

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

FORM 10-Q

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from to

Commission File Number 001-31938

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation
or organization)

2 Blue Hill Plaza, 3rd Floor, Pearl River, New York

(Address of principal executive offices)

13-3831168

(I.R.S. Employer
Identification No.)

10965

(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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		.

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at May 9, 2023
Common Stock, \$0.001 par value per share	24,337,696 shares

ACORDA THERAPEUTICS, INC.
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This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: We may not be able to successfully market Inbrija, Ampyra, 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; 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 its 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 Inbrija and Ampyra; 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 report and in our Annual Report on Form 10-K for the year ended December 31, 2022, particularly in the "Risk Factors" section (as updated by the disclosures in our subsequent quarterly reports, including this report), 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, "Inbrija," "Ampyra," 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 these marks 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. Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	<u>March 31, 2023</u> <u>(unaudited)</u>	<u>December 31, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,255	\$ 37,536
Restricted cash	6,989	6,884
Trade accounts receivable, net of allowances of \$768 and \$842, as of March 31, 2023 and December 31, 2022, respectively	9,190	13,866
Prepaid expenses	4,125	4,312
Inventory, net	13,465	12,752
Other current assets	4,070	6,765
Total current assets	68,094	82,115
Property and equipment, net of accumulated depreciation	2,383	2,603
Intangible assets, net of accumulated amortization	297,393	305,087
Right of use asset, net of accumulated amortization	5,029	5,287
Restricted cash	510	255
Other non-current assets	1,497	248
Total assets	<u>\$ 374,906</u>	<u>\$ 395,595</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,854	\$ 9,809
Accrued expenses and other current liabilities	27,017	23,680
Current portion of lease liabilities	1,556	1,545
Current portion of acquired contingent consideration	3,312	2,532
Deferred Revenue	—	384
Total current liabilities	34,739	37,950
Convertible senior notes	171,496	167,031
Derivative liability	—	—
Non-current portion of acquired contingent consideration	36,488	38,668
Non-current portion of lease liabilities	4,055	4,341
Deferred tax liability	41,805	44,202
Other non-current liabilities	9,363	9,781
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share. Authorized 1,000,000 shares at March 31, 2023 and December 31, 2022; no shares issued as of March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.001 par value per share. Authorized 61,666,666 shares at March 31, 2023 and December 31, 2022; issued 24,343,329 shares, including those held in treasury, as of March 31, 2023 and December 31, 2022, respectively	24	24
Treasury stock at cost (5,543 shares at March 31, 2023 and December 31, 2022)	(638)	(638)
Additional paid-in capital	1,029,952	1,029,881
Accumulated deficit	(953,097)	(936,273)
Accumulated other comprehensive loss	719	628
Total stockholders' equity	76,960	93,622
Total liabilities and stockholders' equity	<u>\$ 374,906</u>	<u>\$ 395,595</u>

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

(In thousands, except per share data)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Revenues:		
Net product revenues	\$ 18,719	\$ 18,575
Royalty revenues	3,528	3,959
License revenues	11	—
Total net revenues	22,258	22,534
Costs and expenses:		
Cost of sales	3,234	5,967
Research and development	1,386	1,694
Selling, general and administrative	22,514	26,938
Amortization of intangible assets	7,691	7,691
Change in fair value of derivative liability	—	(30)
Changes in fair value of acquired contingent consideration	(1,091)	(3,023)
Total operating expenses	33,734	39,237
Operating loss	(11,476)	(16,703)
Other income (expense), net:		
Interest and amortization of debt discount expense	(7,571)	(7,562)
Interest income	93	1
Other income	92	—
Total other expense, net	(7,386)	(7,561)
Loss before taxes	(18,862)	(24,264)
(Provision for) benefit from income taxes	2,038	(258)
Net loss	\$ (16,824)	\$ (24,522)
Net loss per share—basic	\$ (0.69)	\$ (1.85)
Net loss per share—diluted	\$ (0.69)	\$ (1.85)
Weighted average common shares outstanding used in		
computing net loss per share—basic	24,338	13,251
Weighted average common shares outstanding used in		
computing net loss per share—diluted	24,338	13,251

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(unaudited)

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Net loss	\$ (16,824)	\$ (24,522)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustment	91	449
Other comprehensive income (loss), net of tax	91	449
Comprehensive income (loss)	\$ (16,733)	\$ (24,073)

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

Three Months Ended March 31, 2023 and 2022

(unaudited)

(In thousands)	Common stock			Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total stockholders' equity
	Number of shares	Par value						
Balance at December 31, 2022	24,343	\$ 24		\$ (638)	\$ 1,029,881	\$ (936,273)	\$ 628	\$ 93,622
Compensation expense for issuance of stock options to employees	—	—		—	71	—	—	71
Other comprehensive income, net of tax	—	—		—	—	—	91	91
Net loss	—	—		—	—	(16,824)	—	(16,824)
Balance at March 31, 2023	<u>24,343</u>	<u>\$ 24</u>		<u>\$ (638)</u>	<u>\$ 1,029,952</u>	<u>(953,097)</u>	<u>\$ 719</u>	<u>\$ 76,960</u>

(In thousands)	Common stock			Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total stockholders' equity
	Number of shares	Par value						
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	—	—		—	181	—	—	181
Compensation expense for issuance of restricted stock to employees	35	—		—	304	—	—	304
Other comprehensive income, net of tax	—	—		—	—	—	449	449
Net loss	—	—		—	—	(24,522)	—	(24,522)
Balance at March 31, 2022	<u>13,285</u>	<u>\$ 13</u>		<u>\$ (638)</u>	<u>\$ 1,023,621</u>	<u>(894,879)</u>	<u>(568)</u>	<u>\$ 127,549</u>

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Cash flows from operating activities:		
Net loss	\$ (16,824)	\$ (24,522)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	71	485
Amortization of debt discount and debt issuance costs	4,465	4,040
Depreciation and amortization expense	7,913	8,534
Change in acquired contingent consideration obligation	(1,091)	(3,023)
Non-cash royalty revenue	—	(2,852)
Deferred tax (benefit) provision	(2,038)	258
Change in derivative liability	—	(30)
Changes in assets and liabilities:		
Decrease in accounts receivable	4,688	5,012
Decrease in prepaid expenses and other current assets	2,871	66
Decrease (increase) in inventory	(713)	3,712
Increase in other assets	(1,251)	(858)
Decrease in accounts payable, accrued expenses, and other current liabilities	(4,676)	(4,209)
Decrease in other non-current liabilities	(433)	(250)
Net cash used in operating activities	(7,018)	(13,637)
Cash flows from investing activities:		
Purchases of property and equipment	—	(39)
Net cash (used in) provided by investing activities	—	(39)
Cash flows from financing activities:		
Net cash provided by (used in) financing activities	—	—
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	97	(92)
Net decrease in cash, cash equivalents, and restricted cash	(6,921)	(13,768)
Cash, cash equivalents and restricted cash at beginning of period	44,675	65,223
Cash, cash equivalents and restricted cash at end of period	<u>\$ 37,754</u>	<u>\$ 51,455</u>
Supplemental disclosure:		
Cash paid for interest	\$ —	\$ —
Cash paid for taxes	6	5

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

(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 Company markets 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 the Company’s ARCUS pulmonary delivery system, a technology platform designed to deliver medication through inhalation that the Company believes has potential to be used in the development of a variety of inhaled medicines. The Company has entered into agreements to commercialize Inbrija in Spain, Germany, Latin America, and China, and is in discussions with potential partners for commercialization of Inbrija in other jurisdictions outside of the U.S.

The Company also markets branded Ampyra (dalfampridine) Extended Release Tablets, 10 mg to improve walking in adults with multiple sclerosis. Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH, or Biogen, under a license and collaboration agreement that the Company entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia, and the Americas.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”) for interim financial information, Accounting Standards Codification (“ASC”) Topic 270-10, and with the instructions to Form 10-Q. Accordingly, these financial statements do not include all of the information and footnotes required by GAAP for complete financial statements. In management’s opinion, all adjustments considered necessary for a fair presentation have been included in the interim periods presented and all adjustments are of a normal recurring nature. The Company has evaluated subsequent events through the date of this filing. Operating results for the three-month period ended March 31, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. When used in these notes, the terms “Acorda” or “the Company” mean Acorda Therapeutics, Inc. The December 31, 2022 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. You should read these unaudited interim condensed consolidated financial statements in conjunction with the consolidated financial statements and footnotes included in the Company’s Annual Report on Form 10-K, for the year ended December 31, 2022.

The Company’s significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2022. Effective January 1, 2022, the Company adopted 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 Company’s significant accounting policies have not changed materially from December 31, 2022.

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 an account with funds to cover the Company’s self-funded employee health insurance. At March 31, 2023, the Company also held \$0.5 million of restricted cash related to cash collateralized standby letters of credit in connection with obligations under facility leases. See Note 10 to the Company’s Consolidated Financial Statements included in this report for a discussion of interest payments on the Company’s outstanding 6.00% convertible senior secured notes due December 2024 (“2024 Notes”).

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

(In thousands)	Three-month period ended March 31, 2023		Three-month period ended March 31, 2022	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	\$ 37,536	\$ 30,255	\$ 45,634	\$ 31,873
Restricted cash	6,884	6,989	13,400	13,393
Restricted cash non-current	255	510	6,189	6,189
Total Cash, cash equivalents, and restricted cash per statement of cash flows	<u>\$ 44,675</u>	<u>\$ 37,754</u>	<u>\$ 65,223</u>	<u>\$ 51,455</u>

Investments

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

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

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

There were no investments classified as short-term or long-term at March 31, 2023 or December 31, 2022.

Inventory

The following table provides the major classes of inventory:

(In thousands)	March 31, 2023	December 31, 2022
Raw materials	\$ 11,061	\$ 6,212
Finished goods	2,404	6,540
Total	<u>\$ 13,465</u>	<u>\$ 12,752</u>

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected product sales volume and provides reserves against the carrying amount of inventory as appropriate.

Foreign Currency Translation

The functional currency of operations outside the U.S. is deemed to be the currency of the local country, unless otherwise determined that the U.S. 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 U.S. 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 are substantially derived from the sales of Inbrija and Ampyra in the U.S.

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 three-month period ended March 31, 2023, 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 three-month period ended March 31, 2023. The Company performed a recoverability test as of March 31, 2023 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 compared 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 three-month period ended March 31, 2023, 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.

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 the 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, the Company's ability to raise additional capital and repay or restructure its indebtedness will depend on the capital markets and its financial condition at such time, among other factors. In addition, financing may not be available when needed, at all, on terms acceptable to the Company or in accordance with the restrictions described above. As a result of these factors, the Company may not be able to engage in any of the alternative activities, or engage in such activities on desirable terms, which could harm the Company's business, financial condition and results of operations, as well as result in a default on the Company's debt obligations. If the Company is unable to take these actions, it may be forced to significantly alter its business strategy, substantially curtail its current operations, or cease operations altogether.

At March 31, 2023, the Company had \$30.3 million of cash and cash equivalents, compared to \$37.5 million at December 31, 2022. The Company's March 31, 2023 cash and cash equivalents balance does not include \$7.5 million of restricted cash, of which \$6.2 million is currently held in escrow for payment of the June 1, 2023 interest payment on the 2024 Notes, \$0.8 million is related to self-funded employee health insurance, and \$0.5 million is related to collateralized standby letters of credit. The Company incurred a net loss of \$16.8 million for the three-month period ended March 31, 2023.

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 judgment 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.

In June 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 (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 to authorize the Board of Directors to approve the amendment and restatement of the Company's 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 the Company's stockholders in November 2022.

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.

Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were subsequent events that required disclosure in these financial statements. See Note 14 to the Company's Consolidated Financial Statements included in this report for a discussion of subsequent events.

Accounting Pronouncements Not Yet Adopted

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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.

(3) Revenue

In accordance with ASC 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the good or service. ASC 606 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 March 31, 2023, the Company had contract liabilities of \$5.7 million, as compared to \$6.1 million as of December 31, 2022, which is the upfront payment received under the terms of the Company's distribution agreement with Esteve Pharmaceuticals GmbH ("Esteve Germany") entered into in 2021 related to the commercialization of Inbrija in Germany. As of March 31, 2023, approximately \$0.4 million of the contract liability balance is expected to be recognized as revenue from the remaining performance obligations over the next 12 months for the Esteve Germany agreement as goods are shipped. The Company expects to recognize the remaining balance over the next 9 years. The Company will re-evaluate the transaction price in each reporting period and as certain events are resolved or other changes in circumstances occur.

The following table disaggregates the Company's revenue by major source. The Company's Royalty Revenue set forth below relates to Fampyra royalties payable under the Company's License and Collaboration Agreement with Biogen.

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Revenues:		
Net product revenues:		
Ampyra	\$ 12,606	\$ 14,904
Inbrija	5,587	3,671
Inbrija ex-U.S.	526	—
Total net product revenues	18,719	18,575
Royalty revenues	3,528	3,959
License Revenue	11	—
Total net revenues	\$ 22,258	\$ 22,534

(4) Share-Based Compensation

During the three-month periods ended March 31, 2023 and 2022, the Company recognized share-based compensation expense of \$0.1 million and \$0.5 million, respectively. Activity in options and restricted stock during the three-month period ended March 31, 2023 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the three-month periods ended March 31, 2023 and 2022 were approximately \$0.49 and \$1.60, respectively.

The following table summarizes share-based compensation expense included within the Company's consolidated statements of operations:

(In thousands)	For the Three-month period ended March 31,	
	2023	2022
Research and development expense	\$ 1	\$ 27
Selling, general and administrative expense	70	457
Cost of Sales	—	1
Total	\$ 71	\$ 485

A summary of share-based compensation activity for the three-month period ended March 31, 2023 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 January 1, 2023	1,026	\$ 78.00	—	—
Granted	1,065	0.61	—	—
Cancelled	(73)	182.59	—	—
Exercised	—	—	—	—
Balance at March 31, 2023	2,018	\$ 33.37	8.1	\$ 10,176
Vested and expected to vest at March 31, 2023	1,973	\$ 34.10	8.0	\$ 10,083
Vested and exercisable at March 31, 2023	715	\$ 92.13	5.1	\$ 6,510

Restricted Stock and Performance Stock Unit Activity

(In thousands)	
Restricted Stock and Performance Stock Units	Number of Shares
Nonvested at January 1, 2023	—
Granted	—
Vested	—
Forfeited	—
Nonvested at March 31, 2023	—

Unrecognized compensation cost for unvested stock options, restricted stock awards, and restricted stock units as of March 31, 2023 totaled \$1.0 million and is expected to be recognized over a weighted average period of approximately 1.9 years.

During the three-month period ended March 31, 2023, the Company did not make any repurchases of shares.

(5) Loss Per Share

The following table sets forth the computation of basic and diluted loss per share for the three-month periods ended March 31, 2023 and 2022:

(In thousands, except per share data)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Basic and diluted		
Net loss—basic	\$ (16,824)	\$ (24,522)
Weighted average common shares outstanding used in computing net loss per share—basic	24,338	13,251
Plus: net effect of dilutive stock options and restricted common shares	—	—
Weighted average common shares outstanding used in computing net loss per share—diluted	24,338	13,251
Net loss per share—basic	\$ (0.69)	\$ (1.85)
Net loss per share—diluted	\$ (0.69)	\$ (1.85)

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 loss per diluted share because their effects were anti-dilutive:

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
<i>Denominator</i>		
Stock options and restricted common shares	1,087	1,299

Performance share units are excluded from the calculation of net loss per diluted share as the performance criteria has not been met for the three-month periods ended March 31, 2023 and 2022. Additionally, the impact of the 2024 Notes was determined to be anti-dilutive and excluded from the calculation of net loss per diluted share for the three-month periods ended March 31, 2023 and 2022.

(6) Income Taxes

The Company's effective income tax rate differs from the U.S. statutory rate primarily due to an increase in the valuation allowance and expense recorded on the equity forfeiture.

For the three-month periods ended March 31, 2023 and 2022, the Company recorded a benefit of \$2.0 million and a provision of (\$0.3) million for income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended March 31, 2023 and 2022 were 10.8% and (1.1%), respectively. The variances in the effective tax rates for the three-month period ended March 31, 2023, as compared to the three-month period ended March 31, 2022, was primarily due to an increase in the existing valuation allowance recorded on the Company's deferred tax assets for which no tax benefit can be recognized, and the forfeitures of equity of which no tax deduction is recorded.

