ANNUAL REPORT 2022

LETTER FROM THE CEO

Dear Fellow Shareholder:

Our operating and financial performance improved progressively in 2022, following the large negative impact of the COVID-19 Omicron wave on our business in the first quarter. Beginning in the second quarter and continuing into early 2023, we achieved a stream of successes, including:

- Met 2022 guidance for AMPYRA® (dalfampridine) and INBRIJA® (levodopa inhalation powder) U.S. net sales
- Met OpEx guidance, reducing operating expenses by $23 million over 2021, and by $64 million since 2020
- Received an $18.3 million arbitration award from Alkermes regarding AMPYRA and a dramatic lowering of cost of goods, including an expected reduction of $10 - 12 million in 2023
- Double-digit, tiered Ex-U.S. royalties on FAMPYRA reverted to Acorda after our obligation to Healthcare Royalty Partners was fulfilled
- Our commercial partner Esteve launched INBRIJA in Germany and Spain
- Entered into a commercialization agreement with Biopas for INBRIJA in the nine largest Latin American markets
- Re-negotiated our INBRIJA manufacturing agreement, significantly reducing our cost of goods
- Made our December 2022 debt interest payment in cash, not stock
- Received an extension from Nasdaq until June 20, 2023 to return to compliance with listing requirements

ACHIEVED 2022 GUIDANCE FOR AMPYRA, INBRIJA

For 2022, AMPYRA U.S. net sales were $72.9 million, within our guidance range of $71 - $73 million, and INBRIJA U.S. net sales were $28 million, within our range of $27 - $28 million.

CONTINUED TO EXERCISE FISCAL DISCIPLINE

In 2022, we continued to reduce operating expenses to align our expenses with revenue. Adjusted operating expenses, which include R&D and SG&A, ("OpEx"), were $112 million, within our range of $110 - $113 million. This was a $23 million reduction over 2021 and a $64 million reduction since 2020. As part of this effort we relocated our corporate headquarters to a substantially smaller space, saving approximately $4.7 million per year. In 2023, we expect to reduce operating expenses further.

AMPYRA ARBITRATION AWARD

In October 2022, an arbitration panel issued a final decision in a dispute between Acorda and Alkermes regarding licensing royalties for AMPYRA. We were awarded a total of $18.3 million, including interest. In addition, we will no longer have to pay Alkermes any royalties on net sales for license and supply of AMPYRA, and we have secured an alternative, less expensive source for supply. This award significantly reduces our cost of goods for AMPYRA, and increases its value to us meaningfully. Based on our current projections, we expect savings of $10 to $12 million in reduced cost of goods in 2023 alone.

INCREASED EX-U.S. REVENUE FROM COMMERCIAL LAUNCHES OF INBRIJA AND FROM FAMPYRA ROYALTIES

In June 2022, Esteve launched INBRIJA in Germany, the largest pharmaceutical market in Europe and fourth largest in the world. Esteve also launched INBRIJA in Spain in February 2023. Acorda receives a significant double-digit percent of the selling price of INBRIJA in both countries in exchange for supply of the product, and received $2.9 million for 2022. We are in active discussions with several parties to commercialize INBRIJA in additional countries around the world.

FAMPYRA is the ex-U.S. version of AMPYRA and is marketed by Biogen, which has worldwide rights to commercialize it outside the U.S. In late June 2022, our obligation to Healthcare Royalty Partners was fulfilled, and the double-digit, tiered royalties for FAMPYRA, reverted to Acorda. We received $11.7 million in FAMPYRA royalties in 2022. In addition, Biogen launched FAMPYRA in China in mid-2022.

RENEGOTIATED OUR INBRIJA MANUFACTURING AGREEMENT WITH CATALENT

In January 2023, we announced that we renegotiated our INBRIJA manufacturing agreement with Catalent. The new agreement significantly reduces the annual minimum purchase requirements for INBRIJA in 2023 and 2024. Beginning in 2025, we will pay a fixed, per-capsule fee based on the amount of INBRIJA needed worldwide, which we expect will result in a substantial further reduction in our cost of goods. By 2026, we expect an expansion in Catalent's manufacturing capacity to further reduce our per-capsule costs.

DECEMBER 2022 DEBT PAYMENT PAID WITH CASH, NOT STOCK

We made the December 2022 interest payment on our Convertible Senior Secured Notes Indenture of approximately $6.2 million in cash, rather than in stock, which would have been dilutive to shareholders. The June 2023 interest payment will be the last for which there would be an option to make the payment in stock; while the board is not required to make a formal decision regarding that payment until closer to the due date, we currently do not have enough available stock to make that payment with shares at the current stock price. We have maintained open lines of communication with our bondholders, and our leadership team and Board are considering various options for addressing the debt that comes due at the end of 2024.

RECEIVED AN EXTENSION FROM NASDAQ TO ACHIEVE COMPLIANCE WITH LISTING REQUIREMENTS

In December, we submitted a request to the Nasdaq Hearings Panel for an extension to regain compliance with Nasdaq's minimum $1 bid price requirement for remaining listed on the Nasdaq Global Select Market. The panel granted us an extension until June 20, 2023. If our share price does not meet the minimum requirement by the extension deadline, the Board has the ability to implement a reverse stock split to regain compliance, as authorized by a shareholder vote in November 2022.

2023 PRIORITIES

In 2023, we plan to build on the progress we made in 2022, focusing on the following priorities to create long-term value for shareholders:

- Further accelerate INBRIJA's commercial growth in the U.S., taking advantage of the new post-COVID-19 environment with several new commercial programs, including:
  - o New messaging that conveys the emotional burdens of OFF periods on people with Parkinson's ("PWP") and their care partners
  - o A television commercial that is being streamed on 50 streaming services, directed to PWP and their care partners
  - o "Surround sound" messaging via increased digital and social media promotion
- Enter into partnerships for ex-U.S. commercialization of INBRIJA in additional countries
- Support branded AMPYRA by continuing to call on multiple sclerosis practices and maintain patient support resources
- Continue to operate with strong financial discipline
- Seek partnerships to develop new inhaled biopharmaceutical candidates with the ARCUS® technology platform

BOARD OF DIRECTORS

Jeff Randall, who has served on our Board since 2006, and currently serves as Chair of the Audit Committee, will be rotating off the Board as of our June 2023 Annual Meeting. We are delighted that Tom Burns, CFO of XOMA Corporation, has accepted our invitation to stand for election to the Board at that meeting.

On behalf of the Board, Acorda's associates, stockholders, and other stakeholders, I want to recognize Jeff for his devoted service and wise guidance, which have contributed significantly to our successes. We are deeply grateful.

On behalf of our Leadership Team, Board of Directors, and our associates, thank you for your continued support. We look forward to updating you on our further progress in 2023.

RON COHEN, M.D.
PRESIDENT AND CEO

This letter contains forward-looking statements. Forward-looking statements are statements that are not historical facts and are identified by the words "expects," "anticipates," "believes," "intends," "estimates," "aims," "plans," "will," "will continue," "seeks," "outlook," and similar expressions. Forward-looking statements are based on current plans, estimates, assumptions, and projections, and therefore you should not place too much reliance on them. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events. We caution you that actual results or outcomes may differ materially from those expressed in, or implied by, the forward-looking statements as a result of the impact of a number of important factors, as well as other known and unknown risks and uncertainties, or if the assumptions underlying any of these statements prove incorrect. Certain of these factors are discussed in more detail in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2022

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.)**
2 Blue Hill Plaza, 3rd Floor, Pearl River, New York	**10965**
(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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was $11,236,872. 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, 2022. 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 10, 2023, the registrant had 24,337,696 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 2023 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2022. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

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

ACORDA THERAPEUTICS, INC.
2022 FORM 10-K ANNUAL REPORT
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This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: We may not be able to successfully market 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 and take other actions which are necessary for us to continue as a going concern; the impact of the failure of Silicon Valley Bank and its proposed resolution; risks associated with the trading of our common stock and our credit agreements, including the potential delisting of our common stock from the Nasdaq Global Select Market which could result in a default under the indenture dated as of December 23, 2019 for Acorda's 6.00% convertible senior secured notes, and could prevent the implementation of our business plan, and the success of actions that we may take, such as a reverse stock split, in order to attempt to maintain such listing and avoid a default; risks related to the successful implementation of our business plan, including the accuracy of our key assumptions; 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.; our ability to satisfy our obligations to distributors and collaboration partners outside the U.S. relating to commercialization and supply of INBRIJA and AMPYRA; 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 disclaim any intent or obligation to 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

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. 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 to improve walking in adults with multiple sclerosis.

Our Products

Inbrija/Parkinson's Disease

Inbrija is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF periods in people with Parkinson's disease treated with a 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 92% of commercially insured lives and approximately 18% of Medicare plan lives. U.S. net revenue for Inbrija was $28.0 million for the year ended December 31, 2022.

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 labeled 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. We have entered into agreements to commercialize Inbrija in Spain, Germany, and Latin America, and we are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S. Net revenues for ex-U.S. Inbrija sales in Germany were $2.9 million for the year ended December 31, 2022.

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 continue to discuss the use of ARCUS with companies that express interest in formulating their novel molecules for pulmonary delivery, and we have performed 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 $72.9 million for the year ended December 31, 2022.

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, which could have a material adverse effect on royalty revenue from Biogen. For example, we understand that a generic drug manufacturer that has sought to invalidate Fampyra patents in Germany through nullity proceedings has commenced a generic launch in Germany. See *Legal Proceedings* in Part I, Item 3 of this report for more information.

Sale of Chelsea Manufacturing Operations and Catalent MSA

On February 10, 2021, the Company sold its Chelsea manufacturing operations to Catalent Pharma Solutions. In connection with the sale, the Company entered into a long-term, global manufacturing services (supply) agreement (the "2021 MSA") with a Catalent affiliate pursuant to which they agreed to manufacture Inbrija for the Company at the Chelsea facility. The 2021 MSA provided that Catalent would manufacture Inbrija, to the Company's specifications, and the Company would purchase Inbrija exclusively from Catalent during the term of the 2021 MSA; provided that such exclusivity requirement will not apply to Inbrija intended for sale in China. Under the 2021 MSA, the Company was obligated to make minimum purchase commitments for Inbrija of $18 million annually through the expiration of the agreement on December 31, 2030.

In December 2021, the Company and Catalent amended the 2021 MSA 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 was replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to its 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, payments to Catalent for product delivered during the Adjustment Period were approximately $8.4 million less than the $17 million minimum inventory purchase obligation for that period. During the year ended December 31, 2022, we incurred approximately $18.7 million of purchase commitments with Catalent, of which $11.5 million are recognized as inventory within our balance sheet, $3.3 million are recognized as other current assets within our balance sheet and $3.9 million are recognized as cost of sales within our consolidated statement of operations for the period.

On December 31, 2022, we and Catalent entered into a termination letter, which was subsequently amended and restated in March 2023 (the "Termination Letter") to terminate the 2021 MSA. In connection with the termination of the 2021 MSA, we will pay a $4 million termination fee to Catalent, payable in April 2024. The parties also entered into a Settlement and Release Agreement with respect to certain batches of Inbrija that were not delivered in 2022 as scheduled, and are to be delivered in the first quarter of 2023, and to resolve all other outstanding manufacturing issues.

Effective January 1, 2023, we entered into a new manufacturing services agreement (as amended in March 2023, the "New MSA") with Catalent. Under the New MSA, Catalent will continue to manufacture Inbrija (levodopa inhalation powder) through 2030, with reduced minimum annual commitments through 2024 and significantly lower pricing thereafter. The New MSA provides for the scale-up of new spray drying equipment ("PSD-7"), which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija, and is expected to be operational in 2026. In March 2023, we amended the New MSA to adjust certain payment obligations. Under the New MSA, we will be subject to purchase commitments in 2023 and 2024 of 15 and 24 batches of Inbrija, respectively, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, we will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets. In addition, we will be obligated to pay Catalent $2 million in 2023 in connection with certain activities related to the operational readiness of the PSD-7.

It is anticipated that by 2026, the PSD-7 equipment will be fully operational, which will significantly reduce the per capsule fees for all markets. We have agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition to the operational readiness payment described above, we will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts.

The New MSA, 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 with at least 18-months' prior written notice of non-renewal. Either party may terminate the New MSA by written notice under certain circumstances, including material breach (subject to specified cure periods) or insolvency. We may also terminate the New MSA upon specified regulatory events and for convenience upon 180 days' prior written notice.

We agreed to purchase from Catalent all of our requirements for Inbrija for the United States, Germany, Spain and Latin America, except in the case of termination or certain supply disruptions. For China, we are not required to purchase our supply from Catalent and may arrange for an alternate supplier. For other countries, we may be released from exclusivity as long as we purchase at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source of supply arrangements.

The foregoing descriptions of the New MSA, the Termination Letter and the Settlement and Release Agreement do not purport to be complete and are qualified in their entirety by reference to such documents, which are filed as exhibits to this report.

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 in 2021 remained outstanding, but we repaid these notes at maturity on June 15, 2021 using cash on hand. Based on the current market price of our common stock and our remaining authorized shares of common stock that are not reserved for other purposes, we believe that for the foreseeable future we will be unable to make interest payments on the 2024 notes in stock. More information about the terms and conditions of the 2024 convertible notes is set forth in Note 8 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 September 2021, we exercised our early termination option (the "Early Termination Option") under our lease for our corporate headquarters in Ardsley, N.Y. In connection with the lease termination, we paid an early termination fee of approximately $4.7 million in June 2022 and relocated our corporate headquarters to a substantially smaller subleased office in Pearl River, New York.

As of December 31, 2022, we had cash, cash equivalents, and restricted cash of approximately $44.7 million. Restricted cash includes $6.2 million in escrow related to the 6% semi-annual interest portion of our convertible senior secured notes due June 2024, which interest is payable in cash or stock. If we elect to pay interest due in stock, a corresponding amount of restricted cash will be released from escrow. In connection with the June 1, 2022 interest payment on the 2024 notes, we issued an aggregate of 10,992,206 shares of common stock to holders of the notes and, to certain holders who delivered beneficial ownership limitation notices under the indenture governing the 2024 notes, cash interest payments of $0.9 million. In connection with the interest payment, $6.2 million was released from escrow and became available to us for other purposes. In connection with the December 1, 2022 interest payment of the 2024 notes we paid $6.2 million from restricted escrow cash. Based on the current market price of our common stock and our remaining authorized shares of common stock that are not reserved for other purposes, we believe that for the foreseeable future we will be unable to make interest payments on the 2024 notes in 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, including disruptions to the delivery of patient healthcare; for example, the pandemic has made it more difficult for some patients to visit with their physician and obtain pharmaceutical 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 have continued to impact prescriptions in 2022, particularly in the first quarter due to the surge in COVID-related cases.

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. 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 2023, 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 collaboration partners.

- **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	FDA, U.K., and EMA-approved; marketed in the U.S. by Acorda; Esteve launched in Germany in June 2022, Spain in February 2023	Acorda/Worldwide; rights granted to Esteve in Germany and Spain; seeking collaborators for commercialization in other countries outside the U.S.
Ampyra (dalfampridine)	Multiple Sclerosis	FDA-approved and marketed in the U.S. by Acorda	Acorda (U.S.)
Fampyra* (fampridine)	Multiple Sclerosis	Approved in a number of countries across Europe, Asia and the Americas	Biogen (outside the U.S.)

* In June 2022, Fampyra royalty financing obligation to HealthCare Royalty Partners had been satisfied.

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 research programs, we continue to discuss potential collaborations with companies that express interest in formulating their novel molecules for pulmonary delivery using ARCUS, and we have performed 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 the 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 1,000,000 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. Inbrija became commercially available in the U.S. in February 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 92% of commercially insured lives and approximately 18% of Medicare plan lives. U.S. net revenue for Inbrija was $28.0 million for the year ended December 31, 2022.

In September 2019, 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 labeled 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.

We have entered into agreements to commercialize Inbrija in Spain, Germany, and Latin America, and we are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S. In 2021, we entered into exclusive distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany. Under the terms of the Germany distribution agreement, in 2021 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 Inbrija selling price in exchange for supply of the product. Esteve launched Inbrija in Germany in June 2022 and in Spain in February 2023. Net revenues for ex-U.S. Inbrija sales in Germany were $2.9 million for the year ended December 31, 2022.

Also, in May 2022, we announced that we entered into exclusive distribution and supply agreements with Pharma Consulting Group, S.A. (known as Biopas Laboratories), or Biopas, to commercialize Inbrija in nine countries within Latin America, including Brazil and Mexico. Under the terms of the Biopas agreements, we are entitled to receive a significant double-digit, tiered percentage of the Inbrija selling price in exchange for supply of the product, and we are entitled to sales-based milestones. Biopas expects to commence sales in at least one country in early 2024.

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 2024 and 2032. Inbrija was also entitled to three years of new product exclusivity in the U.S. that expired in December 2021. We have patents in Europe for Inbrija expiring in 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 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, we suspended work on ARCUS and other proprietary research and development programs. However, we continue to discuss potential collaborations with companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and we have performed 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 or another supplier is willing to manufacture the product 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 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 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 $72.9 million for the year ended December 31, 2022.

Prior to October 2022, our primary source of supply of Ampyra was provided through a manufacturing and license agreement with Alkermes plc. In July 2020, we filed an arbitration demand with the American Arbitration Association against Alkermes after the parties were unable to resolve a dispute over license and supply royalties following the 2018 invalidation of an Alkermes patent relating to Ampyra. In October 2022, an arbitration panel issued a final decision in this dispute and awarded to us $15 million plus prejudgment interest of $1.5 million. In November 2022, the arbitration panel corrected a calculation error and awarded us an additional $1.6 million plus prejudgment interest of approximately $0.2 million. In addition, as a result of the panel's ruling, we will no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we are now free to use alternative sources for supply of Ampyra, which we have already secured. We expect the cost savings associated with this decision to greatly benefit the product's value to us and lower our overall cost of goods sold. For information regarding a recent action by us to modify the arbitration award, see *Legal Proceedings* in Part 1, Item 3 of this report.

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. Biogen recently initiated a commercial launch of Fampyra in China, after receiving approval from the Chinese National Medical Products Administration in 2021. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen. The Germany nullity actions are further described in the *Legal Proceedings* section of this report. Fampyra currently faces generic competition in Germany, notwithstanding that the Germany Fampyra Patents remain in effect, and challenges to the Fampyra patents could lead to additional generic competition with Fampyra in Germany and other countries, which could have a material adverse effect on our royalty revenue from Biogen.

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, as described in Note 9 to our Consolidated Financial Statements included in this report. This threshold was met during the second quarter of 2022 and our obligations to HCRP expired upon Biogen's payment of royalties for that quarter. Accordingly, we have been receiving the full benefit of royalties on net sales of Fampyra since June 2022.

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, generic drug manufacturers may seek to challenge Fampyra's European patents within individual European countries, and Fampyra could potentially face competition from those generic drug manufacturers. For example, a generic drug manufacturer that has sought to invalidate Fampyra patents in Germany through nullity proceedings, as described in the *Legal Proceedings* section of this report, has commenced a generic launch in Germany even though the patents have not been invalidated. Several other generics have been approved in Germany, one of which has commenced commercial launch, and there are also several generics that have taken steps to potentially initiate a generic launch in other European countries although the patents have not been invalidated in those jurisdictions either.

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 specialty pharmacies, including those associated with our e-prescribing program described below, such as 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), a specialty distributor. In 2022, we implemented an e-prescribing program for the distribution of Inbrija in the U.S. through a specialty pharmacy that supports electronic prescriptions. 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 efficacy and tolerability 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, and we have a cash pay program allowing reduced costs for eligible cash paying patients.

Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 92% of commercially insured lives and approximately 18% 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.

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 (the "Collaboration Agreement"), 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, which could have a material adverse effect on our royalty revenue from Biogen. See *Legal Proceedings* in Part I, Item 3 of this report for more information.

We have also entered into a related supply agreement with Biogen (the "Supply Agreement") concurrently with the Collaboration Agreement pursuant to which we are obligated to supply Biogen with its requirements for the licensed products. 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.

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 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, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. This threshold was met during the second quarter of 2022 and our obligations to HCRP expired upon Biogen's payment of royalties for that quarter. Accordingly, we have been receiving the full benefit of royalties on net sales of Fampyra since June 2022.

Biogen is obligated to purchase all of Biogen's, its affiliates' and its sublicensees' requirements of the licensed products from us, unless we permit alternative sourcing of supply. 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 any existing agreements with Alkermes. In October 2022, an arbitration panel issued a decision in our dispute with Alkermes and awarded to us approximately $18.3 million including prejudgment interest and subsequent correction of an error in calculating the initial award. In addition, as a result of the panel's ruling, we no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we are free to use alternative sources for supply of Ampyra, which we have already secured for U.S. supply. However, the arbitration panel also ruled that the existing license and supply agreements with Alkermes are unenforceable. Accordingly, absent a new supply agreement with Alkermes or another supplier, we will not be able to exclusively supply Fampyra to Biogen under the terms of our supply arrangement with them. While we have engaged in discussions with Biogen relating to the supply of Fampyra, there can be no assurance that such discussions will result in a continuation of supply by us, Alkermes or a third party manufacturer. If Biogen is unable to obtain supply of the licensed product, it could constitute a breach under the existing supply agreement with Biogen resulting in termination of the license and supply agreements with Biogen or otherwise result in the cessation of sales of Fampyra and loss of royalty revenue in the future.

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. While the license agreement was declared unenforceable by the arbitration panel as previously described, it has not been deemed to be terminated. 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 by us, we will waive our exclusive supply right to permit Biogen to negotiate terms with Alkermes or another supplier 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 was 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. However, as mentioned above, in October 2022, an arbitration panel issued a decision in our dispute with Alkermes and ruled that the existing license and supply agreements with Alkermes are unenforceable. Accordingly, absent a new supply agreement with Alkermes or another supplier, we will not be able to exclusively supply Fampyra to Biogen under the terms of our supply arrangement with them. While we have engaged in discussions with Biogen relating to the supply of Fampyra, there can be no assurance that such discussions will result in a continuation of supply by us, Alkermes or a third party manufacturer. If Biogen is unable to obtain supply of the licensed product could constitute a breach under the existing supply agreement with Biogen resulting in termination of the license and supply agreements with Biogen or otherwise result in the cessation of sales of Fampyra and loss of royalty revenue in the future.

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.

Catalent Manufacturing Services Agreement

In connection with the sale of our Chelsea manufacturing operations to Catalent in February 2021, we entered into the 2021 MSA pursuant to which Catalent has agreed to manufacture Inbrija for us at the Chelsea facility. The 2021 MSA

provided that Catalent will manufacture Inbrija to our specifications, and we would purchase Inbrija exclusively from Catalent during the term of the agreement; provided that such exclusivity requirement would not apply to Inbrija intended for sale in China.

Under the 2021 MSA, 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 inventory 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 payments to Catalent for product delivered during the Adjustment Period were approximately $8.4 million less than the $17 million minimum inventory purchase obligation for that period. 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.

On December 31, 2022, we terminated the 2021 MSA and entered into the New MSA effective January 1, 2023. Under the New MSA, Catalent will continue to manufacture Inbrija under a long-term manufacturing agreement under which Catalent will manufacture Inbrija on an exclusive basis (with the potential exclusion of Inbrija for sale in China) at the Chelsea manufacturing facility.

The New MSA provides for the scale-up of a larger size 7 spray dryer ("PSD-7") at the Chelsea manufacturing facility, which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija. The Company will be subject to purchase commitments of at least 15 batches on the size 4 spray dryer in 2023 and at least 24 batches on the size 4 spray dryer in 2024, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, the Company will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets. For China, we are not required to purchase our supply from Catalent and may arrange for an alternate supplier. For other countries, we may be released from exclusivity as long as we purchase at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source supply arrangements. It is anticipated that by 2026, the PSD-7 equipment will be fully operational, which will significantly reduce the per capsule fees for all markets. The Company has agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition, the Company will pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the PSD-7 and will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts at the Chelsea manufacturing facility.

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

The Company agreed to purchase from Catalent all of its requirements for Inbrija for the United States, Germany, Spain and Latin America except in the case of termination or certain supply disruptions. For China, the Company is not required to purchase its supply from Catalent and may arrange for an alternate supplier. For other countries, the Company may be released from exclusivity as long as it purchases at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source of supply arrangements.

The New MSA 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 performed 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 New MSA 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 blistered capsule supplier, is responsible for all Inbrija components other than certain packaging components, the inhaler device and levodopa, or L-dopa, the active pharmaceutical ingredient, or API, in Inbrija. Although in some cases we have contracts for these requirements, we cannot be certain that those contracts will be renewed on commercially reasonable terms, if at all. We do not have contracts with the 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

In October 2022, an arbitration panel issued a decision in our dispute with Alkermes and ruled that the existing license and supply agreements with Alkermes are unenforceable. As a result of the panel's ruling, we no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we are free to use alternative sources for supply of Ampyra, which we have already secured for U.S. supply.

We had previously 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. Patheon now supplies us with our Ampyra needs.

On September 30, 2010, we entered into a world-wide manufacturing services agreement with Patheon, Inc. as a second manufacturer for Ampyra (Dalfampridine-ER tablets, 10mg). Under the manufacturing services agreement, we agreed to purchase from Patheon, on a non-exclusive basis, a portion of our requirements for Ampyra in the United States. The Company pays Patheon a fixed per bottle fee (60 tablets per bottle) based on the annual quantity of Ampyra bottles that are delivered for sale. As a result of the arbitration ruling in October 2022, we were free to obtain supply of Ampyra from alternative sources and Patheon became our sole manufacturer and packager of Ampyra for sales in the United States.

The manufacturing services agreement is automatically renewed for successive one-year periods on December 31 of each year, unless either we or Patheon provide the other party with at least 12-months' prior written notice of non-renewal. Either party may terminate manufacturing services agreement by written notice under certain circumstances, including material breach (subject to specified cure periods) or insolvency. We may also terminate the manufacturing services agreement upon certain regulatory actions or objections. Patheon may terminate the manufacturing services agreement if we assign the agreement to a third party under certain circumstances.

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 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. 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.

Intellectual Property

We have patent portfolios relating to: Inbrija (levodopa inhalation powder); Ampyra/aminopyridines; and the ARCUS drug delivery technology. 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 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 U.S. and foreign patents relating to Inbrija and the ARCUS drug delivery technology, including several issued U.S. patents relating to Inbrija directed to compositions of the drug product and the capsule for the drug product. We have several patents listed in the Orange Book for Inbrija, including patents expiring between 2024 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 in 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 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 oral hearings in February 2022 and April 2022, the German Patent Court dismissed ratiopharm's action against the '536 patent and the '548 patent, respectively, as inadmissible because of ongoing formality proceedings relating to these patents in the European Patent Office. Ratiopharm has appealed the decision on the '536 patent but not the decision on the '548 patent, and could refile the nullity actions. On December 6, 2022, the German Federal Court of Justice held that ratiopharm's '536 nullity action was admissible and remanded the case back to the German Federal Patent

Court. On January 11, 2022, Stada Arzneimittel also filed a nullity action against the ‘536 patent, and on July 27, 2022, Teva GmbH also filed a nullity action against the ‘548 patent, both in the same court as the ratiopharm nullity actions. On January 27, 2023, the German Federal Patent Court issued a preliminary opinion in the ‘548 Teva nullity action that the claimed subject matter of the ‘548 patent lacked inventive step and scheduled a hearing for July 11, 2023. We are working with Biogen to vigorously defend these actions and enforce our patent rights. See *Legal Proceedings* in Part I, Item 3 of this report for more information.

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 episodes, also known as OFF periods. 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, approved in May 2020, 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 AbbVie, 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, Ponvory from Janssen (a Johnson & Johnson company), and Zeposia from Bristol-MyersSquibb.

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 do not have any active development programs for new potential drug products, however we continue to discuss potential collaborations with other companies that express 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, which FDA commonly communicates to the IND sponsor through a clinical hold letter. 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. Once initiated, 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 a 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 the development 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 trial 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 prominently highlighted in the product labeling such as in a black box or comparable prominent format, 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, additional fees and are 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 in the U.S.

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 FDA and 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 against us and/or against any products we are manufacturing or distributing.

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 current U.S. administration has 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" or RLD 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 prior finding of safety and effectiveness of the RLD 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 RLD. This is known as bioequivalence, which commonly is shown in a bioequivalence study that typically is performed in healthy volunteers and generally is considerably less time-consuming and expensive than clinical studies in patients. 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 RLD 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 RLD (i.e., the innovator NDA). ANDA applicants and 505(b)(2) applicants must certify to all patents listed in the Orange Book for the RLD. 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 RLD 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 RLD as an NCE, as follows:

- If the FDA does not classify the RLD as an NCE, then the automatic stay is for 30 months from the date that the sponsor of the RLD receives the patent certification described above.

- If the RLD 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 RLD's FDA approval, except that an ANDA may be submitted four years after the

RLD'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 RLD, 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 unless the court enjoins their launch. However, in the absence of an injunction, 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 and pharmacy benefit managers 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 generally 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 study in healthy volunteers.

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 the 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 primary or lead 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 the 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 the 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 device 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 process. 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 in consultation with CDRH, 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 biological 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 under BLAs, 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, and there are fees associated with filing the Marketing Application as well as additional fees for submissions throughout the life cycle of the product.

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. We have entered into distribution agreements with Esteve Pharmaceuticals to commercialize Inbrija in Germany and Spain, respectively. Esteve launched Inbrija in Germany in June 2022 and launched in Spain in February 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 in the EU 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 December 31, 2028. We have appointed a Notified Body and are planning to undergo an MDR inspection in the first half of 2023.

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 manufacturing, 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 the 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 and pharmaceutical benefit managers have also become a potent force in the marketplace that increase 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 current U.S. administration has 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 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 AND HUMAN CAPITAL MANAGEMENT

As of March 1, 2023, we had 111 full-time and 11 temporary employees. We also engage various consultants and contract workers, including approximately 25 sales representatives. We believe that we have a good relationship with our employees, consultants and contract workers. In order to achieve our goals, it is crucial that we continue to attract and retain top talent and provide a safe and rewarding workplace, with opportunities for growth and career development, supported by competitive compensation, benefits, health and wellness programs.

We believe that a diverse, equitable and inclusive workplace is critical to the Company’s continued growth and success. We take a comprehensive view of diversity, equity and inclusion across different races, ethnicities, tribes, religions, socioeconomic backgrounds, generations, abilities, and expressions of gender and sexual identity. As of March 1, 2023, 48% of our employees were female and 52% were male, and 28% identified as non-white and 72% as white with a relatively equal mix between female and male. We believe our diversity, equity and inclusion aspirations, are important drivers for continued growth. We conduct annual pay equity analyses, with regard to gender and race/ethnicity to help ensure our base pay structures are fair and to identify and remediate potential issues or disparities. We strive to maintain an inclusive environment free from discrimination of any kind, including sexual or other discriminatory harassment. Our employees have multiple avenues available through which inappropriate behavior can be reported, including a confidential hotline.

We frequently benchmark our compensation practices and benefits programs against those of comparable industries and peer companies, and in the geographic areas where our facilities are located. We believe that our compensation and employee benefits are competitive and allow us to attract and retain qualified employees throughout our organization. In addition to salaries, employee benefits include annual discretionary bonuses, equity awards, a 401(k) plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others.

Our success depends in large part upon our ability to attract and retain highly qualified personnel with the knowledge and experience needed for our business. We face intense competition in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations. We are increasingly relying on the services of contract sales representatives or other third-party marketing support in response to sales force attrition.

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, as a result, 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 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.

CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 2 Blue Hill Plaza, 3rd Floor, Pearl River, New York 10965. 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 2023 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2023 Proxy Statement within 120 days after the end of our 2022 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 2023 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 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, as well as Biopas Laboratories for the commercialization of Inbrija in Latin America, and we will need to enter into additional collaborations or distribution agreements to commercialize Inbrija in other countries outside the U.S.
- We rely on Catalent as our sole supplier 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 rely on Patheon as our sole supplier of Ampyra and our business could be harmed if Patheon does not maintain required regulatory approvals for the facility, if there is an interruption in operations, or if there is insufficient manufacturing capacity.
- 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 COVID-19 global pandemic, that could adversely affect our operations or financial results.
- We operate in the highly regulated 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 of 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 financing transactions.
- 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 our shares.
- We received a notice from Nasdaq that we are not in compliance with Nasdaq's minimum bid price listing rule and we have received an extension until June 20, 2023 to comply with this rule; if we have not achieved compliance by June 20, 2023, we are committed to effecting a reverse stock split that had been approved by stockholders in November 2022; we cannot predict the effect that our reverse stock split will have on the market price for shares of our common stock.

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, 2022, we had an accumulated deficit of approximately $936.3 million. We had a net loss of $65.9 million for the year ended December 31, 2022. 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 have been either suspended or are in early stages, and are subject to numerous risks including those described elsewhere in these risk factors.

Our ability to meet our future operating requirements, repay our liabilities, and meet our other obligations, and continue as a going concern are dependent upon a number of factors, including our ability to generate cash from product

sales, reduce planned expenditures, maintain the listing of our common stock on the Nasdaq Global Select Market 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 2024 Notes, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional 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, at all, on terms acceptable to us or in compliance with the restrictions contained in our debt instruments. Furthermore, a determination that there is substantial doubt about a company's ability to continue as a going concern is generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. 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 future operating requirements may change and will depend on numerous factors. These include the possibility that our common stock could be delisted from Nasdaq, which would have significant negative consequences under the indenture governing the 2024 Notes. If our common stock is delisted, holders of the 2024 Notes would have the right to require us to repurchase the 2024 Notes for 100% of their principal amount, plus any accrued and unpaid interest, and result in an increase in the conversion rates of such notes. If holders representing a significant amount of the 2024 Notes were to exercise this repurchase right, we would be unable to pay, which would result in a default under the indenture governing the 2024 Notes. Such a default could, in turn, result in our bankruptcy or liquidation. On November 11, 2022, we held a special meeting of stockholders in order to authorize our Board of Directors to approve the amendment and restatement of our Certificate of Incorporation to effect a reverse stock split at a ratio of any whole number in the range of 1-for-2 to 1-for-20 within one year following the conclusion of the special meeting. At the special meeting, our stockholders voted to authorize the Board of Directors to effect a reverse stock split. We have received an extension until June 20, 2023 to comply with the minimum bid price rule. In the event we have not achieved compliance by June 20, 2023, we are committed to effecting a reverse stock split that had been approved by stockholders in November 2022.

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, including a delisting of our common stock from the Nasdaq Global Select Market, 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 2024 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. If our common stock is delisted, this would constitute a fundamental change under the indenture governing the 2024 Notes and holders of the 2024 Notes would have the right to require us to repurchase the 2024 Notes for 100% of their principal amount. If holders representing a significant amount of the 2024 Notes were to exercise this repurchase right, we would be unable to pay, which would result in a default under the indenture governing the 2024 Notes. Such a default could, in turn, result in our bankruptcy or liquidation. While our stockholders voted on November 11, 2022 to authorize the Board of Directors to effect a reverse stock split, there can be no assurance that this or any other measures will be sufficient to avoid a delisting of our common stock and thereby trigger a fundamental change repurchase offer to holders of our 2024 Notes as described above. We received a notice from Nasdaq that we are not in compliance with Nasdaq's minimum bid price listing rule and we have received an extension until June 20, 2023 to comply with this rule. If we have not achieved compliance by June 20, 2023, we are committed to effecting a reverse stock split that had been approved by stockholders in November 2022. However, there can be no assurance that effecting a reverse stock split will ensure compliance with the minimum bid price rule and we cannot predict the effect that a reverse stock split will have on the market price for shares of our common stock.

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 labeled 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 and are expected to continue to decline over time.

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.

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 had continued 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. 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 or other conditions of approval 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 our 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.

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, and 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, otherwise 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. However, under the MDR's transition period, we can continue to place the device on the market under the MDD CE mark until the end 2027 for high-risk devices and the end 2028 for lower-risk devices, 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 the transition deadline, 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 is CE marked under the MDR.

We have appointed 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 end 2027 for high-risk devices and end 2028 for lower- risk devices, 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, 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 described elsewhere in this report, we sold our Chelsea, Massachusetts manufacturing operations to Catalent 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 third parties to supply the inhaler and levodopa. Also, we rely on a separate company to package the final Inbrija kits. Any failure or delay by a third-party manufacturer, packager, or supplier may delay or impair our ability to commercialize Inbrija or to complete any future clinical studies that 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.

Until October 2022, we relied on Alkermes to supply us with our requirements for Ampyra. Following the arbitration panel decision described elsewhere in this report, we were free to use alternative sources of supply for Ampyra. We have since engaged with Patheon to supply our future Ampyra needs at a significantly reduced cost. We and our suppliers 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. 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.

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 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). As described elsewhere in this report, on December 31, 2022, we terminated the existing supply agreement with Catalent and effective January 1, 2023 entered into a new supply agreement with more favorable terms. We are reliant on Catalent for all of our Inbrija supply and 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 our contractual arrangements, 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 continue to discuss potential ARCUS collaborations with other companies that express interest in formulating their novel molecules using ARCUS, and have already performed 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 new global supply agreement with Catalent contains substantial long-term financial commitments.

Under the New MSA, Catalent will continue to manufacture Inbrija through 2030, with reduced minimum annual commitments through 2024 and significantly lower pricing thereafter. The New MSA provides for the scale-up of new spray drying equipment ("PSD-7"), which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija, which is expected to operational in 2026. We will be subject to purchase commitments in 2023 and 2024 of 15 and 24 batches of Inbrija, respectively, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, we will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets. In addition, we have agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition, we will be obligated to pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the PSD-7 and we will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts. While we believe these purchase commitments are sufficient for our forecasted supply needs for Inbrija, we cannot provide assurance that our currently projected needs will be reached or exceeded, depending on global demand for Inbrija. 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 purchase commitments under the new MSA.

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. Any such supply shortages could lead to a breach of our legal obligations to supply Inbrija for our collaboration partners.

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. While we have the right to use alternative sources of supply in certain circumstances, this is an expensive and lengthy process and there can be no assurance that alternative sources of supply can be arranged on favorable terms, if at all, or in a timely manner to avoid supply interruptions and product distribution delays.

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.

The New MSA provides for the scale-up of PSD-7 spray drying equipment, which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija. We will be obligated to pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the PSD-7 and will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts. The 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 will create additional warehousing space for manufactured product. This expansion will require approvals from the FDA and other regulatory authorities before the PSD-7 can be used to manufacture Inbrija. 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 that 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. This expansion project is critically important to our business, and any significant delay or disruption in planned completion could have a material adverse effect on our ability to meet anticipated demand for Inbrija in the future.

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. An inability to meet demand in an EU member state or another foreign jurisdiction could lead to a breach of our legal obligations to supply Inbrija and potentially result in regulatory violations by our collaboration partners in certain jurisdictions that require adequate supply of commercial products based on patient need.

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 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 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 product 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 the severity and expectedness of any adverse events. 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. Our third-party suppliers' drug manufacturing sites may also be subject to inspection by FDA or foreign regulatory authorities. We face similar risks to our business if those third-party manufacturers are unable to comply with FDA or 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 products 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 products 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.

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 for commercialization of Inbrija in Germany and Spain and with Biopas for Commercialization of Inbrija in Latin America, and we are relying on Esteve and Biopas, 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 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.

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 continue to discuss potential ARCUS collaborations with other companies that express interest in formulating their novel molecules using ARCUS, and have already performed 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.

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, 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 in the U.S. 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 are 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, and 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 arrangements. 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 current administration has 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 current U.S. 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. 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 on 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) for Inbrija by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK that was made effective in January 2021 and formally approved in November 2021. In order to maintain the grandfathered marketing authorization in the UK and not trigger the sunset clause, we will need to begin marketing in the UK by January 2024. We will also be 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 made permanent the decision to unilaterally waive batch testing requirements for imports of products from the EU.

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, and 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 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 AbbVie, 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, Ponvory from Janssen Pharmaceutical Companies of Johnson & Johnson, and Zeposia from Bristol-MyersSquibb.

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 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. 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 oral hearings in February 2022 and April 2022, the German Patent Court dismissed ratiopharm’s action against the ‘536 patent and the ‘548 patent, respectively, as inadmissible because of ongoing formality proceedings relating to these patents in the European Patent Office. Ratiopharm has appealed the decision on the ‘536 patent but not the decision on the ‘548 patent, and could refile the nullity actions. On December 6, 2022, the German Federal Court of Justice held that ratiopharm’s ‘536 nullity action was admissible and remanded the case back to the German Federal Patent Court. On January 11, 2022, Stada Arzneimittel also filed a nullity action against the ‘536 patent, and on July 27, 2022, Teva GmbH also filed a nullity action against the ‘548 patent, both in the same court as the ratiopharm nullity actions. On January 27, 2023, the German Federal Patent Court issued a preliminary opinion in the ‘548 Teva nullity action that the claimed subject matter of the ‘548 patent lacked inventive step and scheduled a hearing for July 11, 2023. We are working with Biogen to vigorously defend these actions and enforce our patent rights. See *Legal Proceedings* in Part I, Item 3 of this report for more information. Loss of patent rights or generic entry into the German and other markets will have a material adverse effect on royalty revenue from Biogen in the future.

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 us 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, litigation and other legal proceedings relating to such proprietary rights;
- 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 investors;
- variations in our anticipated or actual operating results;
- conditions or trends in the pharmaceutical or biotechnology industries generally;
- 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 received a notice from Nasdaq that we are not in compliance with Nasdaq's minimum bid price listing rule, which could result in our stock being delisted from the Nasdaq Global Select Market, which in turn could cause a default under our indenture relating to our 2024 Notes.

On June 22, 2022, we received a deficiency letter (the "Notice") from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, which is the minimum closing price required to maintain continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). The Notice had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days to regain compliance with the Minimum Bid Requirement. To regain compliance with the Minimum Bid Requirement, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this 180-day period, unless the Staff exercises its discretion to extend this period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). In February 2023, the Staff did grant an extension of the period within which we must regain compliance with the Minimum Bid Requirement to June 20, 2023. In November 2022, our stockholders approved authorizing our Board to effect a reverse stock at any time within one year from the special meeting date. In the event we do not achieve compliance with the Minimum Bid Requirement by June 20, 2023, we are committed to effecting a reverse stock split at a ratio of any whole number in the range of 1-for-2 to 1-for-20. However, there can be no assurance that a reverse stock split would result in a sustained higher stock price that would allow us to meet the Nasdaq stock price listing requirements, and the announcement and implementation of a reverse stock split could negatively affect the price of our common stock.

If our common stock is delisted from the Nasdaq Global Select Market, holders of the 2024 Notes would have the right to require us to repurchase the 2024 Notes for 100% of their principal amount, plus any accrued and unpaid interest, and result in an increase in the conversion rates of such notes. If holders representing a significant amount of the 2024 Notes were to exercise this repurchase right, we would be unable to pay, which would result in a default under the indenture governing the 2024 Notes. Such a default could, in turn, result in our bankruptcy or liquidation.

A delisting of our common stock from the Nasdaq Global Select Market would materially and adversely affect a stockholder's ability to dispose of, or to obtain accurate quotations as to the market value of, our common stock. Furthermore, our common stock could become subject to the SEC's "penny stock" regulations. Under such regulations, broker-dealers are required to, among other things, comply with disclosure and special suitability determinations prior to the sale of shares of common stock. If our common stock becomes subject to these regulations, the market price of our common stock and the liquidity thereof would be materially and adversely affected.

Lastly, a delisting from the Nasdaq Global Select Market could greatly impair our ability to raise additional necessary capital through equity or debt financing, or use shares of common stock for business development or other corporate purposes.

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

Even though our stockholders approved a reverse stock split at the Special Meeting on November 11, 2022, we cannot predict the long-term impact of effecting a reverse stock split on 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 a reverse stock split will initially result in an increased market price per share of our common stock, the market price per share may subsequently substantially decline 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 might be lower than the total market capitalization before the reverse stock split and it could continue to decline thereafter. There can be no assurance that implementing a reverse stock split will enable us to maintain our compliance with the Nasdaq listing requirements.

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 10, 2023, 24,337,696 shares of our common stock were issued and outstanding; options to acquire 964,556 shares of our common stock were outstanding, exercisable at an average exercise price of $69.16 per share, issued under our 2006 Employee Incentive Plan, our 2015 Omnibus Incentive Compensation Plan, and our 2016 Inducement Plan. Additional shares of common stock are authorized for issuance pursuant to options and other stock-based awards under our 2015 Omnibus Incentive Compensation Plan and 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 if any of such shares are sold under the ATM.

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.

The Internal Revenue Code of 1986 ("IRC") 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 fifty percent over a three-year period ("ownership change"). In the event of such an ownership change, IRC Section 382 imposes an annual limitation on pre-ownership change tax attributes such as net operating loss and tax credit carryforwards. On June 1, 2022, the Company experienced an ownership change. The Company completed a Section 382 analysis which included consideration of net unrealized built in gains or losses and determined that its tax attributes would be limited and thus require a valuation allowance.

As of December 31, 2022, we had approximately $238.5 million of U.S. federal NOLs, of which $120.8 million at December 31, 2022 were incurred by our Biotie subsidiary. Our ability to use these NOL carryforwards will depend on the analysis of available positive and negative evidence, such as a history of earnings, reversing taxable temporary differences, tax planning strategies and future projections. Accordingly, a full valuation allowance continues to be recorded against the Biotie net operating losses of $120.8 million and a partial valuation allowance of $57.9 million was recorded on Acorda's return filing group net operating losses due to the change in ownership event.

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 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 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 $25 million per claim, and the aggregate amount of claims under the policy is also capped at $25 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. See *Legal Proceedings* contained in Part I, Item 3 of this report for more detailed information on existing or potential material legal proceedings.

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

We were previously headquartered at a leased facility in Ardsley, New York with approximately 160,000 square feet of space. In September 2021, we sent the landlord notice of exercise of the early termination option under the lease, which was effective on June 22, 2022. In connection with the lease termination, we paid an early termination fee of approximately $4.7 million. Concurrent with the Ardsley lease termination, in June 2022, we relocated our corporate headquarters to a substantially smaller subleased office in Pearl River, New York, described below.

Pearl River, New York

In June 2022, we entered into a 6-year sublease for an aggregate of approximately 21,000 square feet of space in Pearl River, New York. We have no options to extend the term of the sublease. The Pearl River sublease provides for monthly payments of rent during the lease term. The base rent is currently $0 through December 31, 2022, with payments commencing on January 1, 2023 with a base rent of $0.3 million per year, subject to an annual 2.0% escalation factor in each subsequent year thereafter.

Waltham, Massachusetts

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. The base rent under the lease is currently $1.2 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.

In July 2020, we filed an arbitration demand with the American Arbitration Association against Alkermes plc ("Alkermes") after the parties were unable to resolve a dispute over license and supply royalties following the 2018 expiration of an Alkermes patent relating to Ampyra. In October 2022, an arbitration panel issued a final decision in this dispute and awarded us damages of $15 million plus prejudgment interest of $1.5 million. In addition, as a result of the panel's ruling, we no longer have to pay Alkermes any royalties on net sales for the license and supply of Ampyra, and we are free to use alternative sources for supply of Ampyra, which we have already secured. On October 21, 2022, we made a submission to the arbitration panel to correct the award to include an additional $1.6 million that was inadvertently omitted from the initial award calculation. In November 2022, the arbitration tribunal corrected the award amount and granted us another $1.6 million plus pre-judgment interest of $0.2 million.

In January 2023, the Company filed a petition in the District Court for the Southern District of New York to confirm and modify the arbitral award. In that arbitration, the arbitration panel found in the Company's favor that Alkermes leveraged its patent to illegally obtain royalties beyond the life of the patent in which was a violation of federal law. The panel held that Alkermes' conduct in continuing to charge royalties after the patent expired was unlawful per se and that the underlying

agreements were unenforceable. The panel awarded the Company approximately $18.3 million, including interest, representing license royalties overpaid since July 2020. The Company is asking the District Court to confirm the Award, with modifications to the extent the panel disregarded federal law by declining to award royalties the Company paid prior to July 2020 and after July 2018, the date on which the panel found that the parties' agreements were unenforceable as a matter of law. The Company is seeking restitution of the remaining illegal royalties that the panel found were demanded and collected by Alkermes in violation of the law in the amount of approximately $65 million together with pre- and post-award interest and costs. On February 8, 2023, Alkermes filed a brief opposing the relief requested in the Company's petition and requesting that the award be confirmed without modification. The Company filed a brief in response on February 22, 2023. The District Court will likely schedule oral argument on the petition and render its decision sometime thereafter..

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 alleged a dispute over the last-to-expire patent covering sales of the drug Ampyra under the license agreement, and claimed damages based on unpaid license royalties of $6 million plus interest. On June 28, 2022, we settled DRI's claim in exchange for a payment by us to DRI of $750,000 expressly without any admission of wrongdoing. Although we believed we had valid defenses to this claim, we also believed that the settlement was in the best interests of the Company and our stockholders to avoid the future expense and distraction associated with continuing the arbitration. We recorded a liability of $2 million for the year ended December 31, 2020 in accrued expense and other current liabilities related to the dispute. As a result of the settlement, during the quarter ended September 30, 2022, this accrual was reduced to the $750,000 and a corresponding gain of $1.3 million was recorded in the consolidated statement of operations as other income.

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 dalfampridine 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 oral hearings in February 2022 and April 2022, the German Federal Patent Court dismissed ratiopharm's action against the '536 patent and the '548 patent, respectively, as inadmissible because of ongoing formality proceedings relating to these patents in the European Patent Office. Ratiopharm has appealed the decision on the '536 patent but not the decision on the '548 patent, and could refile the nullity actions. On December 6, 2022, the German Federal Court of Justice held that ratiopharm's '536 nullity action was admissible and remanded the case back to the German Federal Patent Court. On January 11, 2022, Stada Arzneimittel also filed a nullity action against the '536 patent, and on July 27, 2022, Teva GmbH also filed a nullity action against the '548 patent, both in the same court as the ratiopharm nullity actions. On January 27, 2023, the German Federal Patent Court issued a preliminary opinion in the '548 Teva nullity action that the claimed subject matter of the '548 patent lacked inventive step and scheduled a hearing for July 11, 2023. 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 10, 2023, we had 11 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 connection with the June 1, 2022 interest payment date on the 2024 notes, we issued an aggregate of 10,992,206 shares of common stock to holders of the notes and, to certain holders who delivered beneficial ownership limitation notices under the indenture governing the 2024 notes, cash interest payments of $0.9 million. In connection with the interest payment, $6.2 million was released from escrow and is available to us 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

We did not repurchase any shares of our common stock during the fourth quarter of 2022. We have not announced any plans or programs for the repurchase of shares of our 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 in the U.S. as treatment to improve walking in patients with multiple sclerosis, or MS.

Our Products

Inbrija/Parkinson's Disease

Inbrija is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF periods in people with Parkinson's disease treated with a 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 92% of commercially insured lives and approximately 18% of Medicare plan lives. U.S. net revenue for Inbrija was $28.0 million for the year ended December 31, 2022.

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 labeled 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. We have entered into agreements to commercialize Inbrija in Spain, Germany, and Latin America, and we are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S. Net revenues for ex-U.S. Inbrija sales (only in Germany in 2022) were $2.9 million for the year ended December 31, 2022.

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 continue to discuss potential collaborations with other companies that express interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have performed 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 $72.9 million for the year ended December 31, 2022.

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. For example, we understand that a generic drug manufacturer that has sought to invalidate Fampyra patents in Germany through nullity proceedings has commenced a generic launch in Germany. See *Legal Proceedings* in Part I, Item 3 of this report for more information.

Sale of Chelsea Manufacturing Operations and Catalent Long-Term Supply Arrangements

On February 10, 2021, we sold our Chelsea manufacturing operations to Catalent Pharma Solutions. In connection with the sale, we entered into a long-term, global manufacturing services (supply) agreement (the "2021 MSA") with a Catalent affiliate pursuant to which they agreed to manufacture Inbrija for us at the Chelsea facility. The manufacturing services agreement provided that Catalent would manufacture Inbrija, to our specifications, and we would 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 our agreement with Catalent, we were obligated to make minimum purchase commitments for Inbrija of $18 million annually through the expiration of the agreement on December 31, 2030.

In December 2021, we amended the manufacturing services agreement with Catalent 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 was replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to its 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, payments to Catalent for product delivered during the Adjustment Period were approximately $8.4 million less than the $17 million minimum inventory purchase obligation for that period. During the year ended December 31, 2022, we incurred approximately $18.7 million of purchase commitments with Catalent, of which $11.5 million are recognized as inventory within our balance sheet, $3.3 million are recognized as other current assets within our balance sheet and $3.9 million are recognized as cost of sales within our consolidated statement of operations for the period.

On December 31, 2022, we and Catalent entered into a termination letter, which was subsequently amended and restated in March 2023 (the "Termination Letter"), to terminate the 2021 MSA. In connection with the termination of the 2021 MSA, we will pay a $4 million termination fee to Catalent, payable in April 2024. The parties also entered into a Settlement and Release Agreement with respect to certain batches of Inbrija that were not delivered in 2022 as scheduled, and that are now expected in the first quarter of 2023, and to resolve all other outstanding manufacturing issues.

Effective January 1, 2023, we entered into a new manufacturing services agreement, which was amended in March 2023 (as amended in March 2023, the "New MSA") with Catalent. Under the New MSA, Catalent will continue to manufacture Inbrija (levodopa inhalation powder) through 2030, with reduced minimum annual commitments through 2024 and significantly lower pricing thereafter. The New MSA provides for the scale-up of new spray drying equipment ("PSD-7"), which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija. We will be subject to purchase commitments in 2023 and 2024 of 15 and 24 batches of Inbrija, respectively, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, we will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets.

It is anticipated that by 2026, the PSD-7 equipment will be fully operational, which will significantly reduce the per capsule fees for all markets. We have agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition, we will be obligated to pay Catalent $2 million in 2023 in connection with certain activities relating to operational readiness of the PSD-7 and we will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts.

We agreed to purchase from Catalent all of our requirements for Inbrija for the United States, Germany, Spain and Latin America, except in the case of termination or certain supply disruptions. For China, we are not required to purchase our supply from Catalent and may arrange for an alternate supplier. For other countries, we may be released from exclusivity as long as we purchase at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source of supply arrangements.

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 8 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 - Liquidity and Capital Resources section below.

Financial Management

As of December 31, 2022, we had cash, cash equivalents, and restricted cash of approximately $44.7 million. Restricted cash includes $6.2 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 8 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 - Liquidity and Capital Resources 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 connection

with the June 1, 2022 interest payment on the 2024 notes, we issued an aggregate of 10,992,206 shares of common stock to holders of the notes and, to certain holders who delivered beneficial ownership limitation notices under the indenture governing the 2024 notes, cash interest payments of $0.9 million. In connection with the interest payment, $6.2 million was released from escrow and is available to us for other purposes. The issuance of shares to pay interest on the 2024 notes is based on a formula set forth in the 2024 notes indenture. In connection with the December 1, 2022 interest payment on the 2024 notes, we paid $6.2 million from our restricted cash escrow. Based on the current market price of our common stock and our remaining authorized shares of common stock that are not reserved for other purposes, we will not have the ability to pay the interest payments on the 2024 notes in shares of our common stock for the foreseeable future.

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 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 continued to impact prescriptions in 2022. The ultimate impact of the COVID-19 global pandemic, or any other health epidemic, is highly uncertain and subject to change, and can 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 periods, in people with Parkinson's disease treated with a 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 92% of commercially insured lives and approximately 18% of Medicare plan lives. U.S. net revenue for Inbrija was $28.0 million for the year ended December 31, 2022.

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 labeled 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 January 2021.

We have entered into agreements to commercialize Inbrija in Spain, Germany, and Latin America, and we are in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S. In 2021, we entered into exclusive distribution and supply agreements with Esteve Pharmaceuticals to commercialize Inbrija in Spain and Germany. Under the terms of the Germany distribution agreement, in 2021 we received a €5 million (approximately $5.9 million) upfront payment, and we are entitled to receive sales-based milestones. Under the terms of both the Spain and Germany supply agreements, we are entitled to receive a significant double-digit percentage of the Inbrija selling price in exchange for supply of the product. Esteve launched Inbrija in Germany in June 2022 and in Spain in February 2023. Net revenues for ex-U.S. Inbrija sales in Germany were $2.9 million for the year ended December 31, 2022.

Also, in May 2022, we announced that we entered into exclusive distribution and supply agreements with Pharma Consulting Group, S.A. (known as Biopas Laboratories) to commercialize Inbrija in nine countries within Latin America, including Brazil and Mexico. Under the terms of the Biopas agreements, we are entitled to receive a significant double-digit,

tiered percentage of the Inbrija selling price in exchange for supply of the product, and we are entitled to sales-based milestones. We expect Biopas to commence sales of Inbrija in at least one country in early 2024.

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. 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 continue to discuss potential collaborations with other companies that express interest in formulating their novel molecules for pulmonary delivery using ARCUS, and have performed 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 $72.9 million for the year ended December 31, 2022.

Prior to October 2022, our primary source of supply of Ampyra was provided through a manufacturing and license agreement with Alkermes plc. In July 2020, we filed an arbitration demand with the American Arbitration Association against Alkermes after the parties were unable to resolve a dispute over license and supply royalties following the 2018 expiration of an Alkermes patent relating to Ampyra. In October 2022, a three-judge arbitration panel issued a final decision in this dispute and awarded to us an aggregate of $18.3 million including prejudgment interest and subsequent correction of a calculation error in the initial award. In addition, the arbitration panel ruled the agreements with Alkermes as unenforceable, and as a result we will no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we

are now free to use alternative sources for supply of Ampyra, which we have already secured. We expect the cost savings associated with this decision to greatly benefit Ampyra's value to us.

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. Biogen recently initiated a commercial launch of Fampyra in China, after receiving approval from the Chinese National Medical Products Administration in 2021. Our Fampyra patents have been challenged in Germany and could be similarly challenged in other countries where Fampyra is marketed by Biogen. Fampyra currently faces generic competition in Germany, notwithstanding that the Germany Fampyra Patents remain in effect, and challenges to the Fampyra patents could lead to additional generic competition with Fampyra in Germany and other countries. The Germany nullity actions are further described below under *Legal Proceedings* in Item 3 of this report.

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. This threshold was met during the second quarter of 2022 and our obligations to HCRP expired upon Biogen’s payment of royalties for that quarter. The HCRP transaction is accounted for as a liability, as described in Note 9 to our Consolidated Financial Statements included in this report.

Biogen is obligated to purchase all of Biogen's, its affiliates' and its sublicensees' requirements of the licensed products from us, unless we permit alternative sourcing of supply. 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 any existing agreements with Alkermes. In October 2022, an arbitration panel issued a decision in our dispute with Alkermes and awarded to us approximately $18.3 million, including prejudgment interest and subsequent correction of an error in calculating the initial award. In addition, as a result of the panel’s ruling, we no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we are free to use alternative sources for supply of Ampyra, which we have already secured for U.S. supply. However, the arbitration panel also ruled that the existing license and supply agreements with Alkermes are unenforceable. Accordingly, absent a new supply agreement with Alkermes or another supplier, we will not be able to exclusively supply Fampyra to Biogen under the terms of our supply arrangement with them. While we have engaged in discussions with Biogen relating to the supply of Fampyra, there can be no assurance that such discussions will result in a continuation of supply by us, Alkermes or a third party manufacturer. If Biogen is unable to obtain supply of the licensed product could constitute a breach under the existing supply agreement with Biogen resulting in termination of the license and supply agreements with Biogen or otherwise result in the cessation of sales of Fampyra and loss of royalty revenue in the future.

Results of Operations

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

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, and ASD Specialty Healthcare, Inc. (an Amerisource Bergen affiliate). We recognized net revenues from the U.S. sales of Inbrija of $28.0 million and $29.6 million for the years ended December 31, 2022 and 2021, respectively. The decrease in Inbrija net revenues was composed of a decrease in net volume of $1.8 million partially offset by price increases and discount and allowance adjustments of $0.2 million. Consistent with trends in previous

years, we anticipated declines in first quarter net sales given patient overstocking in the fourth quarter, insurance resetting at the beginning of each year, and quarterly true-up discounts and allowances as discussed below. Additionally, we recognized revenues from our supply agreement with Esteve Pharmaceuticals for sales in Germany of $2.9 million and $0 for the years ended December 31, 2022 and 2021, respectively, which represents initial stocking of Inbrija.

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 $72.9 million and $84.6 million for the years ended December 31, 2022 and 2021, respectively. The decrease in Ampyra net revenues was composed of a decrease in net volume of $17.5 million, decrease in Mylan revenue of $0.4 million, partially offset by price increase and discount and allowance adjustments of $6.2 million. Consistent with trends in previous years, we anticipated declines in first quarter net sales given patient overstocking in the fourth quarter, insurance resetting at the beginning of each year, and quarterly true-up discounts and allowances as discussed below.

Discounts and Allowances on Sales

Discounts and allowances for both Ampyra and Inbrija 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 Ampyra and Inbrija are 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.

Royalty Revenues

We recognized $14.2 million in royalty revenues for the year ended December 31, 2022 as compared to $14.9 million for the year ended December 31, 2021, related to ex-U.S. sales of Fampyra by Biogen. The decrease was primarily due to the decrease of royalties recognized from Fampyra sales of $2.1 million, offset by an increase in royalties recognized from Neurelis sales of $1.4 million.

License Revenues

We recognized $0.5 million and $0 in license revenues related to the license agreement with Asieris Pharmaceuticals for the preclinical asset Nepicastat for the years ended December 31, 2022 and 2021, respectively.

Cost of Sales

We recorded cost of sales of $30.3 million for the year ended December 31, 2022 as compared to $40.8 million for the year ended December 31, 2021. This decrease of $10.5 million was primarily due to a reduction of $13.1 million in inventory costs related to recognized revenues, a reduction of $0.6 million related to royalty fees based on net product shipments, offset by an increase of $2.7 million related to idle capacity costs, and an increase of $0.5 million related to period costs related to expired inventory, freight, stability testing, packaging and other.

Cost of sales for the year ended December 31, 2022 consisted primarily of $25.6 million in inventory costs related to recognized revenues, $2.8 million in idle capacity and scrap inventory, $1.4 million in other period costs, and $0.5 million in royalty fees based on net product shipments.

Cost of sales for the year ended December 31, 2021 consisted primarily of $32.5 million in inventory costs related to recognized revenues net of a reversal of inventory obsolescence provision, $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, $0.9 million in period costs related to expired inventory, 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.

Amortization of Intangibles

We recorded amortization of intangible asset related to Inbrija of $30.8 million for the years ended December 31, 2022 and 2021.

Research and Development

Research and development expenses for the year ended December 31, 2022 were $5.8 million as compared to $10.4 million for the year ended December 31, 2021, a decrease of $4.6 million, or 44%. The decrease was primarily due to restructuring, related decreases in several research and development programs, and a change in classification of certain departmental costs from research and development to general and administrative expenses in 2022.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2022 were $40.9 million compared to $57.2 million for the year ended December 31, 2021, a decrease of approximately $16.3 million, or 28%. The decrease was attributable primarily to a decrease in marketing related spending of $9.7 million due to launch activities for Inbrija, a decrease in overall salaries and benefits of $2.1 million, a decrease in spending related to marketing for Ampyra of $2.9 million, and a decrease in other selling related expenses of $1.6 million.

General and administrative expenses for the year ended December 31, 2022 were $65.3 million compared to $67.2 million for the year ended December 31, 2021, a decrease of approximately $1.9 million, or 3%. This decrease was primarily due to a decrease in overall salaries and benefit costs of $2.3 million, a decrease in Civitas spending of $2.4 million due to the sale of the Chelsea facility manufacturing operations, a decrease in professional fees of $8.4 million, and a decrease in restructuring costs of $5.1 million, partially offset by an increase of $4.4 million in fees related to finance projects pertaining to debt restructuring, an increase of $1.0 million in services provided by sales representatives, an increase of $2.9 million due to a change in classification of certain departmental costs to general and administrative expenses, an increase of $2.9 million due to digital media support, and an increase in other departmental spending of $5.1 million.

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 negligible income and income of $1.2 million due to the change in the fair value of the derivative liability for the years ended December 31, 2022 and December 31, 2021 respectively.

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. We acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded income relating to changes in the fair value of our acquired contingent consideration of $6.7 million for the year ended December 31, 2022 compared to a loss of $2.9 million for the year ended December 31, 2021. 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 an increase in the discount rate.

Other Operating Income

Other operating income for the year ended December 31, 2022 was $12.6 million, primarily due to recognition of the principal-only portion of the Alkermes arbitration award of $16.6 million offset by the termination fee payable to Catalent of $4.0 million to establish our new manufacturing services agreement. Other operating income for the year ended December 31, 2021 was $0.

Interest and Amortization of Debt Discount Expense

Interest and amortization of debt discount expense for the year ended December 31, 2022 was $30.2 million as compared to $30.0 million for the year ended December 31, 2021.

Interest Income

Interest income as of December 31, 2022 was $1.9 million, compared to negligible interest income as of December 31, 2021. The increase is primarily attributable to $1.7 million of prejudgment interest awarded to us through arbitration to resolve a dispute over license and supply royalties following the 2018 invalidation of an Alkermes patent relating to Ampyra.

Gain on Extinguishment of Debt

Gain on extinguishment of debt for the year ended December 31, 2022 was $27.1 million as compared to $0 for the year ended December 31, 2021. This change was directly attributable to the waiver of our Non-Convertible Capital Loans related to our Biotie subsidiary, Biotie Therapies Ltd. in December 2022.

Other Income (Expense), Net

Other income, net was $1.3 million for the year ended December 31, 2022 compared to negligible other expense, net for the year ended December 31, 2021. The change is primarily attributable to the reduction in accrual and corresponding recognition of other income related to the settlement of an arbitration claim against Drug Royalty III, L.P., and LSRC III S.ar.l. (collectively, "DRI").

Benefit from (Provision for) Income Taxes

We recorded a ($30.7) million provision for income taxes for the year ended December 31, 2022 as compared to a $5.1 million benefit from income taxes for the year ended December 31, 2021. The effective income tax rates for the year ended December 31, 2022 and 2021 were (87.0)% and 4.7%, respectively.

The variances in the effective tax rates for the year ended December 31, 2022 and 2021 was due primarily to an increase in the valuation allowance recorded on our deferred tax assets due to the IRC Section 382 ownership change, equity forfeitures and permanent items related to the cancellation of debt income from the non-convertible capital loans granted by Business Finland (formerly Tekes). The debt forgiveness gave rise to an inclusion of global intangible low-taxed income (“GILTI”) in the US which was a provision under the 2017 Tax Cuts and Jobs Act. In Finland, a significant portion of the gain from debt extinguishment is excluded from Finnish taxable income and has a favorable impact on the effective income tax rate.

We continue to evaluate the realizability of our deferred tax assets on a quarterly basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets and liabilities in the future would impact our income taxes.

We have ongoing state examinations in Massachusetts and New Jersey which cover multiple years. There have been no proposed adjustments at this stage of the examination. The Minnesota examination was finalized during the second quarter of 2022 for tax years 2018 and 2019 with no adjustments.

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 ("ownership change"). In the event of such an ownership change, Section 382 imposes an annual limitation on pre-ownership change tax attributes. On June 1, 2022, the Company experienced an ownership change. The Company completed a Section 382 analysis which included consideration of net unrealized built-in gains or losses and determined that its tax attributes are limited and require a valuation allowance. As a result, the Company recorded an additional valuation allowance on its net operating loss and tax credits carryforwards of approximately $35.3 million (tax effected).

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, 2022, we had $37.5 million of cash and cash equivalents, compared to $45.6 million at December 31, 2021. Our December 31, 2022 cash and cash equivalents balance does not include $6.2 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*. We incurred net losses of $65.9 million and $104.0 million for the years ended December 31, 2022 and 2021, 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 (the "2024 Notes") restrict or direct our use of proceeds from such transactions;
- 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, and continue as a going concern 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, at all, on terms acceptable to us or in accordance with the restrictions described above.

On June 22, 2022, we received notice that we are no longer in compliance with Nasdaq's continued listing requirements because the trading price of our common stock had fallen below $1.00 for a period of more than 30 consecutive trading days. We had 180 days, or until December 19, 2022, to regain compliance with this requirement in order to avoid potential delisting of our common stock, which would have significant adverse consequences both for the liquidity of our common stock and under the Indenture governing the 2024 Notes. If our common stock is delisted, holders of the 2024 Notes would have the right to require us to repurchase the 2024 Notes for 100% of their principal amount. If holders representing a significant amount of the 2024 Notes were to exercise this repurchase right, we would be unable to pay, which would result in a default under the Indenture. Such a default could, in turn, result in our bankruptcy or liquidation. On November 11, 2022, we held a special meeting of stockholders in order authorize our Board of Directors to approve the amendment and restatement of our Certificate of Incorporation to effect a reverse stock split at a ratio of any whole number in the range of 1-for-2 to 1-for-20 within one year following the conclusion of the special meeting. At the special meeting, our stockholders voted to authorize the Board of Directors to effect a reverse stock split. After a hearing with the Nasdaq Hearings Panel, we were granted an extension until June 20, 2023 to regain compliance with the Minimum Bid Requirement. In the event we do not achieve compliance with the Minimum Bid Requirement by June 20, 2023, we have committed to effecting the reverse stock split authorized by our stockholders in November 2022. However, there can be no assurance that we will achieve compliance with the Minimum Bid Requirement even with effecting the reverse stock split.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. As of March 13, 2023, we had approximately $8.3 million on deposit with SVB, which represented approximately 22% of our unrestricted cash and cash equivalents as of December 31, 2022. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As a result, we do not anticipate any losses with respect to our funds that had been deposited with SVB.

We believe that our existing cash and cash equivalents will be sufficient to cover our cash flow requirements for at least the next twelve months from the issuance date of these financial statements. However, our future requirements may change and will depend on numerous factors, some of which may be beyond our control.

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 our 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, we 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 canceled in accordance with their terms. 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.

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. Under the 2024 Indenture, 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 connection with the June 1, 2022 interest payment on the 2024 notes, we issued an aggregate of 10,992,206 shares of common stock to holders of the notes and, to certain holders who delivered beneficial ownership limitation notices under the indenture governing the 2024 notes, cash interest payments of $0.9 million. In connection with the interest payment, $6.2 million was released from escrow and became available to us for other purposes. In connection with the December 1, 2022 interest payment of the 2024 notes we paid $6.2 million from restricted escrow cash. Based on the current market price of our common stock and our remaining authorized shares of common stock that are not reserved for other purposes, we believe that for the foreseeable future interest payments on the 2024 notes will be made in cash.

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, such as a delisting of our common stock from the Nasdaq Global Select Market, 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 our 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 our ability and the ability of certain of our 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 our or certain of our subsidiaries; other indebtedness 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 us, 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 our 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, 2022 and December 31, 2021 consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021
Liability component:		
Principal	$ 207,000	$ 207,000
Less: debt discount and debt issuance costs, net	(39,969)	(55,975)
Net carrying amount	167,031	151,025
Equity component	18,257	$ 18,257
Derivative liability-conversion Option	$ —	$ 37

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 Therapies Ltd. 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). The loans were to be repaid only when the consolidated retained earnings of Biotie Therapies Ltd. from the development of specific loan-funded product candidates is sufficient to fully repay the loans. In light of the decision to let lapse all patents having resulted from the funded projects, we filed an application with Business Finland for waiver of the loans and accrued interest. In July 2022, Business Finland granted these waivers, which will become effective upon Biotie Therapies Ltd.'s compliance with specified conditions to be completed, including a residual payment of approximately $0.1 million for certain of these loans. In December 2022, we met all conditions of Business Finland and these loans were formerly waived. We recorded a gain on extinguishment of debt of $27.1 million for the carrying amount of the loans including accrued interest.

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, 2022. These loans were repaid in equal annual installments from January 2017 through January 2021.

Fampyra Royalty Monetization

On 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 Biogen Collaboration Agreement up to an agreed upon threshold of royalties. This threshold was met during the second quarter of 2022 and our obligations to HCRP expired upon Biogen's payment of royalties for that quarter.

Since we have 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. 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 net liability is classified between the current and non-current portion of liability related to the 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 12 months following the financial statement reporting date. The total net royalties to be paid, less the net proceeds received, is recorded to interest expense using the effective interest method over the life of the Royalty Agreement. We estimate the payments to be made to HCRP over the term of the Royalty Agreement based on forecasted royalties and calculates 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, we 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, 2022 and 2021:

(In thousands)	December 31, 2022	December 31, 2021
Liability related to sale of future royalties - beginning balance	$ 4,460	$ 15,257
Deferred transaction costs amortized	33	234
Non-cash royalty revenue payable to HCRP	(4,739)	(12,106)
Non-cash interest expense recognized	246	1,075
Liability related to sale of future royalties - ending balance	$ —	$ 4,460

Cash, Cash Equivalents and Investment Activities

At December 31, 2022, cash and cash equivalents were approximately $37.5 million, as compared to $45.6 million at December 31, 2021. 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. Also, we maintain cash balances with financial institutions in excess of insured limits. As of March 13, 2023, we had approximately $8.3 million on deposit with SVB, which represented approximately 22% of our unrestricted cash and cash equivalents as of December 31, 2022. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As a result, we do not anticipate any losses with respect to such cash balances. Our December 31, 2022 cash and cash equivalents balance does not include $6.2 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 (the amount released would correspond to the amount of interest paid using shares).

Net Cash Used in Operations

Net cash used in operations was $20.9 million compared to $41.3 million for the years ended December 31, 2022 and 2021, respectively. Cash used in operations for the year ended December 31, 2022 was primarily due to:

- a net loss of $65.9 million, a change in acquired contingent consideration obligation of $6.7 million, non-cash royalty revenue of $4.8 million, gain on extinguishment of debt of $27.1 million, an increase in other assets of $0.2 million, a decrease in accounts payable, accrued expenses and other current liabilities of $7.4 million, and an increase in prepaid expenses and other current assets of $3.0 million; partially offset by

- share-based compensation expense of $1.5 million, depreciation and amortization expense of $32.8 million, amortization of debt discount and debt issuance costs of $16.9 million, a decrease in accounts receivable of $2.6 million, a decrease in inventory of $5.8 million, an increase in other non-current liabilities of $3.9 million, and a tax provision of $30.7 million.

Net Cash Provided by Investing

Net cash used in investing activities for the year ended December 31, 2022 was $0.1 million, which was due primarily to purchases of property and equipment and intangible assets.

Net Cash Used in Financing

Net cash used in financing activities for the year ended December 31, 2022 was $0.

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 12 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 or license fees and milestones 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.

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 to our Consolidated Financial Statements. 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, 2022, we had contract liabilities of $6.1 million, as compared to $5.9 million as of December 31, 2021, which is the upfront payment received as part of the Esteve Germany distribution agreement entered into in 2021, and pre-payment of product ordered as part of the Esteve Spain supply agreement entered into in 2021. We did not have any contract assets as of December 31, 2022 or 2021. As of December 31, 2022, approximately $0.7 million of revenue is expected to be recognized from remaining performance obligations for the Esteve agreement. The Company expects to recognize revenue of these remaining performance obligations over the next 12 years in Germany and 13 years in Spain, with the balance recognized thereafter. The Company will re-evaluate the transaction price in each reporting period and as certain events are resolved or other changes in circumstances occur.

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 our 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 estimate 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 $4.0 million and $4.5 million at December 31, 2022 and December 31, 2021, respectively. A 10% change in our government chargebacks and rebate allowances would have had an approximate $1.3 million and $1.4 million effect on our net revenue for the years ended December 31, 2022 and December 31, 2021, 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 $3.2 million and $4.6 million at December 31, 2022 and December 31, 2021, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate $2.0 million and $2.1 million effect on our net revenue for the years ended December 31, 2022 and December 31, 2021, 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 $0.5 million at December 31, 2022 and December 31, 2021, 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, 2022 and December 31, 2021.

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 our 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 $0.7 million and $0.8 million at December 31, 2022 and December 31, 2021, respectively. A 10% change in our cash discount allowances would have had an approximate $0.2 million effect on our net revenues for the years ended December 31, 2022 and December 31, 2021.

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 our product sales that may be returned by our 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 ($0.1) million and $0.6 million at December 31, 2022 and December 31, 2021, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate $0.2 million and $0.3 million effect on our net revenue for the years ended December 31, 2022 and 2021, 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 our 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 2022 and 2021:

(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, 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
Allowances for sales	12,951	19,954	4,987	1,830	—	2,177	—	41,899
Actual credits for sales during 2022	(13,498)	(20,565)	(5,024)	(2,203)	—	(2,401)	—	(43,692)
Actual credits for prior year sales	2	—	—	—	—	—	—	2
Balance at December 31, 2022	$ 3,964	$ 4,022	$ 487	$ 407	$ 78	$ 339	$ —	$ 9,296

Royalty Revenues

Royalty revenues recorded by the Company relate to the Company's License and Collaboration agreement with Biogen for sales of Fampyra, and an agreement with Neurelis Inc. for sales of Valtoco. 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize 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, we determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we use our judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. We evaluate 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.

Through October 2022, the cost of Ampyra inventory 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 our 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 our 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.

After October 2022, the cost of Ampyra inventory is based on our manufacturing and packaging agreement with Patheon. As of December 31, 2022 we have not made any purchases of Ampyra inventory through Patheon.

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.

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, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and milestone obligations were set forth in the agreements entered into with Alkermes. These agreements required us to pay Alkermes a percentage of our net selling price for each inventory lot purchased from Alkermes. The cost for each lot was calculated based on an agreed upon estimated net selling price which was based on an actual historical net selling price. At the end of each quarter, we performed 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 was 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 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 allowed us to purchase up to 25% of our annual inventory requirements from an alternative manufacturer but stipulated a compensating payment to be made to Alkermes for any inventory purchased from this alternative manufacturer. This payment was 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 was recorded as an adjustment to inventory as well as an accrual on our balance sheet. In October 2022, an arbitration panel issued a decision in our dispute with Alkermes and awarded to us approximately $18.3 million, including prejudgment interest and declared our agreements with Alkermes unenforceable. As a result of the panel's ruling, we no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and we are free to use alternative sources for supply of Ampyra, which we have already secured for U.S. supply. We had previously designated Patheon as a second manufacturing source of Ampyra. We pay Patheon a fixed per bottle fee (60 tablets per bottle) based on the annual quantity of Ampyra bottles that are delivered for sale.

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

For those studies that we 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,	
	2022	2021
Preclinical and clinical development:		
Contract expenses—Inbrija	$	$ 1,053
Contract expenses—tozadenant	—	21
Contract expenses—rHIgM22	—	6
Contract expenses—cimaglermin alfa (previously GGF2)	—	8
Contract expenses—Ampyra LCM	80	3
Contract expenses—Other	—	128
Research and development operating expenses:	5,687	9,201
Acquisitions, licenses and milestones:	—	—
Cimaglermin alfa (previously GGF2)	37	—
Total research and development	$ 5,805	$ 10,420

With respect to previously established clinical study accruals for the years ended December 31, 2022 and 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 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.

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 8 to our Consolidated Financial Statements included in this report for more information on the Convertible Senior Notes due 2024). 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 $1.5 million or $2.6 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 $0.4 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. Gain on extinguishment of debt is the net carrying amount of the extinguished debt recognized on the income statement.

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 2022 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 President and Chief Executive Officer and our Chief Financial Officer and Treasurer. Based on that evaluation, these officers have concluded that, as of December 31, 2022, 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 principal executive and principal financial officers, 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 President and Chief Executive Officer and our Chief Financial Officer and Treasurer, concluded that there were no changes in our internal control over financial reporting during the quarter ended December 31, 2022 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, 2022, 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, 2022. 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, and subsidiaries' internal control over financial reporting as of December 31, 2022, 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. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, 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, 2022, and 2021, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and the related notes and our report dated March 14, 2023, 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 14, 2023

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 2023 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 2023 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 2023 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 2023 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 2023 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, 2022 and 2021
- Consolidated Statements of Operations for the years ended December 31, 2022 and 2021
- Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022 and 2021
- Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2022 and 2021
- Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021
- 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, 2022, and 2021, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 14, 2023 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 $103.8 million for the year ended December 31, 2022, 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 13 to the consolidated financial statements, the Company has a $41.2 million contingent consideration liability recorded as of December 31, 2022, 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.

