1, 2019. The difference between the ROU assets and the lease liabilities is primarily due to unamortized initial direct costs, lease incentives and deferred rent related to the Company's operating leases at December 31, 2018.

The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. In calculating the present value of the lease payments, the Company elected to utilize its incremental borrowing rate based on the remaining lease terms as of the January 1, 2019 adoption date.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred, if any. Our leases have remaining lease terms of 2.5 years to 7 years, some of which include options to extend the lease term for up to 15 years, and some of which include options to terminate the lease within 2.5 years.

The Company has elected the practical expedient to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, current operating lease liabilities and non-current operating lease liabilities.

The new standard also provides practical expedients and certain exemptions for an entity's ongoing accounting. We have elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases where the initial lease term is one year or less or for which the ROU asset at inception is deemed immaterial, we will not recognize ROU assets or lease liabilities. Those leases are expensed on a straight line basis over the term of the lease.

Operating Leases

We lease certain office space, manufacturing and warehouse space under arrangements classified as leases under ASC 842. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for these leases on a straight-line basis over the lease term. Most leases include one or more options to renew, with renewal options ranging from 5 to 15 years. The exercise of lease renewal options is at our sole discretion. One of our leases also includes an option to early terminate the lease within 2.5 years.

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. The Company's extension and early termination 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 \$4.8 million per year, which reflects an annual 2.5% escalation factor.

Chelsea, Massachusetts

Through our Civitas subsidiary, we lease a manufacturing facility in Chelsea, Massachusetts which we use to manufacture Inbrija. 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 \$1.7 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 \$0.4 million per year with an annual escalation factor of 3.0%.

In 2018, the Company initiated a renovation and expansion of a building within the Chelsea manufacturing facility that increased the size of the facility to approximately 95,000 square feet. The project has added a new manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing manufacturing line, and has created 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 increased to \$1.7 million. Although the project was substantially completed in late 2019, it will take additional time after completion of construction to obtain the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA, Massachusetts state environmental permits, and approvals from other regulatory authorities. All costs to renovate and expand the facility are borne by the Company, and will be accounted for as leasehold improvements when the renovation and expansion is approved to be used for production.

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 \$1.1 million per year.

Our leases have remaining lease terms of 2.5 years to 7 years, which assumes exercise of the early termination of our Ardsley, NY lease. We do not include any renewal options in our lease terms when calculating our lease liabilities as we are

not reasonably certain that we will exercise these options. When calculating the lease liability, we assume exercise of the Ardsley early termination option. The weighted-average remaining lease term for our operating leases was 5 years at December 31, 2019. The weighted-average discount rate was 7.13% at December 31, 2019.

ROU assets and lease liabilities related to our operating leases are as follows:

(In thousands)	Balance Sheet Classification	December 31, 2019
Right-of-use assets	Right of use assets	\$ 23,450
Current lease liabilities	Current portion of lease liabilities	7,746
Non-current lease liabilities	Non-current portion of lease liabilities	22,996

We have lease agreements that contain both lease and non-lease components. We account for lease components together with non-lease components (e.g., common-area maintenance). The components of lease costs were as follows:

(In thousands)	Year ended December 31,	
	2019	
Operating lease cost	\$	7,070
Variable lease cost		4,585
Short-term lease cost		1,417
Total lease cost	\$	13,072

Future minimum commitments under all non-cancelable operating leases are as follows:

(In thousands)		
2020	\$	7,746
2021		7,935
2022		9,971
2023		3,043
2024		3,128
Later years		4,537
Total lease payments		36,360
Less: Imputed interest		(5,619)
Present value of lease liabilities	\$	30,741

Supplemental cash flow information and non-cash activity related to our operating leases are as follows:

(In thousands)	December 31, 2019	
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	\$	7,507
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations	\$	770

(4) Intangible Assets and Goodwill

Intangible Assets

Inbrija (levodopa inhalation powder) and ARCUS Technology

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

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 commencing upon launch in February 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 (the "District Court") 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 in 2017 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, 2019 or December 31, 2018.

Tozadenant, SYN120, BTT1023 and Selincro IPR&D

In connection with the acquisition of Biotie, the Company acquired global rights to tozadenant, SYN120, and BTT1023 (timolimumab). 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

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, 2019, 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:

(Dollars In thousands)	Estimated Remaining Useful Lives (Years)	December 31, 2019				December 31, 2018				
		Cost	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Cost	Accumulated Amortization	Reclass to Definite-lived asset	Foreign Currency Translation	Net Carrying Amount
In-process research & development (1)	Indefinite-lived	\$ 4,300	\$ —	\$ (88)	\$ 4,212	\$ 427,500	\$ —	\$ (423,000)	\$ (200)	\$ 4,300
Inbrija (2)	13	423,000	(25,636)	—	397,364	—	—	423,000	—	423,000
Ampyra milestones	n/a	—	—	—	—	5,750	(5,750)	—	—	—
Ampyra CSRO royalty buyout	n/a	—	—	—	—	3,000	(3,000)	—	—	—
Website development costs	2	14,559	(13,806)	—	753	13,857	(13,289)	—	—	568
Website development costs—in process	n/a	—	—	—	—	702	—	—	—	702
		<u>\$ 441,859</u>	<u>\$ (39,442)</u>	<u>\$ (88)</u>	<u>\$ 402,329</u>	<u>\$ 450,809</u>	<u>\$ (22,039)</u>	<u>\$ —</u>	<u>\$ (200)</u>	<u>\$ 428,570</u>

- (1) Includes the fair value of BTT1023.
- (2) In December 2018, the Company received FDA approval for Inbrija and accordingly reclassified the indefinite lived intangible assets to definite lived intangible assets and began amortizing the assets upon launch in February 2019.

The Company recorded amortization expense of \$26.2 million of which \$25.6 million pertained to the intangible asset related to Inbrija and \$0.6 million related to the amortization of website development costs and \$2.4 million of which \$1.7 million pertained to the intangible asset related to Ampyra and \$0.7 million related to the amortization of website development costs related to these intangible assets for the years ended December 31, 2019 and 2018, respectively.

Estimated future amortization expense for intangible assets subsequent to December 31, 2019 is as follows:

(In thousands)		
2020	\$	31,136
2021		31,023
2022		30,885
2023		30,764
2024		30,764
Thereafter		243,545
	<u>\$</u>	<u>398,117</u>

The weighted-average remaining useful lives of all amortizable assets is approximately 13.0 years.

Goodwill

During the third quarter of 2019, we experienced a significant decline in our stock price that reduced the market capitalization below the carrying value of the Company. The Company performed a quantitative assessment of the goodwill and concluded that there was an impairment to the goodwill. The Company utilized the income approach in the goodwill assessment process. The determination of the fair value of the reporting unit requires us to make significant estimates and assumptions. This valuation approach considers a number of factors that include, but are not limited to, prospective financial information, growth rates, terminal value, and discount rates and require us to make certain assumptions and estimates. When performing our income approach, we incorporate the use of projected financial information and a discount rate that are developed based on certain assumptions. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. The Company then corroborates the reasonableness of the total fair value of the reporting unit by reconciling the aggregate fair value of the reporting unit to the Company's total market capitalization adjusted to include an estimated control premium. The estimated control premium is derived from reviewing observable transactions involving the purchase of controlling interests in comparable companies. The market capitalization is calculated using the relevant shares outstanding and the closing stock price at the test date. After completing our impairment assessment during the third quarter of 2019, we concluded that the carrying value of the Company exceeded its estimated fair value and therefore, the goodwill was fully impaired. The Company recorded an impairment charge of \$277.6 million for the year ended December 31, 2019 in the statement of operations.