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

The Company has ongoing state examinations in Massachusetts which cover multiple years. There have been no proposed adjustments at this stage of the examination. The New Jersey examination was finalized during the first quarter of 2023 for tax years 2015 through 2018 with no adjustments.

(7) 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 March 31, 2023 and December 31, 2022 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 Therapeutics, Inc. ("Civitas") which are valued using a probability weighted discounted cash flow valuation approach and derivative liabilities related to conversion options for the 2024 Notes 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 March 31, 2023, except for the fair value of the Company's 2024

Notes, which was approximately \$157.3 million as of March 31, 2023. 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
March 31, 2023			
Assets Carried at Fair Value:			
Money market funds	\$ —	\$ —	\$ —
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	39,800
Derivative liability - conversion option	—	—	—
December 31, 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	—	—	—

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)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Acquired contingent consideration:		
Balance, beginning of period	\$ 41,200	\$ 49,600
Fair value change to contingent consideration included in the statement of operations	(1,091)	(3,023)
Royalty payments	(309)	(177)
Balance, end of period	<u>\$ 39,800</u>	<u>\$ 46,400</u>

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach based on estimated future sales expected from Inbrija (levodopa inhalation powder), a U.S. Food and Drug Administration (“FDA”) approved drug for the treatment of OFF periods in 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 payments ranged from \$0 million to \$15.5 million for Inbrija. The discount rate used in the valuation was 22% for the three-month period ended March 31, 2023, as compared to 21.5% for the three-month period ended March 31, 2022. The valuation is performed quarterly and changes in the fair value of the contingent consideration are included in the statement of operations. For the three-month periods ended March 31, 2023 and 2022, changes in the fair value of the acquired contingent consideration were primarily due to change in projected revenue and the recalculation of cash flows for the passage of time.

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 2024 Notes:

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Derivative Liability-Conversion Option:		
Balance, beginning of period	\$ —	\$ 37
Fair value adjustment	—	(30)
Balance, end of period	<u>\$ —</u>	<u>\$ 7</u>

During 2019, a derivative liability was initially recorded as a result of the issuance of the 2024 Notes (See Note 10 to the Consolidated Financial Statements included in this report for more information on the 2024 Notes). 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 2024 Notes, (3) historical volatility of the 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 2024 Notes with the conversion feature as compared to the fair value of the 2024 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 2024 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 March 31, 2023. 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 three-month period ended March 31, 2023.

(8) Investments

There were no available-for-sale investments at March 31, 2023 and December 31, 2022, respectively.

(9) Liability Related to Sale of Future Royalties

In October 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 collaboration and licensing agreement with the Company up to an agreed upon threshold of royalties. This threshold was met during the second quarter of 2022 and the Company's obligations to HCRP expired upon Biogen's payment of royalties for that quarter.

The Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. The Company recorded the receipt of the \$40 million payment from HCRP and established a corresponding liability in the amount of \$40 million, net of transaction costs of approximately \$2.2 million. The net liability is classified between the current and non-current portion of liability related to 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.

The Company had a liability related to the sale of future royalties of \$0 and \$1.7 million for the periods ending March 31, 2023 and 2022, respectively.

The following table shows the activity within the liability account for the three-month period ended March 31, 2023 and 2022, respectively:

(In thousands)	March 31, 2023	March 31, 2022
Liability related to sale of future royalties - beginning balance	\$ —	\$ 4,460
Deferred transaction costs amortized	—	24
Non-cash royalty revenue payable to HCRP	—	(2,852)
Non-cash interest expense recognized	—	108
Liability related to sale of future royalties - ending balance	\$ —	\$ 1,740

(10) 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 then outstanding 1.75% Convertible Senior Notes due 2021 for the 2024 Notes and cash. 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 2024 Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among the Company, its wholly owned subsidiary, Civitas (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.

The 2024 Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms. 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. Under the 2024 Indenture, the Company may elect to pay interest in cash or shares of the Company’s common stock. In May 2023, the Company announced that it will make a cash interest payment of approximately \$6.2 million in satisfaction of the interest payment due on June 1, 2023 which will be made out of restricted cash. Following the June 1, 2023 interest payment, the Company will no longer have the option to pay interest on the 2024 Notes in common 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.

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, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate, or sell 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 U.S. of a product determined by the FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to 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 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 March 31, 2023.

The outstanding 2024 Notes balances as of March 31, 2023 and December 31, 2022 consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
Liability component:		
Principal	207,000	\$ 207,000
Less: debt discount and debt issuance costs, net	(35,504)	(39,969)
Net carrying amount	<u>\$ 171,496</u>	<u>\$ 167,031</u>
Equity component	<u>\$ 18,257</u>	<u>\$ 18,257</u>
Derivative liability-conversion option	<u>\$ —</u>	<u>\$ —</u>

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 three-month period ended March 31, 2023, the Company recognized \$7.6 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 March 31, 2023.

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 three-month periods ended March 31, 2023 and 2022:

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Contractual interest expense	\$ 3,105	\$ 3,105
Amortization of debt issuance costs	317	266
Amortization of debt discount	4,148	3,474
Total interest expense	<u>\$ 7,570</u>	<u>\$ 6,845</u>

Non-Convertible Capital Loans

The Company's Biotie Therapies Ltd. subsidiary received several non-convertible capital loans from Business Finland for research and development of specific drug candidates, with an aggregate adjusted acquisition-date fair value of \$20.5 million. The loans were to be repaid only when the consolidated retained earnings of Biotie Therapies Ltd. from the development of specific product candidates was sufficient to fully repay the loans. The Company filed an application with Business Finland for waiver of the loans and accrued interest. In July 2022, Business Finland granted the waiver request, which became effective in December 2022. The Company recorded a gain on extinguishment of debt of \$27.1 million for the carrying amount of the loans including accrued interest in December 2022.