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

/s/ Ernst & Young LLP

Stamford, Connecticut
March 14, 2023

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 37,536	$ 45,634
Restricted cash	6,884	13,400
Trade accounts receivable, net of allowances of $842 and $1,012, as of December 31, 2022 and 2021, respectively	13,866	17,002
Prepaid expenses	4,312	6,574
Inventory, net	12,752	18,548
Other current assets	6,765	999
Total current assets	82,115	102,157
Property and equipment, net of accumulated depreciation	2,603	4,382
Intangible assets, net of accumulated amortization	305,087	335,980
Right of use asset, net of accumulated amortization	5,287	6,751
Restricted cash	255	6,189
Other assets	248	11
Total assets	$ 395,595	$ 455,470
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,809	$ 10,845
Accrued expenses and other current liabilities	23,680	28,605
Current portion of liability related to sale of future royalties	—	4,460
Current portion of lease liability	1,545	8,186
Current portion of acquired contingent consideration	2,532	1,929
Deferred Revenue	384	—
Total current liabilities	37,950	54,025
Convertible senior notes	167,031	151,025
Derivative liability	—	37
Non-current portion of acquired contingent consideration	38,668	47,671
Non-current portion of loans payable	—	27,645
Deferred tax liability	44,202	13,930
Non-current portion of lease liability	4,341	4,086
Other non-current liabilities	9,781	5,914
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share. Authorized 1,000,000 shares at December 31, 2022 and 2021; no shares issued as of December 31, 2022 and 2021	—	—
Common stock, $0.001 par value per share. Authorized 61,666,666 shares at December 31, 2022 and 2021; issued 24,343,239 and 13,249,802 shares, including those held in treasury, as of December 31, 2022 and 2021, respectively	24	13
Treasury stock at cost (5,543 shares at December 31, 2022 and December 31, 2021)	(638)	(638)
Additional paid-in capital	1,029,881	1,023,136
Accumulated deficit	(936,273)	(870,357)
Accumulated other comprehensive loss	628	(1,017)
Total stockholders' equity	93,622	151,137
Total liabilities and stockholders' equity	$ 395,595	$ 455,470

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, 2022	Year ended December 31, 2021
Revenues:		
Net product revenues	$ 103,845	$ 114,189
Royalty Revenues	14,221	14,882
License Revenue	500	—
Total net revenues	118,566	129,071
Costs and expenses:		
Cost of sales	30,332	40,787
Research and development	5,804	10,420
Selling, general and administrative	106,256	124,399
Amortization of intangible assets	30,764	30,764
Changes in fair value of derivative liability	(37)	(1,156)
Changes in fair value of acquired contingent consideration	(6,659)	2,895
Other operating income	(12,554)	—
Total operating expenses	153,906	208,109
Operating loss	(35,340)	(79,038)
Other income (expense), net:		
Interest and amortization of debt discount expense	(30,200)	(30,035)
Interest income	1,909	5
Realized Gain (Loss) on FX Currency	(8)	—
Gain on extinguishment of debt	27,142	—
Other income (expense)	1,250	(6)
Total other income (expense), net	93	(30,036)
Loss before taxes	(35,247)	(109,074)
Benefit from (Provision for) income taxes	(30,669)	5,120
Net loss	$ (65,916)	$ (103,954)
Net loss per share—basic	$ (3.34)	$ (9.79)
Net loss per share—diluted	$ (3.34)	$ (9.79)
Weighted average common shares outstanding used in computing net loss per share—basic	19,707	10,621
Weighted average common shares outstanding used in computing net loss per share—diluted	19,707	10,621

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year ended December 31, 2022	Year ended December 31, 2021
Net loss	$ (65,916)	$ (103,954)
Other comprehensive income:		
Foreign currency translation adjustment	1,645	1,786
Other comprehensive income, net of tax	$ 1,645	$ 1,786
Comprehensive loss	$ (64,271)	$ (102,168)

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, 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
Compensation expense for issuance of stock options to employees	—	—	—	1,496	—	—	1,496
Compensation expense for issuance of restricted stock to employees	101	—	—	(3)	—	—	(3)
Interest payment for convertible notes	10,992	11		5,252			5,263
Other comprehensive income, net of tax	—	—	—	—	—	1,645	1,645
Net loss	—	—	—	—	(65,916)	—	(65,916)
Balance at December 31, 2022	24,343	24	(638)	1,029,881	(936,273)	628	$ 93,622

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2022	Year ended December 31, 2021
Cash flows from operating activities:		
Net loss	(65,916)	$ (103,954)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,493	2,995
Amortization of debt discount and debt issuance costs	16,923	16,276
Depreciation and amortization expense	32,809	33,953
Change in contingent consideration obligation	(6,659)	2,895
Change in derivative liability	(37)	(1,156)
Gain on debt extinguishment	(27,142)	—
Non-cash royalty revenue	(4,762)	(12,106)
Deferred tax provision (benefit)	30,669	(5,186)
Changes in assets and liabilities:		
Decrease in accounts receivable	2,585	3,191
Decrease (increase) in prepaid expenses and other current assets	(2,959)	8,419
Decrease in inventory	5,796	7,860
Increase in other assets	(237)	-
Increase (decrease) in accounts payable, accrued expenses and other current liabilities	(7,359)	1,108
Increase in other non-current liabilities	3,872	4,357
Net cash (used) in operating activities	(20,924)	(41,348)
Cash flows from investing activities:		
Purchases of property and equipment	(136)	(165)
Purchases of intangible assets	—	(26)
Proceeds from sale of Chelsea facility, net	—	73,969
Net cash provided by investing activities	(136)	73,778
Cash flows from financing activities:		
Repayment of Convertible Senior Notes Due 2021	—	(69,000)
Repayment of loans payable	—	(655)
Net cash (used) in financing activities	—	(69,655)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	512	(447)
Net (decrease) in cash and cash equivalents and restricted cash	(20,548)	(37,672)
Cash, cash equivalents and restricted cash at beginning of period	65,223	102,895
Cash, cash equivalents and restricted cash at end of period	$ 44,675	$ 65,223
Supplemental disclosure:		
Cash paid for interest	7,157	6
Cash paid for taxes	199	50

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. As of March 13, 2023, the Company had approximately $8.3 million on deposit with SVB, which represented approximately 22% of the Company's unrestricted cash and cash equivalents as of December 31, 2022. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As a result, 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 the 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, 2022, 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. See Note 8 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, 2022		December 31, 2021	
(In thousands)	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 45,634	$ 37,536	$ 71,369	$ 45,634
Restricted cash	13,400	6,884	12,917	13,400
Restricted cash-non current	6,189	255	18,609	6,189
Total Cash, cash equivalents and restricted cash per statement of cash flows	$ 65,223	$ 44,675	$ 102,895	$ 65,223

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, 2022 or 2021.

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, 2022 and 2021. The cumulative foreign currency translation adjustment reported in Other

Comprehensive Income (Loss) was $1.6 million and $1.8 million for the period ended December 31, 2022 and 2021, 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 following table provides the major classes of inventory:

(In thousands)	December 31, 2022	December 31, 2021
Raw materials	$ 6,212	$ 3,338
Finished goods	6,540	15,210
Total	$ 12,752	$ 18,548

Ampyra

Prior to October 2022, the cost of Ampyra inventory manufactured by Alkermes plc (Alkermes) was based on agreed upon pricing with Alkermes. In the event Alkermes does not manufacture the products, Alkermes was 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, 2022 and 2021.

In October 2022, an arbitration panel issued a decision in our dispute with Alkermes and ruled that the existing license and supply agreements with Alkermes are unenforceable. As a result of the panel’s ruling, the Company no longer has to pay Alkermes any royalties on net sales for license and supply of Ampyra, and the Company is free to use alternative sources for supply of Ampyra, which they have already secured for U.S. supply.

The Company had previously designated Patheon, Inc. as a 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. Patheon now supplies the Company with its Ampyra needs.

On September 30, 2010, the Company entered into a world-wide manufacturing services agreement with Patheon, Inc. as a second manufacturer for Ampyra (Dalfampridine-ER tablets, 10mg). Under the manufacturing services agreement, the Company agreed to purchase from Patheon, on a non-exclusive basis, a portion of our requirements for Ampyra in the United States. The Company pays Patheon a fixed per bottle fee (60 tablets per bottle) based on the annual quantity of Ampyra bottles that are delivered for sale. As a result of the arbitration ruling in October 2022, the Company was free to obtain supply of Ampyra from alternative sources and Patheon became the Company's sole manufacturer and packager of Ampyra for sales in the United States.

The manufacturing services agreement is automatically renewed for successive one-year periods on December 31 of each year, unless either the Company or Patheon provide the other party with at least 12-months’ prior written notice of non-renewal. Either party may terminate manufacturing services agreement by written notice under certain circumstances, including material breach (subject to specified cure periods) or insolvency. The Company may also terminate the manufacturing services agreement upon certain regulatory actions or objections. Patheon may terminate the manufacturing services agreement if the Company assigns the agreement to a third party under certain circumstances.

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.

The Company relies 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. If these companies experience any disruption in their operations, the Company's supply of Ampyra could be delayed or interrupted until the problem is solved or the Company locates another source of supply or another packager, which may not be available. The Company 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, the Company could experience substantial delays before they are able to obtain qualified replacement products or services from any new supplier or packager.

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.

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 the Company or its 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.

Due to the Company's Asset Purchase and License agreement between Civitas, the Company's wholly owned subsidiary, and Alkermes in December 2010, the Company has recognized contingent consideration. See Note 14 to the Company’s Consolidated Financial Statements included in this report for a discussion on the Alkermes ARCUS agreement. Refer to Note 13 – *Fair Value Measurements* for more information about the contingent consideration liability.

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, 2022, 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, 2022. The Company performed a recoverability test as of December 31, 2022 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. During the year ended December 31, 2022, no other impairment indicators were noted by the Company. Management will continue to monitor any changes in circumstances for indicators of impairment. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

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

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP ("Royalty Agreement"). In exchange for the payment of $40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the Collaboration and Licensing Agreement between the Company and Biogen (the "Biogen Collaboration Agreement"), up to an agreed upon threshold of royalties. This threshold was met during the second quarter of 2022 and its obligations to HCRP expired upon Biogen's payment of royalties for that quarter. As a result, the full benefit of the Fampyra royalty revenue reverted back to the Company and the Company will continue to receive the Fampyra royalty revenue from Biogen until the revenue stream ends. As of December 31, 2022 the liability related to the sale of future royalties is $0.

Prior to satisfying its obligation to HCRP, since the Company maintained rights under the Biogen Collaboration Agreement, the Royalty Agreement has been accounted for as a liability that was amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. In order to determine the amortization of the liability, the Company estimated the total amount of future net royalty payments 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 was 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 was affected by the amount and timing of net royalty revenue recognized and changes in forecasted revenue. On a quarterly basis, the Company reassessed the effective interest rate and adjusted 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. Because of its limited financial resources, the Company previously suspended work on proprietary research and development programs, and has performed feasibility studies for potential collaborations with other companies that express 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. For the years ended December 31, 2022 and December 31, 2021, the Company classified $0 and $4.2 million in credits received as a reduction to payroll tax expense in the Consolidated Statement of Operations, respectively.

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, 2022, the Company had contract liabilities of $6.1 million, which is the upfront payment received as part of the Esteve Germany distribution agreement entered into in 2021. The Company did not have any contract assets as of December 31, 2022 or 2021.

Product Revenues, Net

Inbrija is distributed in the U.S. primarily through: a specialty pharmacy associated with the Company's e-prescribing program, described below; AllianceRx Walgreens Prime, or Walgreens, a specialty pharmacy that delivers the medication to patients by mail; the cash pay program through Sterling and ASD Specialty Healthcare, Inc. (an Amerisource Bergen affiliate). During the three-month period ended December 31, 2020, the Company completed the transition from a network of several specialty pharmacies to Walgreens as the sole specialty pharmacy for U.S. sales of Inbrija. In 2022, the Company implemented an e-prescribing program for the distribution of Inbrija in the U.S. through a specialty pharmacy that supports electronic prescriptions. 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, such as specialty pharmacy companies. 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 its 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 the Company's 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 their 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 Company's 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 their 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 its products. The Company estimates its cash discounts based on the terms offered to its 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 its 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 relate to the Company's License and Collaboration agreement with Biogen for sales of Fampyra, and an agreement with Neurelis Inc. for sales of Valtoco. Royalty revenue from Neurelis are capped at $5.1 million, of which $3.8 million has been recorded through December 31, 2022.

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 and Spain Distribution and Supply Agreement

In November 2021, the Company entered into distribution and supply agreements with Esteve Pharmaceuticals 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 launched in Germany in June 2022, and expects to launch in Spain in February 2023.

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.

As of December 31, 2022, the Company had contract liabilities of $6.1 million, as compared to $5.9 million as of December 31, 2021, which is the upfront payment received as part of the Esteve Germany distribution agreement entered into in 2021, and pre-payment of product ordered as part of the Esteve Spain supply agreement entered into in 2021. The Company did not have any contract assets as of December 31, 2022 or 2021. The Company launched Inbrija in Germany in June 2022 and Spain in March 2023. The Company recognized $2.9 million of revenues during the period ended December 31, 2022 from the supply agreement with Esteve Pharmaceuticals. As of December 31, 2022, approximately $0.7 million of revenue is expected to be recognized from remaining performance obligations for the Esteve agreement. The Company expects to recognize revenue of these remaining performance obligations over the next 12 years in Germany and 13 years in Spain, with the balance recognized thereafter. 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)	Fiscal Year Ended December 31, 2022	Fiscal Year Ended December 31, 2021
Revenues:		
Net product revenues:		
Ampyra	$ 72,945	$ 84,555
Inbrija U.S.	27,989	29,634
Inbrija ex-U.S.	2,911	—
Total net product revenues	103,845	114,189
Royalty Revenues	14,221	14,882
License Revenue	500	—
Total net revenues	$ 118,566	$ 129,071

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 and Inbrija. 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.

Prior to October 2022, the Company relied primarily on Alkermes for its supply of Ampyra. Under its supply agreement with Alkermes, the Company was obligated to purchase at least 75% of its yearly supply of Ampyra from Alkermes, and was also required to make compensatory payments if it did not purchase 100% of its requirements from Alkermes, subject to certain specified exceptions. The Company and Alkermes agreed that the Company may purchase up to 25% of its annual requirements from Patheon, a mutually agreed-upon second manufacturing source, with compensatory payments. The Company and Alkermes also relied on a single third-party manufacturer, Regis, to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra.

In October 2022, an arbitration panel issued a decision in the Company's dispute with Alkermes and awarded to the Company approximately $18.3 million including prejudgment interest and declared the Company's agreements with Alkermes unenforceable. Of the total award amount of $18.3 million, the Company recorded $16.6 million as a reduction to operating expenses and $1.7 million as interest income. As a result of the panel's ruling, the Company no longer has to pay Alkermes any royalties on net sales for license and supply of Ampyra. The Company had previously designated Patheon, Inc. as a 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. Patheon now supplies the Company with its Ampyra needs.

The Company relies 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. If these companies experience any disruption in their operations, the Company's supply of Ampyra could be delayed or interrupted until the problem is solved or the Company locates another source of supply or another packager, which may not be available. The Company 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, the Company could experience substantial delays before they are able to obtain qualified replacement products or services from any new supplier or packager.

The Company's principal direct customers for the year ended December 31, 2022 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. Five customers individually accounted for more than 10% of the Company's revenues and approximately 91% of total revenues in 2022, and approximately 91% of total revenues in 2021. Four customers individually accounted for more than 10% of the Company's accounts receivable and approximately 85% of total accounts receivable as of December 31, 2022, and approximately 92% of total accounts receivable as of December 31, 2021.

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 $1.8 million and $2.0 million for the years ended December 31, 2022 and 2021, respectively. The Company's reserve for cash discount allowances was $0.4 million and $0.8 million as of December 31, 2022 and 2021, respectively.

(in thousands)	Cash Discounts
Balance at December 31, 2020	$ 575
Allowances for sales	1,992
Actual credits	(1,787)
Balance at December 31, 2021	$ 780
Allowances for sales	$ 1,830
Actual credits	$ (2,203)
Balance at December 31, 2022	$ 407

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 $0.1 million and $0.2 million as of December 31, 2022 and December 31, 2021, respectively. The Company recognized a net credit of $0.1 million and provisions and write-offs of $0.2 million for the years ended December 31, 2022 and December 31, 2021, respectively.

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 $3.4 million and $1.0 million for the years ended December 31, 2022 and December 31, 2021, respectively. The Company made a payment of $3.2 million and $1.5 million related to the chargebacks allowances for the years ended December 31, 2022 and December 31, 2021, respectively. The Company's reserve for chargebacks allowance were $0.3 million as of December 31, 2022 and negligible as of December 31, 2021.

Contingencies

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

Fair Value of Financial Instruments

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

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

(a) Cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these instruments;

(b) Short-term investments are recorded based primarily on quoted market prices;

(c) Acquired contingent consideration related to the Civitas acquisition is measured at fair value using a probability weighted, discounted cash flow approach;

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

(e) 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 16 to the Company's 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 7 to the Company's 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 for the years ended December 31, 2022 and December 31, 2021, respectively.

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, meet its other obligations, and continue as a going concern are dependent upon a number of factors, including its ability to generate cash from product sales, reduce 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.

As of December 31, 2022, the Company had cash, cash equivalents, and restricted cash of approximately $44.7 million. Restricted cash includes $6.2 million in escrow related to the 6% semi-annual interest portion of our convertible senior secured notes due June 2024, which interest is payable in cash or stock. If the Company elects to pay interest due in stock, and have the available shares to do so, a corresponding amount of restricted cash will be released from escrow. In connection with the June 1, 2022 interest payment on the 2024 notes, the Company issued an aggregate of 10,992,206 shares of common stock to holders of the notes and, to certain holders who delivered beneficial ownership limitation notices under the indenture governing the 2024 notes, cash interest payments of $0.9 million. In connection with the interest payment, $6.2 million was released from escrow and became available to us for other purposes. In connection with the December 1, 2022 interest payment of the 2024 notes the Company paid $6.2 million from restricted escrow cash. The Company incurred net losses of $65.9 million and $104.0 million for the years ended December 31, 2022 and 2021, respectively. In addition, in October 2022, the Company received $16.5 million and in December received an additional $1.8 million from Alkermes following a final decision of an arbitration panel regarding a dispute over licensing royalties relating to Ampyra.

The Company assesses and determines its ability to continue as a going concern in accordance with the provisions of ASC Topic 205-40, "Presentation of Financial Statements—Going Concern" ("ASC Topic 205-40"), which requires the Company to evaluate whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that its annual and interim consolidated financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting. Determining the extent, if any, to which conditions or events raise substantial doubt about the Company's ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgement by management. The Company has evaluated whether

there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements contained in this report are issued.

On June 22, 2022, the Company received a deficiency letter from Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that, for 30 consecutive business days, the bid price for the Company's common stock had closed below $1.00 per share, which is the minimum closing price required to maintain continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). The Company had 180 calendar days to regain compliance with the Minimum Bid Requirement.

On November 11, 2022, the Company held a special meeting of stockholders in order authorize the Board of Directors to approve the amendment and restatement of our Certificate of Incorporation to effect a reverse stock split at a ratio of any whole number in the range of 1-for-2 to 1-for-20 within one year following the conclusion of the special meeting, which proposal was approved by stockholders.

After a hearing with the Nasdaq Hearings Panel in February 2023, the Company was granted an extension until June 20, 2023 to regain compliance with the Minimum Bid Requirement. In the event the Company does not achieve compliance with the Minimum Bid Requirement by June 20, 2023, the Company has committed to effecting the reverse stock split authorized by our stockholders in November 2022. However, there can be no assurance that the Company will achieve compliance with the Minimum Bid Requirement even with effecting the reverse stock split.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the "FDIC") as receiver. As of March 13, 2023, the Company had approximately $8.3 million on deposit with SVB, which represented approximately 22% of the Company's unrestricted cash and cash equivalents as of December 31, 2022. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As a result, the Company does not anticipate any losses with respect to its funds that had been deposited with SVB.

The Company believes that its existing cash and cash equivalents will be sufficient to cover its cash flow requirements for at least the next twelve months from the issuance date of these financial statements. However, the Company's future requirements may change and will depend on numerous factors, some of which may be beyond the Company's control.

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 intra-period 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.

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. The Company adopted this guidance effective January 1, 2022. 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 March, 2022, the FASB issued ASU 2022-02, Financial Instruments – Credit Losses: Troubled Debt Restructurings and Vintage Disclosures. The amendments in this Update eliminate the accounting guidance for Troubled Debt Restructurings by creditors in Subtopic 310-40, Receivables—Troubled Debt Restructurings by Creditors, while enhancing disclosure requirements for certain loan refinancings and restructurings by creditors when a borrower is experiencing financial difficulty. This update also includes amendments which require that an entity disclose current-period gross writeoffs by year of origination for financing receivables and net investments in leases within the scope of Subtopic 326-20, Financial Instruments—Credit Losses—Measured at Amortized Cost. The ASU is effective for entities that have adopted the amendments in Update 2016-13 for fiscal years beginning after December 15, 2022, 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 was a subsequent event that required disclosure or adjustment in these financial statements. See Note 18 to the Company's Consolidated Financial Statements included in this report for a discussion of subsequent events.

(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 4 years to 5.5 years.

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

The new standard also provides practical expedients and certain exemptions for an entity's ongoing accounting. 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

The Company was previously headquartered at a leased facility in Ardsley, New York with approximately 160,000 square feet of space. In September 2021, the Company sent the landlord notice of exercise of its early termination option under the lease, which was effective on June 22, 2022. In connection with the lease termination, the Company paid an early termination fee of approximately $4.7 million. Concurrent with the Ardsley lease termination, in June 2022, the Company relocated its corporate headquarters to a substantially smaller subleased office in Pearl River, New York, described below.

Pearl River, New York

In June 2022, the Company entered into a 6-year sublease for an aggregate of approximately 21,000 square feet of space in Pearl River, New York. The Company has no options to extend the term of the sublease. The Pearl River sublease provides for monthly payments of rent during the lease term. The base rent is currently $0 through December 31, 2022, with payments commencing on January 1, 2023 with a base rent of $0.3 million per year, subject to an annual 2.0% escalation factor in each subsequent year thereafter.

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, effective January 1, 2023 the Company agreed under the terms of the New MSA in March 2023 to pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the size 7 spray dryer. Furthermore, the Company has agreed to fund up to $2 million of Catalent's costs to complete the size 7 spray dryer expansion, which will be payable by the Company in four quarterly installments beginning September 30, 2023.

Waltham, Massachusetts

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 $1.2 million per year.

The Company's leases have remaining lease terms of 4 years to 5.5 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 its operating leases was 4.4 years at December 31, 2022. The weighted-average discount rate was 7.92% at December 31, 2022.

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

(In thousands)	Balance Sheet Classification	December 31, 2022	December 31, 2021
Right-of-use assets	Right of use assets	$ 5,287	$ 6,751
Current lease liabilities	Current portion of lease liabilities	1,545	8,186
Non-current lease liabilities	Non-current portion of lease liabilities	4,341	4,086

The Company has lease agreements that contain both lease and non-lease components. The Company accounts 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, 2022	Year ended December 31, 2021
Operating lease cost	$ 3,843	$ 6,030
Variable lease cost	2,005	4,156
Short-term lease cost	8	851
Total lease cost	$ 5,855	$ 11,037

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

(In thousands)	
2023	1,545
2024	1,588
2025	1,633
2026	1,678
2027	357
Later years	182
Total lease payments	6,983
Less: Imputed interest	(1,097)
Present value of lease liabilities	5,886

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

(In thousands)	December 31, 2022	December 31, 2021
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	$ 8,191	$ 6,158

(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.

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, 2022, 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, 2022				December 31, 2021			
(Dollars In thousands)	Estimated Remaining Useful Lives (Years)	Cost	Disposals	Accumulated Amortization	Net Carrying Amount	Cost	Additions	Accumulated Amortization	Net Carrying Amount
Inbrija [(1)]	11	423,000	—	(117,927)	305,073	423,000	—	(87,164)	335,836
Website development costs	1-3	14,585	(3,683)	(10,888)	14	14,559	26	(14,441)	144
		$ 437,585	$ (3,683)	$ (128,815)	$ 305,087	$ 437,559	$ 26	$ (101,605)	$ 335,980

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

The Company recorded amortization expenses of $30.9 million of which $30.8 million pertained to the intangible asset related to Inbrija and $0.1 million related to the amortization of website development costs for the year ended December 31, 2022. 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 related to these intangible assets for the year ended December 31, 2021.

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

(In thousands)	
2023	$ 30,772
2024	30,768
2025	30,764
2026	30,764
2027	30,764
Thereafter	151,255
	$ 305,087

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

(5) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021	Estimated useful lives used
Machinery and equipment	$ 2,315	$ 2,315	2-7 years
Leasehold improvements	1,761	15,317	Lesser of useful life or remaining lease term
Computer equipment	4,467	17,973	1-3 years
Laboratory equipment	582	1,644	2-5 years
Furniture and fixtures	233	2,130	4-7 years
	9,358	39,379	
Less accumulated depreciation	(6,755)	(34,997)	
	$ 2,603	$ 4,382	

Depreciation and amortization expense on property and equipment was $1.9 million and $2.9 million for the years ended December 31, 2022 and 2021, respectively.

(6) 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, in February 2021 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.

(7) 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, 2022 was 2,485,342 shares. As of December 31, 2022, 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 211,293 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, 2022 is 3,150,000 shares, plus shares underlying cancelled awards under the 2006 plan after the adoption of the 2015 plan. As of December 31, 2022, the Company had granted an aggregate of 1,337,280 shares either as restricted stock or shares subject to issuance upon the exercise of stock options under the 2015 Plan, of which 644,371 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. In 2022, no new 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, 2022, 170,000 shares 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, 2022, 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,	
	2022	2021
Employees and directors:		
Estimated volatility%	84.19%	84.26%
Expected life in years	6.70	6.25
Risk free interest rate%	2.69%	1.36%
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, 2022 and 2021 amounted to approximately $0.84 and $2.57, respectively. No options were granted to non-employees for the years ended December 31, 2022 and 2021.

During the year ended December 31, 2022, the Company granted 97,950 stock options to employees and directors under all plans. The stock options were issued with a weighted average exercise price of $1.18 per share. As a result of these grants, the total compensation charge to be recognized over the estimated service period is $0.08 million, of which $0.05 million was recognized during the year ended December 31, 2022.

Compensation costs for options and restricted stock granted to employees and directors amounted to $1.5 million and $3.0 million, for the years ended December 31, 2022 and 2021, respectively. Of the total compensation cost, there was $0 million compensation cost capitalized in inventory balances for the years ended December 31, 2022 and December 31, 2021, respectively. 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)	2022	2021
Research and development	$ 75	$ 694
Selling, general and administrative	1,421	2,282
Cost of sales	—	19
Total	$ 1,496	$ 2,995

A summary of share-based compensation activity for the year ended December 31, 2022 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, 2021	1,186	$ 94.38	—	—
Granted	98	1.18	—	—
Forfeited and expired	(258)	124.14	—	—
Exercised	—	—	—	—
Balance at December 31, 2022	1,026	$ 78.00	5.8	19
Vested and expected to vest at December 31, 2022	1,013	$ 78.97	5.7	18
Vested and exercisable at December 31, 2022	753	$ 104.98	4.6	8

	Options Outstanding			Options Exercisable	
Range of exercise price	Outstanding as of December 31, 2022 (In thousands)	Weighted-average remaining contractual life (In years)	Weighted-average exercise price	Exercisable as of December 31, 2022 (Shares in thousands)	Weighted-average exercise price
$0.31 - $3.74	374	9.0	$ 3.04	105	$ 2.87
$3.75 - $14.46	223	6.7	11.85	221	11.92
$15.30 - $182.76	219	3.3	138.77	217	139.38
$182.94 - $240.18	205	1.8	217.99	205	217.99
$246.42 - $246.42	5	1.3	246.42	5	246.42
	1,026	5.8	$ 78.00	753	$ 104.98

Restricted Stock Activity

Restricted Stock	Number of Shares (In thousands)
Nonvested at December 31, 2021	116
Granted	—
Vested	(108)
Forfeited	(8)
Nonvested at December 31, 2022	$ —

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2022 totaled $0.6 million and is expected to be recognized over a weighted average period of approximately 2.6 years.

(8) 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. Under the 2024 Indenture, 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. Based on the current market price of the Company's common stock and the Company's remaining authorized shares of common stock that are not reserved for other purposes, the Company believes that for the foreseeable future the Company will be unable to make interest payments on the 2024 notes in stock.

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, such as a delisting of the Company's common stock from the Nasdaq Global Select Market, 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 the 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, 2022.

The outstanding 2024 Note balances as of December 31, 2022 and December 31, 2021 consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021
Liability component:		
Principal	$ 207,000	$ 207,000
Less: debt discount and debt issuance costs, net	(39,969)	(55,975)
Net carrying amount	167,031	151,025
Equity component	18,257	$ 18,257
Derivative liability-conversion Option	$ —	$ 37

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, 2022, the Company recognized $28.4 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 $157.3 million as of December 31, 2022.

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, 2022 and 2021:

(In thousands)	**Year ended December 31, 2022**	**Year ended December 31, 2021**
Contractual interest expense	$ 12,420	$ 12,420
Amortization of debt issuance costs	1,137	952
Amortization of debt discount	14,870	12,454
Total interest expense	$ 28,427	$ 25,826

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.

The following table sets forth total interest expense recognized related to the 2021 Notes for the years ended December 31, 2022 and 2021:

(In thousands)	Year ended December 31, 2022	Year ended December 31, 2021
Contractual interest expense	$ —	$ 428
Amortization of debt issuance costs	—	95
Amortization of debt discount	—	934
Total interest expense	$ —	$ 1,457

Non-Convertible Capital Loan

The Company's Biotie Therapies Ltd. 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). The loans were to be repaid only when consolidated retained earnings of Biotie Therapies Ltd. from the development of specific loan-funded product candidates is sufficient to fully repay the loans. In light of the decision to let lapse all patents having resulted from the funded projects, the Company filed an application with Business Finland for waiver of the loans and accrued interest. In July 2022, Business Finland granted these waivers, which became effective upon Biotie's compliance with specified conditions to be completed, including a residual payment of approximately $0.1 million for one of the loans. As of December 31, 2022, Biotie Therapies Ltd. met the conditions for the waivers to be effective. The Company recorded a gain on extinguishment of debt of $27.1 million for the carrying amount including interest.

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, 2022, the Company has $0.3 million of cash collateralized standby letters of credit outstanding. See Note 2 to the Company's Consolidated Financial Statements included in this report for a discussion of Restricted Cash.

(9) 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 (the "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 Biogen Collaboration Agreement up to an agreed upon threshold of royalties. This threshold was met during the second quarter of 2022 and its obligations to HCRP expired upon Biogen's payment of royalties for that quarter.

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 was 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 received by HCRP. The total net royalties paid, less the net proceeds received is recorded to interest expense using the effective interest method over the life of the Royalty Agreement. The Company estimated the payments made to HCRP over the term of the Royalty Agreement based on forecasted royalties and calculated the interest rate required to discount such

payments back to the liability balance. Over the course of the Royalty Agreement, the actual interest rate was affected by the amount and timing of net royalty revenue recognized and changes in the forecasted revenue. On a quarterly basis, the Company reassessed the effective interest rate and adjusted the rate prospectively as necessary.

The following table shows the activity within the liability account for the years ended December 31, 2022 and December 2021.

(In thousands)	December 31, 2022	December 31, 2021
Liability related to sale of future royalties - beginning balance	$ 4,460	$ 15,257
Deferred transaction costs amortized	33	234
Non-cash royalty revenue payable to HCRP	(4,739)	(12,106)
Non-cash interest expense recognized	246	1,075
Liability related to sale of future royalties - ending balance	$ —	$ 4,460

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

(10) 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 its 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 was completed in the first quarter of 2022.

For the years ended December 31, 2022 and 2021, the Company incurred pre-tax severance and employee separation related expenses of approximately $0.3 million and $6.0 million, respectively, associated with the restructuring. Of the pre-tax severance and employee separation related expenses incurred, $0 and $0.6 million were recorded in research and development expenses and $0.3 million and $5.4 million were recorded in selling, general and administrative expenses for the years ended December 31, 2022 and 2021, respectively.

A summary of the restructuring costs for the years ended December 31, 2022 and 2021 is as follows:

(In thousands)	Restructuring Costs
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
2022 Restructuring costs	251
2022 Payments	(2,102)
Restructuring Liability as of December 31, 2022	$ —

(11) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021
Product allowances accruals	$ 8,899	$ 10,394
Bonus payable	4,329	4,439
Accrued interest	1,035	—
Sales force commissions and incentive payments payable	667	727
Administrative expenses	366	757
Vacation accrual	1,477	1,505
Research and development expense accruals	895	702
Commercial and marketing expense accruals	2,892	728
Royalties payable	—	264
Restructuring liability	—	1,851
Legal, accounting, and other professional services	50	1,325
Trade relations	278	706
Other accrued expenses	2,792	5,207
Total	$ 23,680	$ 28,605

(12) 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, operating leases and commitments to purchase inventory. The following table summarizes the contractual obligations at December 31, 2022 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)			
(In thousands)	Total	Less than 1 year	1-3 years	4-5 years
Convertible Senior Notes (2)	$ 230,840	$ 12,420	$ 218,420	$ —
Operating leases (3)	6,983	1,545	3,221	2,217
Inventory purchase commitments (4)	49,853	17,753	21,700	10,400
Catalent Termination (5)	4,000	—	4,000	—
Settlement and Release Agreement (6)	3,385	3,385	—	—
Total	295,061	35,103	247,341	12,617

(1) Excludes a liability for uncertain tax positions totaling $6.2 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 8.

(3) Represents payments for the operating leases of the Company's Pearl River NY headquarters, the Company's lab and office space in Waltham, MA.

(4) Includes minimum purchase commitment from Catalent for Inbrija under the manufacturing services (supply) agreement. The Company terminated its existing supply agreement with Catalent on December 31, 2022 and renegotiated a new supply agreement effective January 1, 2023. Under the terms of the new supply agreement with Catalent, the Company is required to make minimum purchase obligations through 2024. Furthermore, pursuant to the new supply agreement as amended, the Company agreed to pay Catalent $2 million in 2023 in connection with certain activities related to the operational readiness of the larger size 7 spray dryer ("PSD-7") at the Chelsea manufacturing facility, which is expected to be operational by 2026. In addition to the operational readiness payment, the Company agreed that it would reimburse a portion of Catalent's costs in completing the installation and qualification of the PSD-

7, which the Company believes will be beneficial to its future production needs, in the amount of up to $2 million. This amount will be paid quarterly over a one-year period commencing no sooner than September 30, 2023.

(5) Represents the termination fee payable to Catalent that discontinued the Company's obligations under the 2021 MSA. The termination fee is payable in April 2024.

(6) Represents the commitments specified in the Settlement and Release Agreement between the Company and Catalent to settle any and all outstanding purchase commitments associated with the 2021 MSA.

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 $18.7 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 14 to the Company's 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

From time to time, the Company may be involved in litigation or other legal proceedings relating to claims arising out of operations in the normal course of its 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 the Company because of defense and settlement costs, diversion of management resources, and other factors.

In July 2020, the Company filed an arbitration demand with the American Arbitration Association against Alkermes plc ("Alkermes") after the parties were unable to resolve a dispute over license and supply royalties following the 2018 expiration of an Alkermes patent relating to Ampyra. In October 2022, an arbitration panel issued a final decision in this dispute and awarded to the Company $15 million plus prejudgment interest of $1.5 million. In addition, as a result of the panel's ruling, the Company no longer has to pay Alkermes any royalties on net sales for license and supply of Ampyra, and is free to use alternative sources for supply of Ampyra, which the Company has already secured. On October 21, 2022, the Company made a submission to the arbitration panel to correct the award to include an additional $1.6 million that was inadvertently omitted from the initial award calculation. In November 2022, the arbitration tribunal corrected the award amount and granted the Company another $1.6 million plus pre-judgment interest of $0.2 million.

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 the Company 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 alleged a dispute over the last-to-expire patent covering sales of the drug Ampyra under the license agreement, and claimed damages based on unpaid license royalties of $6 million plus interest. On June 28, 2022, the Company settled DRI's claim in exchange for a payment by us to DRI of $750,000 expressly without any admission of wrongdoing. Although the Company believed they had valid defenses to this claim, the Company also believed that the settlement was in the best interests of the Company and our stockholders to avoid the future expense and distraction associated with continuing the arbitration. 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. As a result of the settlement, during the quarter

ended September 30, 2022, this accrual was reduced to the $750,000 and a corresponding gain of $1.3 million was recorded in the consolidated statement of operations as other income.

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 dalfampridine 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 oral hearings in February 2022 and April 2022, the German Federal Patent Court dismissed ratiopharm’s action against the ‘536 patent and the ‘548 patent, respectively, as inadmissible because of ongoing formality proceedings relating to these patents in the European Patent Office. Ratiopharm has appealed the decision on the ‘536 patent but not the decision on the ‘548 patent, and could refile the nullity actions. On December 6, 2022, the German Federal Court of Justice held that ratiopharm’s ‘536 nullity action was admissible and remanded the case back to the German Federal Patent Court. On January 11, 2022, Stada Arzneimittel also filed a nullity action against the ‘536 patent, and on July 27, 2022, Teva GmbH also filed a nullity action against the ‘548 patent, both in the same court as the ratiopharm nullity actions. On January 27, 2023, the German Federal Patent Court issued a preliminary opinion in the ‘548 Teva nullity action that the claimed subject matter of the ‘548 patent lacked inventive step and scheduled a hearing for July 11, 2023. The Company is working with Biogen to vigorously defend these actions and enforce our patent rights.

On February 10, 2021, the Company sold its Chelsea manufacturing operations to Catalent Pharma Solutions. In connection with the sale, the Company entered into a long-term, global manufacturing services (supply) agreement (the “2021 MSA") with a Catalent affiliate pursuant to which they agreed to manufacture Inbrija for the Company at the Chelsea facility. The manufacturing services agreement provided that Catalent would manufacture Inbrija, to the Company’s specifications, and the Company would 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 was obligated to make minimum purchase commitments for Inbrija of $18 million annually through the expiration of the agreement on December 31, 2030.

In December 2021, the Company 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 was replaced with payments to Catalent for actual product delivered during the Adjustment Period subject to a cap for the Adjustment Period that corresponds to its 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, payments to Catalent for product delivered during the Adjustment Period were approximately $8.4 million less than the $17 million minimum inventory purchase obligation for that period.

On December 31, 2022, the Company and Catalent entered into a termination letter, which was subsequently amended and restated in March 2023 (the “Termination Letter”), to terminate the 2021 MSA. In connection with the termination of the 2021 MSA, the Company will pay a $4 million termination fee to Catalent, payable in April 2024. The parties also entered into a Settlement and Release Agreement with respect to certain batches of Inbrija that were not delivered in 2022 as scheduled, and that are now expected in the first quarter of 2023, and to resolve all other outstanding manufacturing issues.

Effective January 1, 2023, the Company entered into a new manufacturing services agreement, which was subsequently amended in March 2023 (as amended in March 2023, the “New MSA”) with Catalent. Under the New MSA, Catalent will continue to manufacture Inbrija (levodopa inhalation powder) through 2030, with reduced minimum annual commitments through 2024 and significantly lower pricing thereafter. The New MSA provides for the scale-up of new spray drying equipment (“PSD-7”), which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija. The Company will be subject to purchase commitments in 2023 and 2024 of 15 and 24 batches of Inbrija, respectively, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, the Company will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets.

It is anticipated that by 2026, the PSD-7 equipment will be fully operational, which will significantly reduce the per capsule fees for all markets. The Company agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition, the Company will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts. In addition, the Company will be obligated to pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the PSD-7.

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

The Company agreed to purchase from Catalent all of our requirements for Inbrija for the United States, Germany, Spain and Latin America except in the case of termination or certain supply disruptions. For China, the Company is not required to purchase their supply from Catalent and may arrange for an alternate supplier. For other countries, the Company may be released from exclusivity as long as the Company purchases at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source of supply arrangements.

During the year ended December 31, 2022, the Company incurred approximately $18.7 million of purchase commitments with Catalent, of which $11.5 million are recognized as inventory within our balance sheet, $3.3 million are recognized as other current assets within our balance sheet and $3.9 million are recognized as cost of sales within our consolidated statement of operations for the period. As of December 31, 2022, the Company does not have any remaining minimum remaining purchase commitment to Catalent under 2021 MSA. Under the New MSA with Catalent, the Company has a minimum remaining purchase of $10.5 million through December 31, 2023, $15.5 million through December 31, 2024, and $5.2 million annually from January 1, 2026 through December 31, 2030.

In January 2023, the Company filed a petition in the District Court for the Southern District of New York to confirm and modify the arbitral award. In that arbitration, the arbitration panel found in the Company's favor that Alkermes leveraged its patent to illegally obtain royalties beyond the life of the patent in which was a violation of federal law. The panel held that Alkermes' conduct in continuing to charge royalties after the patent expired was unlawful per se and that the underlying agreements were unenforceable. The panel awarded the Company approximately $18.3 million, including interest, representing license royalties overpaid since July 2020. The Company is asking the District Court to confirm the Award, with modifications to the extent the panel disregarded federal law by declining to award royalties the Company paid prior to July 2020 and after July 2018, the date on which the panel found that the parties' agreements were unenforceable as a matter of law. The Company is seeking restitution of the remaining illegal royalties that the panel found were demanded and collected by Alkermes in violation of the law in the amount of approximately $65 million together with pre- and post-award interest and costs. On February 8, 2023, Alkermes filed a brief opposing the relief requested in the Company's petition and requesting that the award be confirmed without modification. The Company filed a brief in response on February 22, 2023. The District Court will likely schedule oral argument on the petition and render its decision sometime thereafter.

(13) 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 following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 and December 31, 2021 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices, interest rates, exchange rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company's Level 1 assets consist of investments in a Treasury money market fund and U.S. government securities. The Company's Level 3 liabilities represent acquired contingent consideration related to the acquisition of Civitas which are valued using a probability weighted discounted cash flow valuation approach and derivative liabilities related to conversion options for the convertible senior notes due December 2024 which are valued using a binomial model. For assets and liabilities not accounted for at fair value, the carrying values of these accounts approximates their fair values at December 31, 2022, except for the fair value of the Company's convertible

senior notes due December 2024, which was approximately $157.3 million as of December 31, 2022. The Company estimates the fair value of its notes utilizing market quotations for the debt (Level 2).

(In thousands)	Level 1	Level 2	Level 3
2022			
Assets Carried at Fair Value:			
Money market funds	$ 15,322	$ —	$ —
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	41,200
Derivative liability - conversion option	—	—	—
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

The following table presents additional information about 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, 2022	Year ended December 31, 2021
Acquired contingent consideration:		
Balance, beginning of period	$ 49,600	$ 48,200
Fair value change to contingent consideration (unrealized) included in the statement of operations	(6,659)	2,895
Royalty payments	(1,741)	(1,495)
Balance, end of period	$ 41,200	$ 49,600

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 forecast for Inbrija, and (ii) discount period and rate. The milestone payment outcomes ranged from $0 to $18.7 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, 2022, 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 14 to the Company's Consolidated Financial Statements included in this report for a discussion about the Alkermes ARCUS agreement.

The acquired contingent consideration is 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, 2022	Year ended December 31, 2021
Derivative Liability-Conversion Option		
Balance, beginning of period	$ 37	$ 1,193
Fair value adjustment	(37)	(1,156)
Balance, end of period	$ —	$ 37

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 8 to the Consolidated Financial Statements included in this report for more information on the Convertible Senior Notes due 2024). 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 calculated to be $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, 2022. Key inputs used in the calculation of the fair value include stock price, volatility, risky (bond) rate, and the last observed bond price during the year ended December 31, 2022.

(14) 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 the Company.

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 the Company. 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 Agreements

Alkermes

Prior to October 2022, the Company was a party to a 2003 supply agreement with Alkermes relating to the manufacture and supply of Ampyra by Alkermes. The Company was obligated to purchase at least 75% of its annual requirements of Ampyra from Alkermes, unless Alkermes was 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. In those circumstances, where the Company elected to purchase less than 100% of its requirements from Alkermes, the Company was obligated to make certain compensatory payments to Alkermes. Alkermes was required to assist the Company in qualifying a second manufacturer to manufacture and supply the Company with Ampyra subject to its obligations to Alkermes.

In July 2020, the Company filed an arbitration demand with the American Arbitration Association against Alkermes after the parties were unable to resolve a dispute over license and supply royalties following the 2018 expiration of an Alkermes patent relating to Ampyra. In October 2022, a three-judge arbitration panel issued a final decision in this dispute and awarded to the Company an aggregate of $18.3 million including prejudgment interest and subsequent correction of a calculation error in the initial award. In addition, the arbitration panel ruled the agreements with Alkermes as unenforceable, and as a result the Company will no longer have to pay Alkermes any royalties on net sales for license and supply of Ampyra, and the Company is now free to use alternative sources for supply of Ampyra, which the Company has already secured. The Company expects the cost savings associated with this decision to greatly benefit Ampyra's value to the Company.

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.

Patheon

As a result of the arbitration ruling in October 2022, the Company was free to obtain supply of Ampyra from alternative sources and Patheon became the Company's sole manufacturer and packager of Ampyra for sales in the United States.

The manufacturing services agreement with Patheon is automatically renewed for successive one-year periods on December 31 of each year, unless either the Company or Patheon provide the other party with at least 12-months’ prior written notice of non-renewal. Either party may terminate manufacturing services agreement by written notice under certain circumstances, including material breach (subject to specified cure periods) or insolvency. The Company may also terminate the manufacturing services agreement upon certain regulatory actions or objections. Patheon may terminate the manufacturing services agreement if the Company assigns the agreement to a third party under certain circumstances.

The Company relies 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. If these companies experience any disruption in their operations, the Company's supply of Ampyra could be delayed or interrupted until the problem is solved or the Company locates another source of supply or another packager, which may not be available. The Company 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, the Company could experience substantial delays before they are able to obtain qualified replacement products or services from any new supplier or packager.

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. 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 October 2022, an arbitration panel issued a decision in our dispute with Alkermes and awarded to the Company approximately $18.3 million including prejudgment interest and subsequent correction of an error in calculating the initial award. In addition, as a result of the panel's ruling, the Company no longer has to pay Alkermes any royalties on net sales for license and supply of Ampyra, and the Company is free to use alternative sources for supply of Ampyra, which the Company has already secured for U.S. supply. However, the arbitration panel also ruled that the existing license and supply agreements with Alkermes are unenforceable. Accordingly, absent a new supply agreement with Alkermes or another supplier, the Company will not be able to exclusively supply Fampyra to Biogen under the terms of our supply arrangement with them. While the Company has engaged in discussions with Biogen relating to the supply of Fampyra, there can be no assurance that such discussions will result in a continuation of supply by the Company, Alkermes or a third party manufacturer. If Biogen is unable to obtain supply of the licensed product could constitute a breach under the existing supply agreement with Biogen resulting in termination of the license and supply agreements with Biogen or otherwise result in the cessation of sales of Fampyra and loss of royalty revenue in the future.

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

(15) Income Taxes

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

(In thousands)	Year ended December 31, 2022	Year ended December 31, 2021
Domestic	$ (60,179)	$ (112,530)
Foreign	24,932	3,456
Total	$ (35,247)	$ (109,074)

The benefit (expense) from income taxes in 2022 and 2021 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2022	Year ended December 31, 2021
Current:		
Federal	$ (243)	$ 230
State	(115)	(182)
Foreign	(37)	(113)
	(395)	(65)
Deferred:		
Federal	(30,234)	4,412
State	(40)	711
Foreign	—	62
	(30,274)	5,185
Total benefit from income taxes	$ (30,669)	$ 5,120

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 ("ownership change"). In the event of such a deemed ownership change, Section 382 imposes an annual limitation on pre-ownership change tax attributes. On June 1, 2022, the Company experienced an ownership change. The Company completed a Section 382 analysis and determined that its tax attributes are limited and would require a valuation allowance. As a result, the Company recorded additional valuation allowance on its net operating loss and tax credits carryforwards of approximately $35.3 million (tax effected).

As of December 31, 2022, the Company's U.S. consolidated federal NOL carryforwards on a tax return basis are approximately $117.6 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. Due to the Section 382 limitation a partial valuation allowance has been recorded on its pre-ownership change net operating losses of approximately $12.2 million (tax effected).

Biotie Therapies, Inc. ("Biotie US"), a wholly owned subsidiary of Biotie Finland, files a separate company federal income tax return and has a net operating loss carryforward of approximately $120.8 million as of December 31, 2022. These losses, which begin to expire in 2026, were historically not more likely than not to be realized and had been fully offset with a full valuation allowance and therefore the limitation under Section 382 that occurred during 2022 had no further financial statement impact. In the fourth quarter, in connection with the liquidation proceedings of Biotie Finland Ltd the Company reversed both the deferred tax asset and related valuation allowance which also had no impact to tax expense.

The Company's capital loss carryforward of approximately $42.3 million is fully offset with a valuation allowance. The capital loss carryforward will expire in 2026. Under Section 382, the utilization of this capital loss would be limited. The Company's capital loss from tax year 2017 of approximately $428.7 million expired as of December 31, 2022 and accordingly the deferred tax asset and corresponding valuation allowance have been reversed.

The Company had available state NOL carryforwards of approximately $312.9 million and $304.8 million as of December 31, 2022 and 2021, 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. Due to the Section 382 ownership change and limitation, a partial valuation allowance has been recorded on the unitary and certain separate state NOLs, of approximately $2.7 million.

The Company has $27.0 million of net operating loss carryforwards outside of the U.S. as of December 31, 2022, that begin to expire in 2023, all of which are fully reserved with a valuation allowance.

The Company's U.S. federal research and development and orphan drug credit carryforwards of $35.1 million and $35.3 million as of December 31, 2022 and 2021, respectively, begin to expire in 2023. Due to the Section 382 limitation, a full valuation allowance has been recorded on the remaining balance. The Company does not expect to pay U.S. federal or state cash taxes as they are in a current year taxable loss.

The timing differences between the financial reporting 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, 2022. The Company maintains a partial valuation allowance on the Acorda filling group's deferred balances. The Company had a net decrease of $86.5 million of valuation allowance. While the Company recognized a tax expense from recording additional valuation allowance due to the Section 382 limitation, there was an overall decrease in the valuation allowance balance which related to significant deferred tax asset reversals that had been fully reserved as of the beginning of the year. Accordingly, the reversal of the deferred tax asset and related valuation allowance for capital loss carryforwards, Biotie U.S. and other foreign net operating losses had no impact to tax expense.

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, 2022	Year ended December 31, 2021
U.S. federal statutory tax rate	21.0%	21.0%
State and local income taxes	(0.3)%	0.4%
Stock option compensation	(0.2)%	(0.1)%
Stock option shortfall	(8.8)%	(5.0)%
GILTI Inclusion	(8.3)%	—
Uncertain tax positions	0.4%	0.5%
Other nondeductible and permanent differences	(7.7)%	(2.6)%
U.S. write-off/expiration	(255.8)%	—
Valuation allowance, net of foreign tax rate differential	151.6%	(9.5)%
Biotie Finland cancellation of debt exclusion	21.7%	—
Federal return to provision differences	(0.6)%	—
Effective income tax rate	(87.0)%	4.7%

The Company's overall effective tax rate is affected by the increase in the valuation allowance, the forfeitures of equity based compensation for which no tax deduction is recorded and inclusion of GILTI as a permanent item.

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, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss carryforward	$ 74,576	$ 77,510
Capital loss carryforward	11,100	116,717
Tax credits	34,301	34,332
Stock based compensation	8,896	12,257
Contingent consideration	10,807	12,730
Employee compensation	1,438	1,513
Rebate and returns reserve	2,003	2,290
Capitalized R&D	1,191	10,696
Derivative liability	—	9
Other	5,421	7,656
Total deferred tax assets	$ 149,733	$ 275,710
Valuation allowance	(106,702)	(193,253)
Total deferred tax assets net of valuation allowance	$ 43,031	$ 82,457
Deferred tax liabilities:		
Intangible assets	(77,876)	(83,930)
Convertible debt	(9,190)	(12,842)
Depreciation	(167)	400
Other	-	(15)
Total deferred tax liabilities	$ (87,233)	$ (96,387)
Net deferred tax liability	$ (44,202)	$ (13,930)

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, 2022	Year ended December 31, 2021
Beginning of period balance	$ 6,370	$ 7,093
Increases for tax positions taken during a prior period	—	—
Decreases for tax positions taken during a prior period	(133)	(723)
Increases for tax positions taken during the current period	—	—
	$ 6,237	$ 6,370

Accrued interest and penalties 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 has ongoing state examinations in Massachusetts and New Jersey which cover multiple years. There have been no proposed adjustments at this stage of the examination. The Minnesota examination was finalized during the second quarter of 2022 for years 2018 and 2019 with no adjustments.

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, 2021	$ 186,491	10,028	(3,266)	$ 193,253
Year ended December 31, 2022	$ 193,253	233	(86,784)	$ 106,702

(16) Loss Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2022 and 2021:

(In thousands, except per share data)	Year ended December 31, 2022	Year ended December 31, 2021
Basic and diluted		
Net loss	$ (65,916)	$ (103,954)
Weighted average common shares outstanding used in computing net loss per share—basic	19,707	10,621
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	19,707	10,621
Net loss per share—basic	$ (3.34)	$ (9.79)
Net loss per share—diluted	$ (3.34)	$ (9.79)

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 loss 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, 2022	Year ended December 31, 2021
Denominator		
Stock options and restricted common shares	996	1,199

Performance share units are excluded from the calculation of net loss per diluted share as the performance criteria has not been met for the years ended December 31, 2022 and 2021. 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, 2022 and 2021.

(17) 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 $0.8 million and $0.9 million for the years ended December 31, 2022 and 2021, respectively.

(18) Subsequent Events

Catalent Manufacturing Services Agreement

Effective January 1, 2023, the Company entered into a new manufacturing services agreement (as amended in March 2023, the "New MSA") with Catalent and terminated, effective December 31, 2022, the prior Manufacturing Services Agreement, dated February 10, 2021 (the "2021 MSA"). Under the New MSA, Catalent will continue to manufacture Inbrija (levodopa inhalation powder) through 2030, with reduced minimum annual commitments through 2024 and significantly lower pricing thereafter. The New MSA provides for the scale-up of new spray drying equipment ("PSD-7"), which will provide expanded capacity for the long-term world-wide manufacturing requirements of Inbrija, which is expected to be operational in 2026. Under the New MSA Company will be subject to purchase commitments in 2023 and 2024 of 15 and 24 batches of Inbrija, respectively, at a total cost of $10.5 million and $15.5 million, respectively. Thereafter, in 2025, the Company will pay Catalent a fixed per capsule fee based on the amount of Inbrija that is delivered for sale in the United States and other markets. In addition, the Company will be obligated to pay Catalent $2 million in 2023 in connection with certain activities relating to the operational readiness of the PSD-7.

It is anticipated that by 2026, the PSD-7 equipment will be fully operational, which will significantly reduce the per capsule fees for all markets. The Company has agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment. In addition to the operational readiness payment described above, the Company will provide up to $1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts.

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

The Company agreed to purchase from Catalent all of our requirements for Inbrija for the United States, Germany, Spain and Latin America, except in the case of termination or certain supply disruptions. For China, the Company is not required to purchase our supply from Catalent and may arrange for an alternate supplier. For other countries, the Company may be released from exclusivity as long as the Company purchases at least two batches from Catalent in the applicable year, subject to certain rights of first refusal on alternative source of supply arrangements.

Silicon Valley Bank

Silicon Valley Bank ("SVB") was closed on Friday, March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the "FDIC") as receiver. As of March 13, 2023, the Company had approximately $8.3 million on deposit with SVB, which represented approximately 22% of our unrestricted cash and cash equivalents as of December 31, 2022. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As a result, we do not anticipate any losses with respect to our funds that had been deposited with SVB.

The Company continues to believe that its existing cash and cash equivalents balance and cash flow from operations will be sufficient to meet its working capital, capital expenditures, and material cash requirements from known contractual obligations for the next twelve months and beyond.

Alkermes Award Modification

In January 2023, the Company filed a petition in the District Court for the Southern District of New York to confirm and modify the arbitral award. In that arbitration, the arbitration panel found in the Company's favor that Alkermes leveraged its patent to illegally obtain royalties beyond the life of the patent in which was a violation of federal law. The panel held that Alkermes' conduct in continuing to charge royalties after the patent expired was unlawful per se and that the underlying agreements were unenforceable. The panel awarded the Company approximately $18.3 million, including interest, representing license royalties overpaid since July 2020. The Company is asking the District Court to confirm the Award, with modifications to the extent the panel disregarded federal law by declining to award royalties the Company paid prior to July 2020 and after July 2018, the date on which the panel found that the parties' agreements were unenforceable as a matter of law. The Company is seeking restitution of the remaining illegal royalties that the panel found were demanded and collected by Alkermes in violation of the law in the amount of approximately $65 million together with pre- and post-award interest and costs. On February 8, 2023, Alkermes filed a brief opposing the relief requested in the Company's petition and requesting that the award be confirmed without modification. The Company filed a brief in response on February 22, 2023. The District Court will likely schedule oral argument on the petition and render its decision sometime thereafter.

(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. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
10.11*	Form of stock option certificate under the Acorda Therapeutics 2016 Inducement Plan. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
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.

Exhibit No.	Description
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.
10.21*	Amendment dated January 6, 2022, to June 8, 2015 Employment Agreement by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
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. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
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. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
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. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
10.28*	Employment offer letter, dated November 4, 2021, by and between the Registrant and Neil Belloff. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
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.

Exhibit No.	Description
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.
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.

Exhibit No.	Description
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.
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. Incorporated herein by reference to Exhibit 10.51 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
10.52***	Second Amendment to Manufacturing Services Agreement dated as of December 31, 2021, by and between the Registrant and Catalent Massachusetts, LLC. Incorporated herein by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K filed on March 18, 2022.
10.53***	Manufacturing Services Agreement, dated September 30, 2010, and First Amendment to Manufacturing Services Agreement, dated as of August 29, 2011, by and between the Registrant and Patheon, Inc., as amended by Amendment No. 1, dated as of August 29, 2011.
10.54***	Settlement and Release Agreement, dated December 31, 2022, by and between the Registrant and Catalent Massachusetts LLC.
10.55***	Manufacturing Services Agreement, effective January 1, 2023, by and between the Registrant and Catalent Massachusetts LLC.
10.56***	First Amendment to the Manufacturing Services Agreement dated March 9, 2023, by and between the Registrant and Catalent Massachusetts LLC.
10.57***	Amended and Restated Termination Letter, dated March 9, 2023, 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.

Exhibit No.	Description
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 14th day of March, 2023.

ACORDA THERAPEUTICS, INC.

/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 14, 2023
/s/ MICHAEL GESSER, M.B.A. Michael Gesser, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 14, 2023
/s/ PEDER K. JENSEN, M.D. Peder K. Jensen, M.D.	Director	March 14, 2023
/s/ JOHN P. KELLEY John P. Kelley	Director and Chair	March 14, 2023
/s/ SANDRA PANEM, PH.D. Sandra Panem, Ph.D.	Director	March 14, 2023
/s/ LORIN J. RANDALL Lorin J. Randall	Director	March 14, 2023
/s/ JOHN VARIAN John Varian	Director	March 14, 2023

Exhibit 10.53

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

Manufacturing Services Agreement

September 30, 2010

Table of Contents

MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the "Agreement") made as of the 30th day of September, 2010 ("**Effective Date**")

B E T W E E N:

PATHEON INC.,
a corporation existing under the Laws of Canada,

(hereinafter referred to as "**Patheon**"),

- and -

Acorda Therapeutics Inc.,
a corporation existing under the Laws of the state of Delaware,

(hereinafter referred to as the "**Client**" OR "**Acorda**").

THIS AGREEMENT WITNESSES that in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms will have corresponding meanings:

"Active Pharmaceutical Ingredients" or "API" means the materials listed on Schedule D hereto;

"**Active Pharmaceutical Ingredients Credit Value**" means the value of the Active Pharmaceutical Ingredients for certain purposes of this Agreement, as set forth on Schedule D;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For the purposes of this definition, "control" means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation.

"**Annual Report"** means the annual report to the FDA prepared by or on behalf of Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"Annual Product Review Report" means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B hereto;

"**Applicable Laws**" means the Laws of all jurisdictions where the Products are manufactured, distributed and marketed as such are agreed and understood by the parties in this Agreement; any and all Laws of all jurisdictions now or hereafter enacted or promulgated by any Authority and Regulatory Authority that govern the approval, manufacture, distribution, marketing, sale or license of pharmaceutical products, or components for inclusion therein.

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"Batch" means a quantity of Product in dosage form, produced according to a single production order in accordance with the Specifications and as attested to by the signatories to the purchase order.

"Bill Back Items" means the expenses for all third party supplier fees for the purchase of columns, standards, tooling, PAPR or PPE suits (where applicable), RFID tags and supporting equipment and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United States of America or the Province of Ontario, Canada;

"**cGMPs**" means current good manufacturing practices as described in:

(d) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

(e) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations; and

(f) EC Directive 2003/94/EC,

together with the latest Health Canada, FDA, and EMEA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"Client Intellectual Property" means (i) Intellectual Property owned by, licensed to or generated or derived by Client (including, but not limited to the Product and the API), or (ii) generated or derived by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in connection with the conduct of its business which Intellectual Property is specific to, or dependent upon, references or incorporates Client's API, Product or any other Intellectual Property of Client.

"Competitor" means a legal entity with at least [*****] if its annual revenue generated from any combination of contract pharmaceutical drug product manufacturing or contract pharmaceutical product development services. "Competitor" does not include [*****].

"**Components**" means, collectively, all packaging components, raw materials and ingredients (including labels, product inserts and other labelling for the Products), required to manufacture the Products in accordance with the Specifications, other than the API;

"**Confidentiality Agreement**" means the agreement relating to the non-disclosure of confidential information among Patheon and Client dated September 23, 2005;

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

"Delivery Date" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(e);

"EMEA" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Orders**" has the meaning specified in Section 5.1(b);

"First Firm Order" has the meaning specified in Section 5.1;

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"Initial Manufacturing Month" has the meaning specified in Section 5.1;

"Initial Manufacturing Period" has the meaning specified in Section 5.1;

"Initial Set Exchange Rate" means **0.952** as of the Effective Date of the Agreement being the initial exchange rate to convert one unit of Patheon facility local currency to one unit of the billing currency, calculated as the average interbank exchange rate for conversion of one unit of Patheon facility local currency to one unit of the billing currency during the ninety (90) day period immediately preceding the Effective Date as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs; trade secrets and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the API;

"Late Delivery" has the meaning specified in Section 5.5;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance and stability testing, packaging and related services, set forth in this Agreement, required to manufacture Products from API and Components;

"**Manufacturing Site**" means the facility owned and operated by Patheon that is located at 2100 Syntex Court, Mississauga, Ontario L5N 7K9.

"Materials" means all Components, Bill Back Items and other materials used in the manufacture of the Product other than API;

"**Maximum Credit Value**" means the maximum value of API that may be credited by Patheon under this Agreement, as set forth on Schedule D;

"**Minimum Run Quantity**" means the minimum number of Batches of a Product to be produced during the same cycle of manufacturing as set forth in Schedule B hereto;

"Patheon Intellectual Property" means Intellectual Property (i) generated or derived by Patheon before performing any Manufacturing Services, (ii) Intellectual Property developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property, in all cases, is not specific to, or dependent upon, does not reference or incorporate any Client Intellectual Property, Client's API or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components, certain cost items as set forth in Schedule B and annual stability testing costs as set forth in Schedule C.

"**Product(s)**" means the product(s) listed on Schedule A;

"Product Forecast" and "Extended Product Forecast" have the meanings specified in Section 5.1;

"**Quality Agreement**" means the agreement dated as of September 30, 2010 (and any subsequent amendments thereto, and any supplementary quality agreements) between Patheon and the Client setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"**Regulatory Authority**" means the FDA, EMEA and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"Reset Date" means, with reference to any particular Year, the date on which Patheon is to provide Client with updated pricing for the Product for the next Year, which date will be not be later than November 1st of the immediately preceding Year;

"RFID" means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking and identification;

"Set Exchange Rate" means the exchange rate to convert one unit of Patheon facility local currency to one unit of the billing currency for each Year, calculated as the average interbank exchange rate for conversion of one unit of Patheon facility local currency to one unit of the billing currency during the three (3) month period immediately preceding the Reset Date as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory **.**

"**Specifications**" means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to each Product, including, without limitation:

(g) specifications for API and Components;

(h) manufacturing specifications, directions and processes;

(i) storage requirements;

(d) all environmental, health and safety information for each the Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means in the geographic area of the world, as requested by Client or Client's designee;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Year**" means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.2 Currency.

Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section or Schedule of this Agreement.

1.4 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A - Product List and Specifications
Schedule B - Minimum Run Quantity, Annual Volume & Price
Schedule C - Stability Testing, Validation and Tech Transfer Activities
Schedule D - API & API Credit Value
Schedule E - Batch Numbering & Expiration Dates
Schedule F - Technical Dispute Resolution
Schedule G - Quality Agreement
Schedule H - Shipping Logistics Protocol
Schedule I - Quarterly API Inventory Report
Schedule J - Report of Annual API Inventory Reconciliation and Calculation of Actual Annual Yield

Schedule K - Form of Exclusive Components Purchasing Summary

Schedule L - Example of Price Adjustment due to Currency Fluctuation

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the fees specified in Schedules B and C in order to manufacture Product for Client. The parties acknowledge and agree that all Product manufactured by Patheon for commercial distribution after January 22, 2010, through the Effective Date is also subject to the terms and conditions of this Agreement and the Quality Agreement.

Client and Patheon acknowledge that this Agreement will be utilized for the manufacture and supply of Product outside the US through Client's licensee, Biogen Idec. Client and Patheon agree to work together in good faith and negotiate an amendment to this Agreement for such manufacture and supply. Additionally, Patheon acknowledges and agrees that requirements outside the US may require quality agreement(s) for ex-US quality-related matters, and Client and Patheon agree to work together in good faith to negotiate any such quality agreement(s) for ex-US quality-related matters.

Schedule B sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in the aforementioned list are excluded from the Price and are subject to additional fees to be paid by the Client. Patheon may change the Manufacturing Site for the Product only with the prior written consent of Client this consent not to be unreasonably withheld. If Manufacturing Services have not started within 12 months of the Effective Date of this Agreement Patheon may amend the fees set out in Schedules B and C and submit to Client for Client's review and consideration. Patheon acknowledges that Patheon is not the exclusive manufacturer of Product. In providing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of API and Components. Patheon will utilize the API and Components to manufacture Product.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its Batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Product to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the Batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. Batch documents, including, but not limited to Batch production records, lot packaging records, equipment data printouts, raw material data and laboratory notebooks and the form and style of same are the exclusive property of Patheon; provided, however, that Patheon shall promptly provide a certified copy of all such records upon Client's request.

(c) Components and API. Patheon will purchase all Components and will test all Components and API (with the exception of those that are supplied by Client) at Patheon's expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods specified in Schedule C. Patheon will not make any changes

to these testing protocols without prior written approval from Client. If a confirmed stability test failure or International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH significant change occurs, Patheon will notify Client within [*****], after which Patheon and Client will promptly meet to jointly determine, in good faith discussions, the proceedings and methods to be undertaken to investigate the causes of the failure, including which party will bear the cost of the investigation; provided that Patheon will not be liable for any such costs unless there has been a failure by it to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws. Patheon will give Client all stability test data and results at Client's request. Patheon will provide a stability report to Client after each testing interval.

(e) Packaging. Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the Batch numbers and expiration dates for each Product shipped. The Batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for Batch numbering and expiration dates is detailed in Schedule E hereto. Client may, at its sole discretion, make changes to labels, product inserts and other packaging for the Products. Those changes will be submitted by Client to all applicable governmental agencies and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless required by Applicable Laws.

(f) API and Client Supplied Components Importing. At least [*****] prior to the scheduled production date, Client will furnish to Patheon at the Manufacturing Site, DDP (Incoterms 2000), the API, free of charge in such quantities as are necessary to enable Patheon to manufacture the desired quantities of Product on the requested delivery date. If such API are not received [*****] in advance, Patheon will be entitled to delay shipments of Product caused by the re-scheduling of production by the same number of days as the delay in receipt of such API; provided, however, that in the event Patheon is unable to meet such scheduling deadline due to prior third party production commitments, Patheon shall promptly notify Client and will be entitled to delay shipments until such later date as agreed to by the parties, but not to exceed thirty (30) days beyond the calculated re-scheduled date. All shipment of API will be accompanied by certificate(s) of analysis from the API manufacturer and the Client, confirming the identity, purity and compliance with the APIl specifications.

(g) Bill Back Items. Bill Back Items will be charged to Client at Patheon's cost plus a [*****] handling fee.

(h) Validation Activities. Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees associated with Patheon's assistance in providing validation development assistance are set out in Schedule C.

(i) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and mutually agreed upon at the time of process validation and incorporated by reference into this Agreement. If Patheon manufactures Product in accordance with the agreed upon process specifications and a Batch or portion of Batch of Product fails to meet a Finished Product Specification, the parties will meet in good faith to discuss the root cause of the failure and responsibility between the parties for the cost of the failed Product. If the parties

are unable to reach agreement on the root cause and responsibility for the cost within seven (7) days, the matter will resolved as a Technical Dispute under Section 12.2.

2.2 API Yield.

(a) Reporting. Patheon will provide Client with a quarterly inventory report of the API held by Patheon in accordance with the inventory report form annexed hereto as Schedule I, which will contain the following information for such quarter:

Quantity Received: The total quantity of API that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of API dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by [*****].

Quantity Converted: The total amount of API contained in the Products produced with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.1 or 6.2), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 as a result of a failure by Patheon to provide Manufacturing Services in accordance with Specifications, cGMPs and Applicable Laws.

Within [*****] after the end of each Year, Patheon will prepare an annual reconciliation of API in accordance with the reconciliation report form annexed hereto as Schedule J including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the Manufacturing Site during the Year. AAY is [*****] and is calculated as follows:

$$\frac{[*****]}{[*****]} \times 100\%$$

After Patheon has produced a minimum of [*****] commercial production Batches of Product and has produced commercial production Batches for at least [*****] at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**") under this Agreement, the Parties will mutually agree on the target yield in respect of such Product at the Manufacturing Site (each, a "**Target Yield**");

(b) Shortfall Calculation. If the Actual Annual Yield falls more than [*****] percent below the respective Target Yield in a Year, then the shortfall for such Year (the "**Shortfall**") will be determined based on the following calculation:

Shortfall = [*****]

(c) Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of any such Shortfall not later than [*****] after the end of such Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report prepared in the form annexed hereto as Schedule J and will be made in accordance with Section 5.5. Upon expiration or termination of this Agreement, any remaining credit amount owing under this Section 2.2 will be reimbursed to Client by payment thereof to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report prepared in the form annexed hereto as Schedule J.

(d) Maximum Credit Notwithstanding the foregoing provisions of this Section 2.2, Patheon's liability for API calculated in accordance with this Section 2.2 in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D hereto.

(e) No Material Breach. It will not constitute a material breach of this Agreement by Patheon, for the purposes of Section 8.2(a), if the Actual Annual Yield is less than the Target Yield.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for the provision of the Manufacturing Services and related Materials according to the Prices specified in Schedules B and C. These prices may be subject to adjustment under other parts of this Agreement as agreed upon in writing by the parties.

3.2 Active Pharmaceutical Ingredient.

Client will, at its sole cost and expense, deliver the API to Patheon (in accordance with Section 2.1(f)) in sufficient quantities and at such times to facilitate the provision of the Manufacturing Services by Patheon. The API will be held by Patheon on behalf of Client on the terms and subject to the conditions herein contained. Title to the API will at all times belong to and remain the property of Client. Any API received by Patheon will only be used by Patheon to provide the Manufacturing Services. Patheon's liability with respect to any lost or damaged API will be as set forth in Section 10.2(a).

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The tiered Prices and annual stability Prices for the Products for the first Year are listed in Schedules B and C and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments – Subsequent Years' Pricing.

The Prices for the Products during any Year following the first Year of this Agreement will be determined as follows:

(a) Manufacturing Costs. Effective at the beginning of each Year of this Agreement, Patheon will be entitled to adjust the Price for inflation, based upon the increase in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics in September of the preceding Year compared to the same month of the Year prior to this, unless the parties otherwise agree in writing.

(b) Component Costs. If there is a year over year percentage increase or decrease in total Component costs for any Product for the Year, then Patheon will be entitled to an appropriate percentage Price adjustment to pass through the increase or decrease in the cost of the Components. Client may audit the Patheon books and records which form the basis for the documented increase in Component costs as permitted by section 4.6. Patheon reserves the right to require that any such audit be conducted by qualified third party auditors appointed by Client and reasonably acceptable to Patheon. The auditors will provide to Client (copy to Patheon) only a report setting out the conclusions they have reached regarding the sufficiency of the books and records as support for the price increase or decrease while maintaining the confidentiality of those books and records. [*****].

(c) Pricing Basis. Client acknowledges that the Price for a Product in any Year is quoted based upon the Minimum Run Quantity and the Price tiers specified in Schedule B. The Price is subject to change if [*****].

(d) Adjustments Due to Currency Fluctuations. Subsequent to the calculation of all other annual price adjustments, Prices for Product produced by Patheon at a facility located outside the United States or Puerto Rico will be adjusted with effect from January 1 of each Year, beginning with January 1, 2011, proportionately to reflect the increase, if any, in the Set Exchange Rate for the three (3) months immediately preceding the Reset Date over the Set Exchange Rate for the same three (3) months of the Year prior to the Reset Date Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment is attached hereto as Schedule L. The adjustment will be calculated after all other annual Price adjustments have been made.

If a Price adjustment is made under clause (a) of this Section 4.2, Patheon will deliver to Client on or about the Reset Date a revised Schedule B and a statement outlining the percentage increase in the Producer Price Index for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics in September of the preceding Year compared to the same month of the Year prior to this, unless the parties otherwise agree in writing. For all Price adjustments under clauses (b), (c), and (d) of this Section 4.2, Patheon will deliver to Client on or about the Reset Date a revised Schedule B and budgetary pricing information or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers other than in confidence to qualified auditors as permitted by paragraphs (b) and (c) and section 4.6. The revised Price will be effective for any Product delivered after the end of the then current Year.

4.3 Price Adjustments – Current Year Pricing.

During any Year of this Agreement, the Prices set out in Schedule B will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. For the purposes of this clause, changes materially greater than normal forecasted increases will be considered to have occurred if: (i) the cost of a Component increases by [*****] of the cost for this Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [*****] of the total Component costs for such Product upon which the most recent fee quote was based. To the extent this Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments provided for in (i) and (ii) above will operate based on the costs attributed to such Component (or Components) at the time the last of such adjustments were made.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers other than in confidence to qualified auditors as permitted by section 4.6. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review by Patheon and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, such approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented, and the Price change will become effective only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's cost therefor (including all costs incurred by Patheon in connection with the purchase and handling of such Inventory), all Inventory utilized under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be utilized under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client.

4.5 Multi-Country Packaging Requirements

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the USA, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional Component costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

4.6 Price Increase Audits.

Client or Client's designee may audit the Patheon books and records which document the cost increases referenced in paragraphs 4.2 (b) or (c) or section 4.3. The audit will be conducted by qualified independent third party auditors selected by Client or Client's designee from a list of auditors reasonably acceptable to Patheon. The auditors will provide to Client and/or Client's designee (copy to Patheon) a report setting out the conclusions they have reached regarding the sufficiency of the books and records as support for the proposed Price increase while maintaining the confidentiality of those books and records. [*****].

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling [*****] Forecast. When this Agreement is executed, Client will give Patheon a non-binding [*****] forecast of the volume of Product that Client expects to order in the first [*****] of commercial manufacture of the Product. This forecast will then be routinely updated by Client on or before the 23rd day of each month on a rolling forward basis and will be known as the "Product Forecast". Client will update the Product Forecast forthwith if it determines that the volumes estimated in the most recent Product Forecast have changed by more than [*****].

(b) Firm Orders for Initial Manufacturing Month. At least [*****] before the start of commercial manufacture of the Product, Client will update the Product Forecast for the first [*****] of manufacture of the Product (the "Initial Manufacturing Period"). The first month of this updated Product Forecast ("Initial Manufacturing Month") will constitute a firm written order in the form of a purchase order or otherwise ("First Firm Order") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture the quantity of the Product. Client

may cancel any Batches from the First Firm Order at no cost if notice of cancellation is received by Patheon [*****] or more before the scheduled Delivery Date under the First Firm Order. Client may cancel any Batches from the First Firm Order if notice of cancellation is received by Patheon more than 30 days but fewer than [*****] before the scheduled Delivery Date under the First Firm Order, but Client will pay Patheon [*****] for each cancelled Batch. The parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above then the initial Product Forecast will also be adjusted as necessary. The cancellation rights in this section are subject to Client retaining responsibility for any costs or expenses actually incurred or irrevocably committed by Patheon under this Agreement before it received notice of the cancellation.

(c) Firm Orders Thereafter. After the Initial Manufacturing Month, on a rolling basis during the Term, and on or before the 10th day of each month, Client will issue an updated Product Forecast and the first three months of that updated forecast will constitute a firm written order in the form of a purchase order or otherwise ("Firm Order") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products on a date not less than [*****] from the first day of the month immediately following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's Manufacturing Services purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. Upon Patheon's acceptance of a Firm Order, the quantities of Products ordered will be firm and binding on Client and may not be reduced by Client. For the purpose of clarity, any months in a Product Forecast beyond the most current 3 months and the First Firm Forecast can be cancelled at any time by Client upon written notice to Patheon at no cost to Client excepting Client's responsibility to pay for Components purchased by Patheon on Client's behalf.

(d) Three Year Forecast. On or before the last business day of June of each Year, Client will give Patheon a written non-binding three-year forecast, broken down by quarters for the [*****] and third years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the three-year period (the "Extended Product Forecast").

(e) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [*****] of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the Parties or as set forth in Sections 2.1(f) or 5.1(b). The acknowledgement shall be sent to [*****] with a cc to [*****] or to such other persons and addresses as may be designated by the Client in a written notice to Patheon from time to time.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and Product Forecasts submitted under Sections 5.1(a), (b), and (c) in ordering the Components required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first [*****] contemplated in the most recent Product Forecast. Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products

manufactured for Client within [*****] after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) Patheon will give Client, initially upon the Effective Date of this Agreement and thereafter on an annual basis, a listing of all Components which are unique to Client, which Patheon anticipates purchasing under this Agreement (in accordance with rolling forecasts and Firm Orders as per Paragraphs 5.1(a) and (b)) in the form as set out in Schedule K (the "**Exclusive Component Purchasing Summary**"). The Exclusive Component Purchasing Summary will indicate which Components have a limited shelf-life and which are subject to minimum order quantities as specified by the supplier. Subject to subsection (a) above, Client will be liable for the costs of all Components purchased by Patheon for use under this Agreement not used to perform Manufacturing Services prior to the expiry of the Component's shelf life. Reimbursement from Client will be due, where applicable, within [*****] of notification from Patheon that the Component has expired. Patheon will not be obligated to give specific pricing information regarding any Component which is subject to confidentiality obligations between Patheon and its supplier.

(c) If Client fails to take possession or arrange for the destruction of Components within [*****] of purchase or, in the case of finished Product, within three months of manufacture, Client will pay Patheon [*****] per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [*****] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than [*****] to the Client at Client's expense on [*****] written notice to the Client.

5.3 Minimum Orders.

Client may only order Manufacturing Services for Batches of Products in multiples of the Minimum Run Quantities as set out in Schedule B.

5.4 Shipments.

Shipments of Products will be made EXW (INCOTERMS 2000) Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export licence or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications. The details of the Client review process shall be outlined in the Quality Agreement.

5.5 On Time Delivery.

(a) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the Initial Manufacturing Period. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(b) If, after the Initial Manufacturing Period, Patheon is unable to deliver the quantity of Product ordered under a Firm Order on the Delivery Date due to an act or omission by Patheon (a "Late Delivery"), Client will receive a credit from Patheon for the Late Delivery that will be applied against the Price under the next Firm Order. The credit will be [*****] of the Price of the quantities of Product not delivered by Patheon under the Firm Order on the Delivery Date (i.e., Client Credit = [*****].

(c) A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2.

(d) For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials (with respect to Materials, will be a Late Delivery unless a Force Majeure Event), a delay in Product release approval from Client, Client forecasts wherein Client has forecasted less Product than what is actually ordered by Client and only with respect to the portion of the Product that exceeds the amount forecasted, receipt of non-conforming API or Components supplied by Client, or any market driven delays in deliveries from approved vendors.

5.6 Invoices and Payment.

Invoices will be sent by email to [*****] and reference this Agreement. Invoices will be sent when the Product is manufactured and shipped by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [*****] of the date thereof. Interest on past due, undisputed amounts will accrue at [*****] per month which is equal to an annual rate of [*****]. The Late Delivery credits set forth in this Section 5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within [*****] outstanding from the invoice date when the Late Delivery arose.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt thereof and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that deviate from the Specifications, cGMPs and Applicable Laws within [*****] after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [*****] after discovery thereof by Client, but in no event after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [*****] period, then the delivery will be deemed to have been accepted by Client on the [*****] after delivery or discovery, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable [*****] period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have [*****] to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within [*****] after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs or Applicable Laws, then the parties will mutually select an independent consultant to evaluate if the Products deviate from the Specifications, cGMPs or Applicable Laws. This evaluation will be binding on the parties, and if the evaluation certifies that any Products deviate from the Specifications, cGMPs or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1. In this event the evaluation costs will be borne by Patheon, otherwise the Client will be responsible for the evaluation costs. If the evaluation does not so certify in respect of any such Products, then Client will be deemed to have accepted delivery of such Products on the [*****] after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [*****] after discovery thereof by Client, but in no event after the expiration date of the Product).

(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the parties or resolved under the dispute provisions of Article 12.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products and/or which might result in the Recall or seizure of the Products. Upon receiving any such notice or upon any such discovery, each party will cease and desist from further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either Party to refrain from selling or shipping quantities of the Products, to third parties, which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any governmental Authority or Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle such returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset such amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all API required for the manufacture of such replacement Products. For greater certainty, Patheon's responsibility for any loss of API in connection with defective Product will be captured and calculated in the API Yield under Section 2.2.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Client of all API required for the manufacture of such replacement Products. For greater certainty, Patheon's responsibility for any loss of API in connection with Recalled Product will be captured and calculated in the API Yield under Section 2.2. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required API), then Client may request Patheon to reimburse Client for the price Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns or other corrective actions will be made at Client's cost and expense.

(c) Except as set forth in Paragraphs 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product

manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications or through Patheon's reasonable vendor auditing program, (iii) results from a defect in the API or Components supplied by Client that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP's and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3 and will make such disposition in accordance with all Applicable Laws. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all mutually agreed upon information this will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Unless it is determined this the cause of any such complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party hereby appoints one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen. The relationship managers

are as follows, or as may be otherwise designated by Client or Patheon by written notice to Client or Patheon, as the case may be, from time to time:

Acorda:

Bill Dollard
Senior Director, Technical Operations;
[*****]

And

Bonnie Pappacena
Executive Director, Quality Assurance;
[*****]

at the same mailing address provided for written notices under Section 13.9.

Patheon:

Sheri Calpito
Business Manager;
[*****]

And

Charlotte Brice
Business Development Manager;
[*****]

at the same mailing address provided for written notices under Section 13.9.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental Authority, including but not limited to Regulatory Authorities, regarding the Products if, in the opinion of this party's counsel, such communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Laws. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing and shipping of the Products, and retain and store preservation samples from each lot number of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples will be retained for a period of one (1) year following the date of Product expiry, or longer if required by Applicable Law, at which time Client will be contacted via the process outlined in Section 4.18.2 of the Quality Agreement, concerning the delivery and destruction of the documents and/or samples of Products. Client is responsible for retaining samples of the Products necessary to comply with the Applicable Law.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 Access.

Patheon will give Client reasonable access at mutually agreeable times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled or shipped to permit Client to verify this the Manufacturing Services are being performed in accordance with the Specifications, cGMPs and Applicable Laws. The details regarding the conduct of audit and audit-related matters shall be set forth in the Quality Agreement.

7.6 Notification of Regulatory Inspections.

Notification of inspections by a Regulatory Authority shall be set forth in the Quality Agreement.

7.7 Reports.

Reporting requirements shall be set forth in the Quality Agreement.

7.8 FDA Filings

(a) Regulatory Authority. Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions this may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement or upon the reasonable request of Client, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. At least [*****] prior to filing any documents with any Regulatory Authority that incorporates data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Client shall not be under any obligation to provide Patheon with third party data that is subject to obligations of confidentiality.

(c) Verification of CMC. At least [*****] prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of those portions of the CMC incorporating Patheon generated data as well as all supporting documents CMC incorporating Patheon generated data which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work this Patheon has performed and the manufacturing processes this Patheon will perform under this Agreement. Client will give Patheon copies of all FDA filings at the time of submission which contain CMC information regarding the Product. Client shall not be under any obligation to provide Patheon with third party data that is subject to obligations of confidentiality.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines this any of the information given by Client under Paragraphs (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "Deficiencies"), Patheon will notify Client in writing of such Deficiencies. The parties will work together to have such Deficiencies resolved prior to any pre-approval inspection.

(e) Client Responsibility. For clarity, the parties agree this in reviewing the documents referred to in Paragraph (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work

undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsibility for the preparation and filing of the application for approval by the Regulatory Authorities and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under Paragraph (b) above within the time specified and if Patheon reasonably believes this Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

ARTICLE 8

TERM AND TERMINATION

8.1 Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2013, (the " **Term**"), unless terminated earlier by one of the parties in accordance herewith or extended in an amendment executed by the parties. This Agreement will be renewed for successive one-year terms unless either party gives written notice to the other party of its intention to terminate this Agreement at least 12 months prior to the end of the current Term. During any renewal period, this Agreement may be terminated by either party with at least 12 months' written notice.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under this Agreement within sixty (60) days following receipt of a written notice (the "Remediation Period") of said breach this expressly states this it is a notice under this Paragraph 8.2(a) (a "Breach Notice"). The aggrieved party's right to terminate this Agreement under this Paragraph 8.2(a) may only be exercised for a period of sixty (60) days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product upon thirty (30) days prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing or selling the Product. However, in such event Client will still fulfill all of its obligations under Section 8.4 below.

(d) Patheon may terminate this Agreement upon six (6) months prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client, as determined by a poor or high-risk credit rating; or (ii) a Competitor of Patheon. (iii) or an entity with whom Patheon has a material and ongoing legal dispute.

8.3 Product Discontinuation.

Client will give at least six (6) months' advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market.

8.4 Obligations on Termination.

If this Agreement is completed, expires or is terminated in whole or in part for any reason, then (in addition to any other remedies Patheon may have if Client defaults):

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given;

(c) Client will satisfy the purchase price payable under Patheon's non-cancellable orders with suppliers of Components, provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;

(d) Patheon will return to Client all unused API (with shipping and related expenses, if any, to be borne by Client); and

(e) Client acknowledges that no Competitor of Patheon will be permitted access to the Manufacturing Site; provided, however that this does not include Client's Licensor, Elan Corporation or Client's Licensee, Biogen Idec;

(f) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within [*****], all of Client's Components, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("Client Property"). If Client fails to remove the Client Property within five Business Days following the completion, termination or expiration of the Agreement Client will pay Patheon [*****] per pallet, per month, one pallet minimum ([*****] per pallet, per month, one pallet minimum, for any of the Client Property this contains controlled substances or requires refrigeration) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges according to the provisions of Section 5.5 of this Agreement.

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement. For greater certainty, termination of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.4, 5.6, 8.4, 13.1, 13.2, 13.3 and 13.15, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents and warrants that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment this would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client covenants, represents and warrants this:

(a) Non-Infringement

(i) the Specifications for each of the Products are its or its Affiliate's property or licensed to the Client or Affiliates and that Client may lawfully disclose the Specifications to Patheon for the purposes of this Agreement;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property or is licensed to Client or Affilaites, (B) may be lawfully used as directed by Client under this Agreement, and (C) does not infringe and will not infringe any Third Party Rights;

(iii) the performance of the Manufacturing Services by Patheon for any Product under this Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the API and the Components, or the sale, use or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws ; and

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets such Products in accordance with approvals by the Regulatory Authority in such jurisdiction.

9.3 Patheon Warranties.

Patheon covenants, represents and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be

lawfully used by Patheon, and (iii) such use does not infringe and will not infringe any Third Party Rights;

(c) that at the time of shipment, the Product shall have been manufactured in accordance with the Specifications and all Applicable Laws and will not be adulterated or misbranded within the meaning of the Applicable Laws; and

(d) that as of the Effective Date, Patheon is not a party to any oral or written contract or understanding with any third party that is inconsistent with this Agreement and/or Patheon's performance under this Agreement or that will in any way limit or conflict with its ability to fulfill the terms of this Agreement. Patheon further represents that it will not enter into any such agreement during the Term

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the Laws of the United States for conduct relating to the regulation of any drug product under the *Federal Food, Drug, and Cosmetic Act* (United States). If Patheon or any of its representatives or employees are subsequently debarred under the FDCA or excluded from a federal health care program during the Term, Patheon agrees to immediately notify Client of such action. Patheon acknowledges that Client may choose to terminate this Agreement.

9.5 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities to the extent required to enable it to lawfully and properly perform the Manufacturing Services, including, but not limited to, any permits, licenses or approvals for Patheon's facilities.

9.6 No Warranty.

NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except as otherwise expressly set forth in this Agreement, under no circumstances whatsoever will either party be liable to the other or its Affiliates in contract, tort, negligence, breach of statutory duty or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or (ii) for any other liability, damage, costs or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of such damages. Nothing in this Section 10.1 is intended to limit or restrict the confidentiality or indemnification rights or obligations of either party under this Agreement.

10.2 Limitation of Liability.

(a) API. Patheon will not be responsible for any loss or damage to the API unless this API is lost or damaged due to Patheon's negligence or wilful misconduct. Patheon's maximum responsibility for loss or damage to the API will not exceed the Maximum Credit Value set out in Schedule D. Client will pay to Patheon the cost of all API this is lost or damaged not due to Patheon's negligence or wilful misconduct as well as the cost of API this is lost or damaged due to Patheon's negligence or wilful misconduct this is in excess of the Maximum Credit Value.

(b) Maximum Liability. Patheon's maximum liability to Client under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 or Section 10.3 hereof or resulting from any and all breaches of its representations, warranties or other obligations under this Agreement will not exceed [*****] in the aggregate and in any one Year will not exceed [*****] of the preceding year's revenue to Patheon from the Manufacturing Services.

10.3 Patheon.

Patheon agrees to defend, indemnify and hold Client, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to (i) any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, (ii) any claim of infringement or alleged infringement or misappropriation of any Third Party Rights; (iii) any breach or non-performance of any of Patheon's covenants, obligations, representations or warranties under this Agreement; or (iv) failure to obtain, maintain or comply in any respect with any of its Permits required to perform any of its obligations hereunder; (v) any violation of Applicable Laws in the performance of its obligations hereunder, except in the case of (i) – (v) above, to the extent that the losses, damages, costs, claims, demands, judgments and liability are due to the gross negligence or intentional or wilful misconduct of Client, its officers, employees or agents or Affiliates.

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defence of the claim; (d) permit Patheon to control the defence and settlement of the claim, all at Patheon's cost and expense.

10.4 Client.

Client agrees to defend, indemnify and hold Patheon, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to (i) any claim of infringement or alleged infringement of any Third Party Rights in respect of the Products, or any portion thereof, and/or any claim of personal injury or property damage to the extent that the injury or damage is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein; (ii) any claim of infringement or alleged infringement or misappropriation of any Third Party Rights; (iii) any failure to obtain, maintain or comply in any respect with any of its Permits required to perform any of its obligations hereunder or associated with the marketing, distribution and sale of the Product; or (iv) any violation of Applicable Laws in the performance of its obligations hereunder except, in the case of (i) – (iv) above, to the extent that the losses, damages, costs, claims, demands, judgments and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees or agents.

If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defence of the claim; (d) permit Client to control the defence and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement, which agreement remains in effect in accordance with its terms; but if the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement, the terms of the Confidentiality Agreement will continue to govern the parties' obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the Term, as though the Confidentiality Agreement remained in full force and effect.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of or in connection with this Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In this regard, any party may send a notice of dispute to the other, and each party will appoint, within [*****] from receipt of the notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated will meet as necessary in order to resolve the dispute. If these representatives fail to resolve the matter within [*****] from their appointment, or if a party fails to appoint a representative within the [*****] period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or such other officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.15.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes about the matters set out in Sections 6.1(b) and 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party will, as soon as practicable and in any event no later than [*****] after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [*****] of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with the Schedule F. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule F) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the Term, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use and sale of Client's Product that is the subject of the Manufacturing Services, will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon; Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services so as to enable Client to manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by such party.

13.2 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the Term and for a period of three (3) years thereafter, which insurance will afford limits of not less than (i) [*****] for each occurrence for personal injury or property damage liability; and (ii) [*****] in the aggregate per annum with respect to product and completed operations liability. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate will further provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of such provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder without the written consent of Client, such consent not to be unreasonably withheld; however, Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on [*****] prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Prices within a reasonable time;

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond this party's reasonable control, including, but not limited to, strikes or other labour disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, market driven shortages, lack of or inability to obtain fuel, power or components or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 Additional Product.

Additional products may be added to this Agreement and such additional products will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, and C as applicable.

13.9 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

Acorda Therapeutics, Inc
15 Skyline Drive
Hawthorne, NY 10532

Attention: Senior Director, Technical Operations

With a copy to Attention: General Counsel, at the same address

If to Patheon:

Patheon Inc.
2100 Syntex Court
Mississauga, Ontario L5N 7K9
Canada

Attention: General Counsel

Facsimile No.: 905.812.6705

Email address [*****]

or to such other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the United States, Canada or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, that determination will not impair or affect the validity, legality or enforceability of the remaining provisions hereof, because each provision is separate, severable and distinct.

13.11 Entire Agreement.

This Agreement, together with the Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings concerning the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Quality Agreement and the Confidentiality Agreement. THE TERMS OF ANY PURCHASE ORDER, ACKNOWLEDGMENT OR SIMILAR STANDARDIZED FORM GIVEN OR RECEIVED IN THE CONTEXT OF THE SUBJECT MATTER OF THIS AGREEMENT WHICH ARE IN ADDITON TO OR INCONSISTENT WITH THE TERMS OF THIS AGREEMENT WILL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY EXPRESSLY EXCLUDED FROM THIS AGREEMENT.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to such

terms, provisions, or conditions unless such document specifically refers to this Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or in connection with any other word or words, without the prior written consent of Client.

13.16 Governing Law

This Agreement will be construed and enforced in accordance with the Laws of the State of New York, in the United States and be subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement

The duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON INC.

by _____

by_____

Date:_____

ACORDA THERAPEUTICS INC.

by _____

by_____

Date:_____

AMENDMENT #1 TO

MANUFACTURING SERVICES AGREEMENT

This Amendment #1 to the Manufacturing Services Agreement (the "Amendment #1") is made as of August 29, 2011 ("Effective Date") by and between Acorda Therapeutics, Inc., a Delaware corporation with its office and place of business at 15 Skyline Drive, Hawthorne, NY 10532 ("Acorda") and Patheon Inc., with offices located at 2100 Syntex Court, Mississauga, Ontario L5N 7K9, Canada ("Company").

Recitals:

A. Acorda and Company entered into a Manufacturing Services Agreement dated September 30, 2010 (the "Agreement").

B. Acorda and Company now wish to amend the Agreement to revise the pricing terms of Schedule B to the Agreement, as more fully set forth below and on Attachment A attached hereto.

Agreement:

Acorda and Company agree as follows:

1. Schedule B of the Agreement is deleted in its entirety and replaced with a new Schedule B, which is attached hereto as Attachment A.

Except as otherwise expressly modified by this Amendment #1, all terms and provisions of the Agreement shall remain in full force and effect.

The parties hereto have executed this Amendment #1 as of the Effective Date.

Acorda Therapeutics, Inc.

By:_____

Ron Cohen, M.D.

President and CEO

Patheon Inc.

By:_____

Name:

Title:

Exhibit 10.54

EXECUTION VERSION

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

SETTLEMENT AND RELEASE AGREEMENT

This Settlement and Release Agreement (the "**Settlement Agreement**") is made as of 31st day of December, 2022 ("**Execution Date** and effective as of 31st day of December 2022 (the "**Settlement Effective Date**"), by and between Acorda Therapeutics, Inc., a corporation, with a place of business at 2 Blue Hill Plaza, 3rd Floor, Pearl River, New York 10965, USA ("**Acorda**"), and Catalent Massachusetts LLC, a Delaware limited liability company, with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Catalent**").

RECITALS

A. Catalent and Acorda (each a **"Party"** and collectively the **"Parties"**) are parties to that certain Manufacturing Services Agreement, dated February 10, 2021, and the amendments thereto (the "Agreement"), as amended by the First Amendment to Manufacturing Services Agreement, effective October 28, 2021, and the Second Amendment to the Manufacturing Services Agreement, effective December 31, 2021, (collectively, the "**Agreement**").

B. The Parties desire to acknowledge and document final resolution of certain disputes (as further described below) in connection with the Parties' obligations relating to batches that were delivered or due to be delivered in 2022 and regarding the payments associated therewith under the Agreement (collectively, the "**Disputes**").

AGREEMENT

In consideration of the mutual promises set forth herein, the Parties agree as follows:

1. **Defined Terms**. Any capitalized terms used in this Settlement Agreement that are not defined herein shall have the meaning assigned to them in the Agreement.

2. **Dispute**. The following disputes are included within the Disputes:

    a. Catalent alleges it released US Batch P4081-0013 on [*****], 2022. Further, Catalent alleges it has invoiced Acorda on [*****], 2022 (INV00152), in the amount of $[*****] for US Batch P4081-0013, which Acorda has not paid. Acorda rejected the delivery of US Batch P4081-0013. As such, Catalent contends this balance on INV00152 remains outstanding and due from Acorda.

    b. Catalent alleges that it has issued INV00174, dated [*****], 2022, in the amount of $[*****] (which you refer to as $[*****] in your [*****], 2022, correspondence), and this balance remains outstanding and due from Acorda. On [*****], 2022, Acorda

rejected this invoice, alleging that only $[*****] is the minimum commitment balance due on the invoice.

3. **Termination of Agreement**. The parties acknowledge and agree that the Agreement is terminated pursuant to that certain termination agreement entered into of even date herewith (the "**Termination Agreement**") and can be terminated subject to the surviving provisions of the Agreement as further described in Section 8.4(b) of the Agreement and the terms hereof; provided, however, that Section 8.4(a) shall be superseded by the terms of this Settlement Agreement.

4. **Settlement Obligation**. In full consideration of the resolution and release of any and all claims the Parties may now or in the future have against the other Party with respect to the Disputes (the "**Claims**"), the Parties agree to the following (the "**Settlement Terms**"):

   a. Acorda will pay the balance due from INV00152 for US Batch P4081-0013 in the amount of $[*****] by or before January 15, 2023.

   b. Acorda will pay the outstanding Quarterly Minimum Balance invoice INV00174 dated [*****], 2022, in the amount of $[*****] by or before January 15, 2023.

   c. Furthermore, the Parties agree that the following batches to be delivered by Catalent will count toward the unpaid minimum commitment of $[*****] for 4Q 2022. The invoice for the $[*****] minimum commitment will be sent to Acorda in accordance with the Agreement (e.g. early January 2023) and Acorda will pay the $[*****] minimum commitment in accordance with the payment terms found in Section 3.2(c) of the Agreement (within [*****] of the receipt of the invoice):

4Q CY2022 Minimum Commitment			
Purchase Order	Batch Number	Catalent Release Date	Shipment Date
51911	P4083-0013	11/7/2022	12/5/2022
	P4083-0014	11/7/2022	12/12/2022
	P4083-0015	11/7/2022	12/19/2022
51965	P4081-0017	11/23/2022	To be shipped in the 1Q CY 2023
	P4081-0018	11/30/2022	
	P4081-0019	12/22/2022	
51997	P4081-0020	12/28/2022	
	P4081-0021	1/18/2023	

Such batches will be delivered to Acorda in accordance with the terms of the Agreement at no additional cost beyond the $[*****] minimum commitment identified in (c) of this Section 4.

For clarity, Acorda has no obligation to pay any interest on amounts subject to the Disputes as set forth in Section 3.2(c) of the Agreement. For the avoidance of doubt, to the extent the terms

of Section 3.2(b) of the Agreement conflict with the terms herein, the terms herein shall supersede such conflicting terms.

Each party accepts and acknowledges that it is responsible for any and all tax payments, if any, associated with the Settlement Terms, and agrees to indemnify and hold harmless the other party and its agents, assigns and insurers from and against all claims, assessments, demands, penalties and/or interest of any nature or description, asserted by any authorized governmental taxing authority as a result of the Settlement Terms. This Settlement Agreement does not release either Party from any other financial obligations it may have under the Agreement, or any other Purchase Orders executed between Catalent and Acorda, including, without limitation, with respect to the manufacture of batches, Acorda's products, or services performed by Catalent.

5. **Release**.

   a. In consideration for the making of this Settlement Agreement and the Settlement Terms, Acorda, for itself and its stockholders, directors, officers, employees, agents, representatives, attorneys, successors and assigns, and any of its parent and affiliated companies and all persons acting by, through, under or in concert with any of them, knowingly, voluntarily, irrevocably and unconditionally releases, waives, gives up, and forever discharges Catalent, its stockholders, directors, officers, employees, agents, representatives, attorneys, successors and assigns, and any of its parent and affiliated companies and all persons acting by, through, under or in concert with any of them (collectively the "**Catalent Releases**"), both jointly and individually, from any and all complaints, claims, charges, liabilities, obligations, promises, agreement, contracts, suits, costs, debts, fees (including, but not limited to, any claims for attorneys' fees), expenses, sums of money, and causes of action of any nature whatsoever, whether known or unknown, in law or equity, with respect to the Disputes and Claims.

   b. In consideration for the making of this Settlement Agreement and the Settlement Terms, Catalent, for itself and its stockholders, directors, officers, employees, agents, representatives, attorneys, successors and assigns, and any of its parent and affiliated companies and all persons acting by, through, under or in concert with any of them, knowingly, voluntarily, irrevocably and unconditionally releases, waives, gives up, and forever discharges Acorda, its stockholders, directors, officers, employees, agents, representatives, attorneys, successors and assigns, and any of its parent and affiliated companies and all persons acting by, through, under or in concert with any of them (collectively the "**Acorda Releasees**"), both jointly and individually, from any and all complaints, claims, charges, liabilities, obligations, promises, agreement, contracts, suits, costs, debts, fees (including, but not limited to, any claims for attorneys' fees), expenses, sums of money, and causes of action of any nature whatsoever, whether known or unknown, in law or equity, with respect to the Disputes and Claims.

6. **Affirmation Regarding No Pending Matters**. The Parties represent that they have not assigned any of their rights or claims against any of the Acorda Releasees or Catalent

Releasees, respectively, and has not filed any complaint, charge, grievance or lawsuit against any of the Acorda Releasees or Catalent Releasees, respectively, with any local, state or federal agency or court, or any arbitrator with respect to the Disputes, and except with respect to the terms of this Settlement Agreement and the Termination Agreement, that it will not, at any time hereafter, file any such complaint, charge, grievance or lawsuit against any of the Acorda Releasees or Catalent Releasees, respectively, with respect to the Disputes. For clarity, nothing herein is intended to modify or override the terms of the Manufacturing Services Agreement to be entered into by the parties of even date herewith.

7. **No Admission**. By execution of this Settlement Agreement, neither party is admitting any fault or liability of any kind whatsoever to the other party or to any third party with respect to the Disputes or the Claims. Nothing in this Settlement Agreement is or shall be construed to be an admission of liability or wrongdoing by such party.

8. **No Evidence**. The parties agree and acknowledge that neither this Settlement Agreement, nor the terms hereof or negotiations relating hereto, shall be offered, used or considered as evidence in any action or proceeding of any type against or involving the Catalent Releasees or Acorda Releasees, except to the extent necessary to enforce the terms hereof.

9. **Binding Resolution**. Each party understands, acknowledges and agrees that this Settlement Agreement is a full, final and binding resolution of the Disputes and Claims, and that this Settlement Agreement supersedes any prior verbal or written communications between the parties with respect to the foregoing. With respect to the Disputes and Claims, there are no other agreements, promises, understandings, obligations, covenants, or representations between the parties and each party acknowledges that it is not relying on any other representations, warranties, agreement or undertakings other than those expressly contained herein. This Settlement Agreement may be executed in more than one counterpart, each of which is an original, but all taken together, shall be deemed one and the same agreement.

10. **Modification**. This Settlement Agreement may be modified only in a written document signed by an authorized representative on behalf of each party.

11. **Acknowledgment of Settlement.** The parties acknowledge that (i) the consideration set forth in this Settlement Agreement, which includes, but is not limited to, the Settlement Terms, is in full settlement of all Claims, and (ii) by signing this Settlement Agreement, and accepting the Settlement Terms provided herein and the benefits of it, they are giving up forever any right to seek further monetary or other relief from the other party for any acts or omissions with respect to the Disputes and Claims.

12. **Legally Binding**. Each party freely and knowingly, and after due consideration, enters into this Settlement Agreement intending to waive, settle and release all claims each party has or might have against the other party with respect to the Disputes and the Claims. The parties intend that this Settlement Agreement be legally binding upon and shall inure to the benefit of

each of them and their respective successors, assigns, executors, administrators, heirs, and estates.

13. **Governing Law**. This Settlement Agreement shall be interpreted and construed in accordance with the laws of the State of New York, without application of its conflict of law provisions.

14. **Headings**. The headings in this Settlement Agreement are for reference only and do not affect the interpretation of this Settlement Agreement.

15. **Severability**. If any provision of this Settlement Agreement is declared invalid or unenforceable by any court of competent jurisdiction, and if such provision cannot be modified to be enforceable to any extent or in any application, the remaining provisions shall nevertheless survive and continue in full force and effect.

16. **Construction**. This Settlement Agreement was the result of negotiations between the parties and their respective counsel. In the event of vagueness, ambiguity, or uncertainty, this Settlement Agreement shall not be construed against the party preparing it but shall be construed as if all parties prepared it jointly.

17. **Authority to Execute Agreement**. By signing below, each party warrants and represents that the person signing this Settlement Agreement has the authority to bind that party and that the party's execution of this Settlement Agreement is not in violation of any by-laws, covenants, or other restrictions placed upon them by their respective entities.

[End of page - the next page is the signature page]

The parties hereto have executed this Settlement Agreement as of the Execution Date.

Catalent Massachusetts, LLC	Acorda Therapeutics, Inc.
By: _____	By: _____
Name: Ricky Hopson Title: President, Clinical Development and Supply, Catalent Pharma Solutions	Name: Ron Cohen Title: President and CEO

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

Exhibit 10.55

CONFIDENTIAL AGREEMENT
EXECUTION VERSION

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

Manufacturing Services Agreement

between

Catalent Massachusetts LLC

and

Acorda Therapeutics, Inc.

Effective Date: January 1, 2023

MANUFACTURING SERVICES AGREEMENT

This **MANUFACTURING SERVICES AGREEMENT** (this "**Agreement**") is made as of December 31 2022 ("**Execution Date**") and effective as of January 1, 2023 ("**Effective Date**").

B E T W E E N:

CATALENT MASSACHUSETTS LLC, a Delaware corporation, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Manufacturer**"),

- and -

ACORDA THERAPEUTICS, INC., a Delaware corporation ("**Acorda**").

WHEREAS, the Parties terminated that certain Manufacturing Services Agreement, dated as of February 10, 2021, by and between Manufacturer and Acorda pursuant to that certain termination letter between the Parties effective as of December 31, 2022; and

WHEREAS, the Parties are entering into this Agreement to govern the manufacture of Batches (as defined below) to be provided by Manufacturer to Acorda following the Effective Date and other related matters;

NOW, THEREFORE, in consideration of the rights conferred and the obligations assumed herein and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties, intending to be legally bound, agree as follows:

ARTICLE 1

INTERPRETATION

1.1. **Definitions.** The following terms, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms have corresponding meanings:

"**Acorda**" has the meaning set forth in the introductory paragraph hereto and, in addition, includes any Acorda Affiliate added as an Additional Acorda Party pursuant to Section 13.5(e);

"**Acorda Indemnitees**" has the meaning specified in Section 10.2;

"**Acorda Intellectual Property**" means to the extent necessary to conduct the activities of Manufacturer hereunder, Intellectual Property to the extent owned or controlled by Acorda or its wholly-owned subsidiary Civitas Therapeutics, Inc. as of the Effective Date, including without limitation [*****];

"**Acorda New Intellectual Property**" means any New Intellectual Property other than the Manufacturer New Intellectual Property;

"**Acorda Property**" has the meaning specified in Section 8.4(a)(ii);

"**Acorda-Supplied Components/Materials**" means the Components/Materials identified in Schedule 6 of this Agreement as Acorda-Supplied Components/Materials, as Schedule 6 may from time to time be amended in accordance with ARTICLE 4;

"**Active Materials**" means the materials listed and identified in Schedule 3;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth for the Product in Schedule 3;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.7(a)(ii);

"**Additional Acorda Party**" has the meaning specified in Section 13.5(e);

"**Affiliate**" means, with respect to any Person, any other Person controlling, controlled by or under common control with such first Person. For purposes of this definition, "control" means, with respect to any entity, the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities (or other ownership interest), by contract or otherwise;

"**Agents**" means (a) those employees of Manufacturer or any of its Affiliates at any particular time during the Term who require access to Lock Down Information for a Purpose; and (b) individual independent contractors engaged by Manufacturer at any particular time during the Term who require access to Lock Down Information for the purpose of providing Manufacturing Services;

"**Agreement**" has the meaning set forth in the introductory paragraph hereto;

"[*****]" means any Know-How or other Intellectual Property licensed to or acquired by [*****], directly or indirectly, under [*****];

"**Ancillary Agreement**" has the meaning set forth in the Asset Purchase Agreement;

"**Annual Product Review Report**" means the annual product review report prepared by Manufacturer regarding the Supplied Product as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e), and any other similar reports that may be required by Applicable Laws;

"**Annual Report**" means the annual report to the FDA prepared by Acorda regarding Marketed Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2), and any other similar reports that may be required by Applicable Laws;

"**Annual Volume Projection**" means the annual volume projections set forth in the applicable portion of Schedule 2, as from time to time updated thereafter by written agreement of the Parties;

"**Applicable Laws**" means, with respect to Acorda, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which Active Material or Supplied Product or Marketed Product is produced, marketed, distributed, used or sold; and with respect to Manufacturer, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Manufacturer Manufactures Supplied Product, including cGMP; and in the event that Supplied Product is being supplied for sale or use outside the United States, such other standards as may be agreed in the Quality Agreement or otherwise in writing between the Parties;

"**Asset Purchase Agreement**" means that certain Asset Purchase Agreement to transfer certain of Acorda's assets to Manufacturer, dated December 30th, 2020, between Acorda and Manufacturer;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"**Batch**" means a specific quantity of Supplied Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of manufacture as defined by the applicable Batch record; the approximate Batch sizes for PSD-4 are 340,000 capsules and the projected batch sizes for PSD-7, 1,600,000 capsules for filing; or for bulk powder 100kg, and 86,000 capsules for packaging/blistering;

"**Bulk Product**" means spray-dried intermediate in bulk powder of levodopa;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the Commonwealth of Massachusetts;

"**cGMPs**" means the then-current good manufacturing practices that apply to the manufacture of Supplied Product for incorporation into Marketed Product to be marketed, distributed, or sold in countries or jurisdictions in the Territory, including as described in:

(a) the FFDCA, including as set forth in sections 501(a)(2)(B) and (h) of the FFDCA (21 U.S.C. 351(a)(2)(B) and (h)); section 520(f) of the FFDCA (21 U.S.C. 360j(f)); 21 C.F.R. part 4; 21 C.F.R. parts 210 and 211; and 21 C.F.R. part 800, and, in each case, any guidance regarding such requirements;

(b) EC Directive 2003/94/EC and Volume 4 of the European Commission's Rules governing medicinal products in the European Union;

(c) Division 2 of Part C of the Food and Drug Regulations (Canada); and

(d) MHLW Ordinances No. 169 and No. 179 of 2004 governing management of manufacturing and quality of relevant products in Japan;

together with the latest FDA, European Commission and EMA, Health Canada, and MHLW/PMDA (Japan), respectively, guidance documents issued by the relevant Authority pertaining to manufacturing and quality control practice in the applicable jurisdiction. "cGMPs" will also include the laws, regulations and guidance for any other jurisdiction in the Territory;

"COA" means a Certificate of Analysis for the applicable Batch;

"**COA Target Date**" means the date for the delivery of the COA specified in the Purchase Order, which shall not be less than 89 days from the delivery of the Purchase Order;

"**COC**" means a batch Certificate of Conformity which is issued by Manufacturer after Acorda's documentation review and batch acceptance;

"**Compliant Product Requirements**" means, in respect of Supplied Product delivered hereunder, that the Manufacturing Services have been performed by Manufacturer in respect of such Supplied Product in compliance with all Specifications, cGMPs or other Applicable Laws, and other requirements set forth

in this Agreement or the Quality Agreement and that the Supplied Product as delivered complies with the warranties set forth in this Agreement;

"**Components/Materials**" means all Active Materials, packaging components, raw materials, ingredients, disposable items, and other materials required to manufacture, package and label Supplied Product in accordance with the Specifications for delivery to Acorda in accordance with the terms of this Agreement;

"**Confidential Information**" means (a) any and all Know-How that has been, prior to the Effective Date, or is, at any time on or after the Effective Date, provided or communicated to the Receiving Party by or on behalf of the Disclosing Party (including by a third party) pursuant to this Agreement or other arrangements contemplated hereby or thereby or any discussions or negotiations with respect or leading up thereto, whether provided or communicated orally, visually, electronically, in writing, by delivery of materials containing such Know-How or material or in any other form now known or hereafter invented, and (b) without limiting the foregoing, Lock Down Information, Acorda Intellectual Property and any Acorda New Intellectual Property, as to which Acorda shall in all cases be deemed the Disclosing Party. Confidential Information includes all confidential and proprietary technologies, know-how, trade secrets, discoveries, inventions, and any other confidential and proprietary intellectual property (whether or not patented), analyses, compilations, business or technical information and other proprietary materials prepared by either Party, their Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by or on behalf of the Disclosing Party, its Affiliates or any of its or their respective Representatives;

"**Deficiency Notice**" has the meaning specified in Section 6.2(a);

"**Delivery Date**" means the date of the Certificate of Analysis issued by Manufacturer to Acorda;

"**Disclosing Party**" has the meaning specified in Section 11.1;

"**Dispute**" has the meaning set forth in Section 12.1;

"**Effective Date**" has the meaning set forth in the introductory paragraph hereto;

"**EMA**" means the European Medicines Agency and any successor Authority having the same or similar jurisdiction;

"**European Union**" means those countries that are (a) the United Kingdom and (b) members of the European Union as of the Effective Date together with, from the date they become members of the European Union, any countries that become new members of the European Union during the Term. For clarity, the defined term "European Union" will continue to include any countries that may leave the European Union after the Effective Date despite their ceasing to be members of the European Union;

"**Excluded Lists**" means the Department of Health and Human Service's List of Excluded Individuals/Entities and the General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs;

"Existing Quality Agreement" means that certain Quality Agreement, dated as of May 6, 2021, by and between Manufacturer and Acorda, the current version of which is attached hereto as Exhibit C;

"**FDA**" means the United States Food and Drug Administration and any successor Authority having the same or similar jurisdiction;

"**Fees**" means any fees due to Manufacturer hereunder;

"**FFDCA**" has the meaning specified in Section 9.3(c)(v);

"**Force Majeure Event**" has the meaning specified in Section 13.6;

"**Grace Period"** means the [*****] period after the COA Target Date;

"**Health Canada**" means the section of the Canadian government known as Health Canada and includes, among other departments, the Therapeutic Product Directorate and the Health Product and Food Branch Inspectorate and any successor Authorities having the same or similar jurisdictions;

"**Indemnified Party**" has the meaning specified in Section 10.4;

"**Indemnifying Party**" has the meaning specified in Section 10.4;

"**Intellectual Property**" means any and all intellectual property rights of whatever kind or nature, including rights in patents, patent applications, copyrights and Know-How, including trade secrets; "**Know-How**" means any confidential or proprietary information, data, formulae, computer program, device, know-how, process, design, technique, knowledge, records (including Batch records), analytical methods, standard operating procedures for products, specifications and parameters for manufacturing equipment, quality control and other methods, practices or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable and whether or not they constitute trade secrets, including software, databases, algorithms, discoveries, improvements, specifications, diagrams, drawings expertise, technology, research, reports, documentation, equipment, methods of formulation, results of tests and field trials, specifications, and composites of materials;

"**Knowledge**" means, with respect to the applicable Party, the actual knowledge of the executive officers and directors of such Party, without a duty of inquiry or investigation;

"**Late Delivery**" means a failure to deliver to Acorda the COA by the end of the Grace Period;

"**Lock Down Information**" means the [*****] information [*****] outlined in Schedule 9;

"**Losses**" has the meaning specified in Section 10.2;

"**Manufacturer**" has the meaning set forth in the introductory paragraph hereto;

"**Manufacturer Indemnitees**" has the meaning specified in Section 10.3;

"**Manufacturer Intellectual Property**" means Intellectual Property owned or controlled (other than pursuant to the license set forth in Section 13.1(a)), or generated, discovered or developed, by or on behalf of Manufacturer or its Affiliates independently of the Manufacturing Services or other arrangements contemplated by this Agreement and without use of or reference to any Acorda Intellectual Property, [*****], or Acorda's Confidential Information, in each case as demonstrated by competent contemporaneous written evidence, but in any event excluding any New Intellectual Property;

"**Manufacturer New Intellectual Property**" means any New Intellectual Property that is not exclusive to the Supplied Product or the Marketed Product or the Manufacture of Supplied Product or Marketed Product but (a) relates to developing, formulating, manufacturing, filling, processing, packaging,

analyzing, or testing pharmaceutical products generally, or (b) is generated, discovered, or developed solely by or on behalf of Manufacturer or its Affiliates;

"**Manufacturing Services**" (including, with correlative meanings, "**Manufacturing**" and "**Manufacture**") means those services required to manufacture, including to fill the dry powder capsules, label, release (including final release to Acorda) and deliver Supplied Product, and for orders by Acorda for blister pack versions, primary packaging in blister packs, using Components/Materials as provided herein, including, to the extent required:

(e) the acquisition, from such suppliers as Acorda may from time to time designate all Components/Materials other than Acorda-Supplied Components/Materials;

(f) if needed, qualification and supervision of all suppliers of Other Components/Materials, with such qualification subject to Acorda's consent, not to be unreasonably withheld, conditioned or delayed;

(g) receipt, handling, inspection, testing, warehousing, and storage of Components/Materials;

(h) manufacturing, production, validation, quality control, quality assurance, stability testing, laboratory analysis, warehousing, storage, handling, packaging, labeling, and release of Supplied Product;

(i) the activities set forth in Section 2.1(d), Schedule 4 and Schedule 7 and Supplied Product stability testing and sample management, retain samples management and storage; and

(j) services related to the foregoing, including compliance, activities of a health, safety and environment nature, engineering, calibration, maintenance and repair services, and other activities required to keep the Manufacturing Site and all installations, fixtures, and equipment located there at and intended for use in the manufacturing, packaging, labeling, release or delivery of Supplied Product in good and fully operational condition, qualified, and in compliance with Applicable Laws as necessary or appropriate to deliver Supplied Product as required hereby.

For the avoidance of doubt, all ancillary services listed above (other than clause (e), which shall include the ongoing stability program at the Manufacturing Site) shall be provided only for Supplied Product that is Processed by Manufacturer during the Term;

"**Manufacturing Site**" means the facilities located at Brickyard Square, 190 Everett Avenue, and 115 Carter Street, Chelsea, MA and leased to Manufacturer;

"**Marketed Product**" means (a) Acorda's CVT-301 inhaled levodopa product (the subject of a New Drug Application in the United States under the name Inbrija®), (b) [*****] and the same active pharmaceutical ingredient as the Supplied Product that Acorda may, by written notice to Manufacturer, indicate is also to be included within the definition of "Marketed Product", and (c) any other product included in the definition of "Marketed Product" pursuant to Section 2.1(h);

"**Marketing Authorization**" means a New Drug Application as defined in the FFDCA and the regulations promulgated thereunder or, in respect of a country other than the United States, any corresponding application, registration or certification necessary for the marketing and sale of a pharmaceutical product in such country, including applicable pricing and reimbursement approvals;

"**Minimum Commitment**" means, with respect to the applicable Year, the number of Batches required to be ordered by Acorda for delivery in such Year as set forth in Schedule 2.

At the request of Acorda, Minimum Commitments shall be reduced by [*****].

"**New Intellectual Property**" means Intellectual Property generated, discovered, or developed by or on behalf of either Party or its Affiliates (including, for clarity, jointly by Acorda or any of its Affiliates and Manufacturer or any of its Affiliates) while performing, or as a result of the performance of, the Manufacturing Services or in connection with the other arrangements contemplated by this Agreement;

"**Net Sales**" means, for the measured period, the gross invoiced amounts for Marketed Product sold or commercially disposed of for value by Acorda, its Affiliate or sublicensee to first third party, less [*****]. Sales of Marketed Product between Acorda and its sublicensees (including its Affiliates) shall be disregarded for the purposes of calculating Net Sales, and in such case Net Sales shall include only subsequent sales by the relevant sublicensee to a third party. Subject to the foregoing sentence, if any Marketed Products are sold or disposed of by Acorda, its Affiliate or its sublicensees other than in a bona fide arm's length sale exclusively for money, then Net Sales for such Marketed Products shall be deemed to be the price at which Acorda, its Affiliate or sublicensee could have sold such Marketed Products in a separate arm's length transaction to a willing purchaser at the relevant time in the relevant country. The amount of [*****] shall be included in Net Sales in the Quarter in which such reduction or reversal occurs. All calculations shall be made in accordance with GAAP. In the event that Acorda has a sublicensee in a country, then the Net Sales definition will be based on the gross invoice price sold by the sublicensee to a third party per the definition of Net Sales, including [*****]. Further, transfers or dispositions of a Marketed Product for [*****] will not be deemed to be Net Sales, provided that such transfers or dispositions shall be in amounts consistent with [*****];

"**Other Components/Materials**" means Components/Materials that are not Acorda-Supplied Components/Materials;

"**Party**" means, individually, Manufacturer or Acorda, and "**Parties**" means, collectively, Manufacturer and Acorda;

"**Person**" means an individual or a sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, or other similar entity or organization, including a government or department, agency or other subdivision thereof;

"**Pharmaceutical Regulatory Authority**" means the FDA, EMA, Health Canada, and MHLW/PMDA of Japan and any other Authority competent to regulate the manufacture, marketing, distribution or sale of pharmaceutical products, including Supplied Product and any Marketed Product, in the Territory;

"**Product Fees**" means the amount due to Manufacturer for a given quantity of Supplied Product delivered, as set forth in Section 3.1;

"**Product Personnel**" means [*****];

"**PSD-4**" means the spray dryer currently used to Manufacture Inbrija;

"**PSD-7**" means the new spray dryer intended to Manufacture Inbrija;

"**PSD-7 Scale-Up**" means the scale-up with regard to the process for operationalization and validation of the PSD-7;

"**PSD-7 Scale-Up Plan"** means the plan with respect to PSD-7 Scale-Up;

"**Purchase Order**" has the meaning specified in Section 5.1(c);

"**Purpose**" means, in the case of employees, Product Personnel, or Agents who are individual independent contractors, the Manufacturing Services of Supplied Product hereunder; and in the case of Agents who are employees of Manufacturer or any of its Affiliates, any of the following in accordance with Manufacturer's internal policies or as required by Applicable Law and related to the Supplied Product: (a) conducting audits; (b) addressing deviation escalations; (c) escalating quality and/or regulatory issues related to an investigation, change control or corrective and preventative actions; (d) third party vendors supporting electronic quality management systems (e.g., EDMS) who require access to the system for system troubleshooting and maintenance; (e) receiving information as part of required reporting needs related to (a), (b) and (c) or the Annual Product Maintenance Services and/or preparation of the Annual Product Review Report; (f) for the activities involving the technology transfer of the manufacturing activity in connection with the PSD-7 Scale-Up Plan or (g) other *bona fide* business purposes, which the Parties may agree to in writing signed by both Parties. Third party vendors specified in clause (d) are not intended to, and should not be permitted to, access data during system trouble shooting or maintenance, and therefore will not require lockdown training or tracking;

"**Quality Agreement**" means the agreement between the Parties setting out the quality assurance standards for the Manufacturing Services to be performed under this Agreement (either the Existing Quality Agreement or a new quality agreement entered into after the Execution Date, as applicable);

"**Quality System**" means a formalized system that documents processes, procedures and responsibilities necessary to design and deliver a product or perform a service in compliance with applicable laws, regulations and guidance documents;

"**Quantity Converted**" has the meaning specified in Section 2.7(a)(ii);

"**Quantity Dispensed**" has the meaning specified in Section 2.7(a)(ii);

"**Quantity Received**" has the meaning specified in Section 2.7(a)(ii);

"**Quarter**" means each consecutive period of three consecutive calendar months commencing on January 1, April 1, July 1, or October 1 and ending on, respectively, March 31, June 30, September 30, and December 31, except that the first Quarter of the Term will be the period from the Effective Date up to and including the end of such three-month period in which the Effective Date falls, and the last Quarter of the Term shall commence on the first day of such three-month period in which the Term ends and end on the last day of the Term;

"**Recall**" has the meaning specified in Section 6.3(a);

"**Recalled Product**" has the meaning set forth in Section 6.4(b);

"**Receiving Party**" has the meaning set forth in Section 11.1;

"**Recipients**" has the meaning set forth in Section 11.1;

"**Replacement Batch**" means a Batch to be delivered to Acorda as a replacement for a Batch that has not been delivered to Acorda pursuant to a Purchase Order, rejection of a Batch pursuant to Sections 2.1(f) and 6.1 herein, or as a result of a failure to achieve Timely Delivery as set forth in Section 5.1 herein;

"Representatives" of an entity means such entity's officers, directors, employees, agents, members, accountants, attorneys, or other professional advisors;

"**Reserved Capacity**" means with respect to (a) the PSD-4, [*****] (b) [*****], then Manufacturer shall reserve the following until the PSD-7 is first approved for at least one of the Tier 1 Markets, [*****], and (c) in the event that the PSD-7 is approved but becomes unavailable, [*****];

[*****];

"**Serious Performance Failure**" means for a given Year, [*****];

"Shelf Life Start Date" means for any Batch, the date on which Active Material is added into the solution;

"**Shortfall**" has the meaning specified in Section 2.7(a)(iii);

"**Specifications**" means (a) for the initial Supplied Product, the file designated as "Specifications" that has been delivered by Acorda or its Affiliate to Manufacturer on or before the Effective Date containing information as specified on Schedule 1 or (b) for any future Supplied Product, the file designated as "Specifications" for such Supplied Products, in each case all as updated, amended and revised from time to time in accordance with the terms of this Agreement and the change control process set forth in the Quality Agreement;

"**Supplied Product**" means (a) bulk dry powder, produced by spray drying at the Manufacturing Site using Acorda Intellectual Property, including [*****], and filled into capsules and (b) if requested in the order from Acorda, the bulk dry powder described in clause (a) packed in blister packs ready for secondary packaging as Marketed Product for marketing, distribution, and sale of such Marketed Product in the Territory, (c) subject to Section 2.5(a), bulk dry power described in clause (a) not otherwise filled into capsules or blister packs, but in a packaging agreed upon by the Parties (provided that such packaging is that used to generate the relevant stability data), or (d) in the case of a new Marketed Product added to this Agreement, such product in the form supplied hereunder as mutually agreed, each case ((a) through ((c)) as further identified and described in the applicable Specifications, including any release criteria for the applicable Supplied Product;

"**Target Yield**" has the meaning specified in Section 2.7(a);

"**Term**" has the meaning specified in Section 8.1(a);

"**Territory**" means worldwide, but Manufacturer shall not be obligated to ship Supplied Product into any country where that would constitute a violation of comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States;

"**Third Party Claims**" has the meaning specified in Section 10.2;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Tier 1 Market**" means the United States of America and Germany;

"**Tier 2 Market**" means any country in the world other than the Tier 1 Markets;

"**Timely Delivery**" means, with respect to a Batch, that the COA Delivery Date occurs no later than the COA Target Date, subject to the Grace Period;

"**United States**" means the United States of America, its territories and possessions, including the District of Columbia and Puerto Rico; and

"**Year**" means each consecutive period of 12 consecutive calendar months commencing on January 1 and ending on December 31, and the last Year of the Term shall commence on January 1 of the calendar year in which the Term ends and end on the last day of the Term.

1.2. **Currency.** Unless otherwise specifically provided, all monetary amounts expressed in this Agreement, including by way of a dollar sign ("$"), are in United States Dollars (USD). For countries for which the price hereunder is based on Net Sales in such country, if Net Sales are invoiced by Acorda or its Affiliate or any sublicensee to third parties in other currencies, Net Sales shall be converted into USD in accordance with GAAP at the closing rates of exchange as published in *The Wall Street Journal*, in effect on the last Business Day of the month within the Quarter for which Product Fees are due.

1.3. **Sections and Headings.** The division of this Agreement into Articles, Sections, Subsections, Schedules, and Exhibits, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to an Article, Section, Subsection, clause, Schedule or Exhibit refers to the specified Article, Section, Subsection, clause, Schedule, or Exhibit to this Agreement. In this Agreement, the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement and not to any particular part, Section, Schedule or Exhibit of this Agreement.

1.4. **Interpretation.** Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or"; (d) the term "including" or "includes" means "including without limitation" or "includes without limitation"; and, (e) except where otherwise indicated, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified.

ARTICLE 2

MANUFACTURING SERVICES; RELATED MATTERS

2.1. **Manufacturing Services.**

(a) Manufacturing Services. Manufacturer shall perform, for the Fees as specified in Section 3.1, Manufacturing Services for Supplied Product to be incorporated by or on behalf of Acorda into Marketed Product for marketing, distribution, and sale of such Marketed Product by Acorda or its Affiliates in the Territory. For the avoidance of doubt, PSD-7 (once available and approved for the particular market) shall be the primary means for Manufacturing the Reserved Capacity during and after 2025.

(b) Annual Product Maintenance Services. Manufacturer shall provide and Acorda will receive those product maintenance services specified in Schedule 7 (the "**Product Maintenance Services**").

(c) Quality Control and Quality Assurance. The Parties shall act in good faith to adhere to any in-place Quality Agreement between the Parties that pertains to the Supplied Product. The Parties further agree to negotiate and enter into a new Quality Agreement (or an amendment to the Existing Quality Agreement) prior to commercial manufacturing on the PSD-7. The Quality Agreement shall set forth the quality responsibilities of each Party in respect of the arrangements contemplated hereby. Following the execution of any new Quality Agreement, each Party shall comply with its terms.

(d) Testing. Manufacturer shall provide the following services:

(i) [*****].

(ii) [*****].

(iii) [*****].

(iv) [*****].

(e) Components/Materials.

(i) Acorda-Supplied Components/Materials. Manufacturer shall obtain from Acorda, and Acorda shall supply to Manufacturer at no cost to Manufacturer, all Acorda-Supplied Components/Materials. Manufacturer will be responsible for ordering Acorda-Supplied Components/Materials from Acorda as necessary to ensure availability of Acorda-Supplied Components/Materials at the Manufacturing Site in sufficient quantity and on such schedule as is required to enable Manufacturer to manufacture and deliver to Acorda as contemplated herein the desired quantities of Supplied Product covered by Purchase Orders by the applicable Delivery Date. Acorda shall be responsible for any required governmental clearance, permit or certification, packaging, shipping, insuring, carriage, importing and exporting of Acorda-Supplied Components/Materials for delivery to the Manufacturing Site. Prior to delivery of any Acorda-Supplied Components/Materials, Acorda shall provide to Manufacturer a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the Active Materials and Supplied Product, and thereafter shall provide promptly any update thereto.

(ii) Manufacturer shall inspect all Acorda-Supplied Components/Materials received to verify their identity. Unless otherwise expressly required by the Specifications, Manufacturer shall have no obligation to test Acorda-Supplied Components/Materials it receives to confirm that they meet the associated specifications, COA or otherwise; but in the event that Manufacturer detects a nonconformity with the Specifications, Manufacturer shall give Acorda prompt notice of such nonconformity.

Manufacturer shall not be liable for any defect in Acorda-Supplied Components/Materials, or in Supplied Product as a result of defective Acorda-Supplied Components/Materials, unless [*****] Manufacturer shall follow Acorda's reasonable written instructions in respect of return or disposal of defective Acorda-Supplied Components/Materials, at Acorda's cost.

(iii) Other Components/Materials. Manufacturer shall purchase and obtain, at its own expense and risk, all Other Components/Materials at Manufacturer's expense, in all cases in conformity with the Specifications. Manufacturer will be responsible for (A) purchasing Other Components/Materials, and arranging packaging, delivery, shipping, carriage, exportation and importation of Other Components/Materials, as necessary to ensure availability of Other Components/Materials at the Manufacturing Site in sufficient quantity and on such schedule as is required to enable Manufacturer to manufacture and timely deliver to Acorda as contemplated herein the desired quantities of Supplied Product covered by Purchase Orders and (B) for insuring Other Components/Materials (it being understood, for clarity, that any such loss shall be for the sole account of Manufacturer).

(iv) Manufacturer shall not be liable for any delay in delivery of Supplied Product if Acorda fails to deliver, in a timely manner, the necessary Acorda-Supplied Components/Materials. In the event of (A) a Specification change for any reason, (B) obsolescence of any Other Components/Materials or (C) termination or expiration of this Agreement, Acorda shall bear the cost of any Other Components/Materials (including packaging) unusable for Manufacturing or Supplied Product and unused by Manufacturer for another customer, so long as [*****].

(v) Inventory of Other Components/Materials. Manufacturer shall purchase, obtain and maintain sufficient supply of Other Components/Materials to Manufacture the quantity of Supplied Product specified in the Firm Commitment.

(vi) Title to Components/Materials.

(A) Acorda-Supplied Components/Materials. Title and risk of loss (except in the case of a breach of this Agreement by Manufacturer or Manufacturer's gross negligence or intentional misconduct, which shall be subject to Section 10.1) to Acorda-Supplied Components/Materials will at all times remain with Acorda. To the extent that any right, title or interest in or to such Components/Materials should at any time, contrary to the provisions of this Section 2.1(e)(vi), become vested in Manufacturer, Manufacturer shall, and does hereby, assign all of its right, title and interest to such Components/Materials to Acorda. Without limiting the foregoing, Manufacturer shall take all such actions as may be required in order to vest good title to such Components/Materials in Acorda, including by executing, delivering, or filing such instruments or documents as may from

time to time be requested by Acorda to more fully vest in Acorda good title to such Components/Materials. Manufacturer shall make such entries in its books and records, and shall post such notices in those portions of the Manufacturing Site in which Acorda-Supplied Components/Materials are stored, as are necessary or appropriate under Applicable Laws to reflect and preserve Acorda's good title to the Acorda-Supplied Materials.

(B) Other Components/Materials. Title and risk of loss to Other Components/Materials will remain with Manufacturer unless and until (1) destroyed, (2) delivered as part of Supplied Product hereunder or (3) transferred to Acorda pursuant to Section 8.4(a)(ii).

(vii) Inspection of Components/Materials. Manufacturer shall inspect and test all Components/Materials upon receipt as required by the Specifications or the Quality Agreement.

(viii) Use of Components/Materials. Manufacturer shall use Acorda-Supplied Components/Materials solely for manufacturing Supplied Product for Acorda in accordance with the terms of this Agreement and for no other purpose.

(ix) Storage of Components/Materials. Manufacturer at all times shall store all Components/Materials exclusively at the Manufacturing Site or, subject to Acorda's prior written consent, a duly qualified third party warehouse, in a physically secure area under conditions that maintain their stability, integrity, and effectiveness and in accordance with any storage instructions provided therefor in the Specifications or by Acorda or the manufacturer or supplier of the relevant Components/Materials. Manufacturer shall use reasonable efforts to ensure that all Components/Materials at all times will be free from damage, contamination, deterioration and adulteration and protected against theft. Manufacturer shall store all Components/Materials by lot and batch number and physically segregated per its current procedures defined in its Quality System and in any event in compliance with cGMPs and other Applicable Laws. Manufacturer shall use all Components/Materials on a first-in, first-out basis and shall not use any Components/Materials after the applicable retest date thereof.

(x) Notice of Unusable Acorda-Supplied Component/Materials. Manufacturer shall promptly notify Acorda if any Acorda-Supplied Components/Materials are damaged, contaminated, adulterated, lost or stolen, deteriorate, or otherwise are rendered unusable after delivery and acceptance in line with the criteria outlined in the Specifications or Quality Agreement to Manufacturer (whether before or after incorporation into work in progress). If this occurs, then Manufacturer shall reimburse Acorda for such lost Acorda-Supplied Components/Materials subject to Section 10.1.

(f) Remaining Shelf Life. Acorda shall not be required to accept, and Manufacturer shall use reasonable efforts not to deliver, any Supplied Product as to which the Shelf Life Start Date occurred more than [*****] prior to the date of the COC for such Supplied Product hereunder. Both Parties shall use reasonable efforts to complete Quality activities (as shown in the table below) for Manufacturer to issue a COC for PSD-4 Supplied Product with a Shelf Life Start Date not more than [*****] (or in the case of Bulk Product without capsules, [*****] prior to the date of issuance of the COC. For any Supplied Product that is not delivered within the time frame immediately described above due solely to Manufacturer's failure to use reasonable efforts, which results in product not accepted by Acorda due to the shelf life requirement, Manufacturer will deliver a Replacement Batch to Acorda.

Activity*	**Timeline**	**Calendar Day Duration**
COA issued, loading of all completed documentation	[*****]	[*****]
Compliance comments received from Acorda for corrections/clarification	[*****]	[*****]
Corrections are provided back to Acorda	[*****]	[*****]
Resolution by both parties if needed, COC issued	[*****]	[*****]
	Total:	[*****]
*Documentation can be loaded prior to COA issuance to prevent review surge		

The Parties will amend the Quality Agreement as soon as possible to conform to the timelines above.

(g) Packaging. Manufacturer will package Supplied Product as set out in the Specifications. Manufacturer shall determine and imprint the lot and Batch numbers and expiration dates for each delivery of Supplied Product hereunder. Manufacturer shall affix lot and Batch numbers and applicable expiration dates on the packaging and external shipping carton of Supplied Product as outlined in the Specifications and as required by cGMPs and other Applicable Laws.

(h) Additions to "Marketed Product". Acorda may, by written notice given to Manufacturer from time to time during the Term, propose other Acorda products to be included in the definition of "Marketed Product" pursuant to clause (c) of such definition. In the event that Acorda should notify Manufacturer that it wishes to add an Acorda product to the definition of "Marketed Product" pursuant to clause (c) of such definition, the Parties shall meet promptly after Manufacturer's receipt of such notice to determine any amendments to the terms of this Agreement or the Quality Agreement (including in respect of the consideration to be paid by Acorda to Manufacturer hereunder [*****] that may be required by the inclusion of the product(s) proposed by Acorda in the definition of "Marketed Product" and shall [*****]. The Parties acknowledge and agree that consideration to be paid by Acorda to Manufacturer hereunder for a new Supplied Product (or new form of Supplied Product) may be increased in connection with the inclusion of another Acorda product in the definition of "Marketed Product" only if, and then only to the extent, such inclusion and the resulting adjustments to the arrangements contemplated by this Agreement will [*****]. For clarity, the provisions of this Section 2.1(h) shall not apply in respect of products added to the definition of "Marketed Product" pursuant to the provisions of clause (b) of such

definition and shall not in any way restrict the right and ability of Acorda to designate products to be added to the definition of "Marketed Product" pursuant to the provisions of clause (b) of such definition. In addition, if a Supplied Product or Marketed Product is added to this Agreement, then the corresponding active material and new product added hereunder shall be included in the Active Material and Supplied Product definitions and Schedule 3.

2.2. **Additional Services.** Acorda may, by written notice given to Manufacturer from time to time during the Term, request services (including [*****]) beyond the Manufacturing Services. In the event that Acorda should notify Manufacturer that it wishes to obtain such services and such services are within the expertise and capacity of Manufacturer, the Parties shall meet promptly after Manufacturer's receipt of such notice to determine any amendments to the terms of this Agreement or the Quality Agreement (including in respect of the consideration to be paid by Acorda to Manufacturer hereunder) that may be required in connection with the addition of the additional services proposed by Acorda and shall negotiate in good faith as to such matters. The Parties acknowledge and agree that consideration to be paid by Acorda to Manufacturer for any agreed additional services will be negotiated by the Parties in good faith. [*****].

2.3. **Manufacturing Site.**

(a) Performance of Manufacturing Services at Manufacturing Site. Manufacturer shall perform the Manufacturing Services solely at the Manufacturing Site, unless otherwise agreed in writing by Acorda.

(b) Personnel.

(i) Manufacturer shall perform the Manufacturing Services with a Chelsea, Massachusetts-based management and operations team dedicated to the Manufacturing Site unless otherwise mutually agreed in writing.

(ii) Manufacturer will be responsible for providing management, operations, quality assurance and compliance, health, safety and environment, engineering, calibration and maintenance services and any other activities required to keep the Manufacturing Site qualified and in compliance with Applicable Laws as necessary or appropriate to deliver Supplied Product as contemplated hereby.

(iii) Manufacturer will be responsible for maintaining the Manufacturing Site and all facilities and equipment located thereat and used or useful in the provision of Manufacturing Services as contemplated hereby in good and fully operational condition and shall, for such purpose, conduct, at its sole cost and expense, regular maintenance and testing in conformity with cGMPs and other Applicable Laws, its Quality System, and equipment or materials manufacturers' or suppliers' specifications or recommendations and make any and all repairs and replacements that may at any time be required.

(c) Restricted Access.

(i) Manufacturer shall at all times during the Term maintain appropriate physical security and surveillance at the Manufacturing Site, including with regard to the information technology controls, appropriate building

and perimeter security guard requirements, external and internal access protocols, and external and internal surveillance arrangements.

(ii) Any individual visiting, entering or being present in the Manufacturing Site must, [*****]. Manufacturer shall be liable to Acorda for any damages resulting from any disclosure or use of Acorda's Confidential Information by any such individual that is in breach of this Agreement had such disclosure or use been made by Manufacturer, subject to Section 10.1.

(iii) The provisions of this Section 2.3(c) shall survive the end of the Term and continue thereafter for a period equivalent to the period set forth in Section 8.4(a)(ii).

(iv) The provisions of this Section 2.3(c) are without limitation of any other provision of this Agreement.

2.4. **Access to Acorda Intellectual Property and Know-How.** Only Product Personnel, and Agents who have been trained per Schedule 8 and if applicable have entered into the JDC Representative CDA or other CDA with Acorda, as set forth in Section 11.2(b) shall receive, be involved in or otherwise participate in any [*****] regarding the Supplied Product(s) or otherwise have access to the Acorda Intellectual Property, including [*****]. Manufacturer shall use reasonable efforts to minimize the work of the Product Personnel and Agents on the development of [*****] and shall comply with its ethical wall policy [*****], Catalent will use reasonable efforts to ensure that no Acorda Intellectual Property (including the Lock-Down Information) is used in their work on non-Acorda products.

2.5. **Third Party Sourcing by Acorda.**

(a) Acorda Right to Source Supplied Product from Others. During the Term, subject to the other terms and conditions of this Agreement, Acorda and its Affiliates shall purchase exclusively from Manufacturer all of its and their requirements for Supplied Product for the Tier 1 Markets. For the Tier 2 Markets other than China, Acorda and its Affiliates shall purchase exclusively from Manufacturer all of its and their requirements for Supplied Product, but for each Year, Acorda will be relieved of such exclusivity if it orders [*****] PSD-7 Batches of Supplied Product for the Tier 2 Markets, [*****].

For clarity, nothing in this Agreement limits Acorda's right for China (which shall mean the People's Republic of China, including Macau and Hong Kong, and the Republic of China (Taiwan)) at any time or in the Territory in the event Manufacturer fails to achieve Timely Delivery, to manufacture Supplied Product itself or to obtain Supplied Product from a third party. In addition, in anticipation that third party manufacturing may be required or permitted in certain circumstances, Acorda may engage one or more additional sites of Acorda or third parties to manufacture Supplied Product, including to manufacture Supplied Product on a back-up basis and to produce validation batches at such site in order to obtain approval for the back-up supplier under applicable regulatory approvals.

(b) Technical Assistance from Manufacturer. If requested by Acorda at any time during the Term or for [*****] thereafter, Manufacturer shall provide such technical assistance and technology transfer, if any, as Acorda or its third party designee(s) may require to manufacture Supplied Product to the then-current Specifications for Supplied Product at an alternative location. Any such technical assistance and technology transfer shall be provided by Manufacturer at

reasonable hourly cost based on market value to be set by Manufacturer and agreed upon by the Parties, and will be at Acorda's cost and expense. Where such transfer is solely due to Manufacturer's material breach of this Agreement, Acorda's termination of this Agreement under Section 8.2(a), such technical assistance and technology transfer shall be at Manufacturer's cost and expense. However, where the material breach is due to Serious Performance Failure, Manufacturer's cost and expense shall be limited to Manufacturer's internal expertise and knowledge to support the technology transfer activities and all other costs are to be borne by Acorda.

(c) No Implication. For clarity, the provisions of this Section 2.5 are not intended by the Parties to imply that Manufacturer owns or controls as of the Effective Date, or may at any time during the Term own or control, any Intellectual Property or Know-How relevant to the manufacture of Supplied Product, the provision of Manufacturing Services or the Specifications but instead are intended solely to ensure that if at any time Manufacturer may have such Intellectual Property or Know-How, then it will be made available by Manufacturer to Acorda for the purposes set forth in this Section 2.5.

2.6. **Manufacturer Obligation.** During the Term, Manufacturer shall not, and shall cause its Affiliates not to, either alone or in conjunction with any other Person, directly or indirectly, [*****].

(a) Manufacturer acknowledges and agrees that the provisions of this Section 2.6 are necessary and reasonable to protect Acorda and its Affiliates in the conduct of their business and are a material inducement to Acorda's execution and delivery of this Agreement and its willingness to enter into the transactions contemplated hereunder. If the final judgment of a court of competent jurisdiction declares that any term or provision of this Section 2.6 is invalid or unenforceable, the Parties hereby agree that the court making the determination of invalidity or unenforceability shall have the power to reduce the scope, duration, or territory of the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that, in each case, comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified after the expiration of the time within which such judgment may be appealed.

(b) Each Party agrees that any breach of the provisions of this Section 2.6 will cause severe and irreparable damage to Acorda and its Affiliates. In the event of any violation of this Section 2.6, Manufacturer (i) consents to the granting by any court of competent jurisdiction of an injunction or other equitable relief, in order that the breach or threatened breach of such provisions may be effectively restrained, and (ii) acknowledges and agrees that Acorda shall not be required to provide any bond or other security in connection with any such injunction or other equitable relief.

2.7. **Service Levels and Standards.**

(a) Active Material Yield. In respect of the Supplied Product and the Active Materials received at the Manufacturing Site for the manufacture of the Supplied Product:

(i) Determination of Target Yield. The "**Target Yield**" for the initial Supplied Product in the current manufacturing equipment shall be [*****]. For any new manufacturing equipment, the Parties will agree on the Target Yield based on the yields for the validation batches for such new equipment. For any other Supplied Product(s) that is added to this

Agreement, the "**Target Yield**" will be established using [*****] standards at the time the Supplied Product is added to this Agreement.

(ii) Reporting. Within [*****] Business Days after the end of each calendar month beginning with the first calendar month in which Manufacturer holds or receives Active Materials at the Manufacturing Site for the manufacture of Supplied Product, Manufacturer shall provide Acorda with a monthly inventory report for inventories of all Active Materials. Such information will include:

"**Quantity Received**": The total quantity of Active Materials that complies with the Specifications and was received at the Manufacturing Site during the calendar month.

"**Quantity Dispensed**": The Quantity Dispensed for the calendar month is calculated by adding the Quantity Received during the calendar month to the inventory of Active Materials that complied with the Specifications held at the beginning of the calendar month and then subtracting from the resulting sum the sum of (A) the inventory of Active Materials that complied with the Specifications held at the end of the calendar month plus [*****].

"**Quantity Converted**": The total amount of Active Materials contained in the Supplied Product manufactured with the Quantity Dispensed during the calendar month (including any additional Supplied Product produced to replace Supplied Product included in failed Batches or rejected, returned or Recalled Product) delivered by Manufacturer and not rejected, returned, or Recalled (either during the calendar month or after) because of Manufacturer's failure to perform the Manufacturing Services and deliver Supplied Product in accordance with the terms of this Agreement.

Within [*****] days after the end of each Year, Manufacturer shall give Acorda an annual reconciliation of Active Materials using the form of reconciliation report set forth in Exhibit B, including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Supplied Product at the Manufacturing Site during the Year, which will be [*****] calculated as follows:

$$\frac{[*****]}{[*****]} \times 100\%$$

For clarity, the monthly reports and annual reconciliation report referenced above, are subject to modification after they are delivered or made as necessary to take account of any subsequent rejection, return, or Recall of relevant Supplied Product by Acorda because of Manufacturer's failure to perform the Manufacturing Services and deliver Supplied Product in accordance with the terms of this Agreement or the Quality Agreement.

(iii) Shortfall/Bonus Calculation. If the Actual Annual Yield falls more than [*****] percentage points below the Target Yield for the Supplied Product in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [*****].

If the Actual Annual Yield is higher than the Target Yield for the Supplied Product in a Year, then the bonus for the Year (the "**Bonus**") will be calculated as follows:

Bonus = [*****].

Each Shortfall/Bonus determined in accordance with this Section 2.7(a)(iii)) shall be summarized by Manufacturer on the annual reconciliation report referenced in Section 2.7(a)(ii).

(iv) Credit for Shortfall. If there is a Shortfall for the Supplied Product in a Year and the amount of such Shortfall exceeds any carried forward Bonus (within the meaning of Section 2.7(a)(v)), then Manufacturer shall credit Acorda's account in accordance with Section 3.2(a) for the amount of the Shortfall in excess of such Bonus amount, if any, up to the limitation of liability set out under Section 10.1, not later than 60 days after the end of the Year (or any modification of a previously delivered annual reconciliation that shows a Shortfall or an increased Shortfall for the Year).

(v) Offset for Bonus. If there is a Bonus for the Supplied Product in a Year, such Bonus shall be carried forward on a rolling basis to [*****] until there is a Shortfall in a Year and then the Bonus will be used to offset such Shortfall. After the end of such period, then the Bonus shall expire and no longer may be used to offset any Shortfall. In no event shall Acorda be required to pay Manufacturer out of pocket for any remaining offsets.

(vi) No Material Breach. For clarity (and without modification of the standards for determining material breach that would normally apply to this Agreement), the Parties agree that, if the Actual Annual Yield is less than the Target Yield for a given Year, this fact will not by itself constitute a material breach of the Agreement by Manufacturer.

ARTICLE 3

ACORDA PAYMENTS

3.1. **Fees.**

(a) Product Fees. Subject to Section 3.2, Acorda shall pay a fixed amount for each capsule of Supplied Product (or in the case of bulk powder, kilogram) delivered by Manufacturer in accordance with the delivery terms set forth in Section 5.2 based on the pricing set forth in Schedule 4, such amounts "**Product Fees**". For Product Fees for the Tier 2 Market, Manufacturer shall on a Quarterly basis (but no later than [*****] after the close of each quarter) and based upon the Records provided by Acorda in line with Section 3.5(b) reconcile the invoiced Product Fees with the amount due based on [*****] and Manufacturer shall issue a new invoice for any difference that results from the reconciliation.

(b) Maintenance Fees. Acorda shall pay Manufacturer the annual fees for Product Maintenance Services set forth on Schedule 5. Manufacturer shall submit an invoice to Acorda for such fees upon the first day of each Year.

(c) [Reserved]

(d) Other Fees. Acorda shall not have any obligation to pay any other amounts for the services provided hereunder other than those set forth in this Section 3.1, unless otherwise expressly set forth in this Agreement or negotiated and agreed by the Parties in good faith. With respect to the PSD-7 Scale-Up Plan, pursuant to the procedures set forth in Section 3.2, Manufacturer shall invoice Acorda the following amounts to be used for site readiness activity required to validate the PSD-7 for use with Inbrija. Such amounts are as follows: $500,000 following each of the quarters ending on September 30, 2023, December 31, 2023, March 31, 2024, and June 30, 2024, for a total payment of $2 million. Acorda shall pay such invoices within forty five (45) days following each such quarterly period end. Other than such payments by Acorda, Manufacturer will be responsible for the costs of implementing the PSD-7 Scale-Up Plan. [*****].

(e) Product Fees Adjustment. The Product Fees shall be adjusted [*****] to reflect increases or decreases in labor, utilities and overhead, as follows:

(i) Manufacturer shall pass through price increases or decreases for [*****] at the time of such price increase through an adjustment to the Product Fees.

(ii) Effective January 1, 2026, for PSD-4 pricing, and [*****] for PSD-7 pricing to be supplied to Tier 1 Markets, the Product Fees shall be [*****].

3.2. **Payments.**

(a) Credits; Reductions. Amounts payable by Acorda to Manufacturer in respect of Fees shall be reduced, if applicable, in line with Sections 2.7(a)(iv), 3.1(d), , 5.1(f), 6.1, 6.4(a) and 6.4(b) according to the terms set forth herein.

(b) Invoicing. Manufacturer shall invoice Acorda for Product Fees upon issuance of the COA. The invoice shall reflect any applicable credits or reductions, as specified herein. Manufacturer's invoices shall be sent by fax or email to the fax number or email address given by Acorda to Manufacturer in writing. Such invoice timing shall have no bearing on Acorda's right to inspect Batch records or make determinations of deviations from the Compliant Product Requirements in accordance with this Agreement and the Quality Agreement.

(c) Payment. Acorda shall pay all undisputed invoices within [*****] of the receipt of such invoice. Acorda shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. Acorda shall notify Manufacturer in writing of any disputed amounts, within [*****] of Acorda's receipt of the relevant invoice. The Parties shall engage in good faith efforts to resolve any disputed amounts. If the dispute cannot be resolved within the payment term, Acorda shall pay any undisputed amounts within the payment term and the rest immediately following resolution of the dispute. If any payment is not received by Manufacturer by its due date (other than disputed amounts), then Manufacturer may, in addition to other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at [*****] per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

3.3. **Taxes.** All sales, use, gross receipts, compensating, value-added, or other taxes, duties, registrations, tariffs, customs fees, license fees, and other amounts assessed by any tax jurisdiction, U.S. Customs or foreign equivalent, or any other Authority (excluding Manufacturer's net income and franchise

taxes and any other of the foregoing that is recoverable by Manufacturer) ("**Taxes**"), on or for Acorda-Supplied Materials, Manufacturing Services, or Supplied Product prior to or upon provision or sale to Manufacturer or Acorda, as the case may be, whether assessed on Manufacturer or Acorda, are the responsibility of Acorda, whether paid by Manufacturer or Acorda, and either Acorda shall reimburse Manufacturer for all such Taxes paid by Manufacturer or such sums will be added to invoices directed to Acorda. In the event that Manufacturer reasonably determines that there are any new taxes imposed on the Manufacturing Site that it believes are customarily borne by the customer, it may notify Acorda of such determination and in such case the Parties shall negotiate in good faith any pass through of such new taxes.

3.4. **Unused Credits at Expiration or Termination**. Within 60 days following the expiration or termination of this Agreement, the amount of any remaining unused credits arising under this Agreement as per Section 3.2(a) in favor of Acorda against Fees but unused, shall be paid by Manufacturer to Acorda in cash by wire transfer to such bank account as Acorda may notify to Manufacturer in writing.

3.5. **Audits**.

(a) Acorda shall have the right to have an independent accounting firm of internationally recognized standing during normal business hours, upon reasonable prior written notice and in a manner that will not unreasonably adversely affect Manufacturer's business, to examine those records of Manufacturer (and, if applicable, its Affiliates) solely as is reasonably necessary to determine, with respect to any Year ending not more than [*****] prior to Acorda's request, the correctness of any Fees or other amounts payable by Acorda to Manufacturer hereunder (including credits applicable in respect thereof) applicable during such Year. The cost of any such examination shall be borne by [*****]. If such audit concludes that excess payments were made by Acorda during the period under examination, then [*****].

(b) Acorda will keep complete and accurate books and records relating to all amounts payable to Manufacturer hereunder for countries where the Product Fees are calculated based on Net Sales (including all relevant deductions) for at least [*****] after the expiration of the Year to which they relate, in each case, in sufficient detail to enable the calculation and verification of all payments payable to Manufacturer hereunder ("Records"). Upon the written request and not more than [*****], Manufacturer shall be entitled to have an independent accountant audit such Records. Acorda shall provide such auditors with access during normal business hours to appropriate space at Acorda's relevant location and to such of the pertinent Records of Acorda as may be reasonably necessary to verify the matters in question. Such access shall include the right of the independent accounting firm to interview Acorda's personnel as such independent accounting firm determines appropriate. Each such examination shall be limited to pertinent Records for any Year ending not more than [*****] prior to the date of such request. Before permitting such independent accounting firm to have access to such Records and personnel, Acorda may require such independent accounting firm and its personnel involved in such audit, to sign to sign a confidentiality agreement reasonably acceptable to Acorda to prohibit the independent accounting firm from disclosing Acorda's financial and proprietary information except as contemplated by this Agreement. Prior to disclosing the results of any such audit to Manufacturer, the auditors shall present Acorda with a preliminary report of findings and provide Acorda with up to [*****] to respond to any questions raised or issues identified. Following such review period, the auditors will prepare and provide to Acorda and Manufacturer a written report stating whether the payments made to Manufacturer for the audit period are correct or incorrect and the details of any discrepancies. If an audit discloses an underpayment or overpayment by Acorda of any Product Fees based on Net Sales, such amounts shall be paid to Manufacturer or refunded to Acorda within [*****] after the date Acorda receives the auditors' final written report. Any fees and expenses of the audit shall be paid by [*****].

ARTICLE 4

AMENDMENTS TO SPECIFICATIONS OR OTHER ARRANGEMENTS

4.1. **Amendments to Specifications or Other Arrangements Requested by Acorda.** Acorda may, by written notice to Manufacturer, request an amendment to the Specifications, Schedule 6, or the Quality Agreement, with such amendment to be implemented in accordance with the terms of this Agreement and the change control process set forth in the Quality Agreement. Any such amendment will only be implemented following a review of the impact of such amendment on Manufacturer labor, utility, maintenance or other similar costs, the impact of such amendment on the regulatory compliance-related provisions of this Agreement and the Quality Agreement. Such review shall be undertaken by the Parties promptly following Acorda's proposal of such amendment. If in connection with the aforesaid review, either Party reasonably determines that such an amendment requires adjustments to (a) the Fees to reflect changed labor, utility, maintenance or other similar costs to Manufacturer or (b) regulatory compliance-related provisions as set forth in this Agreement or the Quality Agreement, then the Parties shall negotiate in good faith to address such matters and appropriately document their resulting agreements. Manufacturer shall not unreasonably withhold, condition or delay its agreement with regard to any of the foregoing, and will not unreasonably withhold agreement to any amendments required for compliance with the requests or mandates of the FDA or EMA.

4.2. **Amendments to Specifications or Other Arrangements Requested by Manufacturer.** Amendments to the Specifications, Schedule 6, or the Quality Agreement may be proposed by Manufacturer in accordance with the terms of this Agreement and the change control process as set forth in the Quality Agreement. Any such amendment will only be implemented following the written agreement between both Parties.

ARTICLE 5
FORECASTS, ORDERS AND DELIVERY

5.1. **Orders and Forecasts.**

(a) Rolling 24-Month Forecast. Attached hereto is Acorda's current non-binding forecast consistent with the Minimum Commitments. Acorda shall thereafter update such forecast, on a non-binding basis, by the 15th day of each calendar month on a rolling forward basis. Each forecast must start on the first day of the next month. The forecasts contemplated by this Section 5.1 will be non-binding except as otherwise provided in this Section 5.1. For clarity, for the first 6 months of the attached forecast apply even though they were not submitted more than 6 months in advance.

(b) Firm Commitment. [*****] of each forecast delivered pursuant to Section 5.1(a) will be considered a binding firm order ("**Firm Commitment**").

(c) Purchase Orders. By January 6, 2023, the Parties will have discussed and agreed on the timing for delivery of the Batches required to be delivered hereunder in Q1 2023 and Acorda shall in connection therewith issue Purchase Orders for such Batches by such date and they shall be attached hereto as Exhibit D. For each Batch ordered by Acorda hereunder other than the Batches required to be delivered hereunder in Q1 2023 (per above), Acorda shall submit no later than [*****] prior to the COA Target Date a written purchase order ("**Purchase Order**"), consistent with the forecast for the applicable time period. Purchase Orders submitted to Manufacturer shall specify Acorda's purchase order number, the volume of Supplied Product, applicable COA Target Date (which shall be no earlier than [*****] following the date on which the Purchase Order is

submitted), and any other elements necessary to ensure the timely Manufacture and shipment of the ordered Supplied Product. Purchase Orders may be entered into under this Agreement by Acorda or, with the consent of Acorda, any of its Affiliates, licensees, or collaboration partners. Each Purchase Order shall include the commercial capsule pricing (or Bulk Product pricing, if applicable) from Schedule 4, including but not limited to [*****] and the applicable price [*****]. The entity that executes a Purchase Order with Manufacturer shall be considered "Acorda" for all purposes of the Purchase Order and this Agreement and the Purchase Order shall be considered a two party agreement between Manufacturer and such entity. For clarity, Purchase Orders for Supplied Product executed by an Affiliate, licensee, or collaboration partner of Acorda shall contribute to Minimum Commitments, if any, [*****], if any, set forth under this Agreement. Acorda shall remain liable to Manufacturer for the Purchase Orders placed by such entity as if such entity were Acorda. Promptly following receipt of a Purchase Order, Manufacturer shall issue a written acknowledgement (each, an "**Acknowledgement**") that it accepts or rejects such Purchase Order. Manufacturer shall accept any Purchase Order up and until the Reserved Capacity has been exhausted (including accepting the Purchase Order partially) and shall not unreasonably reject any Purchase Order for the PSD-7. The Acknowledgement shall confirm the COA Target Date set forth in the Purchase Order or propose to Acorda a reasonable alternative delivery date, which shall apply only if Acorda consents, at its sole discretion, to such alternative delivery date. The Parties will negotiate in good faith the acceptance by Manufacturer of any Purchase Orders in excess of the greater of the Firm Commitment or the Reserved Capacity for the applicable period.

(d) Manufacturer's Cancellation of Purchase Orders. Notwithstanding anything in Section 5.1(c) to the contrary, Manufacturer reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Acorda, and Manufacturer shall have no further obligation or liability with respect to such Purchase Order, if Acorda refuses or fails to supply conforming Acorda-Supplied Components/Materials within thirty (30) days after Manufacturer provides notice that it does not have sufficient Acorda-Supplied Components/Materials. Any cancellation of Purchase Orders in accordance with this Section 5.1(d) shall not constitute a breach of this Agreement by Manufacturer nor shall it absolve Acorda of its obligation in respect of the Minimum Commitment.

(e) Reservation of Capacity. Manufacturer shall reserve (*i.e.*, have available and not use or enter into any agreement obligating it to use for any other purpose without the prior written consent of Acorda), during the Term the Reserved Capacity on a Year-by-Year basis for each of the PSD-4 and PSD-7, as applicable for the Manufacture, including blister packaging for Batches of Supplied Product other than those to be delivered as Product without capsules.

(f) Remedies for Late Delivery. If there is a Late Delivery (other than Bulk Product), then, without limiting any other remedies available hereunder and for clarity, not subject to or counted towards the caps set forth in Section 10.1, the following consequences shall apply:

Timing of COA Delivery	**Consequence**
COA delivery up to [*****] after COA Target Date	[*****]
COA delivery [*****] after COA Target Date	Batch at [*****] discount
COA delivery [*****] after COA Target Date	Batch at [*****] discount

COA delivery [*****] after COA Target Date	Batch at [*****] discount or [*****]

For Bulk Product, the COA Target Date will be mutually agreed upon by Parties based on the actual data on the PSD-7 from the validation batches as modified by the Parties from time to time based on historical data. The Grace Period shall be agreed by mutual agreement of the Parties taking into account the need to further process the Bulk Product and the applicable stability data at the time. If the COA is delivered after the Grace Period, Acorda may reject the Batch and Manufacturer shall provide a replacement batch.

5.2. **Delivery**.

(a) Delivery of Supplied Product Ordered Under a Purchase Order. Manufacturer shall deliver the quantity of Supplied Product specified by Acorda in the Purchase Order on the Delivery Date specified by Acorda in the Purchase Order (or a mutually agreed alternate Delivery Date) in accordance with Article 1 and Section 5.1(c).

(b) Delivery Terms. Physical delivery of Supplied Product by Manufacturer will be FCA (Incoterms 2010) the Manufacturing Site or such other Incoterms and delivery location as agreed by the Parties in writing, provided, however, that any increased shipping costs associated with the change in delivery location will be borne by Acorda. To the extent not already held by Acorda, title to Supplied Product shall transfer to Acorda upon Manufacturer's tender of delivery. In the event Manufacturer arranges shipping or performs similar loading or logistics services for Acorda at Acorda's request, such services are performed by Manufacturer as a convenience to Acorda only and do not alter the terms and limitations set forth in this Section 5.2. Manufacturer shall not be responsible for Supplied Product in transit, including any cost of insurance or transport fee for Supplied Product, or any risk associated with transit or customs delays, storage and handling.

(c) Storage Fees. If Acorda fails to take shipment of any Supplied Product within sixty (60) days after the scheduled date, Manufacturer shall store such Supplied Product and have the right to invoice Acorda monthly storage costs at [*****] per pallet.

ARTICLE 6

FAILED BATCHES; PRODUCT CLAIMS; RECALLS

6.1. **Manufacturer's Responsibility for Failed Batches.** If Manufacturing Services in respect of a Batch of Supplied Product fail to yield Supplied Product deliverable by Manufacturer to Acorda in compliance with the Compliant Product Requirements and the failure is attributable to Manufacturer's failure to provide the Manufacturing Services in respect of such Batch of Supplied Product in accordance with the terms of this Agreement ("**Manufacturer Defective Manufacturing**"), then Acorda will be entitled to [*****]. The Active Materials in such non-conforming Supplied Product as referenced in this Section 6.1 will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.7(a)(ii).

6.2. **Product Claims.**

(a) Notice of Product Deficiency. Acorda has the right to reject any portion of any shipment of Supplied Product that deviates from the Compliant Product Requirements without invalidating any remainder of the shipment in accordance with the terms of the Quality Agreement. Acorda shall inspect the Supplied Product manufactured by Manufacturer upon receipt. Unless

Acorda gives Manufacturer written notice (a "**Deficiency Notice**") of all claims for Supplied Product that deviates from the Compliant Product Requirements within [*****] days after Acorda's receipt of such Supplied Product and full Batch records therefor (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Supplied Product or within such period, within [*****] days after the earlier of discovery of such defects by Acorda or Acorda's receipt of notice from a third party of such defects), Supplied Product shall be deemed accepted by Acorda and Acorda shall have no right to reject such Supplied Product.

(b) Determination of Product Deficiency. Upon receipt of a Deficiency Notice, Manufacturer will have [*****] days to advise Acorda by written notice if it disagrees with the contents of the Deficiency Notice. Should Manufacturer fail to object to the Deficiency Notice on a timely basis, Manufacturer will be deemed to have accepted and agreed with the Deficiency Notice. If Acorda and Manufacturer fail to agree within ten (10) days after any Manufacturer notice to Acorda objecting to a Deficiency Notice as to whether any Supplied Product identified in the Deficiency Notice deviates from the Compliant Product Requirements, then the Parties shall mutually select an independent laboratory or other source of investigative services that is properly qualified to make the relevant determination to determine whether the Supplied Product deviates from the Compliant Product Requirements and whether the cause thereof is Manufacturer Defective Manufacturing. Absent manifest error, the determination of the independent laboratory or other source of investigative services will be binding on the Parties. If the independent laboratory or other source of investigative services determines that any Supplied Product deviates from the Compliant Product Requirements, then Acorda may reject that Supplied Product in the manner contemplated in this Section 6.2 and [*****]. If the independent laboratory or other source of investigative services finds that none of the Supplied Product deviates from the Compliant Product Requirements, then (i) Acorda will be deemed to have accepted delivery of the Supplied Product and (ii) [*****].

(c) Shortages. Claims for shortages in the amount of Supplied Product shipped by Manufacturer will be dealt with by reasonable agreement of the Parties. In respect of the Supplied Product, each Party shall comply with any and all obligations imposed on such Party by Applicable Laws regarding the reporting or handling of shortages of the Supplied Product, and the other Party shall reasonably cooperate to enable the former Party to comply with such obligations.

6.3. **Product Recalls and Returns.**

(a) Records and Notice. Manufacturer and Acorda shall each maintain records necessary to permit a Recall of any Supplied Product delivered to Acorda or customers of Acorda. Each Party shall promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of Marketed Product incorporating Supplied Product or which might result in the Recall or seizure of Supplied Product or Marketed Product incorporating Supplied Product. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Acorda. "**Recall**" means any action (i) by Acorda to recover title to or possession of quantities of Supplied Product or Marketed Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Marketed Product from the market); or (ii) by any Authorities to detain or destroy any of the Supplied Product or any Marketed Product.

(b) Recalls. If (i) any Authority issues a directive, order or, following the issuance of a safety warning or alert about the Supplied Product or Marketed Product, a written request that any Supplied Product or Marketed Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Acorda determines that any Supplied Product or Marketed Product should be

Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Supplied Product or Marketed Product, then Manufacturer shall co-operate as reasonably required by Acorda, having regard to all Applicable Laws.

(c) Product Returns. Acorda will have the responsibility for handling customer returns of Supplied Product or Marketed Product. Manufacturer shall give Acorda any assistance that Acorda may reasonably require to handle the returns.

6.4. **Manufacturer's Responsibility for Defective and Recalled Product.**

(a) Product Rejection. If Acorda rejects Supplied Product under Section 6.2 and the deviation is determined to have arisen from Manufacturer's failure to provide the Manufacturing Services in respect of the Supplied Product in compliance with the terms of this Agreement or the Quality Agreement, then Section 6.1 shall apply.

(b) Recalled Product. The cost of any Recall, return or corrective action shall be borne by Acorda, and Acorda shall reimburse Manufacturer for expenses incurred in connection with any Recall, in each case except to the extent such Recall is caused solely by Manufacturer's [*****], in which case Manufacturer shall bear the cost of any Recall and shall reimburse Acorda for expenses incurred in connection with any such Recall as described below (such Supplied Product or Marketed Product so subject to a Recall, a "**Recalled Product**"), then Manufacturer will (i) be responsible for all documented out-of-pocket expenses (including reasonable attorneys' fees and amounts paid to Authorities) of Acorda and its Affiliates of the Recall, return or other corrective action (including any out-of-pocket costs incurred by Acorda in respect of affected Marketed Product or its manufacturing, distribution or sale), and (ii) the returned Supplied Product shall be reimbursed to Acorda in line with Section 6.1.

(c) Notice by Manufacturer. Manufacturer shall notify Acorda immediately if at any time Manufacturer discovers that any Supplied Product delivered hereunder does not conform to the Compliant Product Requirements.

6.5. **Disposition of Defective or Recalled Product.** Acorda shall not dispose of any damaged, defective, returned, or Recalled Product for which it intends to assert a claim against Manufacturer without Manufacturer's prior written authorization to do so. Any storage of such Supplied Product that does not meet the Compliant Product Requirements or Marketed Product containing such Supplied Product (including at Acorda's facilities) will be at Manufacturer's reasonable cost and expense; and otherwise such storage shall be at Acorda's cost and expense. Alternatively, Manufacturer may instruct Acorda to return, at Manufacturer's reasonable cost and expense, any damaged, defective, returned or Recalled Product (but not, for clarity, Marketed Product) to Manufacturer. Manufacturer will bear the cost of storage, return and disposition for any damaged, defective, returned or Recalled Product or Marketed Product for which it bears responsibility under Section 6.4. In all other circumstances, Acorda will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Product.

6.6. **Healthcare Provider or Patient Questions and Complaints.** Questions or complaints regarding Supplied Product or Marketed Product received by Manufacturer shall be handled by the Parties in accordance with the terms of the Quality Agreement.

ARTICLE 7

CO-OPERATION

7.1. **Governance.**

(a) Monthly Meetings

(i) The Parties shall convene a supply and operations meeting each month by phone or video conference to discuss matters relating to the performance of Manufacturer's obligations hereunder.

(ii) Each Party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the Parties. The relationship managers shall meet not less frequently than once each month to review the current status of the business relationship and manage any issues that have arisen. Such monthly reviews shall, unless the Parties otherwise agree, take place at the Manufacturing Site or, if the Parties mutually agree, by means of virtual communication.

(b) Joint Steering Committee. Promptly, and in any event within [*****] days following the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to provide the necessary oversight and leadership to guide the overall relationship. With regard to Reserved Capacity, the JSC will, in its oversight of the first approval of the PSD-7, work in good faith to make the necessary adjustments and modifications to the Batch reservations in calendar year 2026 and onward required to maintain adequacy of Supplied Product for Acorda while taking into consideration Manufacturer's other production and supply obligations. The aforementioned also applies to instances where the PSD-7, after first approval, becomes unavailable for any reason. The JSC will be comprised of three (3) representatives of Manufacturer and three (3) representatives of Acorda (or such other equal number of representatives as the JSC may determine) (each, a "**JSC Representative**"). Subject to the foregoing, each Party may change its JSC Representatives to the JSC from time to time, in its sole discretion, effective upon notice to the other Party designating such change. JSC Representatives from each Party will have appropriate technical credentials, experience and knowledge pertaining to and ongoing familiarity with the activities hereunder, as well as appropriate seniority and authority to make decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JSC. The JSC will convene at least quarterly by phone or video conference, and will conduct its responsibilities hereunder in good faith and with reasonable care and diligence.

(c) Joint Development Committee. Promptly, and in any event within [*****] days following the Effective Date, the Parties shall establish a joint development committee ("**Joint Development Committee**" or "**JDC**"), which shall report to the JSC with respect to timelines, budgets, and completed runs. The JDC will be comprised of three (3) representatives of Manufacturer and three (3) representatives of Acorda (or such other equal number of representatives as the JSC may determine) (each, a "**JDC Representative**") who will be of the requisite skill and expertise to plan, resolve and approve protocols, study designs, and make recommendations to the Joint Steering Committee, including with respect to business continuity and risk management plans. Manufacturer's JDC Representatives are set forth in Schedule 11 and shall not be changed without the written consent of Acorda, such consent not to be unreasonably withheld. The JDC Representatives shall not share Lock Down Information with the JSC

Representatives. The JDC shall convene each month by phone or video conference to work jointly on the PSD-7 Scale-Up, including:

(i) Promptly developing and approving the PSD-7 Scale-Up Plan;

(ii) at least quarterly, discussing the PSD-7 operational target date; and

(iii) commencing no later than the first Quarter of 2024 and in each Quarter thereafter until the PSD-7 has been approved, assessing the timing regarding such approval of the PSD-7 [*****].

(d) Decision-Making. Each Party will have one vote at each of the JSC and JDC (each, a "**Committee**"). Each Committee will endeavor to make decisions by consensus. In the absence of consensus, any dispute shall be escalated to the senior officers as set forth in Section 12.1, including any disputes or deadlocks relating to the PSD-7 Scale-Up Plan.

7.2. **Authorities.** Subject to Section 7.8, each Party may, in respect of any matter that is under such Party's responsibility, communicate with any Authority with regard to the activities described in this Agreement, including Pharmaceutical Regulatory Authorities responsible for granting Marketing Authorizations for Marketed Product, if, in the opinion of that Party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Laws. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a Party shall, to the extent the relevant communication with an Authority relates to the Manufacturing Services or, in the case of communications by Manufacturer, the Supplied Product, (a) notify the other Party of its intention to make such communications prior to making them to the Authority, (b) permit the other Party to accompany and take part in any such communications with the Authority, (c) provide the other Party with the contents of the proposed communications on a schedule designed to afford the receiving Party an opportunity to review and comment thereon prior to the submission of the communications to the Authority, and (d) provide the other Party with copies of all communications with the Authority.

7.3. **Records and Accounting by Manufacturer.**

(a) Generation, Retention, and Maintenance of Records. Manufacturer shall generate, retain and maintain:

(i) all records, including manufacturing records, standard operating procedures, equipment log books, master Batch records and other Batch manufacturing records, laboratory notebooks, and raw data relating to the manufacturing of Supplied Product and any component or intermediate thereof, necessary to comply with cGMPs and all other Applicable Laws relating to the Manufacture of the Supplied Product or any component or intermediate thereof;

(ii) samples of each Batch of Supplied Product and of Components/Materials. Such samples must include a quantity of representative material of each Batch and Components/Materials sufficient to perform full duplicate quality control testing and must specify (directly or through the LIMS system) the applicable dates of Manufacture. Samples so retained must be selected in accordance with Manufacturer's Quality System and in any event in compliance with applicable cGMPs and other Applicable Laws. Such samples must be stored at temperatures and under conditions which

will maintain the identity and integrity of the relevant sample in accordance with relevant Specifications; and

(iii) such other records and samples as agreed between the Parties, agreement not to be unreasonably withheld, conditioned or delayed, in order to ensure compliance by Manufacturer with the terms of this Agreement and cGMPs and all other Applicable Laws.

(b) Retention of Records and Samples. Originals of the records and samples shall be retained by Manufacturer for one year following the date of Supplied Product expiry, or longer if required by cGMPs or other Applicable Laws or Manufacturer's Quality System, at which time Manufacturer shall contact Acorda concerning the delivery to Acorda or the destruction of the documents and/or samples of Supplied Product. Subject to Section 13.19, Manufacturer shall not destroy any samples or records without Acorda's prior written consent. Without limiting the preceding sentence, following the expiration of Manufacturer's obligation to retain samples, Acorda will be responsible for retaining samples of the Supplied Product necessary to comply with the legal/regulatory requirements applicable to Acorda.

(c) Acorda Inspection of Records and Samples. Acorda will have such rights to inspect Manufacturer's records and samples as are specified in the Quality Agreement.

7.4. **Acorda Access to Manufacturing Site.** Manufacturer shall give Acorda full access with reasonable notice within regular business hours to the Manufacturing Site to permit Acorda to observe the performance by Manufacturer of the Manufacturing Services and to verify that the Manufacturing Services are being performed in compliance with the terms of this Agreement and the Quality Agreement. Until [*****] after commencement of use of PSD-7 for [*****], Acorda shall have the right to have one person in plant that will have access free of charge to a cubicle, parking, internet, copy machines, cafeteria (if any) and other standard office equipment and supplies.

7.5. **Audit**. Acorda or its duly designated Representative will have the right, upon at least 30 days' prior written notice or such shorter period as agreed by the Parties in the case of a for cause audit, and no more than [*****], to have up to two Acorda employees or Representatives who are subject to confidentiality obligations in favor of Manufacturer no less restrictive than those set forth in favor of Manufacturer in this Agreement access the Manufacturing Site during operational hours in order to audit the Manufacturing Site and Manufacturer records to assess compliance by Manufacturer with the terms of this Agreement in the performance of the Manufacturing Services. Each such audit will be no longer than [*****] in duration [*****]. Acorda employees and Representatives who audit the Manufacturing Site and records will at all times comply with such reasonable rules, regulations and SOPs as Manufacturer may reasonably impose, and of which it has given advance written notice to Acorda, relating to inspections and visits to the Manufacturing Site; and Acorda retains full responsibility and liability for the presence and actions of its employees on Manufacturer's premises. The provisions of this Section 7.5 are without limitation of Acorda's rights of access to the Manufacturing Site under Section 7.4 or any provisions that may be contained in the Quality Agreement dealing with Acorda's right to inspect and audit the Manufacturing Site and Manufacturer's records and samples.

7.6. **Regulatory Proceedings; Governmental Inspections.** Manufacturer shall notify Acorda promptly (and in any event within the timelines agreed in the Quality Agreement) following the date of receipt of notice by Manufacturer of any citation, indictment, claim, lawsuit, or proceeding issued or instituted by any Authority against Manufacturer, or of any revocation of any license or permit issued to Manufacturer, that directly affects, or could be reasonably expected to directly affect, Manufacturer's performance of any of its obligations under this Agreement, redacted as appropriate to protect any

Confidential Information of Manufacturer and the confidential information of Manufacturer's other clients. Manufacturer shall provide Acorda with a draft of any response that Manufacturer proposes to make in respect of any such matter on such a schedule as will afford Acorda not less than two Business Days to respond with comments to Manufacturer, which comments Manufacturer shall consider in good faith for incorporation in its response to the relevant Authority. Acorda acknowledges that it may not direct the manner in which Manufacturer fulfills its obligations to permit inspection by and to communicate with Authorities. For any inspections by Regulatory Authorities involving the Manufacturing Site and specifically relating to the Supplied Product not included in the Annual Maintenance Fee, [*****].

7.7. **Reports.** Manufacturer shall, upon Acorda's request, supply to Acorda on an annual basis (a) all Supplied Product data in its control, including release test results, complaint test results, stability test results and all investigations (in manufacturing, testing, and storage), that Acorda reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Acorda is required to file with the FDA or other Pharmaceutical Regulatory Authorities; and (b) a copy of Manufacturer's Annual Product Review Report in respect of Supplied Product. Manufacturer shall also provide any additional reports that Acorda may reasonably request in respect of the Manufacturing Services or the Supplied Product.

7.8. **Regulatory Filings.**

(a) Responsibility for Regulatory Filings. Except as otherwise contemplated by this Section 7.8 or Section 9.3(b), Acorda will have the sole responsibility and authority for filing all documents with all Pharmaceutical Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Pharmaceutical Regulatory Authority approval for the incorporation into Marketed Product to be marketed, distributed and sold in the Territory of Supplied Product to be Manufactured hereunder. Acorda will be responsible for ensuring the accuracy of the documents provided to the Pharmaceutical Regulatory Authorities by Acorda for Supplied Product and Marketed Product, and shall ensure through use of the change control process that Manufacturer is provided with the currently filed, active Specifications for Supplied Product and the information needed to enable Manufacturer to comply with the requirements of applicable Marketing Authorizations for Marketed Product applicable to the Manufacturing Services. Notwithstanding anything to the contrary in this Agreement, Acorda shall provide Manufacturer with a draft of any document that Acorda proposes to file with any Authority describing operations to be performed within the Manufacturing Site on such a schedule as will afford Manufacturer not less than two Business Days to respond with comments to Acorda, which comments Acorda shall consider in good faith for incorporation in the document it proposes to file with the relevant Authority. Without limiting Manufacturer's obligations under this ARTICLE 7, Acorda may request from Manufacturer additional regulatory support services as listed and for the prices set forth in Schedule 5.

(b) Obtaining and Maintaining Marketing Authorizations and Qualification of the Manufacturing Site. Manufacturer shall reasonably assist Acorda to obtain and maintain (i) Marketing Authorizations for the marketing, distribution, and sale of Marketed Product throughout the Territory and (ii) Pharmaceutical Regulatory Authority approval for the incorporation into Marketed Product for marketing, distribution, and sale of Marketed Product in the Territory of Supplied Product to be Manufactured hereunder. Without limiting the foregoing, the Parties shall cooperate, and each Party shall use its reasonable efforts, to permit Acorda to obtain Pharmaceutical Regulatory Authority approval for the incorporation into Marketed Product for marketing, distribution, and sale in each of the United States, the European Union, Canada, and Japan of Supplied Product to be Manufactured hereunder concurrently with, and in any event as quickly as reasonably possible following, Acorda's receipt of Marketing Authorization for the marketing,

distribution, and sale of Marketed Product in the relevant country. Without limiting the foregoing, Manufacturer shall:

(i) [*****], make its employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Pharmaceutical Regulatory Authorities concerning the Supplied Product or any Marketed Product or any component or intermediate thereof;

(ii) disclose and make available to Acorda, in whatever form Acorda may reasonably request, all Manufacturing and quality control data, CMC data and other information related to the Supplied Product or any component or intermediate thereof and the Manufacturing process therefor as is reasonably necessary or desirable to obtain and maintain Marketing Authorizations for Marketed Product in the Territory, in order to prepare, file, obtain and maintain any approval, license, registration or authorization required in connection with the sourcing of Supplied Product by Acorda hereunder for incorporation in Marketed Product for marketing, distribution, and sale of Marketed Product in the Territory; and

(iii) review any common technical documents prepared by Acorda in respect of Marketed Product in the Territory prior to submission by Acorda of such files to the applicable Pharmaceutical Regulatory Authority.

(c) Manufacturing Authorization. Notwithstanding the other provisions of this Section 7.8, Manufacturer will be responsible for obtaining and maintaining, at all times during the Term, all approvals, permits, licenses, registrations, DUNS number, authorizations, or qualifications required from any Authority (including any Pharmaceutical Regulatory Authority) required in order for it to operate in all respects the Manufacturing Site in order to conduct the Manufacturing Services as contemplated herein. Without limiting the foregoing, Manufacturer shall at all times during the Term have and maintain a manufacturing authorization from the FDA in respect of the Manufacturing Site in order to conduct the Manufacturing Services as contemplated herein. The Parties will coordinate as needed to ensure that Manufacturer has such approvals, permits, licenses, registrations, authorizations and qualifications in place as of the Closing. Manufacturer will be responsible for ensuring the accuracy and completeness of documents provided to Pharmaceutical Regulatory Authorities by Acorda (to the extent of information provided by Manufacturer to Acorda for incorporation in such documents or confirmed by Manufacturer by way of review of draft documents submitted by Acorda to Manufacturer for review) or Manufacturer with respect to the Manufacturing Site, and shall ensure through use of the change control process specified in the Quality Agreement that Acorda is provided with the current manufacturing information needed to enable Acorda to comply with the requirements of applicable Marketing Authorizations for Marketed Product.

ARTICLE 8

TERM AND TERMINATION

8.1. **Term.**

(a) Term. This Agreement will become effective as of the Effective Date and will continue until December 31, 2030 (the "**Initial Term**"). This Agreement will automatically renew after the Initial Term for successive terms of two Years each if this Agreement is then in effect,

unless either Party has given written notice to the other Party of its intention to terminate this Agreement at least 18 months prior to the end of the then-current term (the Initial Term, together with any renewal periods, the "**Term**").

(b) Termination. Notwithstanding the provisions of Section 8.1(a), this Agreement may be terminated in accordance with the provisions of Section 8.2, and as of the effective date of such termination, the Term will also terminate.

8.2. **Termination.**

(a) Material Breach. Either Party, in its sole discretion, may terminate this Agreement hereunder upon written notice to the other Party where such other Party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within [*****] following receipt of a written notice of the breach from the aggrieved Party. If Acorda fails to make payments in accordance with the terms of this Agreement and such payment breach is not cured within [*****] after written notice of non-payment from Manufacturer given in accordance with Section 13.7, Manufacturer may suspend any further performance of Manufacturing Services under this Agreement until such non-payment is rectified. If the other Party reasonably and in good faith disagrees as to whether there has been a material breach under this Agreement or whether a material breach has been cured, such Party may contest the allegation in accordance with ARTICLE 12 and Section 13.19(b) and the cure period shall be tolled until such time as the dispute is resolved, or as provided in Section 13.6. A Serious Performance Failure shall constitute a material breach.

(b) Insolvency. Either Party may terminate this Agreement immediately without further action if the other Party files a petition in bankruptcy, enters into an agreement with its creditors, applies for or consents to the appointment of a receiver, administrative receiver, trustee, or administrator for its affairs, makes an assignment for the benefit of creditors, suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent where such order is not discharged within sixty (60) days, or takes any equivalent or similar action in consequence of debt in any jurisdiction.

(c) Market Withdrawal; Pharmaceutical Regulatory Authority Action. Acorda may terminate this Agreement immediately if:

(i) Acorda generally withdraws Marketed Product from the market in either of the United States or the European Union (or, if Marketed Product is not marketed, distributed and sold by Acorda or its designees in all European Union countries, in whichever of the European Union countries the Marketed Product is at the time marketed, distributed and sold by Acorda or its designees); or

(ii) any Pharmaceutical Regulatory Authority in the United States or the European Union provides notice declining to approve a Marketing Authorization application for Marketed Product or takes any action, or raises any objection that prevents Acorda from importing, exporting, purchasing, or selling Supplied Product or Marketed Product in or for the relevant jurisdiction.

(d) Compliance Regarding Anti-Bribery/Anti-Corruption. Notwithstanding anything to the contrary in this Agreement, each Party may immediately terminate this Agreement in the event

such Party receives any information which it determines, reasonably and in good faith, to be evidence of a breach by the other Party of the representations, warranties and covenants set forth in Sections 9.4(a), (b), and (c).

8.3. **Termination by Acorda for Convenience**. Acorda may, at its sole option, with or without cause, terminate this Agreement hereunder upon not less than one hundred eighty (180) days' prior written notice to Manufacturer.

8.4. **Obligations on Expiration or Termination.**

(a) Obligations. If the Agreement expires or is terminated, then:

(i) Except as otherwise specified herein, Acorda shall pay Manufacturer within thirty (30) days all Fees that have accrued through the date of expiration or termination of this Agreement for all Services performed up to the date of expiration or termination, and shall reimburse Manufacturer for all costs and expenses reasonably incurred, and all non-cancelable commitments reasonably made by Manufacturer, in connection with the performance of Manufacturing Services, including (A) any cost incurred to wind down and cease any ongoing Manufacturing Services, and (B) any cost for any Acorda-specific purchases made by Manufacturer for use in such Manufacturing Services in reasonable reliance on the forecasts;

(ii) Acorda may, at its own expense and in its sole discretion, remove from the Manufacturing Site or other Manufacturer-controlled site (which, for clarity, may include a third party warehouse) any or all Components/Materials and any other items owned by Acorda that are located at the Manufacturing Site or are otherwise under Manufacturer's care and control ("**Acorda Property**") at any time prior to [*****] following the effective date of expiration or termination of this Agreement; and

(iii) Except in the case of termination for Manufacturer's material breach under Section 8.2(a) and by Acorda under Section 8.2(d), Acorda shall pay to Manufacturer within thirty (30) days after the effective date of termination of this Agreement [*****] as permitted under this Agreement).

(b) Survival. Any expiration or termination of this Agreement will not affect any outstanding obligations or payments due that have arisen prior to the expiration or termination, nor will it prejudice any other remedies that the Parties may have under this Agreement in respect of such obligations or payments. The provisions of ARTICLE 1, ARTICLE 10, ARTICLE 11, ARTICLE 12, and ARTICLE 13 (except for Section 13.1(a)) and Sections 2.1(e)(viii), 2.3(c), 2.4, 2.5(b), 3.2, 3.3, 3.4, 3.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.3, 7.5, 7.6, 8.4 and 9.6, together with any other terms or provisions of this Agreement that by their terms or intended operation are required to survive so as to give full effect to the arrangements contemplated by this Agreement and the Quality Agreement, will survive expiration or termination of this Agreement and continue thereafter in accordance with their terms.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1. **Authority.** Each Party hereby represents and warrants in respect of this Agreement as of the Effective Date to the other Party as follows:

(a) The Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and to perform its obligations thereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered by the Party and constitutes a legal, valid and binding obligation of the Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity.

(b) All necessary consents, approvals and authorizations of all Authorities and other persons required to be obtained by such Party in connection with its execution and delivery of this Agreement have been obtained.

(c) The execution and delivery of this Agreement and the performance of the Party's obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws or any other constitutive document of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which the Party is bound.

9.2. **Acorda Representations, Warranties, and Covenants.** Acorda covenants, represents, and warrants to Manufacturer that:

(a) All Acorda-Supplied Components/Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement.

(b) The content of artwork, if any, provided by or on behalf of Acorda to Manufacturer shall comply with all Applicable Laws.

(c) All Supplied Product delivered to Acorda by Manufacturer shall be held, used and disposed of by or on behalf of Acorda in accordance with Applicable Laws, and Acorda will otherwise comply with Applicable Laws relating to Acorda's performance under this Agreement.

(d) Acorda will not release any Batch of Supplied Product if the required certificates of conformance indicate that the Supplied Product does not comply with the Specifications or if Acorda does not hold all necessary regulatory approvals to market and sell the Marketed Product.

(e) [*****].

(f) [*****].

(g) Acorda has all authorizations and permits required to deliver (or have delivered) Active Materials to the Manufacturing Site.

9.3. **Manufacturer Representations, Warranties, and Covenants.** Manufacturer covenants, represents, and warrants to Acorda that:

(a) During the Term, Manufacturer shall afford to Acorda and the Supplied Products first priority in the Manufacturing Site and in the event of any shortage of materials or capacity, shall prioritize Acorda's orders over those of other customers in the Manufacturing Site up to the Capacity Reservation; and it will perform the Manufacturing Services in compliance with the terms of this Agreement and Quality Agreement and in such a manner as to permit it to deliver Supplied Product to Acorda pursuant hereto that complies with the Compliant Product Requirements.

(b) It has approval, permit, license, registration, authorization, or qualification if required, and will maintain in full force and effect and in good standing, any and all approvals, permits, licenses, registrations, authorizations, or qualifications of any Authority, including a manufacturing authorization from the applicable Pharmaceutical Regulatory Authority in respect of the Manufacturing Site and the performance of the Manufacturing Services as contemplated herein, required by Applicable Laws to be held by Manufacturer in order to provide the Manufacturing Services for the Supplied Product at the Manufacturing Site and to perform all of its other obligations hereunder in accordance with the terms of this Agreement.

(c) At the time of delivery of Supplied Product by Manufacturer, with respect to such Supplied Product,

(i) the Manufacturing Site, at the time of manufacture, was in compliance with all cGMPs and other Applicable Laws (including applicable inspection requirements of the applicable Pharmaceutical Regulatory Authorities);

(ii) the Supplied Product has been manufactured in strict compliance with the Compliant Product Requirements;

(iii) the Supplied Product is in conformity with its Specifications;

(iv) title to the Supplied Product will pass to Acorda free and clear of any security interest, lien or other encumbrance other than Acorda's obligation to pay Manufacturer under this Agreement;

(v) the Supplied Product will not be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the "**FFDCA**") or the Canadian Food and Drugs Act (R.S.C., 1985, C. F-27) (the "**CFDA**"); and

(vi) no act or omission of Manufacturer (other than as required by the Specifications or any written instructions provided by Acorda) would cause or result in the Supplied Product, being a product that cannot be introduced into interstate commerce pursuant to the FFDCA or other Applicable Law.

(d) Manufacturer shall not (A) use Manufacturer Intellectual Property in the manufacturing process of the Supplied Product or (B) incorporate or make part of any Supplied Product any Manufacturer Intellectual Property.

9.4. **Anti-Corruption Matters.**

(a) In connection with each Party's activities under and relating to this Agreement, neither Party nor any of its Affiliates, equity holders, partners, members, officers, directors, employees, Representatives, servants, sub-contractors, or other agents shall, directly or indirectly, offer, pay, promise to pay, or authorize the payment of any money, or offer, give, promise to give, or authorize the giving of any financial or other advantage or anything else of value to:

(i) any government official or health care professional for the purpose of (A) improperly influencing or rewarding any act or decision of such official, employee, person, Party, candidate, or health care professional, or (B) inducing such government official or health care professional to do or omit to do any act in violation of his or her lawful duty, or (C) securing any improper advantage for Manufacturer or Acorda, or (D) improperly inducing such government official or healthcare professional to use his or her influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, or

(ii) any officer, employee, agent, or representative of another company or organization, without that company's or organization's knowledge and consent, with the intent to influence the recipient's action with respect to his or her company's business, or to gain a commercial benefit to the detriment of the recipient's company or organization, or to induce the recipient to violate a duty of loyalty to his employer;

(b) Both Parties shall at all times be bound by and strictly comply with all Applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any government official, health care professional, or to any officer, director, employee or representative of any other organization;

(c) Manufacturer shall require any subcontractors or other persons or entities that provide services to Manufacturer in connection with Manufacturer's obligations under this Agreement, and are in a government-facing or customer-facing role, to agree in writing to and abide by the warranties and covenants in Sections 9.4(a) and (b);

(d) Should a Party learn of information suggesting that the other Party may have failed to comply with Sections 9.4(a), (b) and (c), such Party or its designee shall have the right, at any time during the term of this Agreement and for a period of three Years thereafter, to audit the financial and other books and records relating to its compliance with such clauses through an independent third party accounting company;

(e) Each Party shall cooperate fully with the other Party in connection with the investigation of any allegation, event, fact or occurrence which calls into question the other Party's compliance with any representation, warranty, or covenant in Sections 9.4(a), (b) and (c); and

(f) Each Party shall promptly notify the other Party of (i) the occurrence of any fact or event that would render any representation, warranty, covenant or undertaking in Sections 9.4(a),

(b) and (c) incorrect or misleading, (ii) any notice, subpoena, demand or other communication (whether oral or written) from any Authority regarding such Party's actual, alleged, possible or potential violation of, or failure to comply with, any laws or regulations governing bribery, money laundering, or other corrupt payments in connection with its activities under and relating to this Agreement, and (iii) any governmental investigation, audit, suit or proceeding (whether civil, criminal or administrative) regarding such Party's violation of, or failure to comply with, any Applicable Laws.

9.5. **Debarred Persons.** Each Party hereby represents, warrants, and covenants to the other Party that (a) neither such Party nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or any similar law in any country or other jurisdiction in the Territory or listed on either Excluded List, and (b) neither Manufacturer nor any of its Affiliates will use in any capacity, including as officer, director, managing employee, or any other way, in connection with the Manufacturing Services or the operation of the Manufacturing Site, any Person who has been debarred pursuant to Section 306 of the FFDCA or any similar law in any country or other jurisdiction in the Territory, or who is the subject of a conviction described in such section or listed on either Excluded List. Manufacturer shall inform Acorda in writing promptly if it or any Person who is performing the Manufacturing Services or operating the Manufacturing Site is debarred or is the subject of a conviction described in Section 306 of the FFDCA or any similar law in any country or other jurisdiction in the Territory or listed on either Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Manufacturer's knowledge, is threatened, relating to the debarment or conviction Section 306 of the FFDCA or any similar law in any country or other jurisdiction in the Territory, or listing on either Excluded List, of Manufacturer or any Person performing services hereunder.

9.6. **No Additional Warranties.** EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1. **Limitation on Damages.**

(a) Subject to the remainder of this Section 10.1, the total liability of Manufacturer under this Agreement shall in no event exceed [*****].

(b) Manufacturer shall have no liability under this Agreement for any claim for lost, damaged, or destroyed [*****], whether or not such [*****] are used in Manufacturing Services or incorporated into Supplied Product

(c) Notwithstanding anything to the contrary in the foregoing, the total liability for Manufacturer under this Agreement for any of the costs in relation to [*****] shall in no event exceed [*****]. For clarity, the cap in this Section 10.1(c) [*****]shall be in addition to the cap set forth in Section 10.1(a) such that Acorda could claim for [*****]under Section 10.1(a) and for all other [*****] expenses as set forth in Section [*****] under this Section 10.1(c).

(d) Manufacturer shall have no liability under this Agreement for any claim that results from [*****].

(e) Nothing in this Section 10.1 (including its section (f)) shall, to the extent applicable, limit the liability of Manufacturer for:

(i) [*****];

(ii) [*****];

(iii) [*****];

(iv) [*****].

(f) Neither Party will be liable to the other, in contract, tort, negligence, breach of statutory duty, or otherwise, for any punitive or exemplary damages, for any loss of profits, of production, of anticipated savings, of business, or of goodwill, or for any other liability, damage, cost, or expense of any kind incurred by the other Party of a remote or speculative nature, regardless of any notice of the possibility of these damages.

10.2. **Indemnification by Manufacturer of Acorda.** Manufacturer shall indemnify Acorda, its Affiliates and its and their respective directors, officers, employees and agents (the "**Acorda Indemnitees**") for, and defend and hold each of them harmless from and against, any and all losses, damages, liabilities, penalties, royalties, costs and expenses (including reasonable attorneys' fees and disbursements) (collectively, "**Losses**") arising from or occurring as a result of any third party claims, lawsuits, actions or proceedings ("**Third Party Claims**") if such Third Party Claims arise from or by reason of (a) the breach by Manufacturer of a warranty, representation or covenant in this Agreement or the Quality Agreement; (b) any claim (except to the extent Acorda has an indemnification obligation to Manufacturer under Section 10.3(c)) that [*****]; or (d) the handling, release, or disposal of any waste by Manufacturer or any of its Affiliates.

10.3. **Indemnification by Acorda of Manufacturer.** Acorda shall indemnify Manufacturer, its Affiliates and its and their respective directors, officers, employees and agents (collectively, the "**Manufacturer Indemnitees**") for, and defend and hold each of them harmless from and against, any and all Losses to the extent arising from or occurring as a result of any Third Party Claims to the extent arising from or occurring as a result of (a) the breach by Acorda of a warranty, representation or covenant in this Agreement or the Quality Agreement; (b) [*****] of any Acorda Indemnitee in connection with the performance of this Agreement or the Quality Agreement; (c) [*****]; (d) any personal injury or other product liability or strict liability arising from the manufacture, packaging, or sale, promotion, distribution of the Marketed Product or the use of or exposure to Supplied Product or Acorda-Supplied Materials; or (e) Acorda's exercise of control over the Manufacturing Services to the extent that Acorda's instructions or directions violate Applicable Laws; or (f) [*****]; except to the extent that any of the foregoing arises out of or results from any Manufacturer Indemnitee's [*****], breach of this Agreement, or deviation from the Compliant Product Requirements or other instructions of Acorda.

10.4. **Indemnification Procedure.** Each Party seeking indemnification under Section 10.2 or 10.3, as the case may be (the "**Indemnified Party**") will promptly inform the other Party (the "**Indemnifying Party**") upon becoming aware of a Loss or Third Party Claim (including a copy of any related complaint, summons, notice or other instrument) made for which the Indemnifying Party might be liable under Section 10.2 or 10.3, as the case may be; provided that any delay in providing such notice will qualify the obligation of the Indemnifying Party, as relevant, only to the extent of actual prejudice to the

ability of the Indemnifying Party to defend the Third Party Claim. Subject to Section 10.5, the Indemnifying Party may defend, negotiate, and settle such Third Party Claims; provided that, the Indemnified Party will be entitled to participate in, but not control, the defense and to employ counsel at its expense to assist in such defense. Subject to Section 10.5, in the event Indemnifying Party takes up such defense, the Indemnifying Party will have final decision-making authority regarding all aspects of the defense of any Third Party Claim. In the event Indemnifying Party does not employ counsel to defend such Third Party Claim within 30 days of receiving notice of such Third Party Claim, Indemnified Party may employee counsel of its choosing to defend and control the defense of such Third Party Claim at Indemnifying Party's cost and expense, including any settlement or judgment. Indemnified Party may also employee counsel at Indemnifying Party's cost and expense, if the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to make inappropriate or impermissible the representation by the same counsel of both Parties under Applicable Laws, ethical rules or equitable principles. The Party not defending the Third Party Claim will provide the defending Party with such information and assistance as the defending Party may reasonably request, at the expense of the Indemnifying Party. The Parties understand that no insurance deductible will be credited against losses for which a Party is responsible under this ARTICLE 10.

10.5. **Settlement.** The Party controlling the defense of a Third Party Claim under Section 10.4 shall seek consent of the other Party to settle such Third Party Claim. If such settlement does not (i) require or constitute an admission of fault of the Indemnified Party, (ii) restrict the business of the Indemnified Party, or (iii) require payment of amounts for which the Indemnified Party is liable, the Party controlling the defense of a Third Party Claim may settle such Third Party Claim upon prior written notice to the other Party.

10.6. **Reasonable Allocation of Risk.** The Parties acknowledge and agree that this Agreement (including, without limitation, this ARTICLE 10) is reasonable and creates a reasonable allocation of risk for the relative profits the Parties each expect to derive from Manufacturing Services, the Supplied Product, and Marketed Product.

ARTICLE 11

CONFIDENTIALITY

11.1. **Confidential Information.** Subject to, and without limiting, the provisions of Sections 11.2, 11.3, and 11.4 at all times during the Term and for a period following the end of the Term equal to the longest of

(a) seven years following the end of the Term,

(b) such period, in respect of any Know-How that is trade secret protected, as such Know-How continues as a trade secret under any Applicable Laws, and

(c) such period, in respect of any Confidential Information of a Party that the Party has identified in writing as Know-How that it regards as a trade secret, as such Confidential Information continues as a trade secret under any Applicable Laws,

the Party (the "**Receiving Party**") receiving from the other Party (the "**Disclosing Party**") Confidential Information (y) shall keep confidential, using the same level of care that the Receiving Party uses for its own Confidential Information of a similar nature, but in any event, and without prejudice to those policies, procedures and arrangements otherwise specified to be implemented and followed by the Receiving Party pursuant to this Agreement, not less than reasonable means under the circumstances, and shall not publish

or otherwise disclose any such Confidential Information, except to those of the Receiving Party's employees, Affiliates, or consultants who have a need to know such Confidential Information to perform such Party's obligations or exercise or enforce such Party's rights hereunder (and who shall be advised by the Receiving Party of the Receiving Party's obligations hereunder and who must be bound by confidentiality obligations to the Receiving Party with respect to such Confidential Information no less onerous than those set forth in this Agreement) (collectively, "**Recipients**") and (z) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising or enforcing its rights hereunder. The Receiving Party will be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement. Notwithstanding the foregoing, Acorda will be deemed to be the Disclosing Party, and Manufacturer the Receiving Party, with respect to any Confidential Information included in the Acorda Intellectual Property or the Acorda New Intellectual Property, regardless of which Party discloses the information.

11.2. **Lock Down Information.** Without limitation of any other provision of this ARTICLE 11:

(a) Manufacturer acknowledges that (i) the Lock Down Information constitutes competitively valuable [*****], and (ii) Acorda carefully protects all Lock Down Information that is not currently generally available to the public from unauthorized disclosure or use [*****].

(b) Manufacturer shall provide or permit access to Lock Down Information to only Product Personnel [*****].

(c) Manufacturer shall inform all Product Personnel and Agents that they are prohibited from providing or disclosing to, or sharing or discussing with, any person who is not Product Personnel or an Agent engaged in a Purpose any Lock Down Information and shall provide appropriate training (promptly following the Effective Date, in the case of current Product Personnel and Agents, and promptly after reasonable determination of the need for access to Lock Down Information, in the case of any other Product Personnel or Agents) and with reasonable refresher training to all Product Personnel and then-current Agents as to Manufacturer's obligations in respect of the protection of the confidentiality and use of Lock Down Information under this Agreement, the obligations of the Product Personnel to Manufacturer and Agents to perform their duties consistent with an applicable Purpose in that regard, and best practices, to be followed by Product Personnel and Agents (including after they cease to qualify as Product Personnel or Agents), for protecting the confidentiality and use of Lock Down Information as required by this Agreement. Without limitation, such training shall address those matters set forth on Schedule 8.

(d) Manufacturer shall [*****]. Manufacturer shall be responsible for and directly liable to Acorda for any breach of the provisions of this Section 11.2 occasioned by the acts or omissions of Product Personnel or Agents (including after such individuals cease to qualify as Product Personnel or Agents).

(e) Acorda may request that Manufacturer [*****].

(f) Manufacturer shall, and shall cause each of its Affiliates to, implement appropriate access and other restrictions on its internal databases and electronic networks to prevent Manufacturer personnel, third-party contractors, employees, and persons other than Product Personnel and Agents from accessing Lock Down Information.

(g) Manufacturer shall ensure that all manifestations of Lock Down Information in its possession or control, whether written, electronic, or in any other media, are designated in a

prominent manner as confidential and proprietary information subject to restrictions on disclosure and use.

(h) Manufacturer shall cooperate in good faith with Acorda to implement any additional information security measures in respect of Lock Down Information reasonably requested by Acorda or to address in a reasonable and appropriate manner any additional information security issues that Acorda may at any time identify as arising in respect of Lock Down Information in connection with the Manufacturing Services or otherwise in respect of the Manufacturer's performance of its obligations under this Agreement.

(i) Manufacturer shall maintain an accurate and complete list of Product Personnel and Agents who have had access to Lock Down Information during the Term of this Agreement (such list, the "**Access List**"). Upon Acorda's reasonable written request, but not more than [*****] per calendar year [*****], Manufacturer shall provide the current Access List to Acorda.

11.3. **Exceptions to Confidentiality.** The Receiving Party's obligations set forth in this Agreement will not extend to any Confidential Information of the Disclosing Party:

(a) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Recipients;

(b) that is received by the Receiving Party from a third party without restriction and without breach of any obligation of confidentiality to which such third party is subject;

(c) that the Receiving Party can demonstrate by competent contemporaneous written evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;

(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or

(e) that was or is independently developed by or for Receiving Party without reference to, aid, application or use of Confidential Information of Disclosing Party as evidenced by Receiving Party's contemporaneous written records that constitute competent written proof,

provided, however, that in each case, in respect of any item of the Lock Down Information, Manufacturer shall have the burden of proving the applicability of any of the foregoing exceptions that it claims applies in respect of such Know-How.

11.4. **Permitted Disclosure.**

(a) Each Party may disclose Confidential Information to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; *provided*, *however*, that, unless prohibited by Applicable Laws, the Receiving Party shall first have, to the extent practicable, given written notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity, and provided reasonable

assistance to the Disclosing Party, to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and *provided further* that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed by the Receiving Party in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in response to such court or governmental order;

(ii) required in connection with any proceeding with an arbitral body; or

(iii) otherwise required by Applicable Law as determined in good faith by the Receiving Party upon the receipt of its advice of its legal counsel; *provided*, *however*, that reasonable measures shall be taken by the Receiving Party to assure confidential treatment of such information.

(b) Acorda may disclose Confidential Information of Manufacturer to the extent that such disclosure is made to Pharmaceutical Regulatory Authorities as required in connection with any filing or application or to its licensors; *provided*, *however*, that reasonable measures shall be taken by Acorda to assure confidential treatment of such information.

11.5. **Notification.** The Receiving Party shall notify the Disclosing Party promptly, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party's discovery of any loss or compromise of the Disclosing Party's Confidential Information.

11.6. **Remedies.**

(a) Each Party agrees that the unauthorized use or disclosure of any Confidential Information of the Disclosing Party by the Receiving Party in violation of this Agreement will cause severe and irreparable damage to the Disclosing Party. In the event of any violation of this ARTICLE 11, the Receiving Party agrees that the Disclosing Party will be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, without the necessity of proving irreparable harm or monetary damages, as well as any other relief permitted by Applicable Laws. The Receiving Party will remain liable for any disclosure or use of the Confidential Information by any of its Recipients that would have been a breach of this ARTICLE 11 had such disclosure or use been made by the Receiving Party.

(b) The provisions of this ARTICLE 11 are without limitation of the provisions of Sections 2.3(b)(i), 2.3(c), 2.4, 2.5(a) or (b), 9.3(a) or 9.4 and remedies available to Acorda in respect thereof.

11.7. **No Implied License**. Except as expressly set forth in Section 13.1, Receiving Party will obtain no right of any kind relating to, or license under, Disclosing Party's Confidential Information, including no right to file, own, or obtain any patent application or patent, by reason of this Agreement or any performance thereunder. Disclosing Party's Confidential Information will remain Disclosing Party's sole property, subject to Section 13.1.

11.8. **Return of Confidential Information.** Upon expiration or termination of this Agreement, Receiving Party will, and will cause its Affiliates and its and their respective Representatives to, cease use of and, upon written request, within 30 days, either return or destroy (and certify as to such destruction) all

of Disclosing Party's Confidential Information, including any copy thereof. Notwithstanding anything to the contrary in the foregoing, the Receiving Party may retain a single copy of Disclosing Party's Confidential Information for the sole purpose of ensuring compliance with its obligations under this Agreement, and neither Party will be required to destroy Disclosing Party's Confidential Information stored in backed-up computer records, so long as such copies are not readily accessible and are not used or consulted by Receiving Party for any purpose other than disaster recovery.

11.9. **Publicity.** No public announcement related to this Agreement or the transactions contemplated herein shall be issued by either Party or its Affiliates without the joint written approval of both Parties hereto, which approval shall not be unreasonably withheld, conditioned or delayed, except in respect of any public disclosure which either Acorda or Manufacturer, in its good faith judgment, believes is required by Applicable Law or by any stock exchange on which its securities or those of its Affiliates are listed (or to which an application for listing has been submitted). If either Party, in its good faith judgment, believes such disclosure is required in accordance with the immediately preceding sentence, such Party shall use its commercially reasonable efforts to consult with the other Party, and to consider in good faith any revisions proposed by the other Party prior to making (or prior to any of its Affiliates making) such disclosure, and shall limit such disclosure to only that information which such Party, in its good faith judgment, believes is required to be disclosed in accordance with the immediately preceding sentence. Notwithstanding the foregoing, Acorda, Manufacturer and their respective Affiliates may, following the Effective Date and without being required to obtain the approval of the other Party but subject to the other terms and conditions of this Agreement, (a) solely with respect to Acorda and its Affiliates, communicate with licensors, customers, suppliers, distributors or other Persons engaged in the Marketed Product business regarding this Agreement and the transactions contemplated hereby, (b) communicate with an Authority to the extent that such disclosure is deemed reasonably necessary by the disclosing Party in connection with any filing, application, or request for a Marketing Authorization or other approval, license, registration or authorization, response to any requests or inquiries from an Authority, or other communication with an Authority, (c) communicate with prospective acquirers, lenders, investors, collaboration partners, and (sub)licensees that agree to be bound by non-use and non-disclosure obligations in respect of such information and (d) make public announcements and engage in public communications regarding this Agreement and the transactions contemplated hereby to the extent, but only to the extent, such announcements or communications are consistent with (i) any communications plan agreed upon by Acorda and Manufacturer in writing or (ii) the Parties' prior public communications made in compliance with this Section 11.9.

ARTICLE 12

DISPUTE RESOLUTION

12.1. **Dispute Resolution.** Subject to Section 12.2, any Dispute, controversy or claim arising under, out of, in connection with, or relating to this Agreement or the breach, termination or validity thereof (each, a "**Dispute**") shall be referred to a senior executive of each Party. The senior executives shall meet to attempt to resolve the Dispute by good faith negotiations within sixty (60) days of referral of the Dispute. If the Dispute remains unresolved after this 60-day negotiation period, then, at the election of either Party, the senior executives shall so report to the Parties in writing and the Dispute will be decided in accordance with Section 13.19(b).

12.2. **Exceptions.**

(a) In respect of Disputes involving breaches or, if the non-breaching Party believes that there is an imminent threatened breach that is reasonably likely to occur and that damages would be an insufficient remedy, threatened breaches by either Party or its Affiliates of the provisions of

Sections 2.3(b)(i), 2.3(c), 2.4, 9.3(a) or 9.4, the other Party may proceed to seek interim, provisional or conservatory relief in accordance with Section 13.19(b) without any requirement that it pursue the procedures set forth in Section 12.1.

(b) Disputes under Section 6.2(b) will be resolved in accordance with Section 6.2(b).

ARTICLE 13

MISCELLANEOUS

13.1. **Intellectual Property Ownership and Grants of Rights.**

(a) Grants and Authorizations to Manufacturer. During the Term, Acorda hereby grants, on its behalf and on behalf of its subsidiary, Civitas Therapeutics, Inc., to Manufacturer a non-exclusive, paid-up, royalty-free, non-transferable, non-assignable, non-sublicensable license, solely for purposes of Manufacturer's performing the Manufacturing Services for Acorda, under and in respect of the Acorda Intellectual Property (other than the Know-How included in the [*****] and Acorda New Intellectual Property. In addition, Acorda, under its have-made rights pursuant to [*****] of the [*****] Agreement, is permitting Manufacturer to use the [*****] Know-How solely for purposes of manufacturing the Supplied Product hereunder.

(b) License Grant to Acorda. Manufacturer hereby grants to Acorda a worldwide, perpetual, irrevocable, non-exclusive, paid-up, royalty-free, assignable and sublicensable (through multiple tiers) license to the Manufacturer New Intellectual Property as reasonably necessary for the manufacture, use, sale, offer for sale, marketing or otherwise commercializing the Supplied Product or the Marketed Product. In the event that Manufacturer breaches its representation or covenant in Section 9.3(d) of this Agreement, Manufacturer shall grant to Acorda a worldwide, perpetual, irrevocable, non-exclusive, paid-up, royalty-free, assignable and sublicensable (through multiple tiers) license to Manufacturer Intellectual Property to the extent such Manufacturer Intellectual Property is used by Manufacturer in the manufacturing process of the Supplied Product or arises from a change in the manufacturing process; provided, however, that Acorda shall not practice such license in violation of Section 2.5(a).

(c) Ownership of Intellectual Property.

(i) As between the Parties, all Acorda Intellectual Property and Acorda New Intellectual Property will be the exclusive property of Acorda or its Affiliate.

(ii) The [*****] is the exclusive property of Acorda or [*****]. Manufacturer acknowledges and agrees that the licenses and other rights and terms set forth herein are subject to (A) the terms, conditions and obligations of this Agreement and (B) in light of the type and scope of the license granted by Acorda in Section 13.1(a), the confidentiality terms, conditions and obligations contained in [*****] of the [*****] Agreement to the extent applicable to the Manufacturing Services provided by Manufacturer under this Agreement; provided that Acorda shall provide to Manufacturer no later than the Effective Date of this Agreement a full unredacted copy of the [*****] Agreement and thereafter any amendments thereto that relate to the Manufacture of the Supplied Product hereunder within fifteen (15) days of their respective effective date, and provided further, that

Manufacturer shall maintain the [*****] Agreement solely in the files of its legal department and shall use the [*****] Agreement solely for purposes of ensuring compliance with this Agreement. For the avoidance of doubt, Manufacturer shall maintain confidential the [*****] Agreement for so long as the confidentiality obligations of the [*****] Agreement remain in effect.

(iii) All Manufacturer Intellectual Property and Manufacturer New Intellectual Property will, as between the Parties, be the exclusive property of Manufacturer.

(iv) Manufacturer shall, and shall cause its Affiliates to, promptly disclose in writing to Acorda the discovery, development, making, conception, or reduction to practice of any innovation, improvement, development or discovery included in or giving rise to Acorda New Intellectual Property and, upon Acorda's request and expense, execute all instruments and other documents that are reasonably required to vest ownership of Acorda New Intellectual Property in Acorda. Acorda will own, and Manufacturer shall, and does hereby, grant and assign to Acorda, including by way of a present assignment of future rights, all right, title and interest in and to Acorda New Intellectual Property and the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of the Acorda New Intellectual Property whether occurring before, on, or after the date of this Agreement. Manufacturer agrees that it shall perform (or procure the performance of) all further acts and things, and execute and deliver (or procure the execution or delivery of) all further assignments, transfers, waivers or other instruments in respect of the Acorda New Intellectual Property as are reasonably required to vest in Acorda the full benefit of the rights, title and interest in the Acorda New Intellectual Property assigned to Acorda under this Agreement.

(v) Acorda shall, and shall cause its Affiliates to promptly disclose in writing to Manufacturer the discovery, development, making, conception, or reduction to practice of any innovation, improvement, development or discovery included in or giving rise to Manufacturer New Intellectual Property and, upon Manufacturer's request and expense, execute all instruments and other documents that are reasonably required to vest ownership of Manufacturer New Intellectual Property in Manufacturer. Manufacturer will own, and Acorda shall, and does hereby, grant and assign to Manufacturer, including by way of a present assignment of future rights, all right, title and interest in and to Manufacturer New Intellectual Property and the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of the Manufacturer New Intellectual Property whether occurring before, on, or after the date of this Agreement. Acorda agrees that it shall perform (or procure the performance of) all further acts and things, and execute and deliver (or procure the execution or delivery of) all further assignments, transfers, waivers or other instruments in respect

of the Manufacturer New Intellectual Property as are reasonably required to vest in Manufacturer the full benefit of the rights, title and interest in the Manufacturer New Intellectual Property assigned to Manufacturer under this Agreement.

(vi) Each Party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications included in or claiming Intellectual Property as to which it is allocated ownership hereunder.

(d) No Implied Rights. Except as provided in the foregoing provisions of this Section 13.1 or elsewhere in this Agreement, neither Party has, nor will it acquire, any interest (whether by way of ownership, license or otherwise) in any of the other Party's Intellectual Property unless otherwise expressly agreed to in writing.

(e) Covenant Not to Use. Manufacturer shall not use any Acorda Intellectual Property, [*****] contained therein, or any Acorda New Intellectual Property except in each case as specifically licensed hereunder.

13.2. **Insurance.**

(a) Coverage. During the Term, both Parties shall maintain, at their sole cost and expense, with financially sound and reputable insurers, insurance coverage with respect to the conduct of its business in such amounts as specified below.

(i) Commercial general liability insurance, including blanket contractual liability insurance covering the respective obligations of each Party under this Agreement, and product liability insurance adequate to cover its obligations hereunder, each through the end of the Term and for a period of five years thereafter. This insurance must have policy limits of not less than (1) $10,000,000 for each occurrence for personal injury or property damage liability, and (2) $10,000,000 in the aggregate per annum for product and completed operations liability and must name the other Party as an additional insured on a primary noncontributory basis and include an endorsement waiving right of subrogation against the other Party as an additional insured.

(ii) Workers' compensation (or social scheme) as required by any Applicable Laws in respect of this Agreement. Employer's Liability Insurance of not less than $1,000,000 per employee and per accident.

(iii) Professional liability insurance covering errors, omissions or negligent acts arising out of the professional services to be performed. The limit of liability shall be not less than $10,000,000 for each claim and $10,000,000 in the aggregate.

(iv) Acorda shall hold Insurance (all risk property, stock-throughput, or equivalent) for the full replacement value of the Acorda Supplied Components/Materials and Supplied Product while in possession of Manufacturer.

(v) Automotive liability insurance, to include all owned, hired and non-owned vehicles. If either Party does not have any owned vehicles, such Party is still required to maintain coverage for hired and non-owned vehicles as either a stand-alone policy or endorsed onto the commercial general liability insurance described in clause (i) of this Section 13.2(a). The limit of liability shall not be less than $1,000,000 per accident combined single limit.

(vi) Cyber liability insurance coverage for third party liability arising out of breach of privacy, inclusive of confidential and propriety business information, HIPAA violations and other breaches of personally identifiable information and/or protected health information that may arise out of the Manufacturing Services. The limit of liability shall not be less than $1,000,000 for each claim and $1,000,000 in the aggregate.

(b) Additional Requirements. Each Party shall provide, at the written request of the other Party, a signed certificate of insurance, as evidence that policies providing the coverage required by this Section 13.2 for such providing Party are in full force and effect. All insurance required by this Section 13.2 to be held by each Party must be issued by insurance companies with an A.M. Best's rating (or its equivalent) of A or better.

13.3. **Independent Contractors.** The Parties are independent contractors and this Agreement will not be construed to create between Manufacturer and Acorda any other relationship, such as, by way of example only, that of employer-employee, principal-agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the Parties.

13.4. **Remedies; No Waiver.**

(a) Except only to the extent otherwise expressly provided in this Agreement, all rights and remedies of each Party under this Agreement are cumulative and the exercise by a Party of any of its rights and remedies under this Agreement shall not limit its exercise of any other right or remedy to which it is entitled by the terms of this Agreement.

(b) Either Party's failure to require the other Party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, except as expressly set forth in Section 6.2(a).

13.5. **Assignment; Additional Acorda Parties.**

(a) Except as otherwise provided in this Section 13.5, this Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

(b) Notwithstanding anything in Section 13.5(a) or the provisions of any applicable law to the contrary, Acorda may, without Manufacturer's consent, but with written notice to Manufacturer, assign this Agreement, in whole or in part, (i) in connection with the sale or other transfer of all or substantially all of Acorda's assets or Acorda's line of business to which this Agreement relates, (ii) to the surviving or other successor entity in the event of a merger or consolidation to which Acorda is a party, or (iii) to an Affiliate, as long as, in each case ((i), (ii) and (iii)), any Person to whom this Agreement is actually assigned agrees in writing with Manufacturer to comply with all obligations of Acorda under this Agreement.

(c) Notwithstanding anything in Section 13.5(a) or the provisions of any applicable law to the contrary, Manufacturer may, without Acorda's consent, assign this Agreement, in whole but not in part, (i) in connection with the transfer or sale of all or substantially all of Manufacturer's and its Affiliates' assets, (ii) to the surviving or other successor entity in the event of a merger or consolidation to which Manufacturer is a party, or (iii) to an Affiliate, as long as, in each case ((i), (ii) and (iii)), the Person to whom this Agreement is actually assigned agrees in writing with Acorda to comply with all obligations of Manufacturer under this Agreement and Manufacturer remains liable to Acorda for its acts or omissions prior to the closing of the applicable transaction. Notwithstanding the foregoing, if Manufacturer desires to assign this Agreement, in whole but not in part, in connection with a divesture of the Manufacturing Site and that transaction is not part of the scenarios outlined in (i) or (ii), Manufacturer shall obtain Acorda's consent, such consent not to be unreasonably withheld, conditioned or delayed.

(d) Any purported assignment in breach of the provisions of this Section 13.5 will be void and of no effect.

(e) In addition to its rights under Section 13.5(b), Acorda shall also, by written notice to Manufacturer, have the right at any time to add any Acorda Affiliate(s) as an additional party (each, an "**Additional Acorda Party**") to this Agreement, with each Additional Acorda Party in its capacity as an additional party to this Agreement to have all of the rights and to be subject to all the obligations of Acorda under this Agreement. Each Additional Acorda Party shall thereafter be included in the definition of "Acorda" for all purposes of this Agreement. As part of any such notice to Manufacturer, Acorda shall be entitled to specify a notice address to be used pursuant to Section 13.7(b) for the Acorda Additional Party(ies) and such notice address shall thereafter be deemed to be included in Section 13.7(b). Any such notice given by Acorda to Manufacturer shall be executed by the Acorda Affiliate that is the subject of such notice and, by virtue of such execution of such notice, such Acorda Affiliate shall be and become bound by the obligations and entitled to the rights of Acorda under this Agreement. Acorda shall remain liable to Manufacturer for the performance, acts and omissions of such Additional Acorda Party as if such performance, acts and omissions were the performance, acts and omissions of Acorda.

13.6. **Force Majeure.** Except as to payments required under this Agreement, neither Party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that Party's reasonable control, including strikes or other labor disturbances, lockouts, riots, quarantines, epidemic, communicable disease outbreaks, wars, acts of terrorism, armed hostilities, factory shutdowns, embargoes, explosions, destruction of production facilities or materials by fires, earthquakes,

floods or storms or other similar casualty events, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within color of right (a "**Force Majeure Event**"). A Party claiming a right to excused performance under this Section 13.6 shall promptly give written notice to the other Party of the extent of its inability to perform, which notice must specify the event beyond the non-performing Party's reasonable control that prevents the performance and steps to be taken by the non-performing Party to remedy the same. The suspension of performance must be of no greater scope and no longer duration than is reasonably required and the non-performing Party shall use best efforts to remedy its inability to perform as soon as possible. If the suspension of performance continues for [*****] after the date of the occurrence, and the failure to perform would constitute a material breach of this Agreement in the absence of the Force Majeure Event, the nonaffected Party may terminate this Agreement immediately by written notice to the affected Party. Without limiting the foregoing, Acorda shall not be obligated to pay the Fees in respect of any period (prorated as necessary on the basis of number of days elapsed) during which a Force Majeure Event interferes to any material extent with Manufacturer's ability to deliver the Manufacturing Services as contemplated herein.

13.7. **Notices.**

(a) Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement must be in writing, must refer specifically to this Agreement, as applicable, and will be deemed given upon actual receipt if (A) delivered by hand; (B) sent by confirmed e-mail (acknowledged by the email specified below, if any); (C) sent by registered or certified mail (return receipt requested), postage prepaid; or (D) sent by nationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.7(b) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 13.7. Notwithstanding the foregoing, any notice of termination of this Agreement must be delivered through hand delivery, registered or certified mail or nationally recognized overnight delivery service, as provided in this Section 13.7. This Section 13.7 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

(b) Address for notice:

If to Acorda:

Acorda Therapeutics, Inc.
2 Blue Hill Plaza 3rd Fl.
Pearl River, New York 10965
Attn: President & CEO

with a copy (which shall not constitute notice) to:

Acorda Therapeutics, Inc.
2 Blue Hill Plaza 3rd Fl.
Pearl River, New York 10965
Attn: General Counsel

If to Manufacturer:

Catalent Massachusetts LLC
14 Schoolhouse Road
Somerset, NJ 08873
Attn: Group President Pharma and Consumer Health

with a copy to:

Catalent Pharma Solutions
14 Schoolhouse Road
Somerset, NJ 08873
Attn: General Counsel (Legal Department)
Email: [*****]

13.8. **Severability.** If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, (a) that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct, and (b) the Parties shall endeavor in good faith negotiations to replace the illegal, invalid or unenforceable provision with valid provisions the economic effect of which as between the Parties comes as close as possible to that of the illegal, invalid or unenforceable provision.

13.9. **Entire Agreement; Amendments; Conflicts.**

(a) This Agreement, together with the Quality Agreement, constitutes the full, complete, final and integrated agreement between the Parties relating to the subject matter hereof and thereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof or thereof, but for clarity does not supersede or modify anything set forth in the Asset Purchase Agreement or any Ancillary Agreement [*****].

(b) Any modification, amendment, or supplement to this Agreement or the Quality Agreement must be in writing and signed by authorized Representatives of both Parties.

(c) In case of conflict, the Quality Agreement will govern all quality-related issues and this Agreement will govern all non-quality related issues.

(d) [*****], Acorda shall notify Manufacturer and the Parties shall negotiate in good faith to amend this Agreement as necessary to comply with [*****].

13.10. **Other Terms.** No terms, provisions or conditions of any purchase order or other business form or written authorization used by Acorda or Manufacturer will have any effect on the rights, duties, or obligations of the Parties under, or otherwise modify, this Agreement regardless of any failure of Acorda or Manufacturer to object to the terms, provisions, or conditions, unless the document specifically refers to this Agreement and is signed by both Parties.

13.11. **No Third Party Benefit or Right.** For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement, except as provided in Sections 10.2 and 10.3 of this Agreement.

13.12. **Execution in Counterparts.** This Agreement may be executed in two or more counterparts, by original or facsimile or electronically-transmitted signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.13. **Further Assurances.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do or cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments as may be necessary or as the other Party may reasonably request, in connection with this Agreement, or to carry out more effectively the provisions and purposes hereof or thereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.14. **Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Laws. No transaction or dealing under this Agreement shall be conducted with or for any Person that is designated as the target of any sanction, restriction or embargo administered by the United Nations, the European Union, the United Kingdom, or the United States of America.

13.15. **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, will be deemed to be or construed as a waiver of the same or any other term or condition of the relevant agreement on any future occasion.

13.16. **Construction.** The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against any Party.

13.17. **Use of Names.** Except as otherwise expressly permitted under this Agreement, (a) Manufacturer shall not make any use of Acorda's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Acorda, and (b) Acorda shall not make any use of Manufacturer's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Manufacturer. Notwithstanding the foregoing, Acorda may use Manufacturer's name as required to comply with Applicable Laws.

13.18. **Right to Dispose and Settle.** If Manufacturer requests in writing from Acorda direction with respect to disposal of any inventory of Supplied Product, Acorda-Supplied Materials, equipment, samples, or other items belonging to Acorda and is unable to obtain a response from Acorda within a reasonable period after making reasonable efforts to do so, Manufacturer may, in its sole discretion, (a) dispose of all such items and (b) set-off the cost of such disposal and all amounts due to Manufacturer or any of its Affiliates from Acorda against any credit Acorda may hold with Manufacturer or any of its Affiliates.

13.19. **Governing Law; Arbitration.**

(a) This Agreement, the negotiation, execution or performance of this Agreement and any Disputes arising under or related hereto (whether for breach of contract, tortious conduct or

otherwise) shall be governed and construed in accordance with the Laws of the State of New York, without reference to its conflicts of law principles that would refer the construction, validity, interpretation or enforceability of, or the resolution of any Dispute under, this Agreement to the substantive Laws of another jurisdiction.

(b) Upon the Parties' receiving the senior executives' report that the Dispute referred to them pursuant to Section 12.1 has not been resolved, a Party may institute binding arbitration with written notice to that effect to the other Party. Any such arbitration proceedings shall be take place in the English language, and governed by the International Institute for Conflict Prevention & Resolution, New York, NY (the "**CPR**") and the Fast-Track Administered Arbitration Rules then in force. Each such arbitration shall be conducted by a panel of three arbitrators: one arbitrator shall be appointed by each of Manufacturer and Acorda and the third arbitrator, who shall be the chairperson of the tribunal, shall be appointed by the two Party-appointed arbitrators. Any such arbitration shall be held in New York, NY, USA. The arbitrators shall have the authority to direct the Parties as to the manner in which the Parties shall resolve the disputed issues, to render a final decision with respect to such disputed issues, or to grant specific performance with respect to any such disputed issue. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Nothing in this Section 13.19 shall be construed to preclude either Party from seeking provisional remedies, including but not limited to temporary restraining orders and preliminary injunctions, from any court of competent jurisdiction, in order to protect its rights pending arbitration, but such preliminary relief shall not be sought as a means of avoiding arbitration. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the CPR.

(c) For the preliminary relief set forth in Section 13.19(c) and to enforce the arbitral award, each Party consents, for itself and its Affiliates, to the jurisdiction of the courts of the State of New York, county of New York and the U.S. District Court for the Southern District of New York.

(d) Any arbitration proceeding entered into pursuant to this Section 13.19 shall be conducted in the English language.

[Signature page follows.]

IN WITNESS WHEREOF, the duly authorized Representatives of the Parties have executed this Agreement as of the date first written above.

CATALENT MASSACHUSETTS LLC

By: _____

Name: Ricky Hopson

Title: President, Clinical Development and Supply, Catalent Pharma Solutions

ACORDA THERAPEUTICS, INC.

By: _____

Name: Ron Cohen

Title: President and CEO

CONFIDENTIALEXECUTION VERSION

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

FIRST AMENDMENT TO MANUFACTURING SERVICES AGREEMENT

THIS FIRST AMENDMENT to the MANUFACTURING SERVICES AGREEMENT ("**First Amendment**") is made and entered into on this 6th day of March 2023 ("**First Amendment Effective Date**"), by and between ACORDA THERAPEUTICS, INC. ("**Acorda**"), a Delaware corporation, and CATALENT MASSACHUSETTS, LLC ("**Manufacturer**"), a Delaware limited liability company.

RECITALS

WHEREAS, Acorda and Manufacturer entered into a Manufacturing Services Agreement having an effective date of 1 January 2023 ("**Agreement**") pursuant to which Manufacturer provides manufacturing and related services to Acorda; and

WHEREAS, the Parties desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, have agreed to amend the terms of the Agreement as follows:

1. Definitions. Capitalized terms used and not otherwise defined in this First Amendment shall have the meaning assigned to them in the Agreement.

2. Amendments.

a. Section 3.1(c), [Reserved], of the Agreement shall be deleted in its entirety and replaced with the following:

> *(c) Milestone Payment. In consideration of activities required to complete the installation of the PSD-7 equipment for operational readiness, Acorda shall pay Manufacturer a milestone payment in the total amount of two million dollars ($2,000,000), payable as set forth below. (For clarity, operational readiness is defined as equipment modifications and upgrades required to support the manufacturing of Inbrija ("**Operational Readiness**")).*
>
> *i.* [*****] *to be invoiced as of* [*****]*, 2023*
>
> *ii* [*****] *to be invoiced as of* [*****]*, 2023*

b. Schedule 4, Pricing and Reserved Capacity, of the Agreement shall be modified as follows. The Tier 2 Market Pricing for year 2023 for product produced on the PSD-4 shall be increased from $[*****] per Batch to $[*****] per Batch.

3. No Other Variation. Except as expressly provided in this First Amendment, all the terms, conditions and provisions of the Agreement (including the rights, duties, liabilities and obligations of the Parties thereunder) remain in full force and effect and shall apply to the construction of this First Amendment.

4. Entire Agreement. This First Amendment and the Agreement, including its attachments, constitute the entire agreement between the Parties relating to the subject matter hereof and thereof, and may not be varied except in writing signed by a duly authorized representative of each Party. In case of inconsistency between the terms and conditions of the Agreement and this First Amendment, this First Amendment shall prevail to the extent of such inconsistency but no further. This First Amendment shall be governed in all respects by the terms for resolution of any controversy, dispute or claim provided in the Agreement.

5. Counterparts. This First Amendment may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. A facsimile or other reproduction of this First Amendment may be executed by the Parties and may be delivered by facsimile or similar electronic transmission device pursuant to which the signature(s) can be seen, and such execution and delivery shall be considered valid, binding and effective for all purposes.

IN WITNESS WHEREOF, the Parties have executed this First Amendment as of the First Amendment Effective Date above written.

CATALENT MASSACHUSETTS, LLC	**ACORDA THERAPEUTICS, INC.**
Signature: _____	Signature: _____
Name: Ricky Hopson	Name: Ron Cohen
Title: President, Clinical Development and Supply, Catalent Pharma Solutions	Title: President & Chief Executive Officer
Date:	Date:

Exhibit 10.57

CONFIDENTIAL EXECUTION VERSION

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks [*****].

March 6, 2023

Catalent Massachusetts LLC
14 Schoolhouse Road
Somerset, NJ 08873

Attn: Ricky Hopson
President, Clinical Development & Pharma Supply
Catalent Pharma Solutions

RE: Amendment and Restated Letter Termination

Dear Ricky,

Reference is made to the letter, dated December 31, 2022, (the "**Letter Termination**") terminating the Manufacturing Services Agreement between Acorda Therapeutics, Inc. ("**Acorda**") and Catalent Massachusetts LLC ("**Catalent**"), dated February 10, 2021 ("**Agreement**"). This letter ("**Amended and Restated Letter Termination**") shall amend and restate, in its entirety, the Letter Termination on the terms and subject to the conditions set forth herein.

Acorda and Catalent agree that the Agreement shall be terminated effective December 31, 2022 (the "**Termination Effective Date**"), and Acorda shall pay to Catalent a termination fee of four million US dollars ($ 4,000,000.00) on or before April [*****], 2024.

Acorda and Catalent agree that the above termination fee shall be in lieu of any payments under Section 8.4(a) of the Agreement and that no other payments shall be owed by Acorda to Catalent with respect to the termination of the Agreement.

By signing below, Acorda's and Catalent's respective duly authorized representatives indicate their full understanding of the termination of the Agreement effective as of the Termination Effective Date and the amended and restated terms and conditions proposed in this Amended and Restated Termination Letter.

CATALENT MASSACHUSETTS LLC **ACORDA THERAPEUTICS, INC.**

By: _____ By_____

Name: Ricky Hopson Name: Ron Cohen

Title: President, Clinical Development & Title: President and CEO

Exhibit 10.57

CONFIDENTIAL EXECUTION VERSION

Pharma Supply, Catalent Pharma Solutions

2 BLUE HILL PLAZA 3RD FL. PHONE: (914) 347-4300 E-MAIL: ACORDA@ACORDA.COM
PEARL RIVER, NY 10965 FAX: (914) 347-4560 WEBSITE: WWW.ACORDA.COM

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 Nos. 333-210813 and 333-266917) pertaining to the 2016 Inducement Plan of Acorda Therapeutics, Inc., and

(9) Registration Statement (Form S-8 Nos. 333-206346, 333-212917, 333-226692, and 333-266917) pertaining to the 2015 Omnibus Incentive Compensation Plan of Acorda Therapeutics, Inc.

of our reports dated March 14, 2023, 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, 2022.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 14, 2023

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 14, 2023

/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 14, 2023

/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, 2022 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 14, 2023

[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, 2022 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 14, 2023

[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.]

MANAGEMENT

LEADERSHIP TEAM

Ron Cohen, M.D.
President and Chief Executive Officer

Neil Belloff, Esq.
General Counsel

Kerry Clem
Chief Commercial Officer

Denise Duca, Ed.M.
Executive Vice President, Human Resources

Michael Gesser, M.B.A.
Chief Financial Officer

BOARD OF DIRECTORS

Ron Cohen, M.D.
Founder, President and CEO

John P. Kelley
Board Chair, Board Member since 2008

Peder K. Jensen, M.D.
Board Member since 2011

Sandra Panem, Ph.D.
Board Member since 1998

Lorin J. Randall
Board Member since 2006

John Varian
Board Member since 2022

ACORDA THERAPEUTICS LIFE. SCIENCE.®

CONTACT

Tierney Saccavino
914-326-5104