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 September 30, 2020

OR

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

For the transition period from to

Commission File Number 001-31938

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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 October 30, 2020**
Common Stock, $0.001 par value per share	47,962,400 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 or any other products under development; the COVID-19 pandemic, including related quarantines and travel restrictions, and the potential for the illness to affect our 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 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 complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand; third party payers (including governmental agencies) may not reimburse for the use of Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; competition for Inbrija, Ampyra and other products we may develop and market in the future, including increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra (dalfampridine) following our loss of patent exclusivity; the ability to realize the benefits anticipated from acquisitions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report and in our Annual Report on Form 10-K for the year ended December 31, 2019, 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 do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We and our subsidiaries own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks "Acorda Therapeutics," our stylized Acorda Therapeutics logo, "Biotie Therapies," "Ampyra," "Inbrija," and "ARCUS." Also, our marks "Fampyra" and "Inbrija" are registered marks in the European Community Trademark Office and we have registrations or pending applications for 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

(In thousands, except share data)	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 57,910	$ 62,085
Restricted cash	13,200	12,836
Short term investments	5,347	63,754
Trade accounts receivable, net of allowances of $635 and $682, as of September 30, 2020 and December 31, 2019, respectively	13,385	22,083
Prepaid expenses	15,382	11,574
Inventory, net	30,120	25,221
Other current assets	16,470	3,560
Total current assets	151,814	201,113
Property and equipment, net of accumulated depreciation	139,255	142,527
Intangible assets, net of accumulated amortization	374,743	402,329
Right of use asset, net of accumulated amortization	19,805	23,450
Restricted cash	24,819	30,270
Other assets	11	29
Total assets	$ 710,447	$ 799,718
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,361	$ 26,257
Accrued expenses and other current liabilities	41,430	39,077
Current portion of loans payable	68,050	603
Current portion of liability related to sale of future royalties	8,624	10,836
Current portion of lease liabilities	7,893	7,746
Current portion of acquired contingent consideration	2,391	1,866
Total current liabilities	138,749	86,385
Convertible senior notes	134,622	192,774
Derivative liability	832	59,409
Non-current portion of acquired contingent consideration	43,709	78,434
Non-current portion of lease liabilities	18,747	22,996
Non-current portion of loans payable	26,978	25,495
Deferred tax liability	23,120	9,581
Non-current portion of liability related to sale of future royalties	9,147	13,565
Other non-current liabilities	1,012	259
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value. Authorized 1,000,000 shares at September 30, 2020 and December 31, 2019; no shares issued as of September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value. Authorized 370,000,000 shares at September 30, 2020 and 80,000,000 at December 31, 2019; issued 47,734,146 and 47,730,396 shares, including those held in treasury, as of September 30, 2020 and December 31, 2019, respectively	48	48
Treasury stock at cost (29,304 shares at September 30, 2020 and December 31, 2019)	(638)	(638)
Additional paid-in capital	999,762	979,388
Accumulated deficit	(683,355)	(666,809)
Accumulated other comprehensive (loss) income	(2,286)	(1,169)
Total stockholders' equity	313,531	310,820
Total liabilities and stockholders' equity	$ 710,447	$ 799,718

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 September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Revenues:				
Net product revenues	$ 34,687	$ 44,800	$ 90,153	$ 133,325
Milestone revenues	15,000	—	15,000	—
Royalty revenues	3,403	2,922	9,654	8,586
Total net revenues	53,090	47,722	114,807	141,911
Costs and expenses:				
Cost of sales	12,170	7,986	22,670	26,183
Research and development	5,729	16,073	18,689	51,060
Selling, general and administrative	39,935	48,702	119,700	151,622
Amortization of intangible assets	7,691	7,692	23,073	17,945
Asset impairment	—	277,561	4,131	277,561
Change in fair value of derivative liability	(4,864)	—	(40,320)	—
Changes in fair value of acquired contingent consideration	(23,608)	(50,942)	(33,455)	(56,342)
Total operating expenses	37,053	307,072	114,488	468,029
Operating income (loss)	16,037	(259,350)	319	(326,118)
Other income (expense), net:				
Interest and amortization of debt discount expense	(7,760)	(4,500)	(22,810)	(16,302)
Interest income	317	333	807	3,327
Other income (expense)	19	—	(16)	—
Gain on disposal of property and equipment	200	—	200	—
Realized loss on foreign currency transactions	(1)	(1)	(8)	(17)
Total other expense, net	(7,225)	(4,168)	(21,827)	(12,992)
Income (loss) before taxes	8,812	(263,518)	(21,508)	(339,110)
Benefit from (Provision for) income taxes	(1,465)	(17)	4,962	484
Net income (loss)	$ 7,347	$ (263,535)	$ (16,546)	$ (338,626)
Net income (loss) per share—basic	$ 0.15	$ (5.55)	$ (0.35)	$ (7.13)
Net income (loss) per share—diluted	$ 0.05	$ (5.55)	$ (0.35)	$ (7.13)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	47,705	47,511	47,704	47,491
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	166,145	47,511	47,704	47,491

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 September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Net income (loss)	$ 7,347	$ (263,535)	$ (16,546)	$ (338,626)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustment	(1,018)	(3,190)	(1,096)	(3,671)
Unrealized (loss) income on available for sale debt securities	(45)	(63)	(21)	229
Other comprehensive loss, net of tax	(1,063)	(3,253)	(1,117)	(3,442)
Comprehensive income (loss)	$ 6,284	$ (266,788)	$ (17,663)	$ (342,068)

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

(unaudited)

(In thousands)	Common stock Number of shares	Common stock Par value	Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total stockholders equity
Balance at December 31, 2019	47,730	$ 48	$ (638)	$ 979,388	$ (666,809)	$ (1,169)	$ 310,820
Compensation expense for issuance of stock options to employees	—	—	—	1,976	—	—	1,976
Compensation expense for issuance of restricted stock to employees	4	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—
Purchase of Treasury Stock	—	—	—	—	—	—	—
Other comprehensive income, net of tax	—	—	—	—	—	350	350
Net loss	—	—	—	—	(6,472)	—	(6,472)
Balance at March 31, 2020	47,734	$ 48	$ (638)	$ 981,364	(673,281)	$ (819)	$ 306,674
Compensation expense for issuance of stock options to employees	—	—	—	2,056	—	—	2,056
Compensation expense for issuance of restricted stock to employees	—	—	—	—	—	—	—
Adjustments to Treasury Stock	—	—	—	—	—	—	—
Purchase of Treasury Stock	—	—	—	—	—	—	—
Other comprehensive (loss) income, net of tax	—	—	—	—	—	(404)	(404)
Net loss	—	—	—	—	(17,421)	—	(17,421)
Balance at June 30, 2020	47,734	$ 48	$ (638)	$ 983,420	$ (690,702)	$ (1,223)	$ 290,905
Compensation expense for issuance of stock options to employees	—	—	—	2,480	—	—	2,480
Compensation expense for issuance of restricted stock to employees	—	—	—	—	—	—	—
Reclassification of derivative liability to equity, net of tax of $4.4 million	—	—	—	13,862	—	—	13,862
Other comprehensive (loss) income, net of tax	—	—	—	—	—	(1,063)	(1,063)
Net income (loss)	—	—	—	—	7,347	—	7,347
Balance at September 30, 2020	47,734	$ 48	$ (638)	$ 999,762	$ (683,355)	$ (2,286)	$ 313,531

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity (Continued)

(unaudited)

(In thousands)	Common stock Number of shares	Common stock Par value	Treasury stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total stockholders equity
Balance at December 31, 2018	47,508	$ 48	$ (2,133)	$ 1,005,105	$ (393,843)	$ 2,806	$ 611,983
Compensation expense for issuance of stock options to employees	—	—	—	2,745	—	—	2,745
Compensation expense for issuance of restricted stock to employees	49	—	—	922	—	—	922
Exercise of stock options	2	—		24	—	—	24
Purchase of Treasury Stock	4	—	(52)	—	—	—	(52)
Other comprehensive (loss) income, net of tