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, 2021

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	**13-3831168**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
420 Saw Mill River Road, Ardsley, New York	**10502**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	ACOR	Nasdaq Global Select 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

As of June 30, 2021, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was $52,234,372. 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 30, 2021. 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 March 9, 2022, the registrant had 13,250,296 shares of common stock, $0.001 par value 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 2022 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2021. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

Part III, Item 10, Directors, Executive Officers and Corporate Governance.
Part III, Item 11, Executive Compensation.
Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
Part III, Item 13, Certain Relationships and Related Transactions, and Director Independence.
Part III, Item 14, Principal Accounting Fees and Services.

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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 Ampyra, Inbrija or any other products under development; the COVID-19 pandemic, including related restrictions on in-person interactions and travel, and the potential for illness, quarantines, and vaccine mandates affecting our management, employees or consultants or those that work for other companies we rely upon, could have a material adverse effect on our business operations or product sales; our ability to attract and retain key management and other personnel, or maintain access to expert advisors; our ability to raise additional funds to finance our operations, repay outstanding indebtedness or satisfy other obligations, and our ability to control our costs or reduce planned expenditures; risks associated with the trading of our common stock and our reverse stock split; risks related to our corporate restructurings, including our ability to outsource certain operations, realize expected cost savings and maintain the workforce needed for continued operations; risks associated with complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand; our reliance on third-party manufacturers for the production of commercial supplies of Ampyra and Inbrija; third-party payers (including governmental agencies) may not reimburse for the use of Inbrija at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; reliance on collaborators and distributors to commercialize Inbrija and Ampyra outside the U.S.; competition for Inbrija and Ampyra, including increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra following our loss of patent exclusivity; the ability to realize the benefits anticipated from acquisitions because, among other reasons, 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 or from 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 except as may be required by law.

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 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 and Highlights

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 Products

Inbrija/Parkinson's Disease

Inbrija 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. 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. U.S. Food and Drug Administration (FDA) approval of Inbrija is for a single dose of 84 mg (administered as two capsules), which may be taken up to five times per day. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 96% of commercially insured lives and approximately 27% of Medicare plan lives. U.S. net revenue for Inbrija was $29.6 million for the year ended December 31, 2021.

Inbrija is also approved for use in the European Union (EU). The European Commission (EC)-approved Inbrija dose is 66 mg (administered as two capsules) up to five times per day (per EU convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the EU approval, Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. In July and November 2021, we announced that we entered into distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany, respectively. Under the terms of the Germany distribution agreement, we received a €5 million (approximately $5.9) upfront payment, and we are entitled to receive additional sales-based milestones. Under the terms of both the Spain and Germany supply agreements, we are entitled to receive a significant double-digit percent of the selling price of Inbrija in exchange for supply of the product. Esteve expects to launch Inbrija in Germany in mid-2022 and in Spain in early 2023. We are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S.

Inbrija utilizes our ARCUS platform for inhaled therapeutics. Because of our limited financial resources, we previously suspended work on ARCUS and other proprietary research and development programs. However, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

Ampyra/MS

Ampyra is an extended-release tablet formulation of dalfampridine approved by the FDA as a treatment to improve walking in patients with multiple sclerosis, or MS. Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time. U.S. net revenue for Ampyra was $84.6 million for the year ended December 31, 2021.

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. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen, and these challenges could lead to generic competition with Fampyra. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Sale of Chelsea Manufacturing Operations and Catalent MSA

In February 2021, we completed the sale of our Chelsea, Massachusetts manufacturing operations to Catalent Pharma Solutions. Pursuant to the transaction, Catalent paid us $80 million in cash, resulting in net proceeds to us of approximately $74 million after transaction fees and expenses and settlement of customary post-closing adjustments. In connection with the sale of the manufacturing operations, we entered into a long-term, global manufacturing services agreement with a Catalent affiliate for the supply of Inbrija. The Catalent manufacturing services agreement provides that Catalent will manufacture Inbrija, to our specifications, and we will purchase Inbrija exclusively from Catalent during the term of the manufacturing services agreement; provided that such exclusivity requirement will not apply to Inbrija intended for sale in China.

Under the manufacturing services agreement, we agreed to purchase from Catalent at least $16 million of Inbrija in 2021 (pro-rated for a partial year) and $18 million of Inbrija each year from 2022 through 2030, subject to reduction in certain cases. In December 2021, we and Catalent amended the manufacturing services agreement to adjust the structure of the minimum payment terms for the period from July 1, 2021 through June 30, 2022 (the "Adjustment Period"). Under the amendment, the minimum payment obligation for the Adjustment Period is replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to our original minimum purchase obligation for that period (i.e., $17 million), and with certain payments being made in the first half of 2022 instead of during the second half of 2021. As a result of the amendment, our cash balance at the end of 2021 reflected approximately $5.3 million associated with this modified payment schedule. We have submitted a binding forecast for Inbrija batches for the Adjustment Period, the total cost of which may equal, but not exceed, the original payment obligation under the manufacturing services agreement. Additionally, pursuant to the amendment, we agreed that we would reimburse a portion of Catalent's costs in completing the installation and qualification of a larger size 7 spray dryer at the Chelsea manufacturing facility, which we believe will be beneficial to our future production needs, in the amount of $1.5 million. This amount will be paid quarterly over a one-year period commencing no sooner than January 1, 2024.

Convertible Notes

In December 2019, we completed a private exchange of $276 million of our convertible senior notes due 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. As a result of the exchange, approximately $69 million of convertible senior notes due 2021 remained outstanding, but we repaid these notes at maturity on June 15, 2021 using cash on hand. More information about the terms and conditions of the 2024 convertible notes is set forth in Note 9 to our Consolidated Financial Statements included in this report as well as in *Financing Arrangements* in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this report.

Financial Management

In January 2021 and September 2021, we announced corporate restructurings to reduce costs, more closely align operating expenses with expected revenue, and focus our resources on Inbrija. The headcount reductions and other budget cuts we implemented, including those resulting from the sale of the Chelsea manufacturing operations described above, are expected to result in a $60 million annualized reduction in operating expenses in 2022 as compared to 2020.

In January 2021, we entered into an At The Market (ATM) Offering Agreement with H.C. Wainwright & Co., LLC as sales agent. Pursuant to the ATM agreement, we may offer and sell shares of our common stock having an aggregate value of up to $15.25 million in an at-the-market offering, subject to a 3% sales commission payable to H.C. Wainwright.

In September 2021, we sent to BMR-Ardsley Park LLC ("BMR") notice of exercise of our early termination option (the "Early Termination Option") under our lease dated as of June 23, 2011, between us and BMR (as amended, the "lease"). The lease is for the Company's Ardsley, N.Y. corporate headquarters, which we believe is substantially larger than our needs for the foreseeable future. Pursuant to the Early Termination Option, the lease will terminate on June 22, 2022 and we will pay an early termination fee of approximately $4.7 million.

As of December 31, 2021, we had cash, cash equivalents, and restricted cash of approximately $65.2 million. Restricted cash includes $18.6 million in escrow related to the 6% semi-annual interest portion of the convertible senior secured notes due 2024, which interest is payable in cash or stock. As further described in Note 9 to our Consolidated Financial Statements included in this report as well as in *Financing Arrangements* in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this report, if we elect to pay interest due in stock, a

corresponding amount of restricted cash equivalent will be released from escrow. In June and December 2021, we issued 1,635,833 and 2,049,048 shares of our common stock, respectively, to the holders of the 2024 notes in satisfaction of approximately $6.2 million in interest due under the notes on each of June 1 and December 1, 2021, and a corresponding amount of cash (approximately $12.4 million in the aggregate) was thereafter released from the escrow in June and December, 2021.

Reverse Stock Split

On December 31, 2020, we filed an amendment to our Certificate of Incorporation which effected a 1-for-6 reverse stock split of the shares of our outstanding common stock and proportionate reduction in the number of authorized shares of our common stock from 370,000,000 to 61,666,666. Our common stock began trading on a split-adjusted basis on The Nasdaq Global Select Market commencing upon market open on January 4, 2021. The common stock continued to trade under the symbol "ACOR" after the reverse stock split became effective. The reverse stock split applied equally to all outstanding shares of the common stock and did not modify the rights or preferences of the common stock. The reverse stock split also resulted in a corresponding adjustment to outstanding equity awards as well as shares reserved for future issuance under our incentive compensation plans. All figures in this report relating to shares of our common stock (such as share amounts, per share amounts, and conversion rates and prices), including in the financial statements and accompanying notes to the financial statements, have been retroactively restated to reflect the 1-for-6 reverse stock split of our common stock.

COVID-19 Pandemic

Our business and financial condition have been impacted by, and are subject to risks resulting from, the COVID-19 global pandemic. The COVID-19 global pandemic has caused significant disruptions in the healthcare industry. The duration of the pandemic is difficult to predict, and it is likely to have ongoing impacts as it continues. The travel restrictions, "shelter in place" orders, quarantine policies, vaccine mandates, and general concerns about the spread and effects of COVID-19 have disrupted the delivery of healthcare to patients; for example, the pandemic has made it more difficult for some patients to visit with their physician and obtain pharmaceutical prescriptions. Also, healthcare office staffing shortages may delay the administrative work, and particularly insurance-related documentation, needed to obtain reimbursement for prescriptions. We also believe that the governmental and other restrictions and requirements related to the pandemic may have caused certain patients to lessen their mobility and therefore their need for certain therapeutics. We believe these factors contributed to volatility in new Inbrija prescriptions since the start of the pandemic in 2020 and are continuing to impact prescriptions in 2022.

COVID-related policies, restrictions, and concerns may disrupt our operations and those of our customers and suppliers. Also, our operations could be interrupted if we or our customers or suppliers lose the services of key employees or consultants who become ill from COVID-19. These types of disruptions could potentially affect any of our critical business functions, and thus harm our business, including for example our sales and marketing operations, as well as compliance and certain general and administrative functions. The ultimate impact of the COVID-19 global pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems, or the global economy as a whole. As the pandemic continues, it may cause continuing economic volatility or result in a sustained economic downturn that could affect demand for our products and our ability to access capital on reasonable terms, or at all. These factors could have a material adverse effect on our business, operating results and financial condition.

Our Strategy

Our long-term strategy is 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. For 2022, our strategic priorities include:

- **Accelerate Inbrija Growth**: Driving the commercial success of Inbrija by continuing our efforts to enhance patient experience, re-engaging physicians as the COVID pandemic recedes, and commercializing Inbrija outside the U.S. through our Esteve and other potential collaborations.

- **Maintain Ampyra Strength**: Continuing to support the Ampyra franchise, including activities intended to maintain brand loyalty and market access.

- **Optimize Financial Structure**: Continuing to focus on financial discipline and optimizing our cost structure.

- **Leverage ARCUS Platform**: Building on the ARCUS technology platform by seeking collaborations with companies to potentially formulate their novel molecules for pulmonary delivery using ARCUS.

Our Products and ARCUS Technology

Commercial Products	Indication	Status	Marketing Rights
Inbrija (levodopa inhalation powder)	Parkinson's disease OFF periods/episodes	FDA and EMA-approved; marketed in the U.S. by Acorda; Esteve launch in Germany and Spain pending	Acorda/Worldwide; rights granted to Esteve in Germany and Spain; seeking collaborators for commercialization in other countries outside the U.S.
Ampyra (dalfampridine)	MS	FDA-approved and marketed in the U.S. by Acorda	Acorda (U.S.)
Fampyra* (fampridine)	MS	Approved in a number of countries across Europe, Asia and the Americas	Biogen (outside the U.S.)

* In November 2017, we announced a $40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for a 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, which we believe may occur in mid-2022, we will not receive Fampyra royalty revenue although we have retained the right to receive any potential future milestone payments from Biogen.

Inbrija 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. Although we have deferred internal investment in ARCUS programs, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

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. Our current strategic priorities include marketing our approved Inbrija and Ampyra therapeutics targeted to the conditions described below. We believe there is significant unmet medical need for these conditions, which can severely impact the lives of those who suffer from them.

Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. Approximately one million people in the U.S. 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 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 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. OFF periods can be very disruptive to the lives of people with Parkinson's, their families and caregivers. In a survey of 3,000 people with Parkinson's conducted by the Michael J. Fox Foundation, 64% of respondents reported having at least two hours of OFF time per day.

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 and ARCUS

Inbrija/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. It is not known if Inbrija is safe or effective in children. 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 96% of commercially insured lives and approximately 27% of Medicare plan lives. U.S. net revenue for Inbrija was $29.6 million for the year ended December 31, 2021.

In September 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 27 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the exit of the UK from the EU, we were granted a grandfathered Marketing Authorization (MA) by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK that was approved in November 2021.

In July and November 2021, we announced that we entered into distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany, respectively. Under the terms of the Germany distribution agreement, we received a €5 million (approximately $5.9) upfront payment, and we are entitled to receive additional sales-based milestones. Under the terms of both the Spain and Germany supply agreements, we are entitled to receive a significant double-digit percent of the selling price of Inbrija in exchange for supply of the product. Esteve has the exclusive distribution rights to Inbrija in Spain and Germany and we will supply the product to Esteve for sale. Esteve expects to launch Inbrija in Germany in mid-2022 and in Spain in early 2023. We are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S.

ARCUS Platform and Product Development

Inbrija 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. Inbrija was also entitled to three years of new product exclusivity, but this expired in December 2021. We have patents in Europe for Inbrija expiring between 2022 and 2033. One of our European patents, EP 3090773B, had been opposed by an unnamed party but in 2021 was maintained as granted by the European Opposition Board. Inbrija also has ten years of market exclusivity in Europe that is set to expire in September 2029.

We believe there are potential opportunities for using ARCUS with central nervous system, or CNS, as well as non-CNS, disorders. Due to several corporate restructurings since 2017 and associated cost-cutting measures, including the corporate restructurings we announced in January and September 2021, we suspended work on ARCUS and other proprietary research and development programs. However, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

Should we decide to proceed with any ARCUS development programs, we would be reliant on Catalent or another third-party supplier for the manufacture of product for that program. Our global supply agreement with Catalent does not provide for the terms and conditions under which Catalent would supply any product or product candidate other than Inbrija. We would be unable to advance the development of any ARCUS inhaled therapeutic candidate unless Catalent is willing to manufacture the candidate for us on commercially reasonable terms, or we could identify another third-party manufacturer that would be capable and willing to manufacture the candidate for us on commercially reasonable terms. Also, due to reductions in force, employee attrition, and the 2021 sale of our Chelsea manufacturing operations, we may need to hire replacement personnel or engage consultants to continue with ARCUS research and development work beyond feasibility and similar early-stage studies.

Ampyra

Ampyra (dalfampridine) is an oral drug approved by the FDA in January 2010 as a treatment to improve walking in adults with multiple sclerosis. This was demonstrated by an increase in walking speed. To our knowledge, Ampyra is the first drug approved for this indication. 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. Ampyra is an extended-release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), which had previously been 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.

Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time. U.S. net revenue for Ampyra was $84.6 million for the year ended December 31, 2021.

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. In May 2021, Biogen announced that Fampyra was approved by the National Medical Products Administration in China, and Biogen is evaluating commercial launch options in that country. Our Fampyra patents

have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen, and these challenges could lead to generic competition with Fampyra.

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, although we do not anticipate achievement of any of those milestones in the foreseeable future. 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, which we believe may occur in mid-2022, we will not receive Fampyra royalties although we retained the right to receive any potential future milestone payments. The HCRP transaction is accounted for as a liability, as described in Note 10 to our Consolidated Financial Statements included in this report.

Ampyra Patent Update

There are no patents listed in the Orange Book for Ampyra. Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents.

There are two European patents, EP 1732548 and EP 2377536, with claims directed to use of a sustained release dalfampridine composition (known under the trade name Fampyra in the European Union) to increase walking speed in a patient with multiple sclerosis. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra had ten years of market exclusivity in the European Union that expired in 2021. Accordingly, even though the European patents were upheld by the Technical Board of Appeal of the European Patent Office, Fampyra could potentially face competition from generic drug manufacturers that may seek to challenge Fampyra's European patents within individual European countries.

Nullity actions with respect to Fampyra have been filed in Germany against both of the German national patents derived from EP 1732548 (the '548 patent) and EP 2377536 (the '536 patent) by ratiopharm GmbH, a generic manufacturer affiliated with Teva. In November 2021, a German court issued preliminary opinions in the ratiopharm case indicating that the claimed subject matter of the '548 patent lacked inventive step and the claimed subject matter of the '536 patent lacked novelty and inventive step. At an oral hearing in February 2022, the German patent court dismissed ratiopharm's action against the '536 patent as inadmissible because of ongoing formality proceedings relating to the '536 patent in the European Patent Office. Ratiopharm could appeal this decision or refile the nullity action when the formalities are completed at the European Patent Office. An oral hearing is currently scheduled for April 26, 2022, for the '548 patent. On January 11, 2022, STADA Arzneimittel also filed a nullity action against the '536 patent in the same court. We are working with Biogen to vigorously defend these actions and enforce our patent rights. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Sales, Marketing and Market Access

Inbrija

We market Inbrija in the U.S. using field-based teams supported by our corporate marketing personnel. Our own neuro-specialty sales representatives work in combination with sales representatives provided by a contract commercial organization, and collectively they are currently focused on a priority list of physicians who are high volume prescribers of carbidopa/levodopa and other products indicated to treat OFF episodes. Our field-based teams also include reimbursement and market access specialists, who provide information to physicians and payers on our marketed products, as well as market development specialists who work collaboratively with field-sales teams and corporate personnel to assist in the execution of our strategic initiatives. Our Inbrija field-based and marketing activities are focused on physician awareness and market access as well as patient awareness, education and training. Inbrija is distributed in the U.S. primarily through: AllianceRx Walgreens Prime, or Walgreens, a specialty pharmacy that delivers the medication to patients by mail; and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). We recently initiated a pilot program to evaluate distribution of Inbrija through a specialty pharmacy that supports electronic prescriptions, and we intend to expand this into a national program in 2022. We believe the convenience of electronic prescribing may be preferred by some physicians and patients.

We have established Prescription Support Services for Inbrija, sometimes referred to as the Inbrija hub, which helps patients navigate their insurance coverage and identify potential financial support alternatives, when appropriate. The Inbrija hub also includes a virtual nurse educator program to assist patients with proper usage of the Inbrija inhaler. Insurance coverage services fall into one of these categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; and appeals support. 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 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 a first dispense zero-dollar copay program for commercially insured patients to enable those patients to assess the value of Inbrija before incurring out-of-pocket co-pay or co-insurance costs.

Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 96% of commercially insured lives and approximately 27% of Medicare plan lives.

Ampyra

We market Ampyra in the U.S. using field-based teams supported by our corporate marketing personnel. Our own neuro-specialty sales representatives work in combination with sales representatives provided by a contract commercial organization. Ampyra 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. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen, and these challenges could lead to generic competition with Fampyra. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

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 2020 Biogen paid us $15 million based on achievement of a specified sales milestone (all subject to our payment obligations to Alkermes under our license agreement with them). We are entitled to receive additional payments from Biogen that exceed $300 million in the aggregate based on achievement of future regulatory and sales milestones, although we do not anticipate achievement of any of those milestones in the foreseeable future.

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, which we believe may occur in mid-2022, 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.

Alkermes (now the licensor under this agreement due to its 2011 acquisition of Elan's Drug Technologies business) is also obligated 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.

Manufacturing and Supply

Inbrija

Chelsea Manufacturing Facility

All commercial supply of Inbrija is currently manufactured at Catalent's Chelsea, Massachusetts manufacturing facility, which was transferred to Catalent in February 2021 in connection with our sale to Catalent of our Chelsea manufacturing operations. In connection with the sale, we entered into a long-term, global manufacturing services (supply) agreement with a Catalent affiliate pursuant to which they have agreed to manufacture Inbrija for us at the Chelsea facility. Under the supply agreement, which is further described below under *Catalent Manufacturing Services Agreement*, Catalent is our exclusive Inbrija supplier other than for sale in China.

Catalent may need expanded manufacturing capacity at the Chelsea facility to meet demand depending on the timing and extent of sales growth. In 2018, prior to the sale of the Chelsea manufacturing operations, we initiated a renovation and expansion of the Chelsea facility that increased the size of the facility from approximately 90,000 to approximately 95,000 square feet. The project added a new size 7 spray dryer manufacturing production line for Inbrija that has greater capacity than the existing size 4 spray dryer manufacturing production line, and it has created additional warehousing space for manufactured product. Although the project was substantially completed in late 2019, the expansion does not yet have all of the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA and other regulatory authorities. Also, manufacturing scale-up generally is subject to significant risks related to process development and manufacturing yields, which is especially true for the manufacture of a product such as Inbrija which involves a highly specialized spray drying and capsule filling process. Lastly, the expanded Chelsea facility will have to continue to comply with cGMP requirements, as well as other applicable environmental, safety, and other governmental permitting requirements. In December 2021, we agreed to reimburse a portion of Catalent's costs in completing the installation and qualification of the size 7 spray dryer, which we believe will be beneficial to our future production needs.

This amount will be payable by us in four quarterly installments after the later of January 1, 2024 or FDA qualification and approval for use of the size 7 spray dryer.

If Catalent is unable to complete the expansion of the facility in a timely manner or there is unexpected demand for commercial quantities of Inbrija, there could be a supply shortage that would harm our commercialization of Inbrija. If we need the expanded capacity but Catalent is delayed in or prevented from completing the expansion and obtaining necessary regulatory approvals, we may need to seek another party to manufacturer additional Inbrija supply for us. As further discussed below, there can be no assurance that we could identify another 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 obtain increased supply of Inbrija from expanded capacity at the Chelsea facility or engaging another third-party manufacturer, we may not be able to meet demand for Inbrija and our ability to commercialize Inbrija could be harmed. Also, even if we do obtain Inbrija from another supplier, we may be unable to offset the costs of alternate supply against our minimum purchase commitments under the Catalent manufacturing services agreement, as further described below.

Furthermore, if Catalent were to lose the use of the facility or equipment, the manufacturing facility and manufacturing equipment would be difficult to replace and could require substantial replacement lead time and substantial additional funds. The facility may be affected by natural disasters, such as floods or fire, or Catalent may lose the use of the facility due to manufacturing issues that arise, such as contamination or regulatory concerns following a regulatory inspection of the facility. Catalent may also unexpectedly experience manufacturing issues as the unintended result of activities occurring at the facility unrelated to Inbrija manufacture. In the event of a loss of the use of all or a portion of the facility or equipment for the reasons stated above or any other reason, Catalent would be unable to manufacture Inbrija until such time as the facility or equipment could be repaired or rebuilt or they are able to address other manufacturing issues at the facility. Any such interruptions in their ability to manufacture Inbrija would harm our business. Even if Catalent does 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 backup 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 another 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 due to the complexity and substantial regulation of the manufacturing processes involved. Also, engaging a third party would require the sharing of proprietary information, which increases the risk of unauthorized use or disclosure of that information and potential harm to our business for which we may not have an adequate remedy. 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.

Catalent Manufacturing Services Agreement

We sold our Chelsea manufacturing operations to Catalent Pharma Solutions in February 2021. In connection with the sale, we entered into a long-term, global manufacturing services (supply) agreement with a Catalent affiliate pursuant to which they have agreed to manufacture Inbrija for us at the Chelsea facility. The manufacturing services agreement provides that Catalent will manufacture Inbrija (levodopa inhalation powder), to our specifications, and we will purchase Inbrija exclusively from Catalent during the term of the manufacturing services agreement; provided that such exclusivity requirement will not apply to Inbrija intended for sale in China.

The manufacturing services agreement, unless earlier terminated, will continue until December 31, 2030, and will be automatically extended for successive two-year periods unless either we or Catalent provides the other party with at least 18-months' prior written notice of non-renewal. Either party may terminate the manufacturing services by written notice under certain circumstances, including material breach by the other party (subject to specified cure periods) or the insolvency of the other party. We may also terminate the manufacturing services agreement upon certain specified regulatory events and for convenience upon 180 days' prior written notice, subject to payment of a specified substantial termination fee.

Under the manufacturing services agreement, we agreed to purchase from Catalent at least $16 million of Inbrija in 2021 (pro-rated for a partial year) and $18 million of Inbrija each year from 2022 through 2030, subject to reduction in certain cases. In December 2021, we and Catalent amended the manufacturing services agreement to adjust the structure of the minimum payment terms for the period from July 1, 2021 through June 30, 2022 (the "Adjustment Period"). Under the amendment, the minimum payment obligation for the Adjustment Period is replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to our original minimum purchase obligation for that period (i.e., $17 million), and with certain payments being made in the first half of 2022 instead of during the second half of 2021. As a result of the amendment, our cash balance at the end of 2021 reflected approximately $5.3 million associated with this modified payment schedule. We have submitted a binding forecast for Inbrija batches for the Adjustment Period, the total cost of which may equal, but not exceed, the original payment obligation under the manufacturing services agreement. Additionally, pursuant to the amendment, we agreed that we would reimburse a portion of Catalent's costs in completing the installation and qualification of a larger size 7 spray dryer at the Chelsea manufacturing facility, which we believe will be beneficial to our future production needs, in the amount of $1.5 million. This amount will be paid quarterly over a one-year period commencing no sooner than January 1, 2024.

The manufacturing services agreement contains customary representations, warranties and covenants, including with respect to the ownership of any intellectual property created pursuant to the manufacturing services agreement, as well as provisions relating to ordering, payment and shipping terms, regulatory matters, reporting obligations, indemnity, confidentiality and other matters.