(11) 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 3.8 years to 5.3 years.

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 previously leased a facility in Ardsley, New York with approximately 160,000 square feet of space for its corporate headquarters. The Company exercised 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 for its corporate headquarters. 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 commencing on January 1, 2023 is \$0.3 million per year, subject to an annual 2.0% escalation factor in each subsequent year thereafter.

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, Massachusetts. 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 3.8 years to 5.3 years, which reflects the exercise of the early termination of the Company's Ardsley, New York lease as described above. The weighted-average remaining lease term for the Company's operating leases was 4.1 years at March 31, 2023. The weighted-average discount rate was 7.9% at March 31, 2023.

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

(In thousands)	Balance Sheet Classification	March 31, 2023	December 31, 2022
Right-of-use assets	Right of use assets	\$ 5,029	\$ 5,287
Current lease liabilities	Current portion of lease liabilities	1,556	1,545
Non-current lease liabilities	Non-current portion of lease liabilities	4,055	4,341

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)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Operating lease cost	\$ 450	\$ 1,478
Variable lease cost	100	860
Short-term lease cost	—	1
Total lease cost	<u>\$ 550</u>	<u>\$ 2,339</u>

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

(In thousands)		
2023 (excluding the three months ended March 31, 2023)	\$	1,159
2024		1,588
2025		1,633
2026		1,678
2027		357
Later years		182
Total lease payments		6,597
Less: Imputed interest		(986)
Present value of lease liabilities	\$	5,611

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

(In thousands)	Three-month period ended March 31, 2023	Three-month period ended March 31, 2022
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	\$ 386	\$ 1,562

(12) Corporate Restructuring

As part of the September 2021 restructuring, the Company further reduced its employee headcount by approximately 15% through a reduction in workforce. A significant portion of the reductions in workforce took place in September 2021, and was materially completed as of March 31, 2022.

During the three-month period ended March 31, 2023, the Company incurred \$0 of restructuring charges.

(13) Commitments and Contingencies

In February 2021, the Company sold its Chelsea manufacturing operations to Catalent Pharma Solutions ("Catalent"). In connection with the sale, the Company entered into a long-term, global manufacturing services (supply) agreement (the "2021 MSA") with Catalent for the manufacture of Inbrija. The 2021 MSA provided that the Company would purchase Inbrija exclusively from Catalent and 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 entered into an amendment of the 2021 MSA that adjusted 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 is obligated to 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 were delivered in the first quarter of 2023.

Effective January 1, 2023, the Company entered into a new manufacturing services agreement with Catalent, which was subsequently amended in March 2023 (as amended in March 2023, the "New MSA"). 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. 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 U.S. 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, and 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 party 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.

During the quarter ended March 31, 2023, the Company incurred approximately \$2.9 million of purchase commitments with Catalent which was previously reflected as other current assets as of December 31, 2022 and now recognized as inventory within its balance sheet. The Company did not recognize any purchase commitments in cost of sales within its consolidated statement of operations for the period.

(14) Subsequent Events

In May 2023, the Company entered into a distribution agreement and a commercial supply agreement with Hangzhou Chance Pharmaceuticals Co., Ltd. ("Chance"), for the exclusive distribution of Inbrija in China. Chance is obligated to use commercially reasonable efforts to market Inbrija in China. The agreements remain in effect until the earlier of (a) the last commercial sale of Inbrija on a jurisdiction-by-jurisdiction basis, and (b) 12 years from the effective date of the agreements, subject to customary termination for insolvency and certain other termination rights. The Company will receive a non-refundable upfront payment of \$2.5 million, and a near term milestone payment of up to \$6 million, depending on the clinical study requirements to be determined by the Chinese National Medical Products Administration (NMPA). The Company will also receive \$3 million upon regulatory approval of Inbrija in China, up to \$132.5 million in sales milestones based on specified sales volumes, and a fixed fee for each carton of Inbrija supplied to Chance.

Item 2. 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 unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q.

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 episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. Approximately one million people in the U.S. and 1.2 million people in Europe are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods. The 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. U.S. net revenue for Inbrija was \$5.6 million for the quarter ended March 31, 2023 and \$3.7 million for the quarter ended March 31, 2022.

Inbrija is also approved for use in the European Union ("EU"). The European Medicines Agency approved Inbrija dose is 66 mg (administered as two capsules) up to five times per day (per EU convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the EU approval, Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. We have entered into agreements to commercialize Inbrija in Spain, Germany, Latin America, and China, 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 were \$0.5 million for the quarter ended March 31, 2023.

Inbrija utilizes our ARCUS platform for inhaled therapeutics. Because of our limited financial resources, we previously suspended work on ARCUS and other proprietary research and development programs. However, we are discussing potential collaborations with other companies that have expressed interest in formulating their novel molecules for pulmonary delivery using ARCUS, and 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 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 \$12.6 million for the quarter ended March 31, 2023 and \$14.9 million for the quarter ended March 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.

Long-Term Supply Arrangements

Catalent

In February 2021, we sold our Chelsea manufacturing operations to Catalent Pharma Solutions (“Catalent”). In connection with the sale, we entered into a long-term, global manufacturing services (supply) agreement (the “2021 MSA”) with Catalent for the manufacture of Inbrija. The 2021 MSA provided that we would purchase Inbrija exclusively from Catalent, and 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 entered into an amendment of the 2021 MSA that adjusted 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, we 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 are obligated to 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 were delivered in the first quarter of 2023.

Effective January 1, 2023, we entered into a new manufacturing services agreement with Catalent, which was subsequently amended in March 2023 (as amended in March 2023, the “New MSA”). 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. 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 U.S. 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 agreed to a minimum purchase requirement of at least three batches per year on the PSD-7 equipment, and will provide up to \$1 million in each of 2023 and 2024 for capital expenditures to assist in the capacity expansion efforts. In addition, we are 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 party 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 certain specified regulatory events and for convenience upon 180 days’ prior written notice.

Patheon

In October 2022, an arbitration panel issued a decision in our dispute with Alkermes Plc (“Alkermes”) and ruled that the existing license and supply agreements with Alkermes were unenforceable. As a result of the panel’s ruling, we are no longer required 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. (“Patheon”) 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. 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 U.S. 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. 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 U.S.

The manufacturing services agreement is automatically renewed for successive one-year periods on December 31 of each year, unless either party provides 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.

Financial Management

As of March 31, 2023, we had cash, cash equivalents, and restricted cash of approximately \$37.8 million. Restricted cash includes \$7.5 million, of which \$6.2 million is currently held in escrow under the terms of our 6.00% convertible senior secured notes due to December 2024 ("2024 Notes"), \$0.8 million is related to self-funded employee health insurance, and \$0.5 million is related to collateralized standby letters of credit. In May 2023, we announced that we will make a cash interest payment of approximately \$6.2 million in satisfaction of the interest payment due on June 1, 2023 which will be made out of restricted cash. Following the June 1, 2023 interest payment, we will no longer have the option to pay interest on the 2024 Notes in common stock.

COVID-19 Pandemic

Our business and financial condition have been impacted by, and are subject to risks resulting from, the COVID-19 global pandemic. The COVID-19 global pandemic has caused significant disruptions in the healthcare industry and 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. 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 episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. The FDA approved Inbrija for a single dose of 84 mg (administered as two capsules), which may be taken up to five times per day. U.S. net revenue for Inbrija was \$5.6 million for the quarter ended March 31, 2023 and \$3.7 million for the quarter ended March 31, 2022. 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.

Inbrija is also approved for use in the 27 member states of the EU, as well as Iceland, Norway, and Liechtenstein, for a single dose of 66 mg (administered as two capsules) up to five times per day (per EU convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Following the UK's exit from the EU, we were granted a grandfathered Marketing Authorization by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK in January 2021.

We have entered into agreements to commercialize Inbrija in Spain, Germany, Latin America, and China, 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, S.A. (“Esteve Spain”) and Esteve Pharmaceuticals GmbH (“Esteve Germany”) to commercialize Inbrija in Spain and Germany and 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 Esteve Spain and Esteve 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 Germany and Esteve Spain launched Inbrija in Germany in June 2022 and in Spain in February 2023, respectively. Net revenues for ex-U.S. Inbrija sales were \$0.5 million for the quarter ended March 31, 2023.

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 2024.

In May 2023, we entered into a distribution agreement and a commercial supply agreement with Hangzhou Chance Pharmaceuticals Co., Ltd (“Chance”), for the exclusive distribution of Inbrija in China. Chance is obligated to use commercially reasonable efforts to market Inbrija in China. The agreements remain in effect until the earlier of (a) the last commercial sale of Inbrija on a jurisdiction- by- jurisdiction basis, and (b) 12 years from the effective date of the agreements, subject to customary termination for insolvency and certain other termination rights. We will receive a non-refundable upfront payment of \$2.5 million, and a near term milestone payment of up to \$6 million, depending on the clinical study requirements to be determined by the Chinese National Medical Products Administration (NMPA). We will also receive \$3 million upon regulatory approval of Inbrija in China, up to \$132.5 million in sales milestones based on specified sales volumes, and a fixed fee for each carton of Inbrija supplied to Chance.

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.

Ampyra

Ampyra was approved by the FDA in January 2010 to improve walking in adults with multiple sclerosis. 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 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 \$12.6 million for the quarter ended March 31, 2023 and \$14.9 million for the quarter ended March 31, 2022.

Prior to October 2022 our primary source of supply of Ampyra was provided through a manufacturing and license agreement with Alkermes. In connection with a dispute over license and supply royalties, in the fourth quarter of 2022, an arbitration panel awarded to us an aggregate of \$18.3 million including prejudgment interest. In addition, the arbitration panel ruled the agreements with Alkermes as unenforceable, and as a result we 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 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 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 initiated a commercial launch of Fampyra in China in 2022. 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.

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.

Results of Operations

Three-Month Period Ended March 31, 2023 Compared to March 31, 2022

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 distributors. We recognized net revenues from the U.S. sales of Inbrija of \$5.6 million and \$3.7 million for the three-month periods ended March 31, 2023 and 2022, respectively, an increase of \$1.9 million, or 51.4%. The increase in Inbrija net revenues of \$1.9 million was composed of an increase in volume of \$1.6 million and a net price increase and discount and allowance adjustments of \$0.3 million for the three-month period ended March 31, 2023. 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 for sales in ex-U.S. of \$0.5 million and \$0 for the three-month periods ended March 31, 2023 and 2022, respectively.

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 \$12.6 million and \$14.9 million for the three-month periods ended March 31, 2023 and 2022, respectively, a decrease of \$2.3 million, or 15.4%. The decrease in Ampyra net revenues of \$2.3 million was composed of a decrease in volume of \$3.7 million, partially offset by net price increase and discount and allowance adjustments of \$1.4 million for the three-month period ended March 31, 2023. 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 Inbrija and Ampyra are included as an offset in net revenues consisting 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 Patient Protection and 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 Inbrija and Ampyra 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 \$3.5 million and \$4.0 million in royalty revenues for the three-month periods ended March 31, 2023 and 2022, respectively, a decrease of \$0.5 million or 12.5%.

License Revenues

We recognized negligible license revenue and no license revenues for the three-month periods ended March 31, 2023 and 2022, respectively.

Cost of Sales

We recorded cost of sales of \$3.2 million for the three-month period ended March 31, 2023 as compared to \$6.0 million for the three-month period ended March 31, 2022. Cost of sales for the three-month period ended March 31, 2023 consisted primarily of \$3.1 million in inventory costs related to recognized revenues and \$0.1 million in other period costs. Cost of sales for the three-month period ended March 31, 2022 consisted primarily of \$5.7 million in inventory costs related to recognized revenues and \$0.3 million in royalty fees based on net product shipments.

Amortization of Intangibles

We recorded amortization of intangible asset related to Inbrija of \$7.7 million for the three-month periods ended March 31, 2023 and 2022.

Research and Development

Research and development expenses for the three-month period ended March 31, 2023 were \$1.4 million as compared to \$1.7 million for the three-month period ended March 31, 2022, a decrease of approximately \$0.3 million, or 17.6%. The decrease was primarily due to restructuring and related decreases in several research and development programs.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended March 31, 2023 were \$9.6 million compared to \$10.1 million for the three-month period ended March 31, 2022, a decrease of approximately \$0.5 million, or 5.0%. The decrease was primarily due to a decrease in marketing-related spending of \$0.6 million for Inbrija, and a decrease in spending for Ampyra and other selling related expenses of \$0.6 million, partially offset by an increase in salaries and benefits of \$0.7 million.

General and administrative expenses for the three-month period ended March 31, 2023 were \$12.8 million compared to \$16.8 million for the three-month period ended March 31, 2022, a decrease of approximately \$4.0 million, or 23.8%. The decrease was primarily due to a decrease in rent and facility costs of \$1.7 million, a decrease of \$0.6 million in depreciation expenses as a result of the relocation of the corporate offices, a decrease in salaries and benefits of \$1.1 million, and a decrease in professional fees of \$0.7 million, partially offset by an increase of \$0.1 million in other departmental spending.

Change in Fair Value of Derivative Liability

A derivative liability was recorded in December 2019 as a result of the issuance of the 2024 Notes. 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 no income due to the change in the fair value of the derivative liability for the three-month period ended March 31, 2023.

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 a gain relating to changes in the fair value of our acquired

contingent consideration of \$1.0 million for the three-month period ended March 31, 2023 as compared to income of \$3.0 million for the three-month period ended March 31, 2022. 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 Expense, Net

Other expense, net was \$7.4 million and \$7.6 million for the three-month periods ended March 31, 2023 and 2022, respectively. Nearly all Other Expense, net was interest on the 2024 Notes.

Benefit from/(Provision for) Income Taxes

For the three-month periods ended March 31, 2023 and 2022, we recorded a benefit from income taxes of \$2.0 million and a provision for income taxes of (\$0.3) million, respectively. The effective income tax rates for the three-month periods ended March 31, 2023 and 2022 were 10.8% and (1.1)%, respectively.

The variance in the effective tax rates for the three-month period ended March 31, 2023 as compared to the three-month period ended March 31, 2022 was due primarily to an increase in the existing valuation allowance recorded on our deferred tax assets for which no tax benefit can be recognized and the forfeitures of equity of which no tax deduction is recorded.

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 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 which cover multiple years. There have been no proposed adjustments at this stage of the examination. The New Jersey examination was finalized during the first quarter of 2023 for tax years 2015 through 2018 with no adjustments.

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 monetization and a 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.

On March 31, 2023, we had \$30.3 million of cash and cash equivalents, compared to \$37.5 million at December 31, 2022. Our March 31, 2023 cash and cash equivalents balance does not include \$7.5 million of restricted cash, of which \$6.2 million is currently held in escrow for payment of the June 1, 2023 interest payment on the 2024 Notes, \$0.8 million is related to self-funded employee health insurance, and \$0.5 million is related to collateralized standby letters of credit. We incurred a net loss of \$16.8 million for the three month period ended March 31, 2023.

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 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.

In June 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 (the "Minimum Bid Requirement"). 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. On November 11, 2022, our stockholders authorized our Board of Directors to approve an 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. In February 2023, 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.

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 then outstanding 1.75% Convertible Senior Notes due 2021 (the "2021 Notes") for the 2024 Notes and cash. We issued approximately \$207.0 million aggregate principal amount of the 2024 Notes and paid approximately \$55.2 million in cash to participating holders.

The 2024 Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among us, 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 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.

The 2024 Notes will mature on December 1, 2024 unless earlier converted in accordance with their terms. 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. Under the 2024 Indenture, we may elect to pay interest in cash or shares of our common stock. In May 2023, we announced that we will make a cash interest payment of approximately \$6.2 million in satisfaction of the interest payment due on June 1, 2023 which will be made out of restricted cash. Following the June 1, 2023 interest payment, we will no longer have the option to pay interest on the 2024 Notes in common stock.