The following table presents the goodwill balances at December 31, 2019 and 2018 and the associated changes in goodwill through December 31, 2019.

(In thousands)		
Balance at December 31, 2018	\$	282,059
Impairment		(277,561)
Foreign currency translation adjustment		(4,498)
Balance at December 31, 2019	\$	—

(5) Qutenza and Zanaflex Asset Sales

In May 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.

In November 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, 2019 and December 31, 2018, respectively:

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
December 31, 2019				
Commercial Paper	\$ 26,550	\$ 19	\$ —	\$ 26,569
Corporate Bonds	37,177	20	(12)	37,185
Total Short-term Investments	<u>\$ 63,727</u>	<u>\$ 39</u>	<u>\$ (12)</u>	<u>\$ 63,754</u>
December 31, 2018				
Commercial Paper	\$ 47,149	\$ —	\$ (41)	\$ 47,108
Corporate Bonds	104,965	6	(90)	104,881
Total Short-term investments	<u>\$ 152,114</u>	<u>\$ 6</u>	<u>\$ (131)</u>	<u>\$ 151,989</u>

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately \$2.2 million and \$9.6 million as of December 31, 2019 and December 31, 2018, respectively. Short-term investments have original maturities of greater than 3 months but less than 1 year and amounted to approximately \$63.8 million and \$152.0 million as of December 31, 2019 and December 31, 2018, respectively. The aggregate fair value of short-term investments in an unrealized loss position amounted to approximately \$25.5 million and \$139.6 million as of December 31, 2019 and December 31, 2018, respectively. Short-term investments at December 31, 2019 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, 2019 or December 31, 2018. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of December 31, 2019 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 gains on available-for-sale investments during the year ended December 31, 2019, were as follows (in thousands):

(In thousands)	Net Unrealized Gains (Losses) on Short-term Investments
Balance at December 31, 2018	\$ (125)
Other comprehensive loss before reclassifications:	
Amounts reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive gains	152
Balance at December 31, 2019	<u>\$ 27</u>

(7) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2019	December 31, 2018	Estimated useful lives used
Machinery and equipment	\$ 27,106	\$ 24,798	2-7 years
			Lesser of useful life or remaining lease term
Leasehold improvements	25,305	25,047	
Computer equipment	22,604	21,472	1-3 years
Laboratory equipment	9,415	9,021	2-5 years
Furniture and fixtures	2,260	2,599	4-7 years
Construction in progress	120,313	34,489	
	<u>207,003</u>	<u>117,426</u>	
Less accumulated depreciation	(64,476)	(56,907)	
	<u>\$ 142,527</u>	<u>\$ 60,519</u>	

Depreciation and amortization expense on property and equipment was \$8.4 million and \$9.0 million for the years ended December 31, 2019 and 2018, respectively.

(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 might have resulted in an acquisition of control of the Company, including tender offers and open market purchases of the Company's securities. The Rights expired at the close of business on August 31, 2018. There were no rights exercised prior to the expiration.

In general terms, the Rights Plan worked by significantly diluting the stock ownership of any person or group that acquired 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 exempted any person or group owning 15% or more of the Company's outstanding common stock when we announced the rights plan, however the exemption did 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 became

exercisable, entitled 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, 2019 and 2018, there were 1,000,000 preferred shares authorized and no such shares issued and outstanding. In addition, one Right would have automatically attached to each Common Share that became 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 was the close of business on the tenth day after the first date of public announcement that any person had become an Acquiring Person or such earlier date as a majority of the Board became aware of the existence of an Acquiring Person. Until a Right was exercised, the holder thereof, had 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.

(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, 2019 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, 2019, the Company had granted an aggregate of 11,725,092 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 4,710,174 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, 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, 2019 is 8,100,000 shares. As of December 31, 2019, the Company had granted an aggregate of 8,069,994 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 5,725,209 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, 2019, the Company had granted an aggregate of

140,975 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2016 Plan, of which 32,125 shares remained subject to outstanding options.

On June 19, 2019, the Company's stockholders approved the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP Plan") at the annual meeting of stockholders pursuant to which up to 1,500,000 shares of the Company's common stock, par value \$0.001 per share may be issued thereunder (the "Plan Shares"). As of December 31, 2019, there were 1,500,000 shares of common stock remaining authorized for issuance under the 2019 ESPP Plan.

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

	Year ended December 31,		
	2019	2018	2017
Employees and directors:			
Estimated volatility%	67.52%	52.29%	48.02%
Expected life in years	6.25	6.16	6.15
Risk free interest rate%	1.85%	2.76%	2.08%
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, 2019, 2018 and 2017 amounted to approximately \$2.56, \$12.71, and \$10.70, respectively. No options were granted to non-employees for the years ended December 31, 2019, 2018 and 2017.

During the year ended December 31, 2019, the Company granted 3,005,511 stock options to employees and directors under all plans. The stock options were issued with a weighted average exercise price of \$4.48 per share. As a result of these grants, the total compensation charge to be recognized over the service period is \$12.0 million, of which \$3.3 million was recognized during the year ended December 31, 2019.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$14.3 million, \$21.3 million, and \$32.8 million, for the years ended December 31, 2019, 2018 and 2017, respectively. Of the total compensation cost, there was \$0.7 million compensation cost capitalized in inventory balances for the year ended December 31, 2019. Compensation expense for options and restricted stock granted to employees and directors are classified in inventory, research and development, selling, general and administrative, and cost of sales 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,		
	2019	2018	2017
Research and development	\$ 2,812	\$ 5,560	\$ 9,683
Selling, general and administrative	10,814	15,692	23,131
Cost of sales	624	—	—
Total	<u>\$ 14,250</u>	<u>\$ 21,252</u>	<u>\$ 32,814</u>

A summary of share-based compensation activity for the year ended December 31, 2019 is presented below:

Stock Option Activity

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at December 31, 2018	8,194	\$ 29.81		
Granted	3,006	4.48		
Forfeited and expired	(730)	23.88		
Exercised	(2)	16.00		
Balance at December 31, 2019	10,469	\$ 22.96	5.3	\$ 3
Vested and expected to vest at December 31, 2019	10,399	\$ 23.08	5.3	\$ 3
Vested and exercisable at December 31, 2019	7,264	\$ 30.08	3.6	—

Range of exercise price	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2019 (In thousands)	Weighted- average remaining contractual life	Weighted- average exercise price	Exercisable as of December 31, 2019 (In thousands)	Weighted- average exercise price
\$1.61 - \$1.61	3	9.9	\$ 1.61	—	\$ —
\$1.81 - \$2.41	2,335	9.6	2.41	—	—
\$2.55 - \$24.35	2,105	5.8	18.14	1,438	19.26
\$24.45 - \$30.46	2,503	3.5	28.17	2,342	28.25
\$30.49 - \$44.50	3,522	3.4	35.76	3,484	35.77
	10,468	5.3	\$ 22.96	7,264	\$ 30.08

Restricted Stock Activity

Restricted Stock	Number of Shares (In thousands)
Nonvested at December 31, 2018	231
Granted	628
Vested	(286)
Forfeited	(148)
Nonvested at December 31, 2019	425

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2019 totaled \$14.7 million and is expected to be recognized over a weighted average period of approximately 1.9 years.