We are discussing potential ARCUS collaborations with other companies that have expressed interest in formulating their novel molecules using ARCUS, and have already been performing feasibility studies for a number of these opportunities. However, currently we are not investing in any proprietary ARCUS research and development programs. Should we decide to proceed with any ARCUS development program, we would be reliant on Catalent or another third-party supplier for the manufacture of product for that program. The manufacturing services agreement does not provide for the terms and conditions under which Catalent would supply any product or product candidate other than Inbrija, or under which Catalent would provide support for ARCUS research and development. We would be unable to advance the development of any ARCUS inhaled therapeutic candidate unless Catalent is willing to manufacture the candidate for us on commercially reasonable terms, or we could identify another third-party manufacturer that would be capable and willing to manufacture the candidate for us on commercially reasonable terms. Also, due to reductions in force, employee attrition and the 2021 sale of our Chelsea manufacturing operations, we may need to hire replacement personnel or engage consultants to continue with ARCUS research and development work beyond feasibility and similar early-stage studies.

Supply of Inbrija Components

Catalent, as our Inbrija supplier, is responsible for all Inbrija components other than the inhaler device and levodopa, or L-dopa, the active pharmaceutical ingredient, or API, in Inbrija. We have relied, and we expect to continue relying, on single third parties to supply the inhaler and levodopa. 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 or to complete any future clinical studies that may be needed.

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 supplier of the API 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 do not control how Catalent sources the other components of Inbrija, but we are aware that they rely on a single supplier for a critical excipient used for Inbrija manufacturing and they could rely on single suppliers for other components. Our business could similarly be exposed to risk to the extent they rely on single source suppliers or do not have supply contracts.

Our proprietary Inbrija 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. We currently source our proprietary Inbrija inhalers from a single third-party plastic molding manufacturer for the Inbrija 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. If the inhaler supplier fails to provide sufficient inhaler supply, we would need enter into alternative arrangements with a different suppler. Transition to a new inhaler supplier would be a lengthy and complex process. Among other things, we would have to revalidate the molding and assembly processes pursuant to FDA requirements and we would have to ensure that inhalers manufactured by the new supplier adhere to other applicable regulatory requirements.

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 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.

Intellectual Property

We have patent portfolios relating to: Inbrija (levodopa inhalation powder); Ampyra/aminopyridines; the ARCUS drug delivery technology; and cimaglermin alfa/neuregulins. 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 a subsidiary, including for example our Civitas subsidiary. 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.

Inbrija 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 ten 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. Inbrija was also entitled to three years of new product exclusivity, but this expired in December 2021. We have patents in Europe for Inbrija expiring between 2022 and 2033. One of our European patents, EP 3090773B, had been opposed by an unnamed party but in 2021 was maintained as granted by the European Opposition Board. Inbrija also has ten years of market exclusivity in Europe that will expire in September 2029.

Ampyra/aminopyridines

There are no patents listed in the Orange Book for Ampyra. Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents.

There are two European patents, EP 1732548 and EP 2377536, with claims directed to use of a sustained release dalfampridine composition (known under the trade name Fampyra in the European Union) to increase walking speed in a patient with multiple sclerosis. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra had ten years of market exclusivity in the European Union that expired in 2021. Accordingly, even though the European patents were upheld by the Technical Board of Appeal of the European Patent Office, Fampyra could potentially face competition from generic drug manufacturers that may seek to challenge Fampyra's European patents within individual European countries.

Nullity actions with respect to Fampyra have been filed in Germany against both of the German national patents derived from EP 1732548 (the '548 patent) and EP 2377536 (the '536 patent) by ratiopharm GmbH, a generic manufacturer affiliated with Teva. In November 2021, a German court issued preliminary opinions in the ratiopharm case indicating that the claimed subject matter of the '548 patent lacked inventive step and the claimed subject matter of the '536 patent lacked novelty and inventive step. At an oral hearing in February 2022, the German patent court dismissed ratiopharm's action against the '536 patent as inadmissible because of ongoing formality proceedings relating to the '536 patent in the European Patent Office. Ratiopharm could appeal this decision or refile the nullity action when the formalities are completed at the European Patent Office. An oral hearing is currently scheduled for April 26, 2022, for the '548 patent. On January 11, 2022, STADA Arzneimittel also filed a nullity action against the '536 patent in the same court. We are working with Biogen to vigorously defend these actions and enforce our patent rights. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Cimaglermin alfa/Neuregulins

Our neuregulin portfolio includes granted and pending U.S. and foreign patent applications directed to the use of neuregulins (e.g., GGF2) to treat peripheral nerve injury, non-acute central nervous system injuries and heart failure.

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" and "Inbrija" and pending trademark applications therefore, in numerous foreign jurisdictions. In addition, our trademark portfolio includes several trademark registrations and pending trademark applications for potential product names and for disease awareness activities.

Competition

The market for developing and marketing pharmaceutical products is highly competitive. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are engaged in research, development and/or marketing of therapeutics for various neurological conditions, including Parkinson's disease and multiple sclerosis. 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/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, and in 2022 the FDA approved a generic version of Apokyn. Also, Sunovion Pharmaceuticals Inc. markets a sublingual, or under the tongue, formulation of apomorphine branded as Kynmobi that is competitive with Inbrija.

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. 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 ARCUS drug delivery technology product candidates that we may develop in the future. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc, MannKind Corporation, 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 became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. 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, Zinbryta from Biogen and AbbieVie, 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), Rituxan from F. Hoffman-La Roche AG, and Zeposia from BristolMyersSquibb.

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. 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. The discussion below covers FDA regulation of drugs and drug product approval. We currently we do not have any active development programs for new potential drug products, however we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

FDA Regulation of Drugs and Drug Product Approval

In the U.S., Ampyra is regulated by the FDA as a drug 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 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, for any product that we or our collaborators may be developing.

Preclinical studies include laboratory evaluation of a 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. The FDA may also place an ongoing clinical study on a clinical hold, which must be resolved before the study may continue.

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 clinical trial 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 or our collaborators will successfully complete Phase 1, Phase 2 or Phase 3 testing of any 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 or our collaborators 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 relevant manufacturing facilities and processes fail to pass FDA inspection, we or our collaborator will not receive approval to market the 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 GCP requirements. 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 will be limited to the specific approved 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 any product candidates we or our collaborators may seek to develop would harm our business. Marketing products abroad requires 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 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 an 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 are also subject to a variety of state laws and regulations in those states or localities where products or product candidates are or will be marketed, or where we 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 the U.S. Congress, in some cases forcing those companies to dramatically reduce those prices. The Biden presidential administration and members of Congress have indicated an interest in measures designed to lower drug costs and 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, or at a minimum continued scrutiny. 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.

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 that 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 chemicals 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.

Most 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 for generics 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 other products we may develop 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 separate 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 and reporting of adverse events. 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 we develop any product candidates that 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 or distributors 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. Alternatively, marketing authorizations can be obtained 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. The 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 unless the deadline is extended. In December 2021, we received an extension of the sunset deadline for Inbrija to March 31, 2023. Inbrija has not yet been marketed in any EU member states but we have entered into distribution agreements with Esteve Pharmaceuticals to commercialize Inbrija in Germany and Spain, respectively. Esteve expects to launch Inbrija in Germany in mid-2022 and in Spain in early 2023.

In the EU, innovator products approved on the basis of a complete and independent data package are usually entitled to a total of ten years of regulatory exclusivity from the date of first approval. 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 ten years. The market exclusivity period may be extended by a further one year if during the first eight years after a grant of marketing authorization, a new therapeutic indication with significant clinical benefit over existing therapies is authorized.

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, but do contain the sunset rules described above requiring that for a centrally-approved product, the product must be marketed in at least one member European Economic Area state within three years of approval (unless that deadline is extended) or the marketing authorization may cease to be valid. However, once a medicinal product is launched in a particular 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.

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 direct responses to requests for information and 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, and some member states have expanded this prohibition to cover inducements to healthcare organizations. 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.

We have entered into distribution and supply agreements with Esteve Pharmaceuticals for the commercialization of Inbrija in Germany and Spain, and we may enter into similar transactions for the commercialization of Inbrija in other EU countries in the future. We have not transferred our EU marketing authorization to Esteve and do not intend on transferring the authorization to any other party with whom we may enter into such a transaction. Accordingly, if Esteve or another distributor or collaborator for Inbrija in the EU fails to comply with EU legal requirements, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, and there can be no assurance that contractual terms and conditions will provide us with adequate rights and remedies, and actions required to protect against enforcement actions or to enforce such rights could be costly and time consuming.

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 medical device rules respectively. Additionally, Inbrija's marketing authorization requires that the medicinal product may only be used with the Inbrija inhaler, and so the inhaler device is a "referenced device." In order to be lawfully placed on the market, the device must be compliant with the relevant EU law on medical devices. As of May 26, 2021, the Medical Devices Regulation (EU) 2017/745 (MDR) implemented a harmonized medical devices regulatory framework in the EU. It repealed and replaced the Medical Devices Directive 93/42/EEC (MDD). The MDD and now the MDR and their associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import, and post-market surveillance, vigilance, and market surveillance.

In order to be placed on the market in the EU, a medical device must undergo a conformity assessment procedure, to verify compliance with the relevant requirements (including the Essential Requirements set out in Annex I of the MDD, replaced by the General Safety and Performance Requirements (GSPRs) in Annex I of the MDR), and the manufacturer must affix the Conformité Européene mark, or CE Mark, to the product. The conformity assessment procedure depends on the risk class of the device. Medical devices are classified into one of four classes: I, IIa, IIb and III, with Class I being the lowest risk and Class III being the highest. Under the MDD, the Inbrija inhaler was a Class I device, for which the manufacturer may carry out its own conformity assessment procedure and self-certify compliance with the essential requirements, before affixing the CE mark.

However, under the MDR, the Inbrija inhaler is up-classified to a Class II product. The conformity assessment procedure for a Class II product must be conducted by a third-party organization designated to conduct conformity assessments, known as a Notified Body. The Notified Body issues a certificate of conformity, which entitles the manufacturer to affix the CE Mark to its devices after having prepared and signed a related EU Declaration of Conformity.

Transitional provisions in the MDR allow devices that are Class I under the MDD and that are up-classified to a Class II (or above) under the MDR to continue to be placed on the market under the MDD CE mark until May 26, 2024. Therefore, we must appoint a Notified Body for a conformity assessment procedure and CE mark the Inbrija inhaler under the MDR before May 26, 2024, in order for us or our collaborators to continue marketing Inbrija in the EU at that time.

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, and 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 (VHCA). 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, physician assistants, advance practice nurses, and teaching hospitals. Reports submitted under these requirements are placed on a public database. Pharmaceutical manufacturers are required to submit reports to CMS annually. Similarly, the ACA requires pharmaceutical manufacturers 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.

Pharmaceutical 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. Pharmaceutical 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. Although we assigned our Chelsea, Massachusetts manufacturing facility lease to Catalent Pharma Solutions in February 2021, we remain responsible for certain contingent environmental liabilities should an issue arise in the future relating to the operation of the facility prior to the assignment.

Reimbursement and Pricing Controls

In many of markets where we or a collaborator or distributor 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. 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. The Biden presidential administration and members of the U.S. Congress have indicated an interest in measures designed to lower drug costs and 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, or at a minimum continued scrutiny. 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.

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.

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. 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 many jurisdictions does not necessarily guarantee that a product will be reimbursed in a particular jurisdiction. The approach taken varies by jurisdiction 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 countries 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 March 11, 2022, we had 118 full-time and 12 temporary 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 (*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. The SEC also maintains a website that contains the reports, proxy and information statements, and other information that we file electronically with the SEC at *www.sec.gov*. Also, the SEC allows us to “incorporate by reference” some information from our proxy statement for our 2022 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2022 Proxy Statement within 120 days after the end of our 2021 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 2022 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.

Risk Factors Summary

An investment in our securities is subject to various risks, the most significant of which are summarized below.

- We have a history of operating losses and may not be able to achieve or sustain profitability in the future; our prospects for achieving and sustaining profitability in the future will depend primarily on how successful we are in increasing Inbrija (levodopa inhalation powder) sales in the U.S. and establishing collaborations or distribution agreements to sell Inbrija in the EU and other territories outside the U.S., as well as the extent and timing of expected continuing Ampyra sales declines due to generic competition that commenced in 2018.
- Our business depends on our ability to attract and retain key management and other personnel, and maintain access to expert advisors and consultants; we have recently experienced workforce attrition in various functions across our business, we may not be able to adjust our operations in response to prevent disruption to our business, and we lack redundancy in important functions across our business.
- Our 2021 restructurings and associated organizational changes may not adequately reduce our expenses, may lead to additional workforce attrition, and may cause operational disruptions.
- We may not be able to repay our convertible senior secured notes when they come due in 2024; we may not have the ability to raise the funds necessary to settle conversions of our notes or to repurchase the notes upon a fundamental change.
- The indenture governing our convertible senior secured notes due 2024 contains restrictions that may make it more difficult to execute our strategy or to effectively compete, and an event of default under the indenture could adversely affect our liquidity and our ability to retain title to our assets, including our intellectual property.

- We are substantially dependent on our ability to increase sales of Inbrija in the U.S. and to a lesser extent commercialize Inbrija in the EU or other countries outside the U.S.; the commercial success of Inbrija depends on market acceptance among physicians, patients and the medical community, adequate reimbursement by governmental and other third-party payors, and other factors; and Inbrija faces competition from other marketed products.
- We do not have the capabilities to commercialize products outside of the U.S.; we are dependent on our existing collaboration with Biogen for sales of Ampyra in the EU and other countries outside the U.S. where it is approved, and we are dependent on our existing distribution agreements with Esteve for commercialization of Inbrija in Germany and Spain, and we will need to enter into additional collaborations or distribution agreements to commercialize Inbrija in other EU countries and other countries outside U.S.
- We rely on Catalent as our sole third party for the commercial manufacture of Inbrija and ARCUS inhaled therapeutic candidates that we may seek to develop; we rely on the Chelsea, Massachusetts, manufacturing facility that we transferred to Catalent for the manufacture of Inbrija; our business could be harmed if Catalent does not maintain required regulatory approvals for the facility, if there is an interruption in operations, or if there is insufficient manufacturing capacity; and we have substantial long-term financial commitments under our global supply agreement with Catalent for Inbrija.
- We have no manufacturing capabilities for our products or product candidates and we are dependent upon third parties to supply the materials for, and to manufacture, our other products and product candidates (and in many cases these are single source suppliers).
- We face risks related to health epidemics, such as the current COVID-19 global pandemic, that could adversely affect our operations of financial results.
- We operate in the highly regulated pharmaceutical industry, and our business could be harmed and we could incur substantial liabilities if we (or our contractors, partners, collaborators or distributors) fail to comply with stringent federal, state and foreign legal and regulatory requirements relating to matters such as pharmaceutical marketing and promotion, safety and adverse event monitoring and reporting, fraud and abuse, false claims, Medicare rebate and other governmental pricing programs, and reporting of payments to certain health care practitioners.
- The identification of new side effects from our products, or side effects that are more frequent or severe than in the past, could harm our business by leading to a significant decrease in sales or the withdrawal of marketing approval in the U.S., the EU, or other jurisdictions.
- We rely on specialty pharmacies to dispense our products, deliver customer support, and provide us with related services, and our business could be harmed and we could be subject to liabilities if these services are performed inadequately or in a manner that does not comply with applicable laws and regulations.
- We do not have any active drug development programs and may never commercialize any new products; because of our limited financial resources, we previously suspended work on all research and development programs, and as part of our financial management efforts, we are allowing the intellectual property associated with certain of these programs to lapse; even if we were to recommence investment in drug development programs, drug development is highly risky and uncertain, and programs may never result in a commercialized product despite significant investment.
- Our business depends on our ability to maintain and protect our intellectual property and proprietary trade secrets and know how, avoiding infringing the intellectual property of other parties, and complying with third-party licenses to the intellectual property of others.
- 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.
- Our stock price may be volatile and you may lose all or part of your investment.
- Substantial dilution could result from future issuances of our common stock, shares underlying existing or future equity awards to employees and directors, the possible issuance of shares to holders of our convertible senior secured notes due 2024 to settle all or a portion of our conversion or make-whole payment obligations under, and/or interest payments on, those notes, and/or the possible sale of shares pursuant to an at-the-market offering or other financing transaction.
- 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.

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.

As of December 31, 2021, we had an accumulated deficit of approximately $870.4 million. We had a net loss of $104.0 million for the year ended December 31, 2021. We have historically been highly dependent on sales of Ampyra in the U.S. but have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra that began entering the market in the U.S. in late 2018. 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 increasing Inbrija sales in the U.S. and establishing partnerships to sell Inbrija in the EU and other territories outside the U.S., as well as the extent and timing of continuing Ampyra sales declines due to generic competition. 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 ability to achieve and sustain profitability in the future will also depend on our ability to manage our operating costs, and 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.

We may not have sufficient cash flow from our business to continue to sufficiently fund our operations and pay our substantial debt.

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 $207.1 million of convertible senior secured notes that mature in December 2024, 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, research and development programs will not generate any revenues for us 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 we have generally discontinued funding research and development.

Our ability to meet our future operating requirements, repay our liabilities, and meet our other obligations are dependent upon a number of factors, including our ability to generate cash from product sales, reduce planned expenditures, and obtain additional financing. If we are unable to generate sufficient cash flow from the sale of our products, we will be required to adopt one or more alternatives, subject to the restrictions contained in the indenture governing our convertible senior secured notes due 2024, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous and likely to be highly dilutive. Also, our ability to raise additional capital and repay or restructure our indebtedness will depend on the capital markets and our financial condition at such time, among other factors. In addition, financing may not be available when needed, at all, on terms acceptable to us or in accordance with the restrictions described above. As a result of these factors, we may not be able to engage in any of the alternative activities, or engage in such 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. If we are unable to take these actions, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether.

Our restructurings and associated organizational changes may not adequately reduce our expenses, may lead to additional workforce attrition, and may cause operational disruptions.

In 2021, we implemented two corporate restructurings to reduce costs, more closely align operating expenses with expected revenue, and focus our resources on Inbrija. As part of these restructurings, we substantially reduced employee headcount. 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

restructurings 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 (particularly given that we have implemented four corporate restructurings since 2017). We have recently experienced workforce attrition in various functions across our business, which may be attributable to our corporate restructurings, our current business circumstances, a combination of both, or other factors. Our efforts to adjust our operations with the reduced workforce may not be successful in preventing disruption to our business, and with the reduced workforce, we lack redundancy in important functions across our business. We are increasingly relying on the services of contract sales representatives and potentially third-party promotional partnerships or other similar arrangements in response to substantial sales force attrition. Further loss of one or more of our key employees, additional loss of multiple employees in particular functions, and/or our inability to attract replacement or additional qualified personnel could substantially impair our ability to operate our business and implement our business plan, particularly our efforts to successfully commercialize Inbrija.

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

Holders of our convertible senior secured notes due 2024 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. 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 the notes, whether upon maturity, conversion, or occurrence of a fundamental change. 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 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) as required by the notes indenture, would constitute a default under the indenture.

The indenture governing our 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 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 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, including limiting our ability to engage in certain collaborations or transactions involving Inbrija and certain intellectual property, or effectively compete with companies that are not similarly restricted.

An event of default under the indenture governing our 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 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 convertible senior secured notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the 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. Certain of these potential events of default may occur as a result of factors beyond our control.

In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to us, all outstanding 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 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 convertible senior secured notes due 2024 or if alternate funding is not available to us. Furthermore, if we are unable to repay the 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 and any other future products are highly dependent on market acceptance among physicians, patients and the medical community, adequate reimbursement by governmental 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 or decisions 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 do not receive a pricing or reimbursement approval, 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 further described below, FDA and EU-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 has led some patients to discontinue Inbrija. Also, in 2020, we updated the Inbrija U.S. and EU-approved labels to add “sensation of choking immediately following administration” as a potential adverse reaction.
- *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. For example, as further described below in these risk factors, Inbrija competes with Apokyn, an injectable formulation of apomorphine, as well as Kynmobi, a sublingual, or under the tongue, formulation of apomorphine, both of which are approved for the acute, intermittent treatment of OFF periods.

- *Intellectual Property*: The loss of intellectual property protection for our products would enable generic competition. Ampyra became subject to generic competition in the U.S. in late 2018, due to the invalidation of certain Ampyra patents, and our Ampyra sales have been declining since then.

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.

We face risks related to health epidemics, including the COVID-19 global pandemic, that could adversely affect our operations or financial results.

Our business and financial condition have been impacted by, and are subject to the ongoing risks resulting from, the COVID-19 global pandemic. The COVID-19 global pandemic has caused significant disruptions in the healthcare industry. The duration of the pandemic is difficult to predict, and it is likely to have ongoing impacts as it continues. The travel restrictions, "shelter in place" orders, quarantine policies, vaccine mandates, and general concerns about the spread and effects of COVID-19 have disrupted the delivery of healthcare to patients; for example, the pandemic has made it more difficult for some patients to visit with their physician and obtain pharmaceutical prescriptions. Also, healthcare office staffing shortages may delay the administrative work, and particularly insurance-related documentation, needed to obtain reimbursement for prescriptions. We also believe that the governmental and other restrictions and requirements related to the pandemic may have caused certain patients to lessen their mobility and therefore their need for certain therapeutics. We believe these factors contributed to volatility in new Inbrija prescriptions since the start of the pandemic in 2020 and are continuing to impact prescriptions in 2022.

COVID-related policies, restrictions, mandates, and concerns may disrupt our operations and those of our customers and suppliers. Also, our operations could be interrupted if we or our customers or suppliers lose the services of key employees or consultants who become ill from COVID-19. These types of disruptions could potentially affect any of our critical business functions, and thus harm our business, including for example our sales and marketing operations as well compliance and certain general and administrative functions. The ultimate impact of the COVID-19 global pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems, or the global economy as a whole. As the pandemic continues, it may cause continuing economic volatility or result in a sustained economic downturn that could affect demand for our products and our ability to access capital on reasonable terms, or at all. These factors could have a material adverse effect on our business, operating results and financial condition.

We operate in the highly regulated pharmaceutical industry.

Pharmaceutical 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.

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 and is co-packaged with a medical device (the Inbrija inhaler), the overall product is regulated under the EU's medicines rules, but the device must be CE marked and comply with the EU's medical devices rules, as further described below in these risk factors. 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 New Drug Application (NDA) or Biologics License Application (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 a medicinal product has been granted EU marketing authorization through the centralized procedure and we do not market that product in at least one European Economic Area, or EEA, member state within three years of its first marketing authorization, the EU marketing authorization would lapse under the EU's sunset rules unless the deadline is extended. The European Commission, or EC, approved our Inbrija Marketing Authorization Application, or MAA, in September 2019. Based on Inbrija's approval, the sunset deadline for Inbrija was originally September 2022. However, in December 2021, we received an extension of the sunset deadline for Inbrija to March 31, 2023. Although we have entered into distribution and supply agreements with Esteve for the commercialization of Inbrija in Germany and Spain, we cannot be sure that Esteve will commence marketing Inbrija in one of those countries prior to the extended deadline, and we currently do not have any other agreements in place for distribution of Inbrija in the EU/EEA. If we cannot meet the deadline through our Esteve distribution arrangement or other means, our Inbrija marketing authorization will lapse and this could have a material adverse effect on our business, operating results and financial condition.

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 must obtain a CE mark for the Inbrija inhaler under the EU Medical Devices Regulation by May 26, 2024, otherwise at that time we and any collaborators or distributors would have to cease marketing Inbrija in the EU until the CE mark is obtained.

In the EU, Inbrija is considered a medicinal product that is co-packaged with a medical device, the inhaler. This device is required to comply with the applicable EU medical device rules. Medical Devices Regulation (EU) 2017/745 (MDR) has applied from May 26, 2021 and repealed and replaced the Medical Devices Directive 93/42/EEC (MDD). For us or our collaborators or distributors to place the device on the market in the EU, the device must undergo the applicable conformity assessment and have a CE mark affixed. Under the MDD, as the Inbrija inhaler was a Class I device, we self-certified the conformity of the device against the MDD's requirements (including the Essential Requirements included in Annex I) and affixed a CE mark. Now under the MDR, the inhaler is a Class II device and so the conformity assessment procedure to confirm compliance with the MDR (including the General Safety and Performance Requirements included in Annex I) has to be carried out by a Notified Body (a third-party organization designated by a member state of the EEA to conduct conformity assessments) before we can affix a CE mark.

We have not yet CE marked the Inbrija inhaler under the MDR nor appointed a Notified Body. However, under the MDR's transition period, we can continue to place the device on the market under the MDD CE mark until May 26, 2024, so long as it continues to comply with the MDD and we make no significant changes to the design or intended purpose of the device. Failure to obtain an MDR CE mark by May 26, 2024, and/or to retain our MDD CE mark until that date would mean we and any collaborators or distributors could not lawfully market Inbrija with the Inbrija inhaler in the EU. As the marketing authorization for Inbrija requires that the medicinal product can only be used with the Inbrija inhaler device, this would mean the medicinal product could not be made available to patients in the EU until the device was CE marked under the MDR.

We are in the process of appointing a Notified Body and are planning to undergo an MDR inspection in the first half of 2023. However, if the Notified Body disagrees with our classification of the Inbrija inhaler device or otherwise does not agree with our approach and requires further changes, there is a risk we may fail to obtain a CE mark under the MDR before the end of the transitional period on May 26, 2024, in which case we and any collaborators or distributors would have to cease marketing Inbrija until the CE mark is obtained.

We have no manufacturing capabilities for our products or 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. 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 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.

As further described below in these risk factors, we sold our Chelsea, Massachusetts manufacturing operations to Catalent Pharma Solutions and rely on Catalent for the manufacture and supply of Inbrija. As our Inbrija supplier, Catalent is responsible for all Inbrija components other than the inhaler and levodopa, the Inbrija API. We have relied, and we expect to continue relying, on single third parties to supply the inhaler and levodopa. 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 commercialize Inbrija or to complete any future clinical studies that may be needed. 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. This may be made more complex in certain circumstances if we do not have contracts with suppliers, such as in the case of Inbrija where we currently do not have a contract with the supplier of the API, 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 do not control how Catalent sources the other components of Inbrija, but we are aware that they rely on a single supplier for a critical excipient used for Inbrija manufacturing and they could rely on single suppliers for other components. Our business could be similarly exposed to risk if and to the extent they rely on single source suppliers or do not have supply contracts.

We currently rely on a single third-party molding manufacturer for supply of the Inbrija inhalers. 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. If the inhaler supplier fails to provide sufficient inhaler supply, we would need enter into alternative arrangements with a different supplier. Transition to a new inhaler supplier would be a lengthy and complex process. Among other things, we would have to revalidate the molding and assembly processes pursuant to FDA requirements and we would have to ensure that inhalers manufactured by the new supplier adhere to other applicable regulatory requirements.

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 COVID-19 global pandemic). 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 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 completed the sale of our Chelsea, Massachusetts manufacturing operations in February 2021, and accordingly we rely on Catalent as our sole supplier for the manufacture of Inbrija and the manufacture of any ARCUS product candidates we may seek to further develop.

In connection with the sale of the Chelsea manufacturing operations, we entered into a long-term global supply agreement under which a Catalent affiliate will manufacture Inbrija on an exclusive basis (other than for sale in China). We are reliant on Catalent for all of our Inbrija supply and, subject to the negotiation of an amendment or new supply agreement, supply of other ARCUS inhaled therapeutic product candidates. Although Catalent has significant experience in commercial manufacturing, given applicable regulatory requirements and the complexity of the manufacturing processes for pharmaceuticals, Catalent may be unable or otherwise not successful in passing any required regulatory inspection as a condition to manufacturing, carrying out its contractual duties, meeting expected deadlines or effectively manufacturing or releasing Inbrija in a timely manner in accordance with current good manufacturing practices and other regulatory requirements. If we are unable to obtain adequate supplies of Inbrija under our supply agreement with Catalent, or if the supplies we receive do not meet quality and safety standards, we could face supply shortages, significant additional costs, product liability claims and reputational harm. Any of these factors, alone or in combination, could materially harm our business, financial condition, results of operations and prospects.

We are discussing potential ARCUS collaborations with other companies that have expressed interest in formulating their novel molecules using ARCUS, and have already been performing feasibility studies for a number of these opportunities. However, currently we are not investing in any proprietary ARCUS research and development programs. Should we decide to proceed with any ARCUS development program, we would be reliant on Catalent or another third-party supplier for the manufacture of product for that program. Our global supply agreement does not provide for the terms and conditions under which Catalent would supply any product or product candidate other than Inbrija, or under which Catalent would provide support for ARCUS research and development. We would be unable to advance the development of any ARCUS inhaled therapeutic candidate unless Catalent is willing to manufacture the candidate for us on commercially reasonable terms, or we could identify another third-party manufacturer that would be capable and willing to manufacture the candidate on commercially reasonable terms. Also, due to reductions in force, employee attrition and the 2021 sale of our Chelsea manufacturing operations, we may need to hire replacement personnel or engage consultants to continue with ARCUS research and development work beyond feasibility and similar early-stage studies.

Establishing our global supply agreement with Catalent required that we share proprietary trade secrets and know-how relating to Inbrija and our ARCUS platform. We have sought to protect that information pursuant to various operational safeguards and confidentiality and other requirements set forth in the global supply agreement. We are reliant on Catalent's compliance with those provisions, and even if Catalent does comply with those provisions, they 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 against Catalent or any other party for the harm caused.

Our global supply agreement with Catalent contains substantial long-term financial commitments.

Under our agreement with Catalent, we are obligated to make substantial minimum purchases from Catalent through the expiration of the agreement on December 31, 2030. Currently, these minimum purchase commitments substantially exceed our supply needs for Inbrija, and we cannot be certain whether and when our supply needs will meet or exceed these amounts. Even if we are forced to obtain Inbrija from another supplier because Catalent is unable or unwilling to provide adequate Inbrija supply, we may be unable to offset the costs of alternate supply against our minimum purchase commitments under the Catalent supply agreement. Lastly, if we choose to terminate the Catalent agreement for convenience, we would be obligated to pay a substantial termination fee.

We rely on Catalent's Chelsea, Massachusetts manufacturing facility for the manufacture of Inbrija, and our business could be harmed if Catalent does not maintain required regulatory approvals 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.

All commercial supply of Inbrija is currently manufactured at Catalent's Chelsea, Massachusetts manufacturing facility. Under our long-term global supply agreement with Catalent, Inbrija will be exclusively manufactured by Catalent at this manufacturing facility (other than for sale in China, which is not covered by the exclusivity provisions of the agreement). Catalent may need expanded manufacturing capacity at the Chelsea facility to meet demand depending on the timing and extent of sales growth. Catalent's inability to complete any needed expansion of 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 in the U.S. and any foreign jurisdictions where we seek to commercialize Inbrija (including Germany and Spain, where we intend to commercialize Inbrija through our existing agreements with Esteve). If we or a collaborator launches Inbrija in an EU member state or another foreign jurisdiction, such supply shortages could lead to a breach of our legal obligation to supply Inbrija.

Furthermore, if Catalent were to lose the use of the facility or equipment, the manufacturing facility and manufacturing equipment would be difficult to replace and could require substantial replacement lead time and substantial additional funds. The facility may be affected by natural disasters, such as floods or fire, or Catalent may lose the use of the facility due to manufacturing issues that arise, such as contamination or regulatory concerns following a regulatory inspection of the facility. Catalent may also unexpectedly experience manufacturing issues as the unintended result of activities occurring at the facility unrelated to Inbrija manufacture. In the event of a loss of the use of all or a portion of the facility or equipment for the reasons stated above or any other reason, Catalent would be unable to manufacture Inbrija until such time as the facility or equipment could be repaired or rebuilt or they are able to address other manufacturing issues at the facility. Any such interruptions in their ability to manufacture Inbrija would harm our business. Even if Catalent does 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 have back-up manufacturing capability for Inbrija or any ARCUS product candidates, and if Catalent fails to timely perform under our global supply agreement our business, financial condition, results of operations and prospects could be harmed.

If we are unable to obtain adequate supplies of Inbrija under our supply agreement with Catalent, or if the supplies we receive do not meet quality and safety standards, we could face supply shortages, significant additional costs, product liability claims and reputational harm. Also, if we decide to make further investments in any ARCUS product development programs, we would be unable to advance those programs unless we could obtain adequate supply of the inhaled therapeutic product candidate from Catalent or another third-party manufacturer and on commercially reasonable terms.

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 another 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 due to the complexity and substantial regulation of the manufacturing processes involved. Also, engaging a third party would require the sharing of proprietary information, which increases the risk of the unauthorized use or disclosure of that information and potential harm to our business for which we may not have an adequate remedy. 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.

Catalent may not successfully complete the expansion of the Chelsea, Massachusetts manufacturing facility.

Catalent may need expanded manufacturing capacity at the Chelsea facility to meet Inbrija demand depending on the timing and extent of sales growth. In 2018, prior to our sale of the Chelsea manufacturing operations to Catalent, 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 added a new size 7 spray dryer manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing size 4 spray dyer manufacturing production line, and has created additional warehousing space for manufactured product. Although the project was substantially completed in late 2019, the expansion does not yet have all of the approvals needed for use of the new production line for commercial manufacture, such as approvals from the FDA and other regulatory authorities. Also, manufacturing scale-up generally is subject to significant risks related to process development and manufacturing yields, which is especially true for the manufacture of a product such as Inbrija which involves a highly specialized spray drying and capsule filling process. Lastly, the 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. Given the potential importance of the expansion to our business, in December 2021 we agreed to fund $1.5 million of Catalent's costs to complete the size 7 spray dryer expansion, which will be payable by us in four quarterly installments after the later of January 1, 2024 or FDA qualification and approval for use of the size 7 spray dryer.

The challenges described above could delay or prevent Catalent from successfully completing the expansion of the Chelsea manufacturing capacity. If we need the expanded capacity but Catalent is delayed in or prevented from completing the expansion and obtaining necessary regulatory approvals, we may need to seek another 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 obtain increased supply of Inbrija from expanded capacity at the Chelsea facility or engaging another third-party manufacturer, we may not be able to meet demand for Inbrija and this could harm our ability to commercialize Inbrija in the U.S. and any foreign jurisdictions where we seek to commercialize Inbrija (including Germany and Spain, where we intend to commercialize Inbrija through our existing agreements with Esteve). If we or a collaborator launches Inbrija in an EU member state or another foreign jurisdiction, such an inability to meet demand could lead to a breach of our legal obligation to supply Inbrija.

We may incur significant liability if we or our contract sales representatives, promotional partners, distributors, or collaborators fail to comply with stringent U.S. FDA and foreign marketing and promotion regulations.

The advertising and promotion activities for our products 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, advertising and promotional materials for our products 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. Some other jurisdictions also require government pre-approval of promotional materials. If the FDA or other regulators raise concerns regarding promotional materials or messages for our products, we or our contract sales representatives, promotional partners, distributors or collaborators may be required to modify or discontinue using them and may be required to provide corrective information. Should we or our contract sales representatives, promotional partners, distributors or collaborators 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. In the case where our contract sales representatives or one of our promotional partners, distributors, or collaborators has failed to comply with legal requirements, there can be no assurance that contractual terms and conditions intended to protect our rights and mitigate our risk relating to their misconduct will provide us with adequate rights and remedies, and actions required to protect against enforcement actions or to enforce such rights could be costly and time consuming.

Each of our products is approved with specific indications and other conditions of use that inform our ability, and the ability of our contract sales representatives, promotional partners, distributors, and collaborators, to promote our products. For example, in the U.S., Inbrija 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 or our contract sales representatives, promotional partners, distributors, or collaborators 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 or our contract sales representatives, promotional partners, distributors or collaborators promote Inbrija, 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, and we seek to ensure that the activities of our contract sales representatives, promotional partners, distributors and collaborators are similarly compliant, 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 or any other marketed drug products, or side effects from those products that are more frequent or severe than in the past, could harm our business by leading to a significant decrease in sales or to the withdrawal of marketing approval in the U.S., EU and/or 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; for example, in September 2020, we updated the Inbrija label to add "sensation of choking immediately following administration" as a potential adverse reaction;
- 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 lawsuits, 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. The same risks apply to our other marketed products, such as Ampyra.

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 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, promotional partners, distributors, 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. This may be made more complex in certain circumstances if we do not have contracts with suppliers, such as in the case of Inbrija where we currently do not have a contract with the supplier of levodopa, the active pharmaceutical ingredient. 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. In addition, a delay or interruption in supply of our products could lead to claims against us by our distributors and collaborators to whom we are obligated to supply product.

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, damage our reputation, and potentially lead to claims against us by distributors or collaborators to whom we are obligated to supply product. 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 our manufacturers, repackagers, wholesale distributors, and dispensers, take certain actions when product in their possession or control is suspect product, meaning there is reason to believe the product is: 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 is illegitimate, meaning credible evidence shows that it meets any of the above criteria. If a product is deemed an illegitimate product, additional requirements apply such as notifying the FDA and all immediate trading partners in the supply chain within 24 hours and quarantining the product until it is dispositioned. Similar requirements exist under EU law, particularly pursuant to the Falsified Medicines Directive (Directive 2011/62/EU). The notification, quarantine and/or dispositioning of product during an investigation could impact product availability for commercial distribution and harm our business.

We rely on specialty pharmacies to dispense our products, deliver customer support, and provide us with related services, and our business could be harmed and we could be subject to liabilities if these services are performed inadequately or in a manner that does not comply with applicable laws and regulations.

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 and multiple sclerosis, which often require a high level of patient education and ongoing management. Most of our Inbrija and Ampyra sales are sold through specialty pharmacies, and sales of these products are highly dependent on the performance of these specialty pharmacies.

The use of specialty pharmacies involves risks, including, but not limited to, risks that these specialty pharmacies:

- do not provide us with accurate or timely information regarding their inventories or the number of patients who are using Inbrija or Ampyra;
- fail to provide timely and accurate information regarding product adverse events or product complaints;
- fail to properly administer copay mitigation programs;
- do not effectively dispense or support Inbrija or Ampyra;
- reduce their efforts or discontinue dispensing or supporting Inbrija or Ampyra;
- do not devote the resources necessary to dispense Inbrija or Ampyra in a manner that meets patient needs;
- are unable to satisfy financial obligations to us or others; or
- lose the required licenses to distribute drugs; or cease operations.

If our specialty pharmacies do not fulfill their contractual obligations to us or fail to adequately dispense our products and deliver customer support, our product sales and business could be harmed or we could be subject to legal or regulatory liabilities or sanctions. Also, Alliance Rx Walgreens Prime, or Walgreens, is the primary specialty pharmacy that we use for sales of Inbrija in the U.S. While we believe our use of Walgreens as our primary specialty pharmacy for Inbrija has benefits for patients and our business, such reliance on a specialty pharmacy that services a large percentage of Inbrija patients also potentially increases the risks described above because we do not have a backup specialty pharmacy replace Walgreens and provide related services if an issue arises with Walgreens. We expect that it would take a significant amount of time to engage a new specialty pharmacy and transfer patients to the new specialty pharmacy if we were required to make a change, and that process could result in the loss of patients using Inbrija and/or an interruption in new patients using Inbrija.

Furthermore, arrangements between manufacturers and specialty pharmacies can be subject to government scrutiny and challenge under fraud and abuse laws if not structured properly.

We are dependent on third parties such as through collaboration and distribution agreements to develop and commercialize products outside of the U.S.

We do not have the capabilities to develop and commercialize products outside of the U.S. without reliance on another party. Ampyra is marketed as Fampyra outside the U.S. by Biogen under a license and collaboration agreement that we entered into in June 2009. In 2021, we entered into distribution and supply agreements with Esteve Pharmaceuticals for commercialization of Inbrija in Germany and Spain, and we are relying on Esteve, among other things, to obtain necessary country-specific approvals needed for the sale of and reimbursement for Inbrija in those countries. We expect that we will need to enter into additional collaborations or distribution arrangements with third parties to commercialize Inbrija in other EU countries. We would similarly need to rely on third parties for developing and commercializing any other potential products outside of the U.S. We cannot provide any assurance that we will be able to identify suitable collaborators or distributors in addition to our existing agreements, or that we will be able to enter into additional collaboration or distribution agreements with third parties on commercially reasonable terms, if at all. Our inability to identify collaborators or distributors and enter into agreements with them could harm or delay our efforts to develop and commercialize Inbrija or other potential products outside of the U.S.

Our dependence on third parties such as collaborators and distributors for development and commercialization of products outside the U.S., does 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 or distributors devote to the development or commercialization of product candidates or to their marketing and distribution;
- our collaborators or distributors may fail to comply with laws and regulations applicable to the development, or commercialization of products or product candidates;
- our collaborators or distributors 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 or distributors 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;
- our collaborators or distributors 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;
- our collaborators or distributors 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 our collaborator's or distributor’s business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- our collaborator or distributor could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- collaborations or distribution arrangements may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates;
- our collaborators or distributors may experience financial difficulties; and
- our ability to enter into additional collaboration agreements or distribution arrangements may be limited by the restrictive covenants contained in the indenture that governs our 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 will not receive any royalties from Biogen until we satisfy certain financial obligations to HealthCare Royalty Partners under a 2017 royalty monetization transaction; and potential generic Fampyra competition could affect our prospects for receiving 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 HealthCare Royalty Partners receives an agreed-upon threshold of royalties. After this threshold is met, we will receive Fampyra royalty revenue under the terms of our collaboration agreement with Biogen. Although we believe that threshold may be met in mid-2022, we cannot be certain when this will occur, because it depends on Biogen's ability to continue commercializing Fampyra.

Biogen's commercialization of Fampyra depends on factors such as Biogen's ability to obtain and maintain regulatory approvals, its ability to obtain and maintain adequate third party reimbursement as described further in these risk factors, as well as the extent to which Fampyra becomes subject to competition from generic versions marketed in European or other countries. Fampyra is no longer protected by regulatory marketing exclusivity in the EU, which expired in July 2021. Accordingly, generic drug manufacturers who have obtained or may obtain marketing approval for generic versions of Fampyra in European countries can potentially launch their products in those European countries, and we and Biogen would need to rely on enforcement of Fampyra patents to prevent competition from those generic versions. Fampyra is covered by claims of two European patents, which are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. However, it is uncertain whether we and Biogen would be successful in any Fampyra patent litigation with generic drug manufacturers, and we and Biogen may be unable to obtain injunctive or similar relief to prevent the commercial launch of a generic product while patent litigation is proceeding. Also, generic drug manufacturers have filed nullity actions in Germany against both of the German national patents derived from these two patents, and similar legal proceedings could be filed in other European countries challenging Fampyra patents. Lastly, we do not know if Biogen will obtain approval to market and commercialize Fampyra in any new jurisdictions in the future, and there can be no assurance that Biogen will launch Fampyra in any new jurisdiction where they do obtain marketing approval. For example, in May 2021, Biogen announced that Fampyra was approved by the National Medicinal Products administration in China, but Biogen is continuing to evaluate commercial launch options in that country. All of these factors could affect sales of Fampyra sales and accordingly our prospects for receiving additional Fampyra royalties in the future.

Our collaborators and distributors 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 collaborators or distributors 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 collaborators or distributors to market and sell our 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 our collaborators or distributors fail to comply with legal and regulatory requirements.

We do not have any active drug development programs and may never commercialize any new products.

Because of our limited financial resources, we previously suspended work on all research and development programs, and deferred consideration of further investment. Furthermore, as part of our financial management efforts, we are allowing the intellectual property associated with certain of these programs to lapse. Future growth of our business may depend, in part, on our ability to identify new product development candidates, complete preclinical development of these product candidates, and advance them to and through clinical trials.

Even if we were to recommence investment in drug development programs, our suspended programs are all early-stage and either have not advanced to clinical trials or are only in Phase 1 trials. Early-stage product candidates in particular

would require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they could be commercialized, if at all. Pharmaceutical research and development programs are subject to the risks and uncertainties associated with drug development described elsewhere in these risk factors and in general experience a high rate of failure. For example, we may fail to identify promising product candidates, 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. Also, as a result of reductions in force, we previously terminated substantially all of our research and development and clinical development workforce, and accordingly we lack personnel necessary to advance development programs unless and until we can hire qualified replacements.

Our research and development programs have included exploration of opportunities for proprietary products, in addition to Inbrija, in which inhaled delivery of medicine using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients. Although our suspension of research and development investment impacted these efforts, we are discussing potential ARCUS collaborations with other companies that have expressed interest in formulating their novel molecules using ARCUS, and have already been performing feasibility studies for a number of these opportunities. However, there can be no assurance that these companies will want to further pursue, or would agree to commercially reasonable terms and conditions for, such collaborations. Even if we enter into an ARCUS collaboration for a third-party molecule, the development of the ARCUS formulation would be subject to the risks and uncertainties associated with drug development described elsewhere in these risk factors and may never be commercialized. For example, the third party could discontinue the development program for financial reasons, or safety or efficacy concerns could prevent the ARCUS formulation from receiving regulatory approval.

From time to time, we may establish and announce certain development goals for product candidates and development programs. 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.

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 any product candidate can receive regulatory approval, the product candidate must be subjected to 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 or a collaboration partner determine to take into clinical trials 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 or our collaboration partner, 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 or our collaboration partner’s product candidates;
- change in the focus of our development efforts or a re-evaluation of our or our collaboration partner’s clinical development strategy; and
- change in our or our collaboration partner’s financial position.

A delay in or termination of any of a clinical development program that we or a collaboration partner may conduct in the future 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. If we were to conduct any clinical trials, we would depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials 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.

If we proceed with research and development programs, we will rely on third-party contract research organizations, medical centers and others to perform preclinical and non-clinical testing and clinical trials, and research and development programs could be harmed if these third parties do not perform in an acceptable and legally compliant manner.

If we recommence investment in research and development programs, we would 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., Canada, and to a lesser extent other jurisdictions, particularly Europe. Because we have limited experience conducting clinical trials outside the U.S. and Canada, we would 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 preclinical or non-clinical testing or clinical trials and ultimately on the timely advancement of research and development programs. Similarly, we would rely on medical centers to conduct 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 or our contract sales representatives, promotional partners, collaborators or distributors market products in a manner that violates healthcare fraud and abuse laws, if we or any of them violate false claims laws, or if we 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 laws and 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 Federal Trade Commission, 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 and regulations.

The U.S. 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, patients, and formulary managers on the other. Industry relationships with specialty pharmacies have also 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, teaching hospitals, physician assistants and advance practice nurses. Similarly, the Affordable Care Act requires pharmaceutical manufacturers 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 must comply with all applicable rules in each relevant market. In many jurisdictions, these include both general anti-bribery rules and specific rules prohibiting the provision of inducements to healthcare professionals under medicines advertising laws and self-regulatory codes of conduct and guidelines. In many EU countries, the applicable industry self-regulatory codes of conduct require companies to disclose publicly any transfers of value to healthcare professionals or healthcare organizations, and disclosure laws comparable to the U.S. Sunshine Act have been adopted in some EU member states. 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.

In the U.S., we supplement our own sales activities with the services of contract sales representatives and may enter into promotional partnerships or other similar arrangments. Outside the U.S., we rely on collaborators and distributors to market our products. Although these are independent companies, under applicable laws and regulations we can in some cases be held directly responsible for the acts or omissions of these companies because they are marketing our products. While we seek contractual terms and conditions intended to protect our rights and mitigate our risk relating to the misconduct of other parties, contractual rights would not protect us against governmental prosecution or enforcement, there can be no assurance that contractual financial remedies would be adequate to cover associated liabilities, and the actions required to protect against enforcement actions or to enforce such rights could be costly and time consuming.

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

The Biden presidential administration and members of Congress have indicated an interest in measures designed to lower drug costs and 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, or at a minimum continued scrutiny. 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.

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. 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 have experienced 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. Many third-party payers have implemented utilization management techniques for Inbrija and Ampyra, such as prior authorization and/or quantity limits. 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 the U.S. Congress support legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies. While this is a priority for the Biden presidential administration, we cannot predict whether such legislation will pass. 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 Biogen, our collaborator for Fampyra, Esteve, our distribution partner for Inbrija, or any future collaborator or distributor 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 or distributors and exert commercial pressure on pricing within a country.

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 some of the largest markets in the EU, where Biogen markets Fampyra and Esteve has agreed to distribute Inbrija, and where we may seek to market Inbrija through other collaborators or distributors. The measures vary by country and include, among other things, mandatory rebates and discounts, clinical benefit and cost-effectiveness assessments, 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 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 have adverse effects on our business.

As of January 1, 2021, the UK formally left the EU and the UK and EU are now operating separate pharmaceutical regulatory regimes. The UK and EU announced on December 24, 2020 that they had agreed a Trade and Cooperation Agreement (TCA) to govern their future relationship. The TCA sets out the arrangements for trade of goods, including medicines and medical devices, which aims to ensure goods continue to flow between the EU and the UK and also has implications for product regulation and mutual recognition.

Following the exit of the UK from the EU, we were granted a grandfathered Marketing Authorization (MA) by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK that was approved in November 2021. In order to maintain the grandfathered marketing authorization in the UK, we are required to retain the services of a qualified person for pharmacovigilance. Moreover, if we are to market Inbrija in the UK in the future, the movement of finished pharmaceutical products into the UK is treated as an import from a third country post-Brexit. The UK has decided to unilaterally waive batch testing requirements for imports of products from the EU until January 2023. Unless the UK and EU enter into a mutual recognition agreement or otherwise agree to extend this period, we may face additional quality control and batch release requirements for product entering the UK from the EU after this date.

In addition, although the TCA provides some clarity regarding the future relationship between the EU and UK, the impact of Brexit on the fiscal, monetary and regulatory landscape in the UK remains uncertain, it could have a material impact on its economy and the future growth of its various industries, including the pharmaceutical and biotechnology industries. Given the lack of comparable precedent, it remains unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU may have and how such withdrawal would affect us.

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 engaged in research, development, and/or marketing of therapeutics for various neurological conditions, including Parkinson's disease and multiple sclerosis.

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/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, and in 2022 the FDA approved a generic version of Apokyn. Also, Sunovion Pharmaceuticals Inc. markets a sublingual, or under the tongue, formulation of apomorphine branded as Kynmobi that is competitive with Inbrija.

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. 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 ARCUS drug delivery technology product candidates that we may develop in the future. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc, MannKind Corporation, 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 became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. 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, Zinbryta from Biogen and AbbieVie, 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), Rituxan from F. Hoffman-La Roche AG, and Zeposia from BristolMyersSquibb.

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. 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.

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. We may be unable to attract or retain qualified personnel because their competitive salaries and other compensation may increase to levels that we are unwilling or unable to provide. In addition, material adverse developments with our business, including the 2017 adverse patent decision relating to our Orange Book-listed Ampyra patents, the termination or suspension of research and development programs, four reductions in force since 2017, and the current progress of our Inbrija commercial launch, may impede our ability to attract and retain highly qualified personnel. 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 or other factors. Our efforts to adjust our operations with the reduced workforce may not be successful in preventing disruption to our business, and with the reduced workforce we lack redundancy in important functions across our business. We are increasingly relying on the services of contract sales representatives or other third-party marketing support in response to substantial sales force attrition. Further loss of one or more of our key employees, additional loss of multiple employees in particular functions, and/or our inability to attract replacement or additional qualified personnel could substantially impair our ability to operate our business and implement our business plan, particularly our efforts to successfully commercialize Inbrija. Also, due to the recent attrition, four reductions in force since 2017, and the 2021 sale of our Chelsea manufacturing operations, we believe we lack personnel needed for, and would need to hire replacements before continuing with, research and development and clinical programs. Our inability to attract qualified replacements needed for research and development and clinical programs could substantially impair our ability to advance those programs, if we determine to make further investments in 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. Burkhard Blank, M.D., our former Chief Medical Officer, transitioned into a consulting role effective January 1, 2022, and, to our knowledge, has commenced a full time role as an executive at another biopharmaceutical company. We cannot be sure whether and for how long we will have continuing access to Dr. Blank’s expertise for our business, and currently we have not identified any individual with comparable expertise to replace Dr. Blank.

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. We may incur substantial costs in order to comply with current or future such laws and regulations, which may also impair research and development efforts that we may be engaged in. We cannot completely avoid the risk of contamination or injury

in connection with research and development activities, 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.

Also, 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.

Although we assigned our Chelsea, Massachusetts manufacturing facility lease to Catalent Pharma Solutions in February 2021, we remain responsible for certain contingent environmental liabilities should an issue arise in the future relating to the operation of the facility prior to the assignment.

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 and our ARCUS drug delivery technology 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, Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. 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 U.S. federal district court decision invalidating 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.

Nullity actions with respect to Fampyra have been filed in Germany against both of the German national patents derived from EP 1732548 (the ‘548 patent) and EP 2377536 (the ‘536 patent) by ratiopharm GmbH, a generic manufacturer affiliated with Teva. In November 2021, a German court issued preliminary opinions in the ratiopharm case indicating that the claimed subject matter of the ‘548 patent lacked inventive step and the claimed subject matter of the ‘536 patent lacked novelty and inventive step. At an oral hearing in February 2022, the German patent court dismissed ratiopharm’s action against the ‘536 patent as inadmissible because of ongoing formality proceedings relating to the ‘536 patent in the European Patent Office. Ratiopharm could appeal this decision or refile the nullity action when the formalities are completed at the European Patent Office. An oral hearing is currently scheduled for April 26, 2022, for the ‘548 patent. On January 11, 2022, STADA Arzneimittel also filed a nullity action against the ‘536 patent in the same court. We are working with Biogen to vigorously defend these actions and enforce our patent rights. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Patent litigation, IPR proceedings, and other legal proceedings usually involve complex legal and factual questions and require the devotion of significant financial resources and management time and attention. If we are not successful in protecting any of our intellectual property that is subject to such proceedings, we could lose Orange Book listed patents that protect our products 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 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. Establishing our global supply agreement with Catalent required that we share this type of information with Catalent, and we may need to share similar information with others in the future in connection with development of backup or additional manufacturing needed for Inbrija commercialization. We seek to protect trade secrets, know-how and other proprietary information, in part, through the use of confidentiality agreements with employees, consultants, collaborators, advisors and others, and in the case of Catalent by including various operational safeguards and confidentiality and other requirements in our global supply agreement with them. 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, including in particular Inbrija and potential 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 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 COVID-19 global pandemic).

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 Select 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.

We cannot predict the effect that our reverse stock split will have on the market price for shares of our common stock.

We completed a one-for-six reverse stock split on December 31, 2020. We cannot predict the long-term effect of the reverse stock split upon the market price for shares of our common stock, and the history of similar reverse stock splits for companies in like circumstances has varied. Although the reverse stock split initially resulted in an increased market price per share of our common stock, the market price per share has since substantially declined and may continue to decline due to, among other factors, the performance of our business, economic conditions and other factors, some of which may not be

under our control. Even with an increased market price per share, the total market capitalization of our shares is lower than the total market capitalization before the reverse stock split and it could continue to decline.

Future sales of our common stock could cause our stock price to decline, and future issuances of common stock could cause substantial dilution.

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 March 9, 2022, 13,250,296 shares of our common stock were issued and outstanding; options to acquire 1,189,705 shares of our common stock were outstanding, exercisable at an average exercise price of $92.13 per share, issued under our 2006 Employee Incentive Plan, our 2015 Omnibus Incentive Compensation Plan, and our 2016 Inducement Plan; and restricted stock units issued under our 2015 Omnibus Incentive Compensation Plan entitling the holders to an aggregate of 112,264 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 convertible senior secured notes due 2024 in shares of our common stock, our stockholders could experience significant dilution. Lastly, in January 2021, we entered into an At The Market (ATM) Offering Agreement with H.C. Wainwright & Co., LLC as sales agent. Pursuant to the ATM agreement, we may offer and sell shares of our common stock having an aggregate value of up to $15.25 million in an at-the-market offering, which could cause additional dilution.

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.

- Our Bylaws contain an exclusive forum clause providing that (i) the Court of Chancery of the State of Delaware will be the exclusive forum for actions or proceedings for (a) any derivative action or proceeding brought on our behalf; (b) any action asserting a breach of a fiduciary duty; (c) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or the our Certificate of Incorporation or Bylaws; (d) any action or proceeding to interpret, apply, enforce or determine the validity of our Certificate of

Incorporation or Bylaws, including any right, obligation or remedy thereunder; or (e) any action asserting a claim governed by the internal affairs doctrine, and (ii) the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933.

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.

General Risk Factors

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, 2021, we had approximately $234.0 million of U.S. Federal 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 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 $121.6 million existed at December 31, 2021 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. The remaining U.S. Federal NOL carryforward as of December 31, 2021 of approximately $112.4 million is for the Acorda Therapeutics, Inc. return filing group, which is carried forward indefinitely and subject to the 80% limitation on taxable income when utilized in future tax years.

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 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. Our ability to enter into these types of transactions as part of our business strategy may be constrained based on our limited cash resources and/or limited access to other sources of capital needed to fund such transactions. Also, our ability to enter into such transactions is limited in part because of restrictive covenants contained in the indenture governing our convertible senior secured notes due 2024 which constrain the type and terms of such agreements. Acquisitions and in-licenses involve numerous risks, including:

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

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed products or product candidates, for example by underestimating the investment required to advance research and development programs, or overestimating likelihood of approval by the FDA or similar foreign regulators 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, Ampyra or any other approved products we or our collaborator or distributor 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 clinical trials. The total insurance limit is $30 million per claim, and the aggregate amount of claims under the policy is also capped at $30 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.

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 and substantially 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 business partners and vendors from whom we purchase software and/or technology-based services.

The size and complexity of our and 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, unauthorized disclosure, 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 criminal or other malicious intent. As with most other companies, our information technology systems have been, and will likely continue to be, subject from time to time to computer viruses, malicious codes, unauthorized access, and other forms or cyber-attack, and we expect the sophistication and frequency of such efforts to continue to increase. To date, we are not aware of any significant impact to our business or operations resulting from these occurrences affecting our or third-party information technology systems that we utilize; however, there is a growing risk of harm from these types of incidents, which could disrupt our operations, result in a loss of assets, and otherwise have a material adverse effect on our business, financial condition, or results of operations.

We are increasingly relying on the networks and systems of third-party vendors as we seek to migrate the storage and processing of business and other information from our own computer servers and networks to “cloud”-based storage and software systems and services maintained by third-party vendors. While we believe there are potential cost savings and other benefits from this migration strategy, we do not control how third-party vendors maintain their networks and systems, what technology they implement to protect their systems from cyber-attack or other malicious behavior, or what corrective or

remedial measures they would take in response to service issues or a criminal or other malicious attack. Also, many of these vendors are large, well-known technology companies that maintain substantial volumes of information for a large number of companies, and whose systems may therefore be larger targets for criminal or other malicious actors as compared to our own networks and systems. Accordingly, our migration to third-party networks and system could increase the risk that business and other information maintained by us could be subject to a breach, theft, unauthorized disclosure, or other forms of cyber-attacks even if we are not specifically targeted.

Unauthorized access to, or disclosure or theft of, our business information and/or other information we maintain could compromise our intellectual property, expose sensitive business information, and expose 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. Also, unauthorized access to, or disclosure of theft of, our business information and/or other information we maintain could cause us to incur significant remediation costs, result in product development delays, disrupt or force suspension of key business operations and divert attention of management and key information technology resources. These events 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.

Breaches of information technology systems and technology 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 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Ardsley, New York

In June 2011, we entered into a 15-year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. 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. Our base rent is currently $5.0 per year. In September 2021, we sent the landlord notice of exercise of the Company's early termination option (the "Early Termination Option") under the lease. Pursuant to the Early Termination Option, the lease will terminate on June 22, 2022 (the "Early Termination Date"), subject to the conditions that (a) on the last business day before the Early Termination Date, we pay an early termination fee of approximately $4.7 million, (b) on the day immediately prior to the Early Termination Date, we are not in "Default" under the Lease beyond applicable cure periods, and (c) as of the Early Termination Date, we have complied with our end-of-term obligations. We are currently evaluating facility alternatives for our corporate operations after our departure from our Ardsley headquarters.

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.

From time to time, we may be involved in litigation or other legal proceedings relating to claims arising out of operations in the normal course of our business, including the matters described below. The outcome of litigation and other legal proceedings is unpredictable, and regardless of outcome, they can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

On November 9, 2020, Drug Royalty III, L.P., and LSRC III S.ar.l. (collectively, "DRI") filed an arbitration claim against us with the American Arbitration Association under a September 26, 2003 License Agreement that we originally entered into with Rush-Presbyterian St. Luke's Medical Center ("Rush"). DRI previously purchased license royalty rights under the license agreement from Rush. DRI alleges a dispute over the last-to-expire patent covering sales of the drug Ampyra under the license agreement, and is claiming damages based on unpaid license royalties of $6 million plus interest. We believe we have valid defenses against this claim and intend to defend ourselves vigorously.

On August 20, 2020, ratiopharm Gmbh filed nullity actions against us in the German Federal Patent Court seeking to invalidate both of our German patents that derived from our European patents, EP 1732548 (the '548 patent) and EP 2377536 (the '536 patent), with claims directed to the use of a sustained dalmfapridine composition to increase walking speed in a patient with multiple sclerosis. In November 2021, the German Federal Patent Court issued preliminary opinions indicating that the claimed subject matter of the '548 patent lacked inventive step and the claimed subject matter of the '536 patent lacked novelty and inventive step. At an oral hearing in February 2022, the German court dismissed ratiopharm's action against the '536 patent as inadmissible because of ongoing formality proceedings relating to the '536 patent in the European Patent Office. Ratiopharm could appeal this decision or refile the nullity action when the formalities are completed at the European Patent Office. An oral hearing is currently scheduled for April 26, 2022, for the '548 patent. On January 11, 2022, STADA Arzneimittel also filed a nullity action against the '536 patent in the same court. We are working with Biogen to vigorously defend these actions and enforce our patent rights.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock is quoted on the Nasdaq Global Select Market under the symbol "ACOR."

On December 31, 2020, we filed an amendment to our Certificate of Incorporation which effected a 1-for-6 reverse stock split of the shares of our outstanding common stock and proportionate reduction in the number of authorized shares of our common stock from 370,000,000 to 61,666,666. Our common stock began trading on a split-adjusted basis on The Nasdaq Global Select Market commencing upon market open on January 4, 2021. The common stock continued to trade under the symbol "ACOR" after the reverse stock split became effective. The reverse stock split applied equally to all outstanding shares of the common stock and did not modify the rights or preferences of the common stock. As such, all figures in this report relating to shares of our common stock (such as share amounts, per share amounts, and conversion rates and prices), including in the financial statements and accompanying notes to the financial statements, have been retroactively restated to reflect the 1-for-6 reverse stock split of our common stock.

Computershare is the transfer agent and registrar for our common stock. As of March 9, 2022, we had 14 holders of record of our common stock.

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.

Unregistered Sales of Securities

In June and December 2021, we issued 1,635,833 and 2,049,048 shares of our common stock, respectively, to the holders of our 6.00% Convertible Senior Secured Notes due 2024 in satisfaction of approximately $6.2 million in interest due under the notes on each of June 1 and December 1, 2021. Pursuant to the 2024 notes indenture, we may elect to pay interest in cash or shares of our common stock based on the formula set forth in the indenture, subject to conditions specified therein. In connection with the issuances of the shares in June and December 2021, an amount corresponding to each $6.2 million interest payment was released from escrow and became available to the Company for other purposes. The issuances of the shares were exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933.

Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fourth quarter of 2021. Acorda has not announced any plans or programs for the repurchase of its Common Stock.

Item 6. Selected Financial Data.

Not applicable.

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 Products

Inbrija/Parkinson's Disease

Inbrija 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. 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. U.S. Food and Drug Administration (FDA) approval of Inbrija is for a single dose of 84 mg (administered as two capsules), which may be taken up to five times per day. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 96% of commercially insured lives and approximately 27% of Medicare plan lives. U.S. net revenue for Inbrija was $29.6 million for the year ended December 31, 2021.

Inbrija is also approved for use in the European Union (EU). The European Commission (EC)-approved Inbrija dose is 66 mg (administered as two capsules) up to five times per day (per EU convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the EU approval, Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. In July and November 2021, we announced that we entered into distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany, respectively. Under the terms of the Germany distribution agreement, we received a €5 million (approximately $5.9) upfront payment, and we are entitled to receive additional sales-based milestones. Under the terms of both the Spain and Germany supply agreements, we are entitled to receive a significant double-digit percent of the selling price of Inbrija in exchange for supply of the product. Esteve expects to launch Inbrija in Germany in mid-2022 and in Spain in early 2023. We are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S.

Inbrija utilizes our ARCUS platform for inhaled therapeutics. Because of our limited financial resources, we previously suspended work on ARCUS and other proprietary research and development programs. However, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

Ampyra/MS

Ampyra is an extended-release tablet formulation of dalfampridine approved by the FDA as a treatment to improve walking in patients with multiple sclerosis, or MS. Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time. U.S. net revenue for Ampyra was $84.6 million for the year ended December 31, 2021. 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. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen, and these challenges could lead to generic competition with Fampyra. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Sale of Chelsea Manufacturing Operations and Catalent MSA

In February 2021, we completed the sale of our Chelsea, Massachusetts manufacturing operations to Catalent Pharma Solutions. Pursuant to the transaction, Catalent paid us $80 million in cash, resulting in net proceeds to us of approximately $74 million after transaction fees and expenses and settlement of customary post-closing adjustments. In connection with the

sale of the manufacturing operations, we entered into a long-term, global manufacturing services agreement with a Catalent affiliate for the supply of Inbrija. The Catalent manufacturing services agreement provides that Catalent will manufacture Inbrija, to our specifications, and we will purchase Inbrija exclusively from Catalent during the term of the manufacturing services agreement; provided that such exclusivity requirement will not apply to Inbrija intended for sale in China.

Under the manufacturing services agreement, we agreed to purchase from Catalent at least $16 million of Inbrija in 2021 (pro-rated for a partial year) and $18 million of Inbrija each year from 2022 through 2030, subject to reduction in certain cases. In December 2021, we and Catalent amended the manufacturing services agreement to adjust the structure of the minimum payment terms for the period from July 1, 2021 through June 30, 2022 (the "Adjustment Period"). Under the amendment, the minimum payment obligation for the Adjustment Period is replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to our original minimum purchase obligation for that period (i.e., $17 million), and with certain payments being made in the first half of 2022 instead of during the second half of 2021. As a result of the amendment, our cash balance at the end of 2021 reflected approximately $5.3 million associated with this modified payment schedule. We have submitted a binding forecast for Inbrija batches for the Adjustment Period, the total cost of which may equal, but not exceed, the original payment obligation under the manufacturing services agreement.

Additionally, pursuant to the amendment, we agreed that we would reimburse a portion of Catalent's costs in completing the installation and qualification of a larger size 7 spray dryer at the Chelsea manufacturing facility, which we believe will be beneficial to our future production needs, in the amount of $1.5 million. This amount will be paid quarterly over a one-year period commencing no sooner than January 1, 2024.

Convertible Notes

In December 2019, we completed 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. As a result of the exchange, approximately $69 million of convertible senior notes due in 2021 remained outstanding, but we repaid these notes at maturity on June 15, 2021 using cash on hand. More information about the terms and conditions of the 2024 convertible notes is set forth in Note 9 to our Consolidated Financial Statements included in this report as well as in *Financing Arrangements* in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this report.

Financial Management

In January 2021 and September 2021, we announced corporate restructurings to reduce costs, more closely align operating expenses with expected revenue, and focus our resources on Inbrija. The headcount reductions and other budget cuts we implemented, including those resulting from the sale of the Chelsea manufacturing operations described above, are expected to result in a $60 million annualized reduction in operating expenses in 2022 as compared to 2020.

In January 2021, we entered into an At The Market (ATM) Offering Agreement with H.C. Wainwright & Co., LLC as sales agent. Pursuant to the ATM agreement, we may offer and sell shares of our common stock having an aggregate value of up to $15.25 million in an at-the-market offering, subject to a 3% sales commission payable to H.C. Wainwright.

In September 2021, we sent to BMR-Ardsley Park LLC ("BMR") notice of exercise of our early termination option (the "Early Termination Option") under our lease dated as of June 23, 2011, between us and BMR (as amended, the "lease"). The lease is for the Company's Ardsley, N.Y. corporate headquarters, which we believe is substantially larger than our needs for the foreseeable future. Pursuant to the Early Termination Option, the lease will terminate on June 22, 2022 and we will pay an early termination fee of approximately $4.7 million.

As of December 31, 2021, we had cash, cash equivalents, and restricted cash of approximately $65.2 million. Restricted cash includes $18.6 million in escrow related to the 6% semi-annual interest portion of the convertible senior secured notes due 2024, which interest is payable in cash or stock. As further described in Note 9 to our Consolidated Financial Statements included in this report as well as in *Financing Arrangements* in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this report, if we elect to pay interest due in stock, a corresponding amount of restricted cash equivalent will be released from escrow. In June and December 2021, we issued 1,635,833 and 2,049,048 shares of our common stock, respectively, to the holders of the 2024 notes in satisfaction of approximately $6.2 million in interest due under the notes on each of June 1 and December 1, 2021, and a corresponding

amount of cash (approximately $12.4 million in the aggregate) was thereafter released from the escrow in June and December, 2021.

Reverse Stock Split

On December 31, 2020, we filed an amendment to our Certificate of Incorporation which effected a 1-for-6 reverse stock split of the shares of our outstanding common stock and proportionate reduction in the number of authorized shares of our common stock from 370,000,000 to 61,666,666. Our common stock began trading on a split-adjusted basis on The Nasdaq Global Select Market commencing upon market open on January 4, 2021. The common stock continued to trade under the symbol "ACOR" after the reverse stock split became effective. The reverse stock split applied equally to all outstanding shares of the common stock and did not modify the rights or preferences of the common stock. The reverse stock split also resulted in a corresponding adjustment to outstanding equity awards as well as shares reserved for future issuance under our incentive compensation plans. All figures in this report relating to shares of our common stock (such as share amounts, per share amounts, and conversion rates and prices), including in the financial statements and accompanying notes to the financial statements, have been retroactively restated to reflect the 1-for-6 reverse stock split of our common stock.

COVID-19 Pandemic

Our business and financial condition have been impacted by, and are subject to risks resulting from, the COVID-19 global pandemic. The COVID-19 global pandemic has caused significant disruptions in the healthcare industry. The duration of the pandemic is difficult to predict, and it is likely to have ongoing impacts as it continues. The travel restrictions, "shelter in place" orders, quarantine policies, vaccine mandates, and general concerns about the spread and effects of COVID-19 have disrupted the delivery of healthcare to patients; for example, the pandemic has made it more difficult for some patients to visit with their physician and obtain pharmaceutical prescriptions. Also, healthcare office staffing shortages may delay the administrative work, and particularly insurance-related documentation, needed to obtain reimbursement for prescriptions. We also believe that the governmental and other restrictions and requirements related to the pandemic may have caused certain patients to lessen their mobility and therefore their need for certain therapeutics. We believe these factors contributed to volatility in new Inbrija prescriptions since the start of the pandemic in 2020 and are continuing to impact prescriptions in 2022.

COVID-related policies, restrictions, and concerns may disrupt our operations and those of our customers and suppliers. Also, our operations could be interrupted if we or our customers or suppliers lose the services of key employees or consultants who become ill from COVID-19. These types of disruptions could potentially affect any of our critical business functions, and thus harm our business, including for example our sales and marketing operations, as well as compliance and certain general and administrative functions. The ultimate impact of the COVID-19 global pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems, or the global economy as a whole. As the pandemic continues, it may cause continuing economic volatility or result in a sustained economic downturn that could affect demand for our products and our ability to access capital on reasonable terms, or at all. These factors could have a material adverse effect on our business, operating results and financial condition.

Inbrija and ARCUS

Inbrija 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 96% of commercially insured lives and approximately 25% of Medicare plan lives. U.S. net revenue for Inbrija was $29.6 million for the year ended December 31, 2021. Due to uncertainties caused by past and potential future impacts of the COVID-19 global pandemic and other factors, we are unable to provide projected peak U.S. annual net revenue of Inbrija. Actual peak U.S. Inbrija net revenue will likely be lower and could be materially lower than our prior projected peak sales range if, for example, disruptions to the healthcare system caused by the COVID-19 global pandemic or other prescribing challenges continue in 2022 and beyond.

In September 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 27 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the exit of the UK from the EU, we were granted a grandfathered Marketing Authorization (MA) by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK that was approved in November 2021.

In July and November 2021, we announced that we entered into distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany, respectively. Under the terms of the Germany distribution agreement, we received a €5 million (approximately $5.9) upfront payment, and we are entitled to receive additional sales-based milestones. Under the terms of both the Spain and Germany supply agreements, we are entitled to receive a significant double-digit percent of the selling price of Inbrija in exchange for supply of the product. Esteve has the exclusive distribution rights to Inbrija in Spain and Germany and we will supply the product to Esteve for sale. Esteve expects to launch Inbrija in Germany in mid-2022 and Spain in early 2023. We are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S.

We market Inbrija in the U.S. using field-based teams supported by our corporate marketing personnel. Our own neuro-specialty sales representatives work in combination with sales representatives provided by a contract commercial organization, and collectively they are currently focused on a priority list of physicians who are high volume prescribers of carbidopa/levodopa and other products indicated to treat OFF episodes. Our field-based teams also include reimbursement and market access specialists, who provide information to physicians and payers on our marketed products, as well as market development specialists who work collaboratively with field-sales teams and corporate personnel to assist in the execution of our strategic initiatives. Our Inbrija field-based and marketing activities are focused on physician awareness and market access as well as patient awareness, education and training. Inbrija is distributed in the U.S. primarily through: Alliancerx Walgreens Prime, or Walgreens, a specialty pharmacy that delivers the medication to patients by mail; and ASD Specialty healthcare, Inc. (an AmeriSource Bergen affiliate). We recently initiated a pilot program to evaluate distribution of Inbrija through a specialty pharmacy that supports electronic prescriptions, and we intend to expand this into a national program in 2022. We believe the convenience of electronic prescribing may be preferred by some physicians and patients.

We have established Prescription Support Services for Inbrija, sometimes referred to as the Inbrija hub, which helps patients navigate their insurance coverage and identify potential financial support alternatives, when appropriate. The Inbrija hub also includes a virtual nurse educator program to assist patients with proper usage of the Inbrija inhaler. Insurance coverage services fall into one of these categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; and appeals support. 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 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 a first dispense zero-dollar copay program for commercially insured patients (which replaced our previous free trial program) to enable those patients to assess the value of Inbrija before incurring out-of-pocket co-pay or co-insurance costs.

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. The standard baseline treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects. As Parkinson's progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson's symptoms that result from low levels of dopamine between doses 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 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. We have patents in Europe for Inbrija expiring between 2022 and 2033. One of our European patents, EP 3090773B, had been opposed by an unnamed party but in 2021 was maintained as granted by the European Opposition Board. Inbrija also has ten years of market exclusivity in Europe that is set to expire in September 2029.

We believe there are potential opportunities for using ARCUS with central nervous system, or CNS, as well as non-CNS, disorders. Due to several corporate restructurings since 2017 and associated cost-cutting measures, including the corporate restructurings we announced in January and September 2021, we suspended work on ARCUS and other proprietary research and development programs. However, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have already been performing feasibility studies for a number of these opportunities.

Should we decide to proceed with any ARCUS development programs, we would be reliant on Catalent or another third-party supplier for the manufacture of product for that program. Our global supply agreement with Catalent does not provide for the terms and conditions under which Catalent would supply any product or product candidate other than Inbrija. We would be unable to advance the development of any ARCUS inhaled therapeutic candidate unless Catalent is willing to manufacture the candidate for us on commercially reasonable terms, or we could identify another third-party manufacturer that would be capable and willing to manufacture the candidate for us on commercially reasonable terms. Also, due to reductions in force, employee attrition and the 2021 sale of our Chelsea manufacturing operations, we may need to hire replacement personnel or engage consultants to continue with ARCUS research and development work beyond feasibility and similar early-stage studies.

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). Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents. We have experienced a significant decline in Ampyra sales due to competition from several generic versions of Ampyra. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time. U.S. net revenue for Ampyra was $84.6 million for the year ended December 31, 2021.

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. In May 2021, Biogen announced that Fampyra was approved by the National Medical Products Administration in China, and Biogen is evaluating commercial launch options in that country. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen, and these challenges could lead to generic competition with Fampyra.

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, although we do not anticipate achievement of any of those milestones in the foreseeable future. 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, which we believe may occur in mid-2022, we will not receive Fampyra royalties although we retained the right to receive any potential future milestone payments. The HCRP transaction is accounted for as a liability, as described in Note 10 to our Consolidated Financial Statements included in this report.

Ampyra Patent Update

There are no patents listed in the Orange Book for Ampyra. Ampyra became subject to competition from generic versions of Ampyra starting in late 2018 as a result of an adverse U.S. federal district court ruling that invalidated certain Ampyra Orange Book-listed patents.

There are two European patents, EP 1732548 and EP 2377536, with claims directed to use of a sustained release dalfampridine composition (known under the trade name Fampyra in the European Union) to increase walking speed in a patient with multiple sclerosis. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra had ten years of market exclusivity in the European Union that expired in 2021. Accordingly, even though the European patents were upheld by the Technical Board of Appeal of the European Patent Office, Fampyra could potentially face competition from generic drug manufacturers that may seek to challenge Fampyra's European patents within individual European countries.

Nullity actions with respect to Fampyra have been filed in Germany against both of the German national patents derived from EP 1732548 (the '548 patent) and EP 2377536 (the '536 patent) by ratiopharm GmbH, a generic manufacturer affiliated with Teva. In November 2021, a German court issued preliminary opinions in the ratiopharm case indicating that the claimed subject matter of the '548 patent lacked inventive step and the claimed subject matter of the '536 patent lacked novelty and inventive step. At an oral hearing in February 2022, the German patent court dismissed ratiopharm's action against the '536 patent as inadmissible because of ongoing formality proceedings relating to the '536 patent in the European Patent Office. Ratiopharm could appeal this decision or refile the nullity action when the formalities are completed at the European Patent Office. An oral hearing is currently scheduled for April 26, 2022, for the '548 patent. On January 11, 2022, STADA Arzneimittel also filed a nullity action against the '536 patent in the same court. We are working with Biogen to vigorously defend these actions and enforce our patent rights. Refer to *Legal Proceedings* in Part I, Item 3 of this report for more information.

Results of Operations

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Net Revenues

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 revenues from the sale of Inbrija of $29.6 million and $24.2 million for the years ended December 31, 2021 and 2020, respectively. The increase in Inbrija net revenues was due to an increase in net volume of $3.3 million and price increase and discount and allowance adjustments of $2.1 million.

Discounts and allowances which are included as an offset in net revenues 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 new managed care contracts in the future.

We believe that first and fourth quarter revenues for our products is subject to certain recurring seasonal factors relating to the commencement of a new calendar year. For example, some patients refill their prescriptions earlier ahead of the new year, in the fourth quarter, in anticipation of the year-end reset of health plan deductibles and the Medicare donut hole, or a year-end switch of their insurance plans or pharmacy benefit providers. Also, we believe that AllianceRx Walgreens Prime (Walgreens), our primary specialty pharmacy used for Inbrija distribution, may increase their Inbrija

inventory, within contractual limits, in anticipation of the holidays and new year. We believe these factors have had a positive impact on fourth quarter revenues and a negative impact on first quarter revenues in the past two years. Also, discounts and allowances typically are highest in the first quarter, and lowest in the fourth quarter, and when this occurs fourth quarter revenues increase, and first quarter revenues decrease, on a relative basis. Also, in the fourth quarter of 2020, we believe our transition from a network of several specialty pharmacies to Walgreens as the sole specialty pharmacy (at that time) for U.S. sales of Inbrija was another factor that positively impacted Inbrija revenues on a one-time basis, as Walgreens initiated stocking for newly-transferred patients during the quarter.

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 revenues from the sale of Ampyra to these customers of $84.6 million and $98.9 million for the years ended December 31, 2021 and 2020, respectively. These amounts are inclusive of Mylan AG revenue of $0.4 million and $0.8 million for the years ended December 31, 2021 and 2020, respectively. The decrease in Ampyra net revenues was composed of a decrease in net volume of $21.8 million partially offset by price increase and discount and allowance adjustments of $7.8 million. Net revenues from sales of Ampyra decreased for the year ended December 31, 2021 compared to the year ended December 31, 2020 due to the entry of generic versions of Ampyra as a result of the invalidation of our Ampyra patents in 2017, and we expect our Ampyra sales to continue to decline over time.

Discounts and allowances which are included as an offset in net revenues 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. Discounts and allowances may increase as a percentage of sales as we enter into new managed care contracts in the future.

We believe that first and fourth quarter revenues for our products is subject to certain recurring seasonal factors relating to the commencement of a new calendar year. For example, some patients refill their prescriptions earlier ahead of the new year, in the fourth quarter, in anticipation of the year-end reset of health plan deductibles and the Medicare donut hole, or a year-end switch of their insurance plans or pharmacy benefit providers. Also, we believe specialty pharmacies may increase their inventory in anticipation of the holidays and new year. These factors have had a positive impact on fourth quarter revenues and a negative impact on first quarter revenues. Also, discounts and allowances typically are highest in the first quarter, and lowest in the fourth quarter, and when this occurs fourth quarter revenues increase, and first quarter revenues decrease, on a relative basis.

Other Product Revenues

We recognized $0 in revenues from the sale of other products for the year ended December 31, 2021 as compared to $1.7 million for the year ended December 31, 2020.

Milestone Revenues

We recognized $0 and $15 million in milestone revenues for the year ended December 31, 2021 and 2020, respectively. The decrease is due to the $15 million milestone payment from Biogen earned in 2020 based on ex-U.S. Fampyra net sales exceeding $100 million over a period of four consecutive quarters ending with the third quarter of 2020. In the year ended December 31, 2021, Biogen has not exceeded net sales of $250 million over a period of four consecutive quarters to achieve the next milestone payment of $15 million.

Royalty Revenues

We recognized $14.9 million in royalty revenues for the year ended December 31, 2021 as compared to $13.1 million for the year ended December 31, 2020, related to ex-U.S. sales of Fampyra by Biogen.

Cost of Sales

We recorded cost of sales of $40.8 million for the year ended December 31, 2021 as compared to $33.5 million for the year ended December 31, 2020. This increase of $7.3 million was primarily due to $6.2 million in minimum purchase commitments with Catalent in the current period, and a reversal in the year ended December 31, 2020 of inventory obsolescence provision, partially offset by lower cost of sales due to overall lower volume in the current period.

Cost of sales for the year ended December 31, 2021 consisted primarily of $32.5 million in inventory costs related to recognized revenues, $6.2 million in minimum purchase commitments with Catalent, $1.1 million in royalty fees based on net product shipments, idle capacity costs of $0.1 million, and $0.9 million in period costs related to freight, stability testing, packaging and other. 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, 2020 consisted primarily of $14.7 million in inventory costs related to recognized revenues net of a reversal of inventory obsolescence provision, $4.1 million in royalty fees based on net product shipments, idle capacity costs of $6.3 million, $8.2 million in period costs related to expired inventory, freight, stability testing, and packaging and $0.2 million for costs related to sales of the authorized generic version of Ampyra. 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.

Amortization of Intangibles

We commenced amortization of the intangible asset upon launch in February 2019 and recorded amortization of $30.8 million for the years ended December 31, 2021 and 2020.

Research and Development

Research and development expenses for the year ended December 31, 2021 were $10.4 million as compared to $23.0 million for the year ended December 31, 2020, a decrease of $12.6 million, or 55%. The decrease was primarily due to reductions in spending of $6.0 million due to the commercialization of Inbrija, reductions of $6.6 million due to restructuring and a decrease in several programs to shift focus on the Inbrija launch.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2021 were $57.2 million compared to $81.2 million for the year ended December 31, 2020, a decrease of approximately $24.0 million, or 30%. The decrease was attributable primarily to a decrease in marketing related spending of $13.3 million due to launch activities for Inbrija, a decrease in overall salaries and benefits of $11.5 million and a decrease in spending related to marketing for Ampyra of $1.6 million, partially offset by a reclassification of departmental costs from general and administrative expenses of $2.4 million due to a change in the overhead expense allocation method.

General and administrative expenses for the year ended December 31, 2021 were $67.2 million compared to $71.3 million for the year ended December 31, 2020, a decrease of approximately $4.1 million, or 6%. This decrease was primarily due to a decrease in overall salaries and benefit costs of $9.0 million and a decrease in Civitas spending of $8.1 million due to the sale of the Chelsea facility manufacturing operations, partially offset by an increase in professional fees of $5.8 million, an increase in restructuring costs of $5.4 million, and an increase of $1.9 million in other departmental spending.

Intangible Asset Impairments

We recognized an intangible asset impairment charge of $4.1 million for the year ended December 31, 2020. During the first quarter of 2020, the Company determined that there were relevant changes to the key assumptions that would negatively affect the value of the IPR&D asset for BTT-1023. Management determined that the results of the clinical trial did not meet the primary or secondary end-points, and the clinical trial was not large enough or expansive enough to be persuasive to generate interest by third parties for a possible licensing arrangement. Management determined that this assessment was the triggering event that indicated that the asset was fully impaired as there was no potential value with an out-licensing arrangement. Based on the qualitative assessment, management determined that the carrying value of the asset

exceeded its estimated fair value and therefore, the asset was fully impaired. Management determined that additional quantitative procedures were not relevant in this circumstance given the overwhelming qualitative evidence that indicated the asset was fully impaired.

Loss on Assets Held for Sale

As a result of the sale of the Chelsea manufacturing operations to Catalent, the Company determined that the criteria to classify the Chelsea manufacturing operations as assets held for sale within the Company's consolidated balance sheet effective December 31, 2020 were met. Accordingly, the assets were classified as current assets held for sale at December 31, 2020 as the Company, at that time, expected to divest the Chelsea manufacturing operations within the next twelve months. The Company entered into a definitive agreement to sell the Chelsea manufacturing operations on January 12, 2021 and closed the transaction on February 10, 2021. The classification to assets held for sale impacted the net book value of the assets expected to be transferred upon sale. The estimated fair value of the Chelsea manufacturing operations was determined using the purchase price in the purchase agreement along with estimated broker, accounting, legal, and other selling expenses, which resulted in a fair value less costs to sell of approximately $71.8 million. The carrying value of the assets being classified as held for sale was approximately $129.7 million, which includes property and equipment of $129.6 million and prepaid expenses of $0.1 million. As a result, the Company recorded a loss on assets held for sale of $57.9 million against the Chelsea manufacturing operations for the year ended December 31, 2020.

Change in Fair Value of Derivative Liability

A derivative liability was recorded in December 2019 as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024. The derivative liability is measured at fair value on a quarterly basis and changes in the fair value are recorded in the consolidated statement of operations. We recorded income of $1.2 million due to the change in the fair value of the derivative liability for the year ended December 31, 2021. The changes in the fair value of the derivative liability were primarily due to changes in the Company's stock price over the period.

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 Inbrija. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded expense relating to changes in the fair value of our acquired contingent consideration of $2.9 million for the year ended December 31, 2021 compared to income of $30.9 million for the year ended December 31, 2020, a change of $33.8 million. The changes in the fair-value of the acquired contingent consideration were primarily due to the change in projected revenue and the recalculation of cash flows for the passage of time, as well as a decrease in the discount rate.

Other Income (Expense), Net

Other expense, net was $30.0 million for the year ended December 31, 2021 compared to other expense, net of $29.6 million for the year ended December 31, 2020, an increase in expense of $0.4 million, or 2%. The increase was due primarily to a decrease in interest income of approximately $0.8 million, and a decrease in other income $0.2 million, partially offset by a decrease in interest and amortization of debt discount expense of approximately $0.6 million.

Benefit from Income Taxes

We recorded a $5.1 million benefit from income taxes for the year ended December 31, 2021 as compared to a $8.1 million benefit from income taxes for the year ended December 31, 2020. The effective income tax rates for the year ended December 31, 2021 and 2020 were 4.7% and 7.5%, respectively.

The variances in the effective tax rates for the year ended December 31, 2021 and 2020 were due primarily to the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, and the benefit recorded on the net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

The Company's overall effective tax rate in 2021 differed from the U.S. federal statutory rate of 21% primarily due to the forfeitures of equity of which no tax deduction is recorded and the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized.

The Company continues to evaluate the realizability of its 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.

The Company was notified during the first quarter of 2021 that it is being audited by the state of Minnesota and Massachusetts for the tax years 2018 and 2019. There have been no proposed adjustments at this stage of the examination.

The Company also has an ongoing state examination in New Jersey which for the tax periods, 2015 through 2018. There have been no proposed adjustments at this stage of the examination. The Minnesota examinations for 2016 and 2017 were closed during 2021 with no changes.

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. Also, in February 2021, we obtained additional capital from the sale of our Chelsea manufacturing operations.

At December 31, 2021, we had $45.6 million of cash and cash equivalents, compared to $71.4 million at December 31, 2020. Our December 31, 2021 cash and cash equivalents balance includes approximately $5.3 million associated with a December 2021 amendment to our Catalent manufacturing services agreement that modified our payment schedule. Our December 31, 2021 cash and cash equivalents balance does not include $18.6 million of restricted cash that is currently held in escrow under the terms of our 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. We incurred net losses of $104.0 million and $99.6 million for the years ended December 31, 2021 and 2020, respectively.

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 convertible senior secured notes due 2024 restrict or direct our use of proceeds from such transactions;
- to the extent which we make required interest payments relating to our 2024 Notes, as defined below under *Financing Arrangements*, using shares of our common stock rather than cash;
- 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, to in-license new products, programs or compounds, or for research and development relating to existing or future acquired or in-licensed programs or compounds.

Our ability to meet our future operating requirements, repay our liabilities, and meet our other obligations are dependent upon a number of factors, including our ability to generate cash from product sales, reduce planned expenditures, and obtain additional financing. 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 2024 Notes, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional equity capital on terms that may

be onerous and which are likely to be highly dilutive. Also, our ability to raise additional capital and repay or restructure our indebtedness will depend on the capital markets and our financial condition at such time, among other factors. In addition, financing may not be available when needed, on terms acceptable to us or in compliance with the restrictions described above.

Financing Arrangements

Convertible Senior Secured Notes Due 2024

On December 24, 2019, we 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 "2024 Notes") and cash. For each $1,000 principal amount of exchanged 2021 Notes, we issued $750 principal amount of the 2024 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 2024 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. The 2021 Notes received by us in the Exchange were cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, $69.0 million of the 2021 Notes remained outstanding. On June 15, 2021, the Company repaid the outstanding balance of the 2021 Notes at their maturity date using cash on hand.

The 2024 Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among us, our 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 "2024 Indenture"). The 2024 Notes are senior obligations of us and the Guarantors, secured by a first priority security interest in substantially all of the assets of us 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 2024 Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms prior to such date. Interest on the 2024 Notes is 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. We may elect to pay interest in cash or shares of our common stock, subject to the satisfaction of certain conditions. If we elect 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. In June 2021, we issued 1,635,833 shares of our common stock, and in December 2021, we issued 2,049,048 shares of common stock, in satisfaction of the interest payable to holders of the 2024 Notes on June 1, 2021 and December 1, 2021, respectively. In connection with these stock-based interest payments, in each of June and December 2021, approximately $6.2 million (approximately $12.4 million in the aggregate) was released from restricted cash and became available to us for other purposes.

The 2024 Notes are convertible at the option of the holder into shares of our common stock at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date. The adjusted conversion rate for the 2024 Notes is 47.6190 shares of our common stock per $1,000 principal amount of 2024 Notes, representing an adjusted conversion price of approximately $21.00 per share of common stock. The conversion rate was adjusted to reflect the 1-for-6 reverse stock split effected on December 31, 2020 and is subject to additional adjustments in certain circumstances as described in the 2024 Indenture.

We may elect to settle conversions of the 2024 Notes in cash, shares of our common stock or a combination of cash and shares of our common stock. Holders who convert their 2024 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 2024 Notes on each interest payment date occurring after the conversion date for such conversion and on or before June 1, 2023. In addition, we will have the right to cause all 2024 Notes then outstanding to be converted automatically if the volume-weighted average price per share of our common stock equals or exceeds 130% of the adjusted conversion price for a specified period of time and certain other conditions are satisfied.

Holders of the 2024 Notes will have the right, at their option, to require us to purchase their 2024 Notes if a fundamental change (as defined in the 2024 Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date. If a make-whole fundamental change occurs, as described in the 2024 Indenture, and a holder

elects to convert its 2024 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the adjusted conversion rate as described in the 2024 Indenture.

Subject to a number of exceptions and qualifications, the 2024 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 2024 Indenture also requires us to make an offer to repurchase the 2024 Notes upon the occurrence of certain asset sales.

The 2024 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 2024 Notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the 2024 Notes in accordance with the 2024 Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the 2024 Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the 2024 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 other indebtedness of us 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 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 2024 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 2024 Notes may declare all the notes to be due and payable immediately.

We assessed all terms and features of the 2024 Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, we assessed the economic characteristics and risks of the 2024 Notes, including the conversion, put and call features. We concluded the conversion features required bifurcation as a derivative. The fair value of the conversion features derivative was determined based on the difference between the fair value of the 2024 Notes with the conversion options and the fair value of the 2024 Notes without the conversion options using a binomial model. We determined that the fair value of the derivative upon issuance of the 2024 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 2024 Notes on the closing date, or December 24, 2019. There are several embedded features within the 2024 Notes which, upon issuance, did not meet the conditions for equity classification. As a result, these features were aggregated together and recorded as the derivative liability conversion option. The conversion feature is measured at fair value on a quarterly basis and the changes in the fair value of the conversion feature for the period will be recognized in the consolidated statements of operations.

We received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company's common stock from 13,333,333 shares to 61,666,666 shares. As a result of the share approval, we determined that multiple embedded conversion options met the conditions for equity classification. We performed a valuation of these conversion options as of September 17, 2020, which was the date we completed certain securities registration obligations for the shares underlying the 2024 Notes. The resulting fair value of these conversion options was $18.3 million, which was reclassified to equity and presented in the statement of stockholder's equity as of September 30, 2020, net of the $4.4 million tax impact. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. We performed a valuation of the derivative liability related to certain embedded conversion features that are precluded from equity classification. The fair value of these conversion features was calculated to be negligible as of December 31, 2021.

The outstanding 2024 Note balances as of December 31, 2021 and December 31, 2020 consisted of the following:

(In thousands)	**December 31, 2021**	**December 31, 2020**
Liability component:		
Principal	$ 207,000	$ 207,000
Less: debt discount and debt issuance costs, net	(55,975)	(69,381)
Net carrying amount	151,025	137,619
Equity component	18,257	$ 18,257
Derivative liability-conversion Option	$ 37	$ 1,193

Convertible Senior Notes Due 2021

In June 2014, we issued $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the "2021 Notes"). On December 24, 2019, we completed the private exchange of $276.0 million aggregate principal amount of then-outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 and cash. Accordingly, upon completion of the exchange, $69.0 million of the 2021 Notes remained outstanding. On June 15, 2021, we repaid the outstanding balance of the 2021 Notes at their maturity date using cash on hand.

Non-Convertible Capital Loans

Our Biotie subsidiary received fourteen non-convertible capital loans granted by Business Finland (formerly Tekes) for research and development of specific drug candidates, with an aggregate adjusted acquisition-date fair value of $20.5 million (€18.2 million) and an aggregate carrying value of $27.6 million as of December 31, 2021. The loans bear interest based on the greater of 3% or the base rate set by Finland's Ministry of Finance minus one percentage point. The maturity dates for these loans range from eight to ten years from the date of issuance. However, the loans are to be repaid only when the consolidated retained earnings of Biotie from the development of the specific product candidates that are the subject of the loans is sufficient to fully repay the loans. As of December 31, 2021, Biotie had approximately $14.8 million in cash, which is not available for use in domestic operations without repatriation.

Research and Development Loans

In addition to the non-convertible capital loans described above, Research and Development Loans ("R&D Loans") were granted to Biotie by Business Finland with an acquisition-date fair value of $2.9 million (€2.6 million) and a carrying value of $0 as of December 31, 2021. These loans were repaid in equal annual installments from January 2017 through January 2021.

Fampyra Royalty Monetization

As of October 1, 2017, we completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP ("Royalty Agreement"). In exchange for the payment of $40 million to us, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the Collaboration and Licensing Agreement between us and Biogen, up to an agreed upon threshold of royalties. When this threshold is met, which we believe may occur in mid-2022, the Fampyra royalty revenue will revert back to us and we will continue to receive the Fampyra royalty revenue from Biogen until the revenue stream ends.

We 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. We 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, 2021 and 2020:

(In thousands)	December 31, 2021	December 31, 2020
Liability related to sale of future royalties - beginning balance	$ 15,257	$ 24,401
Deferred transaction costs amortized	234	401
Non-cash royalty revenue payable to HCRP	(12,106)	(11,486)
Non-cash interest expense recognized	1,075	1,941
Liability related to sale of future royalties - ending balance	$ 4,460	$ 15,257

Cash, Cash Equivalents and Investment Activities

At December 31, 2021, cash and cash equivalents were approximately $45.6 million, as compared to $71.4 million at December 31, 2020. Our December 31, 2021 cash and cash equivalents balance includes approximately $5.3 million associated with a December 2021 amendment to our Catalent manufacturing services agreement that modified our payment schedule. 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 investments in a Treasury money market fund. Our short-term investments consist of high-grade corporate debt securities, commercial paper and U.S. government securities 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. Our December 31, 2021 cash and cash equivalents balance does not include $18.6 million of restricted cash that is currently held in escrow under the terms of our convertible senior secured notes due 2024, further described above under *Financing Arrangements*, which may potentially be released from escrow if we pay interest on those notes using shares of our common stock.

Net Cash Used in Operations

Net cash used in operations was $41.3 million compared to $61.0 million for the years ended December 31, 2021 and 2020, respectively. Cash used in operations for the year ended December 31, 2021 was primarily attributable to the net loss of $104.0 million, a change in the derivative liability of $1.2 million, non-cash royalty revenues of $12.1 million, and a deferred tax benefit of $5.2 million.

Cash used in operations was partially offset by share-based compensation expense of $3.0 million, depreciation and amortization expense of $34.0 million, amortization of debt discount and debt issuance costs of $16.3 million, a decrease in accounts receivable of $3.2 million, an increase in accounts payable, accrued expenses and other current liabilities of $1.1 million, a change in the contingent consideration obligation of $2.9 million, a decrease in prepaid expenses and other current assets of $8.4 million, a decrease in inventory of $7.9 million, and an increase in other non-current liabilities of $4.4 million.

Net Cash Provided by Investing

Net cash provided by investing activities for the year ended December 31, 2021 was $73.8 million, which was due primarily to net proceeds from the sale of the Chelsea facility of $74.0 million, partially offset by purchases of property and equipment of $0.2 million and negligible purchases of intangible assets.

Net Cash Used in Financing

Net cash used in financing activities for the year ended December 31, 2021 was $69.7 million, which was due primarily to the repayment of Convertible Senior Notes due in June 2021 of $69.0 million and the repayment of loans payable of $0.7 million.

Contractual Obligations and Commitments

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Refer to Note 13 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 $18.5 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, 2021, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

Effects of Inflation

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

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.

We only apply the five-step model to contracts when it is probable that we 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, we determine the performance obligations that are distinct. We recognize 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, our 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. As of December 31, 2021, we had contract liabilities of $5.9 million, which is the upfront payment received as part of the Esteve Germany distribution agreement entered into in 2021. We did not have any contract liabilities as of December 31, 2020. We did not have any contract assets as of December 31, 2021 or 2020.

Product Revenues, Net

Net revenues from product sales is recognized at the transaction price when the customer obtains control of our products, which occurs at a point in time, upon receipt of the product by the customer. Our payment terms are between 30 to 35 days.

Our 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 our estimate of cash consideration expected to be given by us to a customer that is presumed to be a reduction of the transaction price of our products and, therefore, are characterized as a reduction of revenues. 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

Revenues 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 our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenues 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, we also estimates the number of patients in the prescription drug coverage gap for whom we 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. Our 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 $4.5 million and $5.9 million at December 31, 2021 and December 31, 2020, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate $1.4 million and $1.7 million effect on our net revenue for the years ended December 31, 2021 and December 31, 2020, 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. Our 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 $4.6 million and $7.4 million at December 31, 2021 and December 31, 2020, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate $2.1 million and $3.1 million effect on our net revenue for the years ended December 31, 2021 and December 31, 2020, 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 $0.5 million and $0.6 million at December 31, 2021 and December 31, 2020, respectively. A 10% change in our copay mitigation rebate allowances would have had an approximate $0.5 million effect on our net revenue for the years ended December 31, 2021 and December 31, 2020.