Subject to a number of exceptions and qualifications, the 2024 Indenture restricts our ability and 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, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell all or substantially all of our assets. The 2024 Indenture also requires us to make an offer to repurchase the 2024 Notes upon the occurrence of certain asset sales.

The 2024 Indenture provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the 2024 Notes when due at maturity, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to convert the 2024 Notes in accordance with the 2024 Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the 2024 Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the 2024 Indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by us to make required payments under other indebtedness of our or certain subsidiaries having an outstanding principal amount of \$30.0 million or more, (vii) failure by us or certain subsidiaries to pay final judgments aggregating in excess of \$30.0 million, (viii) certain events of bankruptcy or insolvency and (ix) the commercial launch in the U.S. of a product determined by the FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to us, all outstanding 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 outstanding 2024 Notes balances as of March 31, 2023 consisted of the following:

(In thousands)	March 31, 2023
Liability component:	
Principal	\$ 207,000
Less: debt discount and debt issuance costs, net	(35,504)
Net carrying amount	\$ 171,496
Equity component	\$ 18,257
Derivative liability-conversion Option	\$ —

Non-Convertible Capital Loans

Our Biotie Therapies Ltd. subsidiary received several non-convertible capital loans from Business Finland for research and development of specific drug candidates, with an aggregate adjusted acquisition-date fair value of \$20.5 million. The loans were to be repaid only when the consolidated retained earnings of Biotie from the development of specific product candidates is sufficient to fully repay the loans. We filed an application with Business Finland for waiver of the loans and accrued interest. In July 2022, Business Finland granted the waiver request, which became effective in December 2022. We recorded a gain on extinguishment of debt of \$27.1 million for the carrying amount of the loans including accrued interest in December 2022.

Cash and Cash Equivalents

At March 31, 2023 cash and cash equivalents were approximately \$30.3 million, as compared to \$37.5 million at December 31, 2022. 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. We do not anticipate any losses with respect to such cash balances. Our March 31, 2023 cash and cash equivalents balance does not include \$7.5 million of restricted cash, of which \$6.2 million is currently held in escrow for payment of the June 1, 2023 interest payment on the 2024 Notes, \$0.8 million is related to self-funded employee health insurance, and \$0.5 million is related to collateralized standby letters of credit.

Net Cash Used in Operations

Net cash used in operations was \$7.0 million for the three-month period ending March 31, 2023. Cash used by operations for the three-month period ended March 31, 2023 was primarily due to:

- a net loss of \$16.8 million, an increase in inventory of \$0.7 million, an increase in other assets of \$1.3 million, a decrease in accounts payable, accrued expenses and other current liabilities of \$4.8 million, a deferred tax

benefit of \$2.1 million, change in acquired contingent consideration obligation of \$1.1 million, and a decrease in other non-current liabilities of \$0.3 million; partially offset by

- share based compensation expense of \$0.1 million, amortization of debt discount and debt issuance costs of \$4.5 million, depreciation and amortization of \$7.9 million, a decrease in accounts receivable of \$4.7 million, and a decrease in prepaid expenses and other current assets of \$2.9 million.

Net Cash Used in Investing

Net cash used in investing activities for the three-month period ended March 31, 2023 was \$0.

Net Cash Provided by Financing

Net cash provided by financing activities for the three-month period ended March 31, 2023 was \$0.

Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our material outstanding contractual commitments is included in Note 12 of our Annual Report on Form 10-K for the year ended December 31, 2022. Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

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

Our critical accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2022. Effective January 1, 2022, we adopted 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.” Other than the adoption of these new accounting guidance, our significant accounting policies have not changed materially from December 31, 2022.

Item 3. 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 4. 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 the first quarter of 2023, 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 March 31, 2023, 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 Securities and Exchange Commission'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 March 31, 2023, 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.

PART II—OTHER INFORMATION

Item 1. 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 January 2023, the Company filed a petition in the District Court for the Southern District of New York (“District Court”) to confirm and modify the arbitral award received in October 2022 relating to a dispute with Alkermes plc (“Alkermes”). In that arbitration proceeding, the arbitration panel found in the Company’s favor that Alkermes had leveraged its patent to illegally obtain royalties beyond the life of the patent in violation of federal law. The arbitration 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 (“Award”). The Company is asking the District Court to confirm the Award, with modifications to the extent the arbitration 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 arbitration 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 arbitration 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 requested 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.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A. Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated in our Quarterly Reports subsequently filed during the current fiscal year, including this report, all of which could materially affect our business, financial condition and/or operating results. There have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022. These risks are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results in the future.

Item 6. Exhibits

Exhibit No.	Description
31.1	<u>Certification by the Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.</u>
31.2	<u>Certification by the Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.</u>
32.1	<u>Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACORDA THERAPEUTICS, INC.

By: /s/ Ron Cohen

Ron Cohen, M.D.

*President, Chief Executive Officer and Director
(Principal Executive Officer)*

Date: May 11, 2023

By: /s/ Michael A. Gesser

Michael A. Gesser

*Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)*

Date: May 11, 2023

**CERTIFICATION BY THE PRINCIPAL 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 quarterly report on Form 10-Q 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: May 11, 2023

/s/ Ron Cohen

RON COHEN

Chief Executive Officer

(Principal Executive Officer)

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

I, Michael Gesser, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: May 11, 2023

/s/ Michael Gesser

MICHAEL GESSER
Chief Financial Officer and Treasurer
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the “Company”) for the fiscal quarter ended March 31, 2023, 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)
May 11, 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.]

**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 Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the “Company”) for the fiscal quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Michael Gesser, Chief Financial Officer and Treasurer 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 and Treasurer
(Principal Financial Officer)
May 11, 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.]