(10) Debt

New Convertible Senior Secured Notes Due 2024

On December 24, 2019, the Company completed the private exchange of \$276.0 million aggregate principal amount of its outstanding 1.75% Convertible Senior Notes due 2021 (the “2021 Notes”) for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the “New Notes”) and cash. For each \$1,000 principal amount of exchanged 2021 Notes, the Company issued \$750 principal amount of the New Notes and made a cash payment of \$200 (the “Exchange”). In the aggregate, the Company issued approximately \$207.0 million aggregate principal amount of the New Notes and paid approximate \$55.2 million in cash to participating holders. The Exchange was conducted with a limited number of institutional holders of the 2021 Notes pursuant to Exchange Agreements dated as of December 20, 2019 (each, an “Exchange Agreement”).

The New Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among the Company, its wholly owned subsidiary, Civitas Therapeutics, Inc. (along with any domestic subsidiaries acquired or formed after the date of issuance, the “Guarantors”), and Wilmington Trust, National Association, as trustee and collateral agent (the “Indenture”). The New Notes are senior obligations of the Company and the Guarantors, secured by a first priority security interest in substantially all of the assets of the Company and the Guarantors, subject to certain exceptions described in the Security Agreement, dated as of December 23, 2019, between the grantors party thereto and Wilmington Trust, National Association, as collateral agent (the “Security Agreement”).

The New Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms prior to such date. Interest on the New Notes will be payable semi-annually in arrears at a rate of 6.00% per annum on each June 1 and December 1, beginning on June 1, 2020. The Company may elect to pay interest in cash or shares of the Company’s common stock, subject to the satisfaction of certain conditions. If the Company elects to pay interest in shares of common stock, such common stock will have a per share value equal to 95% of the daily volume-weighted average price for the 10 trading days ending on and including the trading day immediately preceding the relevant interest payment date.

The New Notes will be convertible at the option of the holder into shares of common stock of the Company at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion rate for the New Notes is 285.7142 shares of the Company’s common stock per \$1,000 principal amount of New Notes, representing an initial conversion price of approximately \$3.50 per share of common stock. The conversion rate is subject to adjustment in certain circumstances as described in the Indenture.

The Company may elect to settle conversions of the New Notes in cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock. Holders who convert their New Notes prior to June 1, 2023 (other than in connection with a make-whole fundamental change) will also be entitled to an interest make-whole payment equal to the sum of all regularly scheduled stated interest payments, if any, due on such New Notes on each interest payment date occurring after the conversion date for such conversion and on or before June 1, 2023. In addition, the Company will have the right to cause all New Notes then outstanding to be converted automatically if the volume-weighted average price per share of the Company’s common stock equals or exceeds 130% of the conversion price for a specified period of time and certain other conditions are satisfied.

Holders of the New Notes will have the right, at their option, to require the Company to purchase their New Notes if a fundamental change (as defined in the Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the New Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

Notwithstanding the foregoing, the Company’s ability to settle conversions and make interest payments using shares of its common stock is subject to certain limitations set forth in the Indenture until the time, if any, that the Company’s stockholders have approved (i) the issuance of more than 19.99% of the Company’s outstanding shares in accordance with Nasdaq listing standards and (ii) an amendment to the Company’s certificate of incorporation to increase the number of authorized shares. The Company intends to seek stockholder approval of these matters at its 2020 Annual Meeting of Stockholders.

Subject to a number of exceptions and qualifications, the Indenture restricts the ability of the Company and certain of its subsidiaries to, among other things, (i) pay dividends or make other payments or distributions on their capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) make certain investments, (iii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, which includes, among other items, indebtedness incurred to refinance the 2021 Notes, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell of all or substantially all of their assets. The Indenture also requires the Company to make an offer to repurchase the New Notes upon the occurrence of certain asset sales.

The Indenture provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the New Notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the New Notes in accordance with the Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the Indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by the Company to make required payments under other indebtedness of the Company or certain subsidiaries having an outstanding principal amount of \$30.0 million or more, (vii) failure by the Company or certain subsidiaries to pay final judgments aggregating in excess of \$30.0 million, (viii) certain events of

bankruptcy or insolvency and (ix) the commercial launch in the United States of a product determined by the U.S. FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to the Company, all outstanding New Notes will become due and payable immediately without further action or notice. If any other event of default occurs and is continuing, the trustee or the holders of at least 25% in aggregate principal amount of the then outstanding new convertible notes may declare all the notes to be due and payable immediately.

The 2021 Notes received by the Company in the Exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, \$69.0 million of the 2021 Notes remained outstanding.

The Company determined that the exchange of the 2021 Notes for New Notes qualified for a debt extinguishment and recognized a gain on extinguishment of \$55.1 million for the year ended December 31, 2019, representing the difference between the fair value of the liability component immediately before the exchange and the carrying value of the debt. The Company recorded an adjustment of \$38.4 million to additional paid-in capital to adjust the equity component of 2021 Notes in connection with the extinguishment.

The Company assessed all terms and features of the New Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the New Notes, including the conversion, put and call features. Per the terms of the Indenture, the Company's ability to settle conversions and make interest payments using shares of its common stock is limited until such time as the Company's stockholders have approved a waiver of a share limit imposed under Nasdaq rules and a necessary increase in the number of authorized shares of common stock. The Company has until July 31, 2020 to obtain the necessary stockholder approvals and, prior to the earlier of July 31, 2020 and the date such approvals are received, the Company is entitled to settle conversions and make interest whole payments using shares of common stock, and is not required to make cash payments with respect to shares of common stock that are not delivered due to the applicable share limits. In consideration of these provisions, the Company concluded the conversion feature required bifurcation as a derivative. The fair value of the conversion feature derivative was determined based on the difference between the fair value of the New Notes with the conversion option and the fair value of the New Notes without the conversion option. The Company employed a Monte Carlo simulation approach and determined that the fair value of the derivative upon issuance of the New Notes was \$59.4 million and recorded this amount as a derivative liability with an offsetting amount as a debt discount as a reduction to the carrying value of the Notes on the closing date, or December 24, 2019. The conversion feature will be measured at fair value on a quarterly basis and the change in the fair value of the conversion feature for the period will be recorded on the consolidated statements of operations. The Company determined that the change in fair value from December 24, 2019 to December 31, 2019 was not material.

The outstanding New Note balance as of December 31, 2019 consisted of the following:

(In thousands)	December 31, 2019
Liability component:	
Principal	\$ 207,000
Less: debt discount and debt issuance costs, net	(80,028)
Net carrying amount	126,972
Derivative liability-conversion Option	\$ 59,409

The Company determined that the expected life of the New Notes was equal to the period through December 1, 2024 as this represents the point at which the New Notes will mature unless earlier converted in accordance with their terms prior to such date. Accordingly, the total debt discount of \$75.1 million, inclusive of the fair value of the embedded conversion feature derivative at issuance, is being amortized using the effective interest method through December 1, 2024. For the year ended December 31, 2019, the Company recognized \$0.5 million of interest expense related to the New Notes at the effective interest rate of 18.01%. The fair value of the Company's New Notes was approximately \$210.6 million as of December 31, 2019.

In connection with the issuance of the Notes, the Company incurred approximately \$5.2 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs 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 New Notes is amortized to interest expense over the expected life of the 2024 Notes using the effective interest method.

Convertible Senior Notes Due 2021

On June 17, 2014, the Company issued \$345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the 2021 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. On December 24, 2019, the Company completed the private exchange of \$276.0 million aggregate principal amount of its outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the "New Notes") and cash. The 2021 Notes received by the Company in the exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the exchange, \$69.0 million of the 2021 Notes remained outstanding.

The 2021 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 the 2021 Notes (representing an initial conversion price of approximately \$42.56 per share).

The Company may redeem for cash all or part of the 2021 Notes, at the Company's option, on or after June 20, 2017, under certain circumstances as outlined in the indenture.

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

The 2021 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 2021 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 2021 Notes, the Company separated the 2021 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 2021 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, 2019 and 2018 consisted of the following:

(In thousands)	December 31, 2019	December 31, 2018
Liability component:		
Principal	\$ 69,000	\$ 345,000
Less: debt discount and debt issuance costs, net	<u>(3,198)</u>	<u>(26,330)</u>
Net carrying amount	<u>65,802</u>	<u>\$ 318,670</u>
Equity component	<u>\$ 22,791</u>	<u>\$ 61,195</u>

In connection with the issuance of the 2021 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 2021 Notes using the effective interest method. The Company wrote off \$1.2 million of issuance cost associated with the exchange of the 2021 Notes.

The Company determined the expected life of the debt was equal to the seven year term on the 2021 Notes. The fair value of the Company's convertible senior notes was approximately \$52.1 million as of December 31, 2019.

As of December 31, 2019, the remaining contractual life of the 2021 Notes is approximately 1.5 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through December 31, 2019.

The following table sets forth total interest expense recognized related to the 2021 Notes for the years ended December 31, 2019 and 2018:

(In thousands)	Year ended December 31, 2019	Year ended December 31, 2018
Contractual interest expense	\$ 5,957	\$ 6,038
Amortization of debt issuance costs	944	913
Amortization of debt discount	9,258	8,952
Total interest expense	<u>\$ 16,159</u>	<u>\$ 15,903</u>

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 \$24.9 million as of December 31, 2019. The loans comprised 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 \$1.2 million as of December 31, 2019. 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, 2019, 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 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 for the years ended December 31, 2019 and December 2018.

(In thousands)	December 31, 2019	December 31, 2018
Liability related to sale of future royalties - beginning balance	\$ 30,716	\$ 35,788
Deferred transaction costs amortized	639	784
Non-cash royalty revenue payable to HCRP	(10,271)	(10,291)
Non-cash interest expense recognized	3,317	4,435
Liability related to sale of future royalties - ending balance	<u>\$ 24,401</u>	<u>\$ 30,716</u>

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 October 23, 2019, the Company announced a corporate restructuring to reduce costs and focus our resources on the commercial launch of Inbrija. As part of the restructuring, the Company reduced headcount by approximately 25% through a reduction in force. The majority of the reduction took place in the fourth quarter of 2019 immediately after the announcement, and the remainder will be completed by the first quarter of 2020.

In April 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, 2019, December 31, 2018 and December 2017, the Company incurred pre-tax severance and employee separation related expenses of approximately \$4.4 million, \$1.3 million and \$7.6 million, respectively associated with the restructuring. Of the pre-tax severance and employee separation related expenses incurred, \$1.4 million, \$1.2 million and \$5.5 million were recorded in research and development expenses and \$3.0 million, \$0.1 million and \$2.1 million were recorded in selling, general and administrative expenses for the years ended December 31, 2019, December 31, 2018, and December 31, 2017, respectively.

A summary of the restructuring costs for the years ended December 31, 2019 and 2018 is as follows:

(In thousands)	Restructuring Costs	
Restructuring Liability as of December 31, 2017	\$	504
2018 Restructuring costs		1,316
2018 Payments		(1,820)
Restructuring Liability as of December 31, 2018	\$	—
2019 Restructuring costs		4,401
2019 Payments		(3,137)
Restructuring Liability as of December 31, 2019	\$	1,264

(13) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2019	December 31, 2018
Product allowances accruals	\$ 17,855	\$ 26,931
Bonus payable	3,211	18,381
Accrued inventory	—	14,254
Sales force commissions and incentive payments payable	1,123	3,453
Administrative expenses	1,582	2,651
Vacation accrual	2,146	2,395
Research and development expense accruals	1,364	2,374
Commercial and marketing expense accruals	3,202	1,933
Royalties payable	580	509
Other accrued expenses	8,014	4,001
Total	\$ 39,077	\$ 76,882

(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, 2019 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)	\$ 320,198	\$ 13,628	\$ 94,394	\$ 212,176
Research and development loans (4)	1,206	603	603	—
Operating leases (5)	31,723	7,637	17,872	6,214
Inventory purchase commitments (6)	2,798	2,798	—	—
Total	\$ 355,925	\$ 24,666	\$ 112,869	\$ 218,390

- (1) Excludes a liability for uncertain tax positions totaling \$7.1 million. This liability has been excluded because the Company cannot currently make a reliable estimate of the period in which the liability will be payable, if ever.
- (2) Represents the future payments of principal and interest to be made on the convertible senior notes issued in June 2014 and new convertible senior secured notes due 2024 issued in December 2019. The notes will mature and will be payable on June 15, 2021 and December 31, 2024, respectively. See Note 10.
- (3) Excludes a liability for the non-convertible capital loans totaling \$24.9 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. See Note 3.
- (6) Represents Ampyra and Inbrija inventory purchase 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.

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 \$2.8 million as of December 31, 2019.

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 \$41.6 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.

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, 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 existing disputes and claims may lead to losses, the Company cannot estimate any ranges of potential losses as of December 31, 2019. As a result, the Company did not record any loss contingencies for any of these matters. While the outcome of existing disputes and claims is uncertain, the Company does not expect that the resolution of existing disputes and claims would have a material adverse effect on its consolidated financial position or liquidity or the Company's consolidated results of operations. Litigation expenses are expensed as incurred.

(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, 2019. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Recurring

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and December 31, 2018, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(In thousands)	Level 1	Level 2	Level 3
2019			
Assets Carried at Fair Value:			
Money market funds	\$ 2,219	\$ —	\$ —
Commercial paper	—	26,569	—
Corporate bonds	—	37,185	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	80,300
Derivative liability - conversion option	—	—	59,409
2018			
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

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, 2019	Year ended December 31, 2018
Acquired contingent consideration:		
Balance, beginning of period	\$ 168,000	\$ 113,000
Fair value change to contingent consideration (unrealized) included in the statement of operations	(86,935)	55,000
Royalty payments	(765)	—
Balance, end of period	<u>\$ 80,300</u>	<u>\$ 168,000</u>

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. 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 (ii) discount period and rate. The milestone payment outcomes ranged from \$0 to \$45 million for Inbrija. The valuation is performed quarterly and changes to the fair value of the contingent consideration are included in the statement of operations. For the year ended December 31, 2019, changes in the fair value of the acquired contingent consideration were primarily due to the updates to certain estimated assumptions and recalculation of cash flows for the passage of time. 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 sales estimates for Inbrija and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value determined.

Derivative Liability-Conversion Option

The following table represents a reconciliation of the derivative liability recorded in connection with the issuance of the new convertible senior secured notes due 2024:

(In thousands)	Year ended	
	December 31,	2019
Derivative Liability-Conversion Option		
Balance, beginning of period	\$	—
Fair value recognized upon issuance of Convertible Senior Notes		59,409
Fair value adjustment		—
Balance, end of period	\$	<u>59,409</u>

During 2019, a derivative liability was initially recorded as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024 (see Note 10). The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) share price as of the valuation date, (2) assumed timing of conversion of the Notes, (3) historical volatility of share price and (4) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement. The fair value of the derivative liability was determined using a Monte Carlo simulation approach by calculating the fair value of the Notes with the conversion feature as compared to the fair value of the Notes without the conversion feature, with the difference representing the value of the conversion feature, or the derivative liability. The conversion feature will be measured at fair value on a quarterly basis and the change in the fair value of the conversion feature for the period will be recorded on the consolidated statements of operations. The Company determined that the change in the fair value of the conversion option from December 24, 2019 to December 31, 2019 was not material.

(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 2019 or 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, 2019, 2018 and 2017, the Company made or accrued royalty payments totaling \$0.0 million, \$66.6 million and \$59.9 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. 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 year ended December 31, 2017, the Company recognized royalty revenue of \$2.6 million related to the gross margin of the Zanaflex Capsule authorized generic. During the year ended December 31, 2017, the Company also recognized revenue and a corresponding cost of sales of \$3.0 million, 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.

(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 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, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Domestic	\$ (182,816)	\$ 19,211	\$ (172,560)
Foreign	(91,432)	1,212	(79,325)
Total	\$ (274,248)	\$ 20,423	\$ (251,885)

The benefit from income taxes in 2019, 2018 and 2017 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Current:			
Federal	\$ —	\$ 2,991	\$ (11,948)
State	(621)	(4,143)	(12,653)
Foreign	(75)	(93)	(91)
	<u>(696)</u>	<u>(1,245)</u>	<u>(24,692)</u>
Deferred:			
Federal	888	13,790	42,322
State	1,090	714	5,377
Foreign	—	—	5,519
	<u>1,978</u>	<u>14,504</u>	<u>53,218</u>
Total benefit from income taxes	\$ 1,282	\$ 13,259	\$ 28,526

As of December 31, 2019, Acorda's U.S. consolidated tax return has a federal NOL carryforward of approximately \$94.1 million which can be carried forward indefinitely and, under the Act, limited to 80% of taxable income in any year in which it will be utilized. Biotie Therapies, Inc. ("Biotie US"), which files a separate company federal income tax return has

an NOL carryforward of approximately \$120.0 million as of December 31, 2019. The Biotie US NOLs are offset entirely by a valuation allowance and are expected to begin to expire in 2026. The Company's capital loss carryforward of approximately \$428.6 million is fully offset with a valuation allowance. The Company had available state NOL carryforwards of approximately \$220.3 million, \$170.1 million and \$167.9 million as of December 31, 2019, 2018 and 2017, 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 has \$56.6 million of net operating loss carryforwards outside of the U.S. as of December 31, 2019, that begin to expire in 2029 all of which are fully reserved with a valuation allowance.

The Company's research and development and orphan drug credit carry-forwards of \$16.3 million and \$17.1 million as of December 31, 2019 and 2018, respectively, begin to expire in 2031. The Company does not expect to pay cash taxes in various U.S. states as they are in a current year taxable loss. The Company generated a tax liability for its operations in Puerto Rico.

As of December 31, 2019, the Company is expecting a total refund from unused alternative minimum tax credits of \$0.1 million, half of which was claimed in the prior year and the remainder which under the Act will become refundable by 2021.

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. As of December 31, 2019, based on a completed IRC Section 382 analysis, the Company was subject to limitation triggered by the acquisition of Biotie US, which resulted in an estimated \$31.4 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 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 at December 31, 2019. The Company had a net increase of \$106.0 million of valuation allowance primarily related to a capital loss carryforward and net deferred tax assets in states where Acorda files a stand alone tax return.

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, 2019	Year ended December 31, 2018	Year ended December 31, 2017
U.S. federal statutory tax rate	21.0%	21.0%	35.0%
State and local income taxes	0.1%	8.7%	(0.1)%
Stock option compensation	—	0.7%	(0.5)%
Stock option shortfall	(0.8)%	12.6%	(1.5)%
Research and development and orphan drug credits	—	5.6%	1.2%
Uncertain tax positions	0.0%	(0.7)%	(0.3)%
Other nondeductible and permanent differences	(0.1)%	(5.0)%	(0.4)%
Cancellation of debt Income	2.9%	—	—
Goodwill impairment	(21.2)%	0.0%	0.0%
Valuation allowance, net of foreign tax rate differential	(35.1)%	(107.9)%	(19.8)%
NOL write-off	—	16.6%	—
Federal return to provision differences	33.7%	(16.6)%	—
Tax reform	—	—	(2.3)%
Effective income tax rate	<u>0.5%</u>	<u>(65.0)%</u>	<u>11.3%</u>

The Company's overall effective tax rate is affected primarily by the non-deductible goodwill impairment and the federal return to provision difference primarily related to a capital loss deduction which is fully offset by a valuation allowance.

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, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryforward	\$ 69,756	\$ 51,543
Capital loss carryforward	106,031	—
Tax credits	14,351	19,401
Stock based compensation	23,009	22,733
Contingent consideration	18,457	38,594
Employee compensation	1,329	3,677
Rebate and returns reserve	3,584	5,798
Capitalized R&D	10,576	10,791
Derivative liability	14,696	—
Other	15,827	13,881
Total deferred tax assets	\$ 277,616	\$ 166,418
Valuation allowance	(177,572)	(71,570)
Total deferred tax assets net of valuation allowance	\$ 100,044	\$ 94,848
Deferred tax liabilities:		
Intangible assets	(89,629)	(94,771)
Convertible debt	(19,242)	(5,971)
Depreciation	(583)	(1,256)
Other	(171)	(333)
Total deferred tax liabilities	\$ (109,625)	\$ (102,331)
Net deferred tax liability	\$ (9,581)	\$ (7,483)

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

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

(In thousands)	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Beginning of period balance	\$ 7,258	\$ 7,397	\$ 6,856
Increases for tax positions taken during a prior period	—	55	687
Decreases for tax positions taken during a prior period	(113)	(194)	(146)
Increases for tax positions taken during the current period	—	—	—
	\$ 7,145	\$ 7,258	\$ 7,397

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 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 no longer subject to federal income tax audits for tax years prior to 2016, however, such net operating losses utilized by the Company in years subsequent to 2002 are subject to review. The Internal Revenue Service commenced its examination of the Company's wholly-owned subsidiary, Biotie US' income tax return for the short period ended December 31, 2016 in the third quarter of 2018. The audit has been substantially completed, and the IRS has proposed an immaterial adjustment that we do not believe will have an impact to the tax provision. 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 Massachusetts Department of Revenue commenced an examination of the Company's income tax returns for the years 2015 through 2017 in the fourth quarter of 2019. There have been no proposed adjustments at this stage of the examination. The New Jersey Department of Revenue commenced an examination of the Company's income tax returns for the year 2016 through 2018 in the fourth quarter of 2019. There have been no proposed adjustments at this stage of the examination.

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, 2017	\$ 63,225	39,007	(3,623)	\$ 98,609
Year ended December 31, 2018	\$ 98,609	5,465	(32,504)	\$ 71,570
Year ended December 31, 2019	\$ 71,570	110,962	(4,960)	\$ 177,572

(18) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2019, 2018 and 2017:

(In thousands, except per share data)	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Basic and diluted			
Net (loss) income	\$ (272,966)	\$ 33,682	\$ (223,359)
Weighted average common shares outstanding used in computing net (loss) income per share—basic	47,512	47,010	45,999
Plus: net effect of dilutive stock options and unvested restricted common shares	—	331	—
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	47,512	47,341	45,999
Net (loss) income per share—basic	\$ (5.75)	\$ 0.72	\$ (4.86)
Net (loss) income per share—diluted	\$ (5.75)	\$ 0.71	\$ (4.86)

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

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

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

(In thousands)	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Denominator			
Stock options and restricted common shares	10,123	7,370	8,804

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, 2019, 2018 and 2017.

(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 \$2.3 million, \$2.4 million and \$2.4 million for the years ended December 31, 2019, 2018, and 2017, respectively.

(20) Quarterly Consolidated Financial Data (unaudited)

(In thousands, except per share amounts)	2019			
	March 31	June 30	September 30	December 31
Total net revenues	\$ 44,137	\$ 50,053	\$ 47,722	\$ 50,496
Gross profit	35,338	40,656	39,736	41,829
Net (loss) income (1)	(47,605)	(27,486)	(263,535)	65,660
Net loss per share—basic	\$ (1.00)	\$ (0.58)	\$ (5.55)	\$ 1.38
Net loss per share—diluted	\$ (1.00)	\$ (0.58)	\$ (5.55)	\$ 1.38
	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 (2)	(8,199)	46,197	(13,911)	9,595
Net loss per share—basic	\$ (0.18)	\$ 0.99	\$ (0.29)	\$ 0.20
Net loss per share—diluted	\$ (0.18)	\$ 0.98	\$ (0.29)	\$ 0.20

(1) In the third quarter of 2019, the Company recognized a goodwill impairment charge of \$277.6 million. See Note 4 for a discussion of the goodwill impairment charges. In the fourth quarter of 2019, the Company recognized a restructuring charge of \$4.4 million. See Note 12 for a discussion of restructuring charges. In the fourth quarter of 2019, the Company recognized an income of \$30.6 million resulting from the change in fair value of the contingent consideration liability. See Note 15 for a discussion of contingent consideration liability. In the fourth quarter of 2019, the Company recognized a gain on extinguishment of its debt of \$55.1 million. See Note 10 for a discussion of the debt.

(2) 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.

(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.

<u>Exhibit No.</u>	<u>Description</u>
1.1	Underwriting Agreement dated June 17, 2014, by and between the Registrant and J.P. Morgan Securities LLC. Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
3.1	Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006.
3.2	Bylaws of the Registrant, as amended on December 15, 2011. Incorporated herein by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
4.1	Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
4.2	Description of Common Stock.
4.3	Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
4.4	First Supplemental Indenture dated as of June 23, 2014, by and between the Registrant and Wilmington Trust, National Association. Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
4.5	Form of 1.75% Convertible Senior Note due 2021 (included in exhibit 4.4). Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed June 23, 2014.
4.6	Indenture, dated as of December 23, 2019, among the Company, the guarantors party thereto, and Wilmington Trust, National Association, as trustee and collateral agent. Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
4.7	Form of 6.00% Convertible Senior Secured Note due 2024 (included in Exhibit 4.6). Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
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 the 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**	Acorda Therapeutics 2015 Omnibus Incentive Compensation Plan as amended June 8, 2016. Incorporated herein by reference to Appendix A to the Registrant's 2016 Proxy Statement filed as Schedule 14A on April 29, 2016.
10.6**	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.
10.7**	Forms of equity award documents for awards under the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.8**	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.
10.9**	Form of Performance Unit Agreement for awards under the Acorda Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2016.
10.10**	Acorda Therapeutics, Inc. 2019 Employee Stock Purchase Plan. Incorporated by reference to Appendix A to the Registrant's 2019 Proxy Statement filed as Schedule 14A on April 26, 2019.
10.11**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.12**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.13**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.14**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.15**	Amendment to August 11, 2002 Employment Agreement dated June 21, 2011, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.16**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and 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.
10.17**	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 the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.18**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and 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
10.19**	Amendment to December 19, 2005 Employment Agreement, dated August 13, 2019, by and between the Registrant and David Lawrence. Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2019.
10.20**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.21**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.22**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.69 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.23**	Amendment to December 19, 2005 Employment Agreement, dated August 13, 2019, by and between the Registrant and Jane Wasman. Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 7, 2019.
10.24**	Consulting Agreement, dated November 11, 2019, by and between the Registrant and Jane Wasman.
10.25**	Employment offer letter, dated January 22, 2010, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.57 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2010.
10.26**	Letter agreement dated November 7, 2011, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.70 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.27**	Employment Agreement, dated as of June 8, 2015, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.28**	Employment offer letter, dated 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.
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.

Exhibit No.	Description
10.33	<u>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.</u>
10.34	<u>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.</u>
10.35	<u>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.</u>
10.36	<u>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.</u>
10.37	<u>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.</u>
10.38	<u>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.</u>
10.39	<u>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.</u>
10.40	<u>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.</u>
10.41	<u>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.</u>
10.42*	<u>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.</u>
10.43	<u>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.</u>
10.44*	<u>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.</u>
10.45*	<u>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.</u>

Exhibit No.	Description
10.46	<u>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.</u>
10.47*	<u>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.</u>
10.48	<u>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.</u>
10.49*	<u>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.</u>
10.50*	<u>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.</u>
10.51	<u>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.</u>
10.52	<u>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 the Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.</u>
10.53	<u>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.</u>
10.54	<u>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.</u>
10.55*	<u>Collaboration and License Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2019.</u>
10.56*	<u>Supply Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2014.</u>
10.57*	<u>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.</u>
10.58*	<u>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.</u>

Exhibit No.	Description
10.59*	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.
10.60*	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.
10.61*	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.
10.62	Form of Exchange Agent Agreement, dated as of December 20, 2019, among the Registrant, the guarantors party thereto, and the holder named therein. Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
10.63	Security Agreement, dated as of December 23, 2019, from the grantors named therein to Wilmington Trust, National Association, as collateral agent. Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
10.64	Registration Rights Agreement, dated as of December 20, 2019, among the Registrant and the investors party thereto. Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
21	List of Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101).

* 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.

Item 16. Form 10-K Summary.

Not applicable.

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 28th day of February, 2020.

ACORDA THERAPEUTICS, INC.

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RON COHEN, M.D.</u> Ron Cohen, M.D.	President, Chief Executive Officer and Director	February 28, 2020
<u>/s/ DAVID LAWRENCE, M.B.A.</u> David Lawrence, M.B.A.	Chief, Business Operations and Principal Accounting Officer	February 28, 2020
<u>/s/ BARRY GREENE</u> Barry Greene	Director	February 28, 2020
<u>/s/ PEDER K. JENSEN, M.D.</u> Peder K. Jensen, M.D.	Director	February 28, 2020
<u>/s/ JOHN P. KELLEY</u> John P. Kelley	Director and Chair	February 28, 2020
<u>/s/ SANDRA PANEM, PH.D.</u> Sandra Panem, Ph.D.	Director	February 28, 2020
<u>/s/ LORIN J. RANDALL</u> Lorin J. Randall	Director	February 28, 2020
<u>/s/ STEVEN M. RAUSCHER, M.B.A.</u> Steven M. Rauscher, M.B.A.	Director	February 28, 2020
<u>/s/ CATHERINE D. STRADER, PH.D.</u> Catherine D. Strader, Ph.D.	Director	February 28, 2020

DESCRIPTION OF COMMON STOCK

We are a corporation formed under the General Corporation Law of the State of Delaware pursuant to our Amended and Restated Certificate of Incorporation. The following is a description of the material terms of our common stock. This summary does not purport to be complete and is qualified in its entirety by reference to the General Corporation Law of the State of Delaware and our Amended and Restated Certificate of Incorporation and amended Bylaws, as they may be amended from time to time. Copies of our Amended and Restated Certificate of Incorporation and amended Bylaws have been filed with the Securities and Exchange Commission as Exhibit 3.1 and Exhibit 3.2, respectively, to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part.

Common Stock

We have the authority to issue 80,000,000 shares of common stock, par value \$0.001 per share.

Holders of common stock have one vote per share and have no preemption rights. Holders of common stock have the right to participate ratably in all distributions, whether of dividends or assets in liquidation, dissolution or winding up, subject to any superior rights of holders of preferred stock outstanding at the time. There are no redemption or sinking fund provisions applicable to the common stock. Holders of our common stock are not liable under our Amended and Restated Certificate of Incorporation for further calls or to assessment by us.

Computershare Trust Company, N.A. is the transfer agent and registrar for our common stock. Their address is P.O. Box 505000, Louisville, KY 40233-5000 and their telephone number is (800) 368-5948.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
 - upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
 - at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.
-

In general, Section 203 defines “business combination” to include the following:

- any merger or consolidation involving the corporation and the stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exception, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines “interested stockholder” as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Certificate of Incorporation and Bylaws

Our Amended and Restated Certificate of Incorporation and amended Bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or our management. For example, our Amended and Restated Certificate of Incorporation authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$.001 per share, of which 1,000,000 shares have been designated as Series A Junior Participating Preferred Stock. Our board of directors has the authority, without approval of the stockholders, to issue and determine the rights and preferences of series of preferred stock. 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 Amended and Restated Certificate of Incorporation and amended Bylaws also provide that our board of directors is divided into three classes, each serving staggered three-year terms ending at the annual meeting of our stockholders in the third year of their term. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the board of directors may only be removed for cause and only by the affirmative vote of 75% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of our board of directors.

Our Amended and Restated Certificate of Incorporation and amended Bylaws provide that a meeting of stockholders may only be called by our board of directors, the chairman of our board of directors or our chief executive officer. Our amended Bylaws also specify requirements as to the form and content of a stockholder’s notice. The provisions may delay or preclude stockholders from calling a meeting of stockholders, bringing matters before a meeting of stockholders or from making nominations for directors at a stockholders’ meeting, which could delay or deter takeover attempts or changes in management. Our Amended and Restated Certificate of Incorporation also does not provide for cumulative voting. The absence of cumulative voting may make it more difficult for stockholders owning less than a majority of our stock to elect any directors to our board of directors.

Our amended Bylaws provide that any matter to be voted upon, other than the election of directors, shall be decided based on the majority of votes cast, except where a different vote is otherwise required by the amended Bylaws, applicable law or our Amended and Restated Certificate of Incorporation. The amended Bylaws further provide that directors shall be elected by a plurality of votes cast by the stockholder entitled to vote on the election; provided, however that in an uncontested election, a director who receives a majority “withhold” vote shall be required to tender his or her resignation for consideration by the Board of Directors.

CONSULTING AGREEMENT

This Consulting Agreement (this "**Agreement**") is entered into on November 11, 2019, between Acorda Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Jane Wasman ("**Consultant**"). This Agreement shall be effective (the "**Effective Date**") as of January 1, 2020, subject to the terms and conditions below:

1. **Separation from Service.** Consultant shall continue to serve as President, International & General Counsel until December 31, 2019, which shall be her last day of employment with the Company (the "**Employment Termination**").
2. **Services.** During the Term (as defined below), Consultant shall perform such services (the "**Services**"), at such times and locations, as shall be mutually agreed between Consultant and the Company. Services shall not include providing legal advice, and Consultant will not be performing legal services for the Company during the Term. The parties intend that the Employment Termination shall be a separation from service under section 409A of the Internal Revenue Code ("**Section 409A**"), and, accordingly, Consultant shall provide Services under this Agreement at a level that is, on average, no more than 20 percent of the average level of services performed by Consultant for the Company over the 36-month period immediately preceding the Effective Date.
3. **Term.** The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect through December 31, 2020 (the "**Term**"), unless sooner terminated by the Company under Section 4. This Agreement may be modified only by the written agreement of the Company and Consultant.
4. **Termination.** Both parties shall have the right to terminate this Agreement and/or any or all of the Services, at any time prior to the expiration of the Term, for any reason whatsoever or without reason, upon thirty (30) days prior written notice to the other party. However, Sections 6(ii)-(iv) shall survive termination of the agreement, except in the case of a termination of this Agreement for "Cause" (as defined in the employment agreement between Consultant and the Company (the "**Employment Agreement**")).
5. **Payment/Fees.** The Company will pay Consultant a fee for the Services actually performed by Consultant, at the hourly rate of \$750. In addition, the Company will reimburse Consultant for reasonable out-of-pocket expenses actually incurred by Consultant in accordance with the Company's reimbursement policy applicable to employees. Consultant will invoice the Company for any such expenses no later than ten (10) business days after the end of each calendar quarter in which expenses are incurred. The Company shall pay invoices for the Services and/or expenses within thirty (30) days of receipt of such invoices.
6. **Enhanced Vesting of Equity Awards and Severance Benefits.**
 - (a) *Equity Awards.* Each equity award granted by the Company to Consultant that is outstanding immediately prior to the Effective Date, shall be subject to the following terms:

- (i) Consultant shall continue to vest in such awards as if she remained employed by the Company during the Term.
 - (ii) If an award is exempt from Section 409A on account of being settled no later than the deadline for a short-term deferral under Treasury Regulation section 1.409A-1(b)(4) (the "**Short-Term Deferral Deadline**"), then such award shall be settled no later than the Short-Term Deferral Deadline (which is generally March 15 following the year in which there is no longer a substantial risk of forfeiture).
 - (iii) If a change in control (as determined under the Employment Agreement) occurs during the Term or pursuant to an agreement entered into by the Company during the Term, Consultant shall vest in all of her outstanding equity awards at the time of the change in control.
 - (iv) Consultant shall have the right to exercise all vested stock options for a period of twelve (12) months following the termination of this Agreement.
- (b) *Enhanced Severance Benefits.* If a change in control (as determined under the Employment Agreement) occurs during the Term or pursuant to an agreement entered into by the Company during the Term, Consultant shall be entitled to the cash severance benefits and COBRA coverage set forth in the Employment Agreement relating to a change in control, determined as if she terminated from employment involuntarily immediately following such change in control, except that: (i) the amount of the severance payments shall be reduced by the payments of severance previously made to Consultant; (ii) to the extent that severance payments were due prior to such change in control and such payments are subject to Section 409A, such payments shall continue to be made on the same schedule without regard to this paragraph; and (iii) the period of COBRA coverage shall be reduced by the amount of time that has passed between the Effective Date and the date of such change in control. For the avoidance of doubt, nothing in this paragraph shall result in a duplication of severance benefits.