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 $0.8 million and $0.6 million at December 31, 2021 and December 31, 2020, respectively. A 10% change in our cash discount allowances would have had an approximate $0.2 million effect on our net revenue for the years ended December 31, 2021 and December 31, 2020.

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. Our 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. We currently estimate 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.

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 us. 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 $0.6 million and $1.4 million at December 31, 2021 and December 31, 2020, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate $0.3 million and $0.6 million effect on our net revenue for the years ended December 31, 2021 and 2020, respectively.

We have adjusted our allowances in the past based on actual experience, and we will likely be required to make adjustments to these allowances and accruals in the future. The historical adjustments have not been significant to operations. We continually monitor our allowances and accruals and 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 our sales discounts and allowances during 2021 and 2020:

(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, 2019	$ 5,554	$ 8,474	$ 301	$ 412	$ 606	$ 1,540	$ 1,327	$ 18,215
Allowances for sales	17,042	30,899	5,316	954	(153)	5,572	—	59,630
Actual credits for sales during 2020	(13,732)	(25,555)	(4,720)	(1,882)	—	(4,284)	—	(50,174)
Actual credits for prior year sales	(3,001)	(6,417)	(256)	1,091	(231)	(1,440)	(1,327)	(11,581)
Balance at December 31, 2020	$ 5,863	$ 7,401	$ 641	$ 575	$ 222	$ 1,388	$ —	$ 16,090
Allowances for sales	14,597	20,640	4,853	1,992	—	3,298	—	45,380
Actual credits for sales during 2021	(15,936)	(23,408)	(4,970)	(1,787)	(9)	(2,716)	—	(48,826)
Actual credits for prior year sales	(15)	—	—	—	(135)	(1,407)	—	(1,557)
Balance at December 31, 2021	$ 4,509	$ 4,633	$ 524	$ 780	$ 78	$ 563	$ —	$ 11,087

Royalty Revenues

Royalty revenues recorded by us relates exclusively to our License and Collaboration agreement with Biogen which provides for ongoing royalties based on sales of Fampyra outside of the U.S. We recognized revenues 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. We satisfied our performance obligations and therefore recognizes royalty revenue when the sales to which the royalties relate are completed.

License Revenues

License revenues 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. We recognize license revenues under ASC 606, which provides constraints for entities to recognize license revenues which is deemed to be variable by requiring us to estimate the amount of consideration to which it is entitled in exchange for transferring the promised goods or services to a customer. We recognize an estimate of revenues to the extent that it is probable that a significant reversal in the amount of cumulative revenues recognized will not occur when the milestone is achieved. For regulatory milestones, we evaluate 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 our 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, we recognize revenues upon the achievement of the specific sale milestones.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other rights and obligations, the Company determines whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company uses its judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Inventory

We capitalize inventory costs associated with our 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 us. 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. We record 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. We periodically review inventory for slow moving or obsolete amounts based on expected sales. We review projected market share as well as current buying patterns from its customers. We analyze our 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 our ability to sell inventory on hand and commitments based on the sales projections. If annual and expected volumes are less than expected, we may be required to make additional allowances for excess or obsolete inventory in the future.

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.

Research and Development

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 have administered 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 have used a CRO, we account for our clinical study costs according to the terms of the CRO contract. These costs include upfront, milestone and monthly expenses as well as reimbursement for pass through costs. All research and development costs are expensed as incurred except when we are accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. In these cases, these payments are capitalized at the time of payment and expensed ratable over the period the research and development activity is 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 have used 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,	
	2021	2020
Preclinical and clinical development:		
Contract expenses—Inbrija	$ 1,053	$ 1,339
Contract expenses—tozadenant	21	9
Contract expenses—rHIgM22	6	(46)
Contract expenses—SYN-120	—	3
Contract expenses—cimaglermin alfa (previously GGF2)	8	(33)
Contract expenses—ARCUS program for acute migraine	—	(213)
Contract expenses—Ampyra LCM	3	6
Contract expenses—Other	128	95
Research and development operating expenses:	9,201	21,778
Acquisitions, licenses and milestones:		
rHIgM22	—	55
Other	—	20
Total research and development	$ 10,420	$ 23,012

With respect to previously established clinical study accruals in prior periods and for the year ended December 31, 2021 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. We recorded an impairment charge of $4.1 million for the year ended December 31, 2020 in the statement of operations and therefore, the indefinite-lived intangible asset was fully impaired. See Note 4 to our Consolidated Financial Statements included in this report for a discussion of intangible assets.

Finite-Lived Intangible Assets

Intangible assets with finite lives are amortized on a straight line basis over the period in which we expect 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 our evaluation of the intangible assets, we consider 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, we perform 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, we 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.

Derivative Liability

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 9 to our Consolidated Financial Statements included in this report). We 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 binomial model that calculates 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 our 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.

To the extent that the discount rates were to increase or decrease by one percentage point, we estimate that our acquired contingent consideration liability would decrease or increase by approximately $2.6 million or $2.9 million, respectively. If the estimated net sales were to increase or decrease by one percentage point, we estimate that our acquired contingent consideration liability would change by approximately $0.5 million.

Other Income (Expense)

Interest income consists of income earned on our cash and cash equivalents. Interest expense consists of cash and non-cash interest expense for the 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:

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

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

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

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 the related report of our independent auditor are presented beginning on page F-1. Our independent auditor is Ernst & Young LLP (PCAOB ID: 42), located in Stamford, Connecticut, USA.

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 2021 fiscal year (the period covered by this report). This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on that evaluation, these officers have concluded that, as of December 31, 2021, 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 our Chief Financial Officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

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

Management's Report on Internal Control Over Financial Reporting

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

Under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting as of the end of 2021 (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, 2021, 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, 2021. This attestation report appears below.

Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021, and the related notes and our report dated March 18, 2022 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

Stamford, Connecticut
March 18, 2022

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2022 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 2022 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 2022 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 2022 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 2022 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, 2021 and 2020
- Consolidated Statements of Operations for the years ended December 31, 2021 and 2020
- Consolidated Statements of Comprehensive Loss for the years ended December 31, 2021 and 2020
- Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2021 and 2020
- Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020
- 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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INDEX TO FINANCIAL STATEMENTS

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, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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, 2021, 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 March 18, 2022 expressed an unqualified opinion thereon.

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 included 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Estimate of variable consideration in contracts with customers

Description of the Matter	As described in Note 2 to the consolidated financial statements, the Company has net product revenues of $114.2 million for the year ended December 31, 2021, which includes estimates of variable consideration for government rebates. The estimates of variable consideration are based on the amounts earned or to be claimed on the related sales and 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). As described in Note 2, these estimates are established by management based on available information and will be adjusted to reflect known changes in the factors that impact such amounts. The measurement and valuation of management's estimate of variable consideration related to government rebates is a critical audit matter because the calculation includes subjective assumptions regarding the levels of expected future claims, forecasted shipments from specialty pharmacies to eligible patients and governmental pricing calculations.

How We Addressed the Matter in Our Audit	To test the estimate of variable consideration related to government rebates, we performed audit procedures that included testing the operating effectiveness of internal controls over the measurement and valuation of the estimate including controls over management's review of the government pricing calculations, the significant assumptions and the data inputs used to estimate government rebates. Our procedures also included, among others, evaluating the methodology used, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the significant assumptions that are used by management to estimate its variable consideration. We also compared the assumptions used by management to historical trends, evaluated the change in the estimates from prior periods and assessed the historical accuracy of management's estimates against actual results. In addition, we involved a subject matter specialist to assist with our procedures in evaluating management's methodology and calculations used to measure the estimate of government rebates.

Fair Value Measurement of the Contingent Consideration

Description of the Matter	As described in Note 14 to the consolidated financial statements, the Company has a $49.6 million contingent consideration liability recorded as of December 31, 2021 representing the fair value of future royalties management believes are likely to be paid to the counterparty. The determination of the recorded amount of the contingent consideration liability requires the Company to make significant estimates and assumptions. We identified the measurement of the contingent consideration liability as a critical audit matter because auditing the Company's estimate involved complex and challenging auditor judgment about the inputs to the valuation, such as the estimated revenue forecast for future sales of Inbrija and the discount rate, which are largely unobservable.
How We Addressed the Matter in Our Audit	To test the estimated fair value of the contingent consideration liability, we performed audit procedures that included testing the operating effectiveness of internal controls over management's fair value measurement including controls over the Company's model, significant assumptions, and data. Our procedures also included, among others, assessing the terms of the arrangement, evaluating the methodology used, testing the significant assumptions discussed above and the completeness, accuracy and relevance of the underlying data used by management in its analysis. We performed analyses of certain assumptions to assess the impact of changes in those assumptions on the Company's determination of the fair value of the contingent consideration liability. We also evaluated whether the assumptions used by management were consistent with external market data and evidence obtained in other areas of the audit.

/s/ Ernst & Young LLP

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

Stamford, Connecticut
March 18, 2022

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 45,634	$ 71,369
Restricted cash	13,400	12,917
Trade accounts receivable, net of allowances of $1,012 and $1,266, as of December 31, 2021 and 2020, respectively	17,002	20,193
Prepaid expenses	6,574	14,807
Inventory, net	18,548	28,677
Assets held for sale	—	71,795
Other current assets	999	1,577
Total current assets	102,157	221,335
Property and equipment, net of accumulated depreciation	4,382	7,263
Intangible assets, net of accumulated amortization	335,980	366,981
Right of use asset, net of accumulated amortization	6,751	18,481
Restricted cash	6,189	18,609
Other assets	11	11
Total assets	$ 455,470	$ 632,680
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,845	$ 12,155
Accrued expenses and other current liabilities	28,605	38,167
Current portion of loans payable	—	68,631
Current portion of liability related to sale of future royalties	4,460	8,731
Current portion of lease liability	8,186	7,944
Current portion of acquired contingent consideration	1,929	1,624
Total current liabilities	54,025	137,252
Convertible senior notes	151,025	137,619
Derivative liability	37	1,193
Non-current portion of acquired contingent consideration	47,671	46,576
Non-current portion of loans payable	27,645	28,555
Deferred tax liability	13,930	19,116
Non-current portion of liability related to sale of future royalties	—	6,526
Non-current portion of lease liability	4,086	17,200
Other non-current liabilities	5,914	688
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share. Authorized 1,000,000 shares at December 31, 2021 and 2020; no shares issued as of December 31, 2021 and 2020	—	—
Common stock, $0.001 par value per share. Authorized 61,666,666 shares at December 31, 2021 and 2020; issued 13,249,802 and 9,475,631 shares, including those held in treasury, as of December 31, 2021 and 2020, respectively	13	9
Treasury stock at cost (5,543 shares at December 31, 2021 and December 31, 2020)	(638)	(638)
Additional paid-in capital	1,023,136	1,007,790
Accumulated deficit	(870,357)	(766,403)
Accumulated other comprehensive loss	(1,017)	(2,803)
Total stockholders' equity	151,137	237,955
Total liabilities and stockholders' equity	$ 455,470	$ 632,680

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(In thousands, except per share data)

	Year ended December 31, 2021	Year ended December 31, 2020
Revenues:		
Net product revenues	$ 114,189	$ 124,831
Milestone revenues	—	15,000
Royalty revenues	14,882	13,136
Total net revenues	129,071	152,967
Costs and expenses:		
Cost of sales	40,787	33,513
Research and development	10,420	23,012
Selling, general and administrative	124,399	152,576
Intangible asset impairments	—	4,131
Loss on assets held for sale	—	57,896
Amortization of intangible assets	30,764	30,763
Changes in fair value of derivative liability	(1,156)	(39,959)
Changes in fair value of acquired contingent consideration	2,895	(30,889)
Total operating expenses	208,109	231,043
Operating loss	(79,038)	(78,076)
Other income (expense), net:		
Interest and amortization of debt discount expense	(30,035)	(30,574)
Interest income	5	816
Other income (expense)	(6)	167
Total other income (expense), net	(30,036)	(29,591)
Loss before taxes	(109,074)	(107,667)
Benefit from income taxes	5,120	8,073
Net loss	$ (103,954)	$ (99,594)
Net loss per share—basic	$ (9.79)	$ (12.32)
Net loss per share—diluted	$ (9.79)	$ (12.32)
Weighted average common shares outstanding used in computing net loss per share—basic	10,621	8,084
Weighted average common shares outstanding used in computing net loss per share—diluted	10,621	8,084

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year ended December 31, 2021	Year ended December 31, 2020
Net loss	$ (103,954)	$ (99,594)
Other comprehensive income (loss):		
Foreign currency translation adjustment	1,786	(1,607)
Unrealized losses on available-for-sale securities, net of tax	—	(27)
Other comprehensive income (loss), net of tax	$ 1,786	$ (1,634)
Comprehensive loss	$ (102,168)	$ (101,228)

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
(In thousands)

	Common stock						
	Number of shares	Par value	Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders equity
Balance at December 31, 2019	7,964	$ 8	$ (638)	$ 979,428	$ (666,809)	$ (1,169)	$ 310,820
Compensation expense for issuance of stock options to employees	—	—	—	5,468	—	—	5,468
Compensation expense for issuance of restricted stock to employees	27	—	—	2,632	—	—	2,632
Reclassification of derivative liability to equity, net of tax of $4.4 million	—	—	—	14,053	—	—	14,053
Interest payment for convertible notes	1,485	1	—	6,201	—	—	6,202
Reverse stock split adjustment	—	—	—	8	—	—	8
Other comprehensive loss	—	—	—	—	—	(1,634)	(1,634)
Net loss	—	—	—	—	(99,594)	—	(99,594)
Balance at December 31, 2020	9,476	$ 9	$ (638)	$ 1,007,790	$ (766,403)	$ (2,803)	$ 237,955
Compensation expense for issuance of stock options to employees	—	—	—	1,635	—	—	1,635
Compensation expense and issuance of restricted stock to employees	89	—	—	1,295	—	—	1,295
Interest payment for convertible notes	3,685	4	—	12,416	—	—	12,420
Other comprehensive income	—	—	—	—	—	1,786	1,786
Net loss	—	—	—	—	(103,954)	—	(103,954)
Balance at December 31, 2021	13,250	13	(638)	1,023,136	(870,357)	(1,017)	151,137

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2021	Year ended December 31, 2020
Cash flows from operating activities:		
Net loss	(103,954)	$ (99,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,995	8,100
Amortization of net premiums and discounts on investments	—	562
Amortization of debt discount and debt issuance costs	16,276	16,422
Depreciation and amortization expense	33,953	41,298
Intangible asset impairments	—	4,131
Loss on assets held for sale	—	57,896
Change in contingent consideration obligation	2,895	(30,889)
Change in derivative liability	(1,156)	(39,959)
Gain on disposal of property and equipment	—	(200)
Non-cash royalty revenue	(12,106)	(11,486)
Deferred tax provision (benefit)	(5,186)	4,667
Changes in assets and liabilities:		
Decrease in accounts receivable	3,191	1,890
Decrease (increase) in prepaid expenses and other current assets	8,419	(1,237)
Decrease (increase) in inventory	7,860	(3,456)
Decrease in other assets	—	19
Increase (decrease) in accounts payable, accrued expenses and other current liabilities	1,108	(8,971)
Increase (decrease) in other non-current liabilities	4,357	(199)
Net cash (used) in operating activities	(41,348)	(61,006)
Cash flows from investing activities:		
Purchases of property and equipment	(165)	(4,390)
Purchases of intangible assets	(26)	—
Proceeds from maturities of investments	—	63,750
Proceeds from sale of Chelsea facility, net	73,969	—
Net cash provided by investing activities	73,778	59,360
Cash flows from financing activities:		
Repayment of Convertible Senior Notes Due 2021	(69,000)	—
Debt issuance costs	—	(1,071)
Repayment of loans payable	(655)	(597)
Net cash (used) in financing activities	(69,655)	(1,668)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(447)	1,018
Net (decrease) in cash and cash equivalents and restricted cash	(37,672)	(2,296)
Cash, cash equivalents and restricted cash at beginning of period	102,895	105,191
Cash, cash equivalents and restricted cash at end of period	$ 65,223	$ 102,895
Supplemental disclosure:		
Cash paid for interest	6	6,670
Cash paid for taxes	50	251

See accompanying 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.

Basis of Presentation

On December 31, 2020, the Company filed an amendment to its Certificate of Incorporation which effected a 1-for-6 reverse stock split of the shares of its outstanding common stock and proportionate reduction in the number of authorized shares of its common stock from 370,000,000 to 61,666,666. The Company's common stock began trading on a split-adjusted basis on The Nasdaq Global Select Market commencing upon market open on January 4, 2021. The reverse stock split applied equally to all outstanding shares of the common stock and did not modify the rights or preferences of the common stock. As such, all figures in this report relating to shares of the Company's common stock (such as share amounts, per share amounts, and conversion rates and prices), including in the financial statements and accompanying notes to the financial statements, have been retroactively restated to reflect the 1-for-6 reverse stock split of the Company's common stock.

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 convertible senior secured notes due 2024, which is marked to market each quarter based on a binomial model, 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. The Company maintains cash balances in excess of insured limits. The Company does 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 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, 2021, 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 $5.9 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 9 to the Company's Consolidated Financial Statements included in this report for a discussion of interest payments on the outstanding convertible senior secured notes due 2024.

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

	December 31, 2021		December 31, 2020	
(In thousands)	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 71,369	$ 45,634	$ 62,085	$ 71,369
Restricted cash	12,917	13,400	12,836	12,917
Restricted cash-non current	18,609	6,189	30,270	18,609
Total Cash, cash equivalents and restricted cash per statement of cash flows	$ 102,895	$ 65,223	$ 105,191	$ 102,895

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. There were no investments classified as short-term or long-term at December 31, 2021 or 2020.

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, 2021 and 2020. The cumulative foreign currency translation adjustment reported in Other

Comprehensive Income (Loss) was $1.8 million and $(1.6) million for the period ended December 31, 2021 and 2020, 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. 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. The Company recorded an idle capacity charge related to the Chelsea manufacturing operations to cost of goods sold of $0.1 million and $6.3 million for the years ended December 31, 2021 and 2020, respectively.

The following table provides the major classes of inventory:

(In thousands)	December 31, 2021	December 31, 2020
Raw materials	$ 3,338	$ 3,434
Work-in-progress	—	6,602
Finished goods	15,210	18,641
Total	$ 18,548	$ 28,677

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. No payments were made for the years ended December 31, 2021 and 2020.

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.

Intangible Assets

In Process Research and Development

The Company had indefinite lived intangible assets for the value of acquired in-process research and development. The Company recorded an impairment charge of $4.1 million for the year ended December 31, 2020 in the statement of operations and therefore, the indefinite-lived intangible asset was fully impaired. See Note 4 to the Company’s Consolidated Financial Statements included in this report for a discussion of intangible assets.

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 15 to our Consolidated Financial Statements included in this report for a 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 year-ended December 31, 2021, 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, 2021. The Company performed a recoverability test as of December 31, 2021 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.

The Company determined that there were relevant changes to the key assumptions that would negatively affect the value of the IPR&D asset for BTT-1023. The Company noted that it received a final read-out of the results of the BUTEO study on March 31, 2020 and noted that the study did not meet its primary or secondary endpoints. Based on conclusions drawn from these results, management determined that the Company would not continue further development of the asset on March 31, 2020. Management also conferred with its independent consultant in March 2020 to review and opine on the results of the BUTEO study to assess whether the asset was a candidate for potential out-licensing since the Company would no longer continue to develop the asset. Based on the assessment and review of the BUTEO study results with the consultant, management determined that the results of the clinical trial did not meet the primary or secondary end-points, and the clinical trial was not large enough or expansive enough to be persuasive to generate interest by third parties for a possible licensing arrangement. Management determined that this assessment was the triggering event that indicated that the asset was fully impaired as there was no potential value with an out-licensing arrangement. Based on the qualitative assessment, management determined that the fair value of the IPR&D asset was $0 and that the carrying value of the asset which was approximately $4.1 million at March 31, 2020 exceeded the fair value of the asset. As a result, the Company fully impaired the asset and recorded an impairment charge of $4.1 million in the three-month period ended March 31, 2020. Management

determined that additional quantitative procedures were not relevant in this circumstance given the overwhelming qualitative evidence that indicated the asset was fully impaired.

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 (the "Biogen Collaboration Agreement"), up to an agreed upon threshold of royalties. When this threshold is met, which we believe may occur in mid-2022, 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 Royalty Agreement does not include potential future milestones to be paid by Biogen to Acorda.

Since the Company maintained rights under the Biogen Collaboration Agreement, the Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the expected 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. Because of its limited financial resources, the Company previously suspended work on proprietary research and development programs, but it has been performing feasibility studies for potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using the Company's proprietary ARCUS technology.

Employee Retention Credit under the CARES Act

The Employee Retention Credit (ERC) was established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, P.L. 116-136 to provide a quarterly per employee credit to eligible businesses based on a percentage of qualified wages and health insurance benefits paid to employees. In 2021, the Company classified the $4.2 million credit received as a reduction to payroll tax expense in the Consolidated Statement of Operations.

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

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. As of December 31, 2021, we had contract liabilities of $5.9 million, which is the upfront payment received as part of the Esteve Germany distribution agreement entered into in 2021. We did not have any contract liabilities as of December 31, 2020. We did not have any contract assets as of December 31, 2021 or 2020.

Product Revenues, Net

Inbrija is distributed in the U.S. primarily through: Alliancerx Walgreens Prime, or Walgreens, a specialty pharmacy that delivers the medication to patients by mail; and ASD Specialty healthcare, Inc. (an AmeriSource Bergen affiliate). During the three-month period ended December 31, 2020, we completed the transition from a network of several specialty pharmacies to Walgreens as the sole specialty pharmacy for U.S. sales of Inbrija. The Company recently initiated a pilot program to evaluate distribution of Inbrija through a specialty pharmacy that supports electronic prescriptions, and the Company intends to expand this into a national program in 2022. The Company believes the convenience of electronic prescribing may be preferred by some physicians and patients.

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

Net revenues 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 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

Revenues 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 the Company's allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows:

> *Government Chargebacks and Rebates:* The Company contracts 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 on the Company's contracts and the most recent experience with respect to sales through each of these channels, the Company provides an allowance for chargebacks and rebates. The Company monitors 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: The Company contracts 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 on the Company's contracts and the most recent experience with respect to sales through managed care channels, the Company provides an allowance for managed care contract rebates. The Company monitors 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: The Company offers 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 on the Company's contracts and the most recent experience with respect to actual copay assistance provided, the Companys provides an allowance for copay mitigation rebates. The Company monitors the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience.

Cash Discounts: The Company sells 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). The Company generally provides invoice discounts for prompt payment for our products. The Company estimates 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. The Company adjusts estimates based on actual activity as necessary.

Product Returns: The Company offers 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: The Company has contracted with certain specialty pharmacies to obtain transactional data related to our products in order to develop a better understanding of its selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. The Company pays a variable fee to the specialty pharmacies to provide the Company the data. The Company also pays the specialty pharmacies a fee in exchange for providing distribution and inventory management services, including the provision of inventory management data to the Company. The Company estimates its fee for service accruals and allowances based on sales to each specialty pharmacy and the applicable contracted rate.

Royalty Revenues

Royalty revenues 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 Revenues

License revenues relates to the 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 revenues under ASC 606, which provides constraints for entities to recognize license revenues 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 revenues 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 revenues upon the achievement of the specific sale milestones.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other rights and obligations, the Company determines whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company uses its judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Esteve Germany Distribution and Supply Agreement

In November 2021, the Company entered into distribution and supply agreements with Esteve to commercialize Inbrija in Germany. Under the terms of the distribution agreement, the Company received a $5.9 million upfront payment, and is entitled to receive additional sales-based milestones. Under the terms of the supply agreement, the Company is entitled to receive a significant double-digit percent of the selling price of Inbrija in exchange for supply of the product. Esteve expects to launch Inbrija in Germany in mid-2022.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Esteve, is a customer. The Company identified the following promises in the arrangement: the trademark license and marketing and distribution rights and the supply of minimum purchase commitments. The Company further determined that the promise for additional supply exceeding minimum purchase commitments represented a customer option, which would create an obligation for the Company if exercised by Esteve. No additional or material upfront consideration is owed to the Company by Esteve upon exercise of the customer option for the right to additional supply and it is offered at the same percent of selling price as the supply of minimum purchase commitments. Accordingly, it was assessed as a material right and, therefore, a separate performance obligation in the arrangement. The Company then determined that the trademark license and marketing and distribution rights and the supply of minimum purchase commitments were not distinct from one another and must be combined as a performance obligation. Based on this determination, as well as the considerations noted above with respect to the material right for additional supply, the Company identified two distinct performance obligations at the inception of the contract: (i) the combined performance obligation, (ii) the material right for additional supply.

The Company did not recognize any revenues during the year ended December 31, 2021 from its distribution agreement with Esteve. At December 31, 2021, other current and non-current liabilities related to the unsatisfied performance obligations were $5.9 million in aggregate. The Company will recognize the $5.9 million upfront payment ratably in proportion to sales. The Company will re-evaluate the transaction price in each reporting period and as certain events are resolved or other changes in circumstances occur.

Additionally, the Company is eligible to receive additional payments based on the achievement by Esteve of sales-based milestones. Variable consideration related these sales-based milestones was fully constrained due to the fact that it was probable that a significant reversal of cumulative revenue would occur, given the inherent uncertainty of success with these future milestones.

The following table disaggregates the Company's revenues by major source (in thousands):

(In thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Revenues:		
Net product revenues:		
Ampyra	$ 84,555	$ 98,887
Inbrija	29,634	24,233
Other	—	1,711
Total net product revenues	114,189	124,831
Milestone revenues	—	15,000
Royalty revenues	14,882	13,136
Total net revenues	$ 129,071	$ 152,967

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. Prior to the sale of the facility in February 2021, the Company leased a manufacturing facility in Chelsea, Massachusetts which produced 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.

The Company's principal direct customers for the year ended December 31, 2021 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 revenues and approximately 91% of total revenues in 2021, and approximately 90% of total revenues in 2020. Four customers individually accounted for more than 10% of the Company's accounts receivable and approximately 92% of total accounts receivable as of December 31, 2021, and approximately 84% of total accounts receivable as of December 31, 2020. 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 $2.0 million and $1.0 million for the years ended December 31, 2021 and 2020, respectively. The Company's reserve for cash discount allowances was $0.8 million and $0.6 million as of December 31, 2021 and 2020, respectively.

(in thousands)	Cash discounts
Balance at December 31, 2019	$ 412
Allowances for sales	$ 954
Actual credits	$ (791)
Balance at December 31, 2020	$ 575
Allowances for sales	1,992
Actual credits	(1,787)
Balance at December 31, 2021	**$ 780**

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 recognized an allowance for doubtful accounts of $0.2 million as of December 31, 2021 and had no recognized allowance for doubtful accounts as of December 31, 2020. There were provisions and write-offs of $0.2 million for the year ended December 31, 2021 and no provisions and write-offs for the years ended December 31, 2020.

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 $1.0 million and $2.3 million for the years ended December 31, 2021 and December 31, 2020, respectively. The Company made a payment of $1.5 million and $2.0 million related to the chargebacks allowances for the years ended December 31, 2021 and December 31, 2020, respectively. The Company's reserve for chargebacks allowance was negligible as of December 31, 2021 and $0.5 million as of December 31, 2020.

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) Capital and R&D loans were measured at fair value based on a discounted cash flow approach;

(e) Convertible senior secured notes due 2024 were measured at fair value based on market quoted prices of the debt securities; and

(f) Derivate liability related to conversion options of the convertible senior secured notes due 2024 is measured at fair value using a binomial model.

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 options 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. The dilutive effect of outstanding shares is reflected in diluted earnings per share by application of the treasury stock method or if-converted method, as applicable, at each reporting period. See Note 17 to our Consolidated Financial Statements included in this report for a discussion on earnings (loss) per share.

Share-based Compensation

The Company has various share-based employee and non-employee compensation plans. See Note 8 to our Consolidated Financial Statements included in this report for a discussion of share-based compensation.

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 operations 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, 2021 and December 31, 2020.

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.

Liquidity

The Company's ability to meet its future operating requirements, repay its liabilities, and meet its other obligations are dependent upon a number of factors, including its ability to generate cash from product sales, reduce planned expenditures, and obtain additional financing. If the Company is unable to generate sufficient cash flow from the sale of its products, the Company will be required to adopt one or more alternatives, subject to the restrictions contained in the indenture governing its convertible senior secured notes due 2024, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous and which are likely to be highly dilutive. Also, the Company's ability to raise additional capital and repay or restructure its indebtedness will depend on the capital markets and its financial condition at such time, among other factors. In addition, financing may not be available when needed, at all, on terms acceptable to the Company or in accordance with the restrictions described above. As a result of these factors, the Company may not be able to engage in any of the alternative activities, or engage in such activities on desirable terms, which could harm the Company's business, financial condition and results of operations, as well as result in a default on the Company's debt obligations. If the Company is unable to take these actions, it may be forced to significantly alter its business strategy, substantially curtail its current operations, or cease operations altogether.

At December 31, 2021, the Company had $45.6 million of cash and cash equivalents, compared to $71.4 million at December 31, 2020. The Company's December 31, 2021 cash and cash equivalents balance includes approximately $5.3 million associated with a December 2021 amendment to the Company's Catalent manufacturing services agreement that modified the Company's payment schedule. The Company's December 31, 2021 cash and cash equivalents balance does not include restricted cash, currently held in escrow under the terms of its convertible senior secured notes due 2024, which may potentially be released from escrow if the Company pays interest on those notes using shares of its common stock. The Company incurred net losses of $104.0 million and $99.6 million for the years ended December 31, 2021 and 2020, respectively.

Based on the Company's cash and cash equivalents at December 31, 2021 and its obligations that are due within the next twelve months, management has concluded that there is no substantial doubt regarding the Company's ability to meet its obligations within one year after the date the consolidated financial statements are issued.

Recent Accounting Pronouncements - Adopted

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 adopted this guidance effective January 1, 2021. The adoption of this guidance did not have a significant impact on the consolidated financial statements.

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued ASU 2020-03, "Codification Improvements to Financial Instruments": The amendments in this update are to clarify, correct errors in, or make minor improvements to a variety of ASC topics. The changes in ASU 2020-03 are not expected to have a significant effect on current accounting practices. The ASU improves various financial instrument topics in the Codification to increase stakeholder awareness of the amendments and to expedite the improvement process by making the Codification easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. The ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2022 with early application permitted. The Company is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This update simplifies the accounting for convertible instruments by eliminating the cash conversion and beneficial conversion feature models which require separate accounting for embedded conversion features. This update also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions and requires the application of the if-converted method for calculating diluted earnings per share. ASU 2020-06 is effective for smaller reporting companies for fiscal periods beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The FASB is issuing this update to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is 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. The Company elected the package of practical expedients which permits the Company 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. The Company 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 the Company's previously reported consolidated statements of operations and did not result in a cumulative catch-up adjustment to opening equity.

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. The Company's leases have remaining lease terms of 0.5 years to 5 years. The Company has exercised the option to terminate the Ardsley lease with a termination date of June 22, 2022.

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. The Company has 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, the Company 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

The Company leases 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; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Ardsley, New York

In June 2011, the Company entered into a 15-year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. In 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. Our base rent is currently $5.0 million per year. In September 2021, the Company sent the landlord notice of exercise of the Company's early termination option (the "Early Termination Option") under the lease. Pursuant to the Early Termination Option, the lease will terminate on June 22, 2022 (the "Early Termination Date"), subject to the conditions that (a) on the last business day before the Early Termination Date, the Company pays an early termination fee of approximately $4.7 million, (b) on the day immediately prior to the Early Termination Date, the Company is not in "Default" under the lease beyond applicable cure periods, and (c) as of the Early Termination Date, the Company has complied with its end-of-term obligations. The Company is currently evaluating facility alternatives for its corporate operations after its departure from the Ardsley headquarters.

Chelsea, Massachusetts

The Company's Civitas subsidiary leased a manufacturing facility in Chelsea, Massachusetts which it used to manufacture Inbrija through February 10, 2021. On February 10, 2021, the Company completed the sale of its Chelsea manufacturing operations to Catalent Pharma Solutions and assigned the lease of the Chelsea facility to a Catalent affiliate.

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 added a new size 7 spray dryer manufacturing production line for Inbrija and other ARCUS products that has greater capacity than the existing size 4 spray dryer manufacturing production line, and created additional warehousing space for manufactured product. All costs to renovate and expand the facility through the date of assignment to Catalent were borne by the Company. Since the February 10, 2021 sale of the manufacturing operations, Catalent has been responsible for finalizing the expansion, including obtaining needed regulatory approvals. However, given the potential importance of the expansion to the Company's business, in December 2021 we agreed to fund $1.5 million of Catalent's costs to complete the size 7 spray dryer expansion, which will be payable by the Company in four quarterly installments after the later of January 1, 2024 or FDA qualification and approval for use of the size 7 spray dryer.

Additional Facilities

In October 2016, the Company 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.

The Company's leases have remaining lease terms of 0.5 years to 5 years, which reflects the exercise of the early termination of the Company's Ardsley, NY lease as described above. The weighted-average remaining lease term for our operating leases was 2.4 years at December 31, 2021. The weighted-average discount rate was 7.13% at December 31, 2021.

ROU assets and lease liabilities related to the Company's operating leases are as follows:

(In thousands)	Balance Sheet Classification	December 31, 2021	December 31, 2020
Right-of-use assets	Right of use assets	$ 6,751	$ 18,481
Current lease liabilities	Current portion of lease liabilities	8,186	7,944
Non-current lease liabilities	Non-current portion of lease liabilities	4,086	17,200

The Company has lease agreements that contain both lease and non-lease components. the Company 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, 2021	Year ended December 31, 2020
Operating lease cost	$ 6,030	$ 7,066
Variable lease cost	4,156	3,636
Short-term lease cost	851	1,653
Total lease cost	$ 11,037	$ 12,355

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

(In thousands)	
2022	$ 8,354
2023	1,216
2024	1,252
2025	1,290
Later years	1,327
Total lease payments	13,439
Less: Imputed interest	(1,167)
Present value of lease liabilities	12,272

Supplemental cash flow information activity related to the Company's operating leases are as follows:

(In thousands)	December 31, 2021	December 31, 2020
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	$ 6,158	$ 7,769

(4) Intangible Assets

Intangible Assets

Inbrija 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.

BTT1023 IPR&D

In connection with the acquisition of Biotie, the Company acquired global rights to BTT1023 (timolumab). BTT1023 is a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the transaction to the underlying assets acquired and liabilities assumed, 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.

In the three-month period ended March 31, 2020, the Company determined that there were relevant changes to the key assumptions that would negatively affect the value of the IPR&D asset for BTT-1023. The Company noted that it received a final read-out of the results of the BUTEO study on March 31, 2020 and noted that the study did not meet its primary or secondary endpoints. Based on conclusions drawn from these results, management determined that the Company would not continue further development of the asset on March 31, 2020. Management also conferred with its independent consultant in March 2020 to review and opine on the results of the BUTEO study to assess whether the asset was a candidate for potential out-licensing since the Company would no longer continue to develop the asset. Based on the assessment and review of the BUTEO study results with the consultant, management determined that the results of the clinical trial did not meet the primary or secondary end-points, and the clinical trial was not large enough or expansive enough to be persuasive to generate interest by third parties for a possible licensing arrangement. Management determined that this assessment was the triggering event that indicated that the asset was fully impaired as there was no potential value with an out-licensing arrangement. Based on the qualitative assessment, management determined that the fair value of the IPR&D asset was $0 and the carrying value of the asset which was approximately $4.1 million at March 31, 2020 exceeded the fair value of the asset. As a result, the Company fully impaired the asset and recorded an impairment charge of $4.1 million for the year ended December 31, 2020. Management determined that additional quantitative procedures were not relevant in this circumstance given the overwhelming qualitative evidence that indicated the asset was fully impaired.

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, 2021, the Company determined that the intangible assets were not impaired and that there are no facts or circumstances that would indicate a need for changing the estimated remaining useful lives of these assets.

Intangible assets consisted of the following:

		December 31, 2021				December 31, 2020				
(Dollars In thousands)	Estimated Remaining Useful Lives (Years)	Cost	Additions	Accumulated Amortization	Net Carrying Amount	Cost	Impairment	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount
In-process research & development [1]	Indefinite-lived	$ —	$ —	$ —	$ —	$ 4,212	$ (4,131)	$ —	$ (81)	$ —
Inbrija [2]	11	423,000	—	(87,164)	335,836	423,000	—	(56,400)	—	366,600
Website development costs	1-3	14,559	26	(14,441)	144	14,559	—	(14,178)	—	381
		$ 437,559	$ 26	$ (101,605)	$ 335,980	$ 441,771	$ (4,131)	$ (70,578)	$ (81)	$ 366,981

(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 amortizating the assets upon launch in February 2019.

The Company recorded amortization expense of $31.0 million of which $30.7 million pertained to the intangible asset related to Inbrija and $0.3 million related to the amortization of website development costs for the year ended December 31, 2021. The Company recorded amortization expense of $31.1 million of which $30.7 million pertained to the intangible asset related to Inbrija and $0.4 million related to the amortization of website development costs related to these intangible assets for the year ended December 31, 2020.

Estimated future amortization expense for intangible assets subsequent to December 31, 2021 is as follows:

(In thousands)		
2022	$	30,894
2023		30,772
2024		30,768
2025		30,764
2026		30,764
Thereafter		182,018
	$	335,980

The weighted-average remaining useful lives of all amortizable assets is approximately 11.0 years.

(5) Investments

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately $12.2 million and $36.7 million as of December 31, 2021 and December 31, 2020, respectively. There were no short-term investments with original maturities of greater than 3 months but less than 1 year as of December 30, 2021 and December 31, 2020. Additionally, there were no short-term investments in an unrealized loss position as of December 30, 2021 and December 31, 2020, respectively. Long-term investments have original maturities of greater than one year. There were no investments classified as long-term at December 31, 2021 or December 31, 2020. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of December 31, 2021 as the Company does not have any short or long-term investments as of December 31, 2021.

(6) Property and Equipment

In January 2021, the Company entered into an asset purchase agreement with Catalent Pharma Solutions to sell its Chelsea, Massachusetts manufacturing operations. The Company closed the transaction on February 10, 2021. The Company determined that the criterion to classify the property and equipment being transferred as part of the agreement as held for sale within the Company's consolidated balance sheet as of December 31, 2020. Accordingly, the property and equipment being transferred as part of the agreement were classified as current assets and current liabilities held for sale at December 31, 2020. See Note 7 to our Consolidated Financial Statements included in this report for a discussion of Assets Held for Sale.

Property and equipment consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020	Estimated useful lives used
Machinery and equipment	$ 2,315	$ 2,569	2-7 years
Leasehold improvements	15,317	15,317	Lesser of useful life or remaining lease term
Computer equipment	17,973	17,758	1-3 years
Laboratory equipment	1,644	5,343	2-5 years
Furniture and fixtures	2,130	2,129	4-7 years
Construction in progress	—	171	
	39,379	43,287	
Less accumulated depreciation	(34,997)	(36,024)	
	$ 4,382	$ 7,263	

Depreciation and amortization expense on property and equipment was $2.9 million and $10.2 million for the years ended December 31, 2021 and 2020, respectively.

(7) Assets Held for Sale

On January 12, 2021, the Company and Catalent entered into an asset purchase agreement, pursuant to which the Company agreed to sell to Catalent certain assets related to the Company's manufacturing activities located at the facilities situated in Chelsea, Massachusetts (the "Chelsea Facility") and Waltham, Massachusetts (the "Waltham Facility"), for a purchase price of $80 million, plus an additional $2.3 million for raw materials transferred, and the assumption by Catalent of certain liabilities relating to such manufacturing activities. The Company closed the transaction on February 10, 2021. The Company determined that the criterion to classify the Chelsea manufacturing operations as assets held for sale within the Company's consolidated balance sheet effective December 31, 2020 were met. Accordingly, the assets were classified as current assets held for sale at December 31, 2020 as the Company, at that time, expected to divest the Chelsea manufacturing operations within the next twelve months.

The classification to assets held for sale impacted the net book value of the assets expected to be transferred upon sale. The estimated fair value of the Chelsea manufacturing operations was determined using the purchase price in the purchase agreement along with estimated broker, accounting, legal, and other selling expenses, which resulted in a fair value less costs to sell of approximately $71.8 million. The carrying value of the assets being classified as held for sale was approximately $129.7 million, which includes property and equipment of $129.6 million and prepaid expenses of $0.1 million. As a result, the Company recorded a loss on assets held for sale of $57.9 million against the Chelsea manufacturing operations. Upon completion of the divestiture, final net proceeds were $74.0 million. Additionally, the expected divestiture of the Chelsea Facility group was not deemed to represent a fundamental strategic shift that would have a major effect on the Company's operations, and accordingly, the operating results of the Chelsea manufacturing operations were not reported as discontinued operations in the Company's consolidated statement of income as of December 31, 2020.

(8) Common Stock Options and Restricted Stock

On December 31, 2020, the Company filed an amendment to its Certificate of Incorporation which effected a 1-for-6 reverse stock split of the shares of the Company's outstanding common stock and proportionate reduction in the number of authorized shares of its common stock from 370,000,000 to 61,666,666 and from 80,000,000 to 13,333,333 as of December

31, 2020 and 2019, respectively. As such, all figures in this report relating to shares of the Company's common stock (such as share amounts, per share amounts, and conversion rates and prices), including in the financial statements and accompanying notes to the financial statements, have been retroactively restated to reflect the 1-for-6 reverse stock split of the common 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, 2021 was 2,485,342 shares. As of December 31, 2021, the Company had granted an aggregate of 1,955,881 shares as restricted stock or subject to issuance upon exercise of stock options under the 2006 Plan, of which 313,569 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 were made under the 2006 Plan after the effective date 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, 2021 is 1,350,000 shares, plus shares underlying cancelled awards under the 2006 plan after the adoption of the 2015 plan. As of December 31, 2021, the Company had granted an aggregate of 1,408,784 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 701,976 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. Equity awards were issued under this plan to individuals employed by Biotie Therapies Ltd., formerly Biotie Therapies Corp., and its subsidiary Biotie Therapies, Inc. (collectively, "Biotie") in connection with our 2016 acquisition of Biotie, however the last of these awards terminated in 2020. In 2021, 170,000 stock option awards were issued under this plan to newly-hired executive officers as an inducement for them to become employed by the Company, and as of December 31, 2021, such awards remained outstanding and were the only awards that were outstanding under the 2016 Plan.

On June 19, 2019, the Company's stockholders approved the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP") at the annual meeting of stockholders pursuant to which up to 250,000 shares of the Company's common stock, par value $0.001 per share may be issued thereunder (the "Plan Shares). As of December 31, 2021, there were 250,000 shares of common stock remaining authorized for issuance under the 2019 ESPP.

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,	
	2021	2020
Employees and directors:		
Estimated volatility%	84.26%	80.28%
Expected life in years	6.25	6.31
Risk free interest rate%	1.36%	0.69%
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, 2021 and 2020 amounted to approximately $2.57 and $3.95, respectively. No options were granted to non-employees for the years ended December 31, 2021 and 2020.

During the year ended December 31, 2021, the Company granted 596,795 stock options to employees and directors under all plans. The stock options were issued with a weighted average exercise price of $3.72 per share. As a result of these grants, the total compensation charge to be recognized over the estimated service period is $2.0 million, of which $0.9 million was recognized during the year ended December 31, 2021.

Compensation costs for options and restricted stock granted to employees and directors amounted to $3.0 million and $8.1 million, for the years ended December 31, 2021 and 2020, respectively. Of the total compensation cost, there was $0 and $0.3 million compensation cost capitalized in inventory balances for the years ended December 31, 2021 and December 31, 2020, repectively. 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:

	Year ended December 31,	
(In thousands)	2021	2020
Research and development	$ 694	$ 1,745
Selling, general and administrative	2,282	6,020
Cost of sales	19	335
Total	$ 2,995	$ 8,100

A summary of share-based compensation activity for the year ended December 31, 2021 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, 2020	1,331	$ 127.13		
Granted	336	3.72		
Forfeited and expired	(481)	121.78		
Exercised	—	—		
Balance at December 31, 2021	1,186	$ 94.38	5.5	$
Vested and expected to vest at December 31, 2021	1,172	$ 95.42	5.5	$
Vested and exercisable at December 31, 2021	872	$ 125.89	4.0	—

Range of exercise price	Options Outstanding: Outstanding as of December 31, 2021 (In thousands)	Options Outstanding: Weighted-average remaining contractual life (In years)	Options Outstanding: Weighted-average exercise price	Options Exercisable: Exercisable as of December 31, 2021 (In thousands)	Options Exercisable: Weighted-average exercise price
$3.16 - $3.74	276	9.8	$ 3.70	1	$ 3.18
$3.75 - $14.46	284	7.1	11.98	257	$ 12.77
$15.30 - $164.85	265	3.6	124.60	253	$ 126.67
$165.30 - $214.44	277	2.5	197.68	277	$ 197.70
$215.28 - $246.42	84	2.1	234.91	84	$ 234.91
	1,186	5.5	$ 94.38	872	$ 125.89

Restricted Stock Activity

Restricted Stock	Number of Shares (In thousands)
Nonvested at December 31, 2020	31
Granted	261
Vested	(104)
Forfeited	(72)
Nonvested at December 31, 2021	116

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2021 totaled $1.6 million and is expected to be recognized over a weighted average period of approximately 3.3 years.

(9) Debt

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 "2024 Notes") and cash. For each $1,000 principal amount of exchanged 2021 Notes, the Company issued $750 principal amount of the 2024 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 2024 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. The 2021 Notes received by the Company in the Exchange were cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, $69.0 million of the 2021 Notes remained outstanding. On June 15, 2021, the Company repaid the outstanding balance of the 2021 Notes at their maturity date using cash on hand.

The 2024 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 "2024 Indenture"). The 2024 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 2024 Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms prior to such date. Interest on the 2024 Notes is 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. In June 2021, the Company issued 1,635,833 shares of common stock, and in December 2021, the Company issued 2,049,048 shares of

common stock, in satisfaction of the interest payable to holders of the 2024 Notes on June 1, 2021 and December 1, 2021, respectively. In connection with these stock-based interest payments, in each of June and December, 2021, approximately $6.2 million (approximately $12.4 million in the aggregate) was released from restricted cash and became available to the Company for other purposes.

The 2024 Notes are 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 adjusted conversion rate for the 2024 Notes is 47.6190 shares of the Company's common stock per $1,000 principal amount of 2024 Notes, representing an adjusted conversion price of approximately $21.00 per share of common stock. The conversion rate was adjusted to reflect the 1-for-6 reverse stock split effected on December 31, 2020 and is subject to additional adjustments in certain circumstances as described in the 2024 Indenture.

The Company may elect to settle conversions of the 2024 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 2024 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 2024 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 2024 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 adjusted conversion price for a specified period of time and certain other conditions are satisfied.

Holders of the 2024 Notes will have the right, at their option, to require the Company to purchase their 2024 Notes if a fundamental change (as defined in the 2024 Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date. If a make-whole fundamental change occurs, as described in the 2024 Indenture, and a holder elects to convert its 2024 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the adjusted conversion rate as described in the 2024 Indenture.

Subject to a number of exceptions and qualifications, the 2024 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 2024 Indenture also requires the Company to make an offer to repurchase the 2024 Notes upon the occurrence of certain asset sales.

The 2024 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 2024 Notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the 2024 Notes in accordance with the 2024 Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the 2024 Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the 2024 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 2024 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 2024 Notes may declare all the notes to be due and payable immediately.

The Company determined that the exchange of the 2021 Notes for 2024 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 2024 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 2024 Notes, including the conversion, put and call features. The Company concluded the conversion features required bifurcation as a derivative. The fair value of the conversion features derivative was determined based on the difference between the fair value of the 2024 Notes with the conversion options and the fair value of the 2024 Notes without the conversion options using a binomial model. The Company determined that the fair value of the derivative upon issuance of the 2024 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 2024 Notes on the closing date, or December 24, 2019. There are several embedded features within the 2024 Notes which, upon issuance, did not meet the conditions for equity classification. As a result, these features were aggregated together and recorded as the derivative liability conversion option. The conversion feature is measured at fair value on a quarterly basis and the changes in the fair value of the conversion feature for the period will be recognized in the consolidated statements of operations.

The Company received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company's common stock from 13,333,333 shares to 61,666,666 shares. As a result of the share approval, the Company determined that multiple embedded conversion options met the conditions for equity classification. The Company performed a valuation of these conversion options as of September 17, 2020, which was the date the Company completed certain securities registration obligations for the shares underlying the 2024 Notes. The resulting fair value of these conversion options was $18.3 million, which was reclassified to equity and presented in the statement of stockholder's equity as of September 30, 2020, net of the $4.4 million tax impact. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The Company performed a valuation of the derivative liability related to certain embedded conversion features that are precluded from equity classification. The fair value of these conversion features was calculated to be negligible as of December 31, 2021.

The outstanding 2024 Note balances as of December 31, 2021 and December 31, 2020 consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020
Liability component:		
Principal	$ 207,000	$ 207,000
Less: debt discount and debt issuance costs, net	(55,975)	(69,381)
Net carrying amount	151,025	137,619
Equity component	18,257	$ 18,257
Derivative liability-conversion Option	$ 37	$ 1,193

The Company determined that the expected life of the 2024 Notes was equal to the period through December 1, 2024 as this represents the point at which the 2024 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, 2021, the Company recognized $25.8 million of interest expense related to the 2024 Notes at the effective interest rate of 18.13%. The fair value of the Company's 2024 Notes was approximately $ 142.6 million as of December 31, 2021.

In connection with the issuance of the 2024 Notes, the Company incurred approximately $5.7 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 2024 Notes is amortized to interest expense over the expected life of the 2024 Notes using the effective interest method.

The following table sets forth total interest expense recognized related to the 2024 Notes for the years ended December 31, 2021 and 2020:

(In thousands)	**Year ended December 31, 2021**	**Year ended December 31, 2020**
Contractual interest expense	$ 12,420	$ 12,420
Amortization of debt issuance costs	952	798
Amortization of debt discount	12,454	10,430
Total interest expense	$ 25,826	$ 23,648

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"). On December 24, 2019, the Company completed the private exchange of $276.0 million aggregate principal amount of its then-outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the "2024 Notes") and cash. The 2021 Notes received by the Company in the exchange were cancelled in accordance with their terms. Accordingly, upon completion of the exchange, $69.0 million of the 2021 Notes remained outstanding. On June 15, 2021, the Company repaid the outstanding balance of the 2021 Notes at their maturity date using cash on hand.

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 2021 Note balances as of December 31, 2021 and 2020 consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020
Liability component:		
Principal	$ —	$ 69,000
Less: debt discount and debt issuance costs , net	—	(1,029)
Net carrying amount	—	$ 67,971
Equity component	$ —	$ 22,791

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 following table sets forth total interest expense recognized related to the 2021 Notes for the years ended December 31, 2021 and 2020:

(In thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Contractual interest expense	$ 428	$ 1,208
Amortization of debt issuance costs	95	201
Amortization of debt discount	934	1,968
Total interest expense	$ 1,457	$ 3,377

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) for research and development of specific drug candidates. The non-convertible capital loans had an adjusted acquisition-date fair value of $20.5 million (€18.2 million) and a carrying value of $27.6 million as of December 31, 2021. 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 percentage point. The maturity dates of the loans range from eight to ten years from the date of issuance. However, the loans are to be repaid only when the consolidated retained earnings of Biotie from the development of the specific product candidates that are the subject of the loans is sufficient to fully repay the loans. As of December 31, 2021, Biotie had approximately $14.8 million in cash, which is not available for use in domestic operations without repatriation.

Research and Development Loans

In addition to the non-convertible capital loans described above, Research and Development Loans ("R&D Loans") were granted to Biotie by Business Finland with an acquisition-date fair value of $2.9 million (€2.6 million) and a carrying value of $0 as of December 31, 2021. These loans were repaid in equal annual installments from January 2017 through January 2021.

Letters of Credit

As of December 31, 2021, the Company has $0.3 million of cash collateralized standby letters of credit outstanding. See Note 2 to our Consolidated Financial Statements included in this report for a discussion of Restricted Cash.

(10) 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. In exchange for the payment of $40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the Biogen Collaboration Agreement up to an agreed upon threshold of royalties. When this threshold is met, which we believe may occur in mid-2022, 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 Royalty Agreement does not include potential future milestones to be paid by Biogen.

Since the Company maintained rights under the Biogen Collaboration Agreement, 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 Royalty 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, 2021 and December 2020.

(In thousands)	December 31, 2021	December 31, 2020
Liability related to sale of future royalties - beginning balance	$ 15,257	$ 24,401
Deferred transaction costs amortized	234	401
Non-cash royalty revenue payable to HCRP	(12,106)	(11,486)
Non-cash interest expense recognized	1,075	1,941
Liability related to sale of future royalties - ending balance	$ 4,460	$ 15,257

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

(11) Corporate Restructuring

In January 2021 and September 2021, the Company announced corporate restructurings to reduce costs, more closely align operating expenses with expected revenue, and focus its resources on Inbrija. As part of the January 2021 restructuring, the Company reduced headcount by approximately 16% through a reduction in force (excluding the employees that transferred to Catalent at the closing of the sale of our Chelsea manufacturing operations). All of the reduction in personnel in

connection with the January 2021 restructuring took place during the three-month period ended March 31, 2021. As part of the September 2021 restructuring, the Company reduced headcount by approximately 15% through a reduction in force. Most of this reduction in force took place in September 2021, and it will be nearly complete in the first quarter of 2022.

For the years ended December 31, 2021 and 2020, the Company incurred pre-tax severance and employee separation related expenses of approximately $6.0 million and $0.3 million, respectively, associated with the restructuring. Of the pre-tax severance and employee separation related expenses incurred, $0.6 million and $0.3 million were recorded in research and development expenses and $5.4 million and $0 were recorded in selling, general and administrative expenses for the years ended December 31, 2021 and 2020, respectively.

A summary of the restructuring costs for the years ended December 31, 2021 and 2020 is as follows:

(In thousands)	Restructuring Costs
Restructuring Liability as of December 31, 2019	$ 1,264
2020 Restructuring costs	343
2020 Payments	(1,607)
Restructuring Liability as of December 31, 2020	$ —
2021 Restructuring costs	6,000
2021 Payments	(4,149)
Restructuring Liability as of December 31, 2021	$ 1,851

(12) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020
Product allowances accruals	$ 10,394	$ 14,969
Bonus payable	4,439	8,615
Accrued inventory	—	1,678
Sales force commissions and incentive payments payable	727	1,109
Administrative expenses	757	1,028
Vacation accrual	1,505	1,969
Research and development expense accruals	702	926
Commercial and marketing expense accruals	728	1,005
Royalties payable	264	727
Restructuring liability	1,851	—
Legal, accounting, and other professional services	1,325	564
Trade relations	706	697
Other accrued expenses	5,207	4,880
Total	$ 28,605	$ 38,167

(13) 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, 2021 and the effect such obligations are expected to have on the Company's liquidity and cash flow in future periods:

	Payments due by period (1) (3)			
(In thousands)	Total	Less than 1 year	1-3 years	4-5 years
Convertible Senior Notes (2)	$ 243,260	$ 12,420	$ 230,840	$ —
Operating leases (4)	13,439	8,354	2,468	2,617
Inventory purchase commitments (5) (6)	100,594	27,094	37,500	36,000
Total	357,293	47,868	270,808	38,617

(1) Excludes a liability for uncertain tax positions totaling $6.4 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 secured notes due 2024 issued in December 2019. The notes will mature and will be payable on December 31, 2024. Refer to Note 9.

(3) Excludes a liability for the non-convertible capital loans totaling $27.6 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 payments for the operating leases of the Company's Ardsley, NY headquarters, the Company's lab and office space in Waltham, MA, and excludes field auto leases which are for a one year term. Refer to Note 3.

(5) 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 the Company. Under the Company's supply agreement with Alkermes, it provides Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for the Company's 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. The Company has agreed 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 the Company.

(6) Represents minimum purchase commitment from Catalent for Inbrija under the manufacturing services (supply) agreement. An amendment to the agreement has been signed by the parties for the period July 1, 2021 through June 30, 2022, which eliminates the minimum purchase obligation by Acorda and states that payment shall only be required upon successful production and delivery of Inbrija by Catalent. The maximum payment amount Acorda shall be obligated to pay upon receipt of Inbrija product is $23.2 million less any payments previously made in 2021. Additionally, pursuant to the amendment, Acorda agreed that it would reimburse a portion of Catalent's costs in completing the installation and qualification of a larger size 7 spray dryer at the Chelsea manufacturing facility, which Acorda believes will be beneficial to its future production needs, in the amount of $1.5 million. This amount will be paid quarterly over a one-year period commencing no sooner than January 1, 2024.

License Agreements

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 $18.5 million over the life of the contracts.

Under certain agreements, the Company is required to pay royalties for the use of technologies and products in its 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. See Note 15 to our Consolidated Financial Statements included in this report for a discussion on license, research, and collaboration agreements.

Employment Agreements

The Company has, or has agreed to enter into, 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). The Company's contractual commitments table does not include these severance payment obligations.

Other

On November 9, 2020, Drug Royalty III, L.P., and LSRC III S.ar.l. (collectively, "DRI") filed an arbitration claim against the Company with the American Arbitration Association under a September 26, 2003 License Agreement that it originally entered into with Rush-Presbyterian St. Luke's Medical Center ("Rush"). DRI previously purchased license royalty rights under the license agreement from Rush. DRI alleges a dispute over the last-to-expire patent covering sales of the drug Ampyra under the license agreement, and is claiming damages based on unpaid license royalties of $6 million plus interest. The Company believe that it has valid defenses against this claim and intends to defend itself vigorously. While the Company is unable to determine the ultimate outcome of the dispute, the Company determined that it is probable that the Company may incur a liability related to the dispute which the Company estimated could be up to $2 million, inclusive of its legal costs. The Company recorded a liability of $2 million for the year ended December 31, 2020 in accrued expense and other current liabilities related to the dispute. However, the Company notes that depending upon the ultimate outcome of the dispute, the potential liability could be more or less than the amount recorded.

In addition to the arbitration described above, from time to time the Company is involved in litigation or other legal proceedings relating to claims arising out operations in the normal course of business. The Company has assessed all litigation and legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability or range of losses can be reasonably estimated. As a result, the Company did not record any loss contingencies for these other matters. Litigation expenses are expensed as incurred.

On February 10, 2021, the Company sold its Chelsea manufacturing operations to Catalent Pharma Solutions. In connection with the sale, we entered into a long-term, global manufacturing services (supply) agreement with a Catalent affiliate pursuant to which they have agreed to manufacture Inbrija for the Company at the Chelsea facility. The manufacturing services agreement provides that Catalent will manufacture Inbrija, to the Company's specifications, and the Company will purchase Inbrija exclusively from Catalent during the term of the manufacturing services agreement; provided that such exclusivity requirement will not apply to Inbrija intended for sale in China. Under the Company's agreement with Catalent, it is obligated to make minimum purchase commitments for Inbrija through the expiration of the agreement on December 31, 2030.

Under the manufacturing services agreement, we agreed to purchase from Catalent at least $16 million of Inbrija in 2021 (pro-rated for a partial year) and $18 million of Inbrija each year from 2022 through 2030, subject to reduction in certain cases. In December 2021, we and Catalent amended the manufacturing services agreement to adjust the structure of the minimum payment terms for the period from July 1, 2021 through June 30, 2022 (the "Adjustment Period"). Under the amendment, the minimum payment obligation for the Adjustment Period is replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to our original minimum purchase obligation for that period (i.e., $17 million), and with certain payments being made in the first half of 2022 instead of during the second half of 2021. As a result of the amendment, our cash balance at the end of 2021 reflected

approximately $5.3 million associated with this modified payment schedule. We have submitted a binding forecast for Inbrija batches for the Adjustment Period, the total cost of which may equal, but not exceed, the original payment obligation under the manufacturing services agreement.

Additionally, pursuant to the amendment, we agreed that we would reimburse a portion of Catalent's costs in completing the installation and qualification of a larger size 7 spray dryer at the Chelsea manufacturing facility, which we believe will be beneficial to our future production needs, in the amount of $1.5 million. This amount will be paid quarterly over a one-year period commencing no sooner than January 1, 2024.

The manufacturing services agreement contains customary representations, warranties and covenants, including with respect to the ownership of any intellectual property created pursuant to the manufacturing services agreement, as well as provisions relating to ordering, payment and shipping terms, regulatory matters, reporting obligations, indemnity, confidentiality and other matters.

During the year ended December 31, 2021, the Company incurred approximately $6.2 million of minimum purchase commitments with Catalent, which are recognized as cost of sales within the Company's consolidated statement of operations for the year. As of December 31, 2021, the minimum remaining purchase commitment to Catalent was $0 million through December 31, 2021, $9 million for the year-ended December 31, 2022, and $18.0 million annually each year thereafter.

(14) 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, 2021. 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, 2021 and December 31, 2020, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(In thousands)	Level 1	Level 2	Level 3
2021			
Assets Carried at Fair Value:			
Money market funds	$ 12,192	$ —	$ —
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	49,600
Derivative liability - conversion option	—	—	37
2020			
Assets Carried at Fair Value:			
Money market funds	$ 36,693	$ —	$ —
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	48,200
Derivative liability - conversion option	—	—	1,193

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, 2021	Year ended December 31, 2020
Acquired contingent consideration:		
Balance, beginning of period	$ 48,200	$ 80,300
Fair value change to contingent consideration (unrealized) included in the statement of operations	2,895	(30,889)
Royalty payments	(1,495)	(1,211)
Balance, end of period	$ 49,600	$ 48,200

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 $24 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, 2021, changes in the fair value of the acquired contingent consideration were primarily due to the change in projected revenue and the recalculation of cash flows for the passage of time, as well as a decrease in the discount rate. See Note 15 to our Consolidated Financial Statements included in this report for a discussion 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

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

(In thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Derivative Liability-Conversion Option		
Balance, beginning of period	$ 1,193	$ 59,409
Fair value recognized upon issuance of Convertible Senior Notes	—	—
Fair value adjustment	(1,156)	(39,959)
Fair value reclassification to shareholder's equity	—	(18,257)
Balance, end of period	$ 37	$ 1,193

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 9). 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 binomial model that calculates 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. There are several embedded features within the Notes which, upon issuance, did not meet the conditions for equity classification. As a result, these features were aggregated together and recorded as a derivative liability conversion option. The derivative liability conversion feature is measured at fair value on a quarterly basis and changes in the fair value will be recorded in the consolidated statement of operations. The Company received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company's common stock from 13,333,333 shares to 61,666,666 shares. As a result of the share approval, the Company determined that multiple embedded conversion options met the conditions for equity classification. The Company performed a valuation of these conversion options as of September 17, 2020, which was the date the Company completed certain securities registration obligations. The resulting fair value of these conversion options was $18.3 million, which was reclassified to equity and presented in the statement of stockholder's equity as of September 30, 2020, net of the $4.4 million tax impact. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The Company performed a valuation of the derivative liability related to certain embedded conversion features that are precluded from equity classification. The fair value of these conversion features was calculated to be negligible as of December 31, 2021.

(15) 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. 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 2021.

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.

In 2020 Biogen paid the Company $15 million based on achievement of a specified sales milestone (all subject to the Company's payment obligations to Alkermes under the Company's license agreement with them). The Company is entitled to receive additional payments from Biogen that exceed $300 million in the aggregate based on achievement of future regulatory and sales milestones, although the Company does not anticipate achievement of any of those milestones in the foreseeable future. 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.

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 14 – *Fair Value Measurements* for more information about the contingent consideration liability.

(16) Income Taxes

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

(In thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Domestic	$ (112,530)	$ (112,371)
Foreign	3,456	4,704
Total	$ (109,074)	$ (107,667)

The benefit (expense) from income taxes in 2021 and 2020 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Current:		
Federal	$ 230	$ 11,770
State	(182)	(184)
Foreign	(113)	(65)
	(65)	11,521
Deferred:		
Federal	4,412	(478)
State	711	(3,896)
Foreign	62	926
	5,185	(3,448)
Total benefit from income taxes	$ 5,120	$ 8,073

As of December 31, 2021, Acorda's U.S. consolidated tax return has a federal NOL carryforward of approximately $112.4 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 $121.6 million as of December 31, 2021. 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 $471.0 million is fully offset with a valuation allowance. The Company had available state NOL carryforwards of approximately $304.8 million and $267.0 million as of December 31, 2021 and 2020, 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 $48.2 million of net operating loss carryforwards outside of the U.S. as of December 31, 2021, that begin to expire in 2022 all of which are fully reserved with a valuation allowance.

The Company's U.S. Federal research and development and orphan drug credit carry-forwards of $35.3 million and $35.3 million as of December 31, 2021 and 2020, respectively, begin to expire in 2022. The Company does not expect to pay U.S. Federal or state cash taxes as they are in a current year taxable loss. The Company generated a tax liability for its operations in Puerto Rico.

The Internal Revenue Code of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. These provisions were unchanged by the Act. The Company's ability to utilize the NOL's may be further limited if it undergoes an ownership change, as defined in section 382 of the Code. This ownership change could be triggered by substantial changes in the ownership of the Company's outstanding stock, which are generally outside of its 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 the Company's stock, or are otherwise treated as 5% stockholders under

section 382 and the regulations promulgated thereunder, increase their aggregate percentage ownership of the Company's stock by more than 50 percentage points over the lowest percentage of the Company's 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 the Company's NOLs expiring unused. As of December 31, 2021, based on a completed IRC Section 382 analysis, the Company is not subject to a limitation.

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, 2021. The Company had a net increase of $6.8 million of valuation allowance.

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, 2021	Year ended December 31, 2020
U.S. federal statutory tax rate	21.0%	21.0%
State and local income taxes	0.4%	(3.0)%
Stock option compensation	(0.1)%	0.3%
Stock option shortfall	(5.0)%	(5.8)%
Research and development and orphan drug credits	—	(0.4)%
Uncertain tax positions	0.5%	0.1%
Other nondeductible and permanent differences	(2.6)%	(2.5)%
Valuation allowance, net of foreign tax rate differential	(9.5)%	(7.6)%
Tax effect of NOL carryback - CARES Act	—	5.4%
Effective income tax rate	4.7%	7.5%

The Company's overall effective tax rate is affected by the increase in the valuation allowance and the forfeitures of equity of which no tax deduction is recorded.

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, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforward	$ 77,510	$ 61,774
Capital loss carryforward	116,717	106,371
Tax credits	34,332	33,577
Stock based compensation	12,257	17,454
Contingent consideration	12,730	11,975
Employee compensation	1,513	2,638
Rebate and returns reserve	2,290	3,339
Capitalized R&D	10,696	11,564
Derivative liability	9	296
Asset impairment	—	14,384
Other	7,656	9,651
Total deferred tax assets	$ 275,710	$ 273,023
Valuation allowance	(193,253)	(186,491)
Total deferred tax assets net of valuation allowance	$ 82,457	$ 86,532
Deferred tax liabilities:		
Intangible assets	(83,930)	(88,547)
Convertible debt	(12,842)	(16,227)
Depreciation	400	(803)
Other	(15)	(72)
Total deferred tax liabilities	$ (96,387)	$ (105,649)
Net deferred tax liability	$ (13,930)	$ (19,117)

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, 2021	Year ended December 31, 2020
Beginning of period balance	$ 7,093	$ 7,145
Increases for tax positions taken during a prior period	—	—
Decreases for tax positions taken during a prior period	(723)	(52)
Increases for tax positions taken during the current period	—	—
	$ 6,370	$ 7,093

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 2018, however, such net operating losses utilized by the Company in years subsequent to 2002 are subject to review.

The Company was notified during the first quarter of 2021 that it is being audited by the state of Minnesota and Massachusetts for the tax years 2018 and 2019. There have been no proposed adjustments at this stage of the examination.

The Company also has an ongoing state examination in New Jersey for the tax periods, 2015 through 2018. There have been no proposed adjustments at this stage of the examination. The Minnesota examinations for 2016 and 2017 were closed during 2021 with no changes.

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, 2020	$ 177,572	8,964	(45)	$ 186,491
Year ended December 31, 2021	$ 186,491	10,028	(3,266)	$ 193,253

(17) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2021 and 2020:

(In thousands, except per share data)	Year ended December 31, 2021	Year ended December 31, 2020
Basic and diluted		
Net loss	$ (103,954)	$ (99,594)
Weighted average common shares outstanding used in computing net loss per share—basic	10,621	8,084
Plus: net effect of dilutive stock options and unvested restricted common shares	—	—
Weighted average common shares outstanding used in computing net loss per share—diluted	10,621	8,084
Net loss per share—basic	$ (9.79)	$ (12.32)
Net loss per share—diluted	$ (9.79)	$ (12.32)

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, 2021	Year ended December 31, 2020
Denominator		
Stock options and restricted common shares	1,199	1,356

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, 2021 and 2020.

(18) 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 $0.9 million and $1.6 million for the years ended December 31, 2021 and 2020, respectively.

(b) Exhibits.

The following Exhibits are incorporated herein by reference or are filed with this Annual Report on Form 10-K as indicated below. Except as specified below, all exhibits incorporated herein by reference have been filed under the Company's former and current SEC File Numbers 000-50513 and 001-31938, respectively.

Exhibit No.	Description
1.1	At The Market Offering Agreement, dated January 13, 2021, between the Registrant and H.C. Wainwright & Co., LLC. Incorporated herein by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed January 13, 2021.
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	Certificate of Amendment of Amended and Restated Certificate of Incorporation dated August 31, 2020. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed August 31, 2020.
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation dated December 31, 2020. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed December 31, 2020.
3.4	Bylaws of the Registrant, as amended and restated on January 12, 2021. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 13, 2021.
4.1	Specimen stock certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K filed on March 16, 2021.
4.2	Description of Common Stock. Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K filed on March 16, 2021.
4.3	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 herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
4.4	Form of 6.00% Convertible Senior Secured Note due 2024 (included in Exhibit 4.3). Incorporated herein 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.
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.

Exhibit No.	Description
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 2016 Inducement Plan.
10.11*	Form of stock option certificate under the Acorda Therapeutics 2016 Inducement Plan.
10.12*	Acorda Therapeutics, Inc. 2019 Employee Stock Purchase Plan. Incorporated herein by reference to Appendix A to the Registrant's 2019 Proxy Statement filed as Schedule 14A on April 26, 2019.
10.13*	Employment letter 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.
10.14*	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.
10.15*	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.
10.16*	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.
10.17*	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.
10.18*	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.
10.19*	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.
10.20*	Employment letter 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.

Exhibit No.	Description
10.21*	Amendment dated January 6, 2022, to June 8, 2015 Employment Agreement by and between the Registrant and Lauren Sabella.
10.22*	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.
10.23*	Employment letter 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.
10.24*	Separation Agreement and General Release dated December 31, 2021, by and between the Registrant and Burkhard Blank, M.D.
10.25*	Master Consulting Agreement, dated as of January 1, 2022, and Schedule #1 under the Master Consulting Agreement, by and between the Registrant and Burkhard Blank, M.D.
10.26*	Employment letter agreement, dated as of September 1, 2020, by and between the Registrant and Kerry Clem. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 9, 2021.
10.27*	Employment offer letter, dated November 4, 2021, by and between the Registrant and Michael Gesser.
10.28*	Employment offer letter, dated November 4, 2021, by and between the Registrant and Neil Belloff.
10.29	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.
10.30	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.
10.31	First Amendment to Lease, dated as of May 21, 2015, by and between BMR-Ardsley Park LLC and the Registrant. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2015.
10.32	Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.33**	Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.34	Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.35**	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.

Exhibit No.	Description
10.36**	Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.37	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.
10.38	Amendment No. 2 to Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated March 29, 2012. Incorporated herein by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K filed on February 28, 2013.
10.39	Amendment No. 3 to the Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated February 14, 2013. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013.
10.40**	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.
10.41**	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.
10.42**	Addendum Number 3 to Collaboration and License Agreement and to Supply Agreement between the Registrant and Biogen Idec International GmbH dated February 14, 2013. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013.
10.43**	Amended and Restated Addendum #2 effective June 6, 2016 to the Supply Agreement between the Registrant and Biogen Idec International GmbH dated June 30, 2009, as Amended. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2016.
10.44**	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.
10.45**	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.
10.46**	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.
10.47	Security Agreement, dated as of December 23, 2019, from the grantors named therein to Wilmington Trust, National Association, as collateral agent. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed December 26, 2019.
10.48	Registration Rights Agreement, dated as of December 20, 2019, among the Registrant and the investors party thereto. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed December 26, 2019.

Exhibit No.	Description
10.49***	Asset Purchase Agreement, dated as of January 12, 2021, by and between the Registrant and Catalent Pharma Solutions, Inc. Incorporated herein by reference to Exhibit 10.49 to the Registrant's Annual Report on Form 10-K filed on March 16, 2021.
10.50***	Manufacturing Services Agreement, dated February 10, 2021, by and between the Registrant and Catalent Massachusetts LLC. Incorporated herein by reference to Exhibit 10.50 to the Registrant's Annual Report on Form 10-K filed on March 16, 2021.
10.51***	First Amendment to Manufacturing Services Agreement dated as of October 28, 2021, by and between the Registrant and Catalent Massachusetts, LLC.
10.52***	Second Amendment to Manufacturing Services Agreement dated as of December 31, 2021, by and between the Registrant and Catalent Massachusetts, LLC.
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).

* Indicates management contract or compensatory plan or arrangement.

** Portions of this exhibit are redacted pursuant to a confidential treatment order granted by 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.

*** Portions of this exhibit are redacted because they both are not material and it would be competitively harmful if publicly disclosed.

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 18th day of March, 2022.

ACORDA THERAPEUTICS, INC.

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

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

Signature	Title	Date
/s/ RON COHEN, M.D. Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2022
/s/ Michael Gesser, M.B.A. Michael Gesser, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accouning Officer)	March 18, 2022
/s/ PEDER K. JENSEN, M.D. Peder K. Jensen, M.D.	Director	March 18, 2022
/s/ JOHN P. KELLEY John P. Kelley	Director and Chair	March 18, 2022
/s/ SANDRA PANEM, PH.D. Sandra Panem, Ph.D.	Director	March 18, 2022
/s/ LORIN J. RANDALL Lorin J. Randall	Director	March 18, 2022
/S/ JOHN VARIAN John Varian	Director	March 18, 2022

Exhibit 21

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.

Exhibit 23

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. 333-248738) of Acorda Therapeutics, Inc.,
(2) Registration Statement (Form S-3 No. 333-248728) of Acorda Therapeutics, Inc.,
(3) Registration Statement (Form S-3 No. 333-239519) of Acorda Therapeutics, Inc.,
(4) Registration Statement (Form S-3 No. 333-235929) of Acorda Therapeutics, Inc.,
(5) Registration Statement (Form S-8 No. 333-233177) pertaining to the 2019 Employee Stock Purchase Plan of Acorda Therapeutics, Inc.,
(6) 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.,
(7) 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.,
(8) Registration Statement (Form S-8 No. 333-210813) pertaining to the 2016 Inducement Plan of Acorda Therapeutics, Inc., and
(9) 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 March 18, 2022, 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, 2021.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 18, 2022

Exhibit 31.1

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: March 18, 2022

/s/ Ron Cohen
Ron Cohen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO

RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Michael Gesser, 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: March 18, 2022

/s/ Michael Gesser
Michael Gesser
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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, 2021 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
RON COHEN
Chief Executive Officer
(Principal Executive Officer)
March 18, 2022

[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.]

Exhibit 32.2

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Gesser, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL GESSER
MICHAEL GESSER
Chief Financial Officer
(Principal Financial Officer)
March 18, 2022

[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.]