7. **Director & Officer Liability Insurance; Indemnification.** During the Term, the Company will maintain Consultant as an insured, at the Company's expense, under the Director and Officer Liability Insurance policy applicable to Company directors and officers. In addition, Consultant shall be entitled to indemnification by the Company for losses (including any defense costs and attorneys' fees) incurred in connection with performance of the Services or her status as a consultant to the same extent as if Consultant were an officer of the Company during the Term.

8. **Proprietary Information.**

8.1 The Proprietary Information Agreement, dated November 10, 2004, between Consultant and the Company (the "**Proprietary Information Agreement**"), which imposes, among other things, obligations on Consultant with respect to confidentiality and assignment of inventions, shall remain in full force and effect.

8.2 Immediately upon the expiration or earlier termination of this Agreement, Consultant shall return to the Company all Confidential Information (including all copies thereof) then in the possession of Consultant.

9. **Independent Contractor.** Consultant agrees that, in Consultant's relationship with the Company under this Agreement, Consultant is acting in the capacity of an independent contractor.

10. **Liability.** The Company shall assume no liability for any loss, damage, cost or expense that may result from any gross negligence by Consultant in the performance or non-performance by Consultant of Services and obligations hereunder.

11. **No Modifications.** This Agreement may only be amended in an executed writing signed by the Company and Consultant.

12. **Publicity.** Neither party may use the name of the other party in any publicity or advertising nor issue a press release or otherwise publicize or disclose any information related to the existence of this Agreement or the terms and conditions hereof, without the prior written consent of the other party.

13. **Section 409A.** This Agreement shall be interpreted to ensure that the payments contemplated hereby to be made by the Company to Consultant are exempt from, or comply with, Section 409A. Nothing in this Agreement shall be interpreted to change the time or form of any payment that is subject to Section 409A.

14. **Non-Waiver.** No failure or delay on the part of either Consultant or the Company in exercising any right hereunder will operate as a waiver of, or impair, any such right.

15. **Governing Law.** This Agreement shall be governed by the laws of the State of New York.

16. **Successors and Assigns.** This Agreement is an agreement for personal services and Consultant shall not have the right to assign, subcontract or otherwise transfer any of Consultant's obligations or rights under this Agreement. This Agreement shall be assignable by the Company only with the prior written consent of Consultant. Subject to the foregoing, this Agreement shall inure to the benefit of each of the parties and their respective heirs, successors, assigns and personal representatives.

17. **Notices.** All notices requests or other communications given under this Agreement shall be (a) delivered by hand, or (b) sent by certified mail (return receipt requested), (c) sent by facsimile (with receipt confirmed by a machine-generated transmission record), (d) sent by e-mail (with receipt confirmed by reply e-mail), or (e) sent by a courier guaranteeing overnight delivery (with signature required) to the addresses or facsimile numbers listed below or as may subsequently in writing be requested:

If to the Company: Acorda Therapeutics, Inc.
400 Saw Mill River Road
Ardsley, New York 10502 Attn: Ron Cohen
Email: rcohen@acorda.com

If to Consultant:
Jane Wasman
246 West End Avenue, Apt. 9C New York, NY
10023
Email: jwasman@nyc.rr.com

18. **Severability.** If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions shall be modified to the minimum extent necessary to comply with applicable law and the intent of the parties.

19. **Counterparts.** This Agreement (and any amendment, modification and waiver in respect hereof) may be executed by facsimile or other electronic transmission and in counterparts, each of which shall be deemed to be an original, and all of which taken together shall constitute one agreement binding on the parties.

20. **Entire Agreement; Waiver.** This Agreement, together with the Proprietary Information Agreement, constitute the entire agreement between the parties with respect to the subject matter contained herein, and supersedes all prior agreements concerning such subject matter; provided, however, that, except as expressly set forth in this Agreement, nothing in this Agreement modifies Consultant's Employment Agreement or the benefits due thereunder. Nothing in this Agreement may be changed or modified, nor may anything be added to this Agreement, except as may be specifically agreed to in a subsequent writing executed by the parties. Neither party may waive compliance by the other party with any term or provision of this Agreement except by a writing signed by the party making such waiver. Either party's waiver of any breach or failure to enforce any of the terms and conditions of this Agreement at any time shall not in any way affect, limit, or waive such party's right thereafter to enforce and compel strict compliance with every term and condition hereof.

[Remainder of page intentionally left blank; signature page follows]

The Company and Consultant have caused this Consulting Agreement to be duly executed and delivered as of the Effective Date.

Acorda Therapeutics, Inc.

By: /s/ Ron Cohen

Ron Cohen

President and CEO

Consultant

/s/ Jane Wasman

Jane Wasman

List of Subsidiaries of the Registrant

Acorda Therapeutics Limited (UK)

Acorda Therapeutics Ireland Limited (Ireland)

Biotie Therapies AG (Switzerland)

Biotie Therapies GmbH (Germany)

Biotie Therapies, Inc. (Delaware)

Biotie Therapies Ltd. (Finland) (formerly Biotie Therapies Corp.)

Biotie Therapies International Oy (Finland)

Civitas Therapeutics, Inc. (Delaware)

MS Research & Development Corporation (Delaware)

Neuronex, Inc. (Delaware)

Note: Acorda Therapeutics, Inc. subsidiaries may conduct business under the Acorda name as well as under their entity name or variants thereof. Acorda Therapeutics Limited, MS Research & Development Corporation and Neuronex, Inc. are dormant entities without any operations and holding no or *de minimis* assets.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-235929) of Acorda Therapeutics, Inc.,
- (2) Registration Statement (Form S-8 No. 333-233177) pertaining to the 2019 Employee Stock Purchase Plan of Acorda Therapeutics, Inc.,
- (3) Registration Statement (Form S-8 No. 333-131846) pertaining to the 1999 Employee Stock Option Plan and the 2006 Employee Incentive Plan of Acorda Therapeutics, Inc.,
- (4) Registration Statement (Form S-8 Nos. 333-149726, 333-158085, 333-164626, 333-174785, 333-179906, 333-187091, 333-194375, and 333-202525) pertaining to the 2006 Employee Incentive Plan of Acorda Therapeutics, Inc.,
- (5) Registration Statement (Form S-8 No. 333-210813) pertaining to the 2016 Inducement Plan of Acorda Therapeutics, Inc., and
- (6) Registration Statement (Form S-8 Nos. 333-206346, 333-212917, and 333-226692) pertaining to the 2015 Omnibus Incentive Compensation Plan of Acorda Therapeutics, Inc.

of our reports dated February 28, 2020, with respect to the consolidated financial statements of Acorda Therapeutics, Inc. and subsidiaries and the effectiveness of internal control over financial reporting of Acorda Therapeutics, Inc. and subsidiaries included in this Annual Report (Form 10-K) of Acorda Therapeutics, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Hartford, Connecticut
February 28, 2020

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO
RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, Ron Cohen, certify that:

1. I have reviewed this annual report on Form 10-K of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2020

/s/ Ron Cohen

Ron Cohen, M.D.

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO**RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, David Lawrence, certify that:

1. I have reviewed this annual report on Form 10-K of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2020

/s/ David Lawrence

David Lawrence

Chief, Business Operations and Principal Accounting Officer

(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ron Cohen, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RON COHEN

Chief Executive Officer
(Principal Executive Officer)
February 28, 2020

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc. and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lawrence, Chief, Business Operations and Principal Accounting Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DAVID LAWRENCE

Chief, Business Operations and Principal Accounting Officer
(Principal Financial Officer)
February 28, 2020

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc. and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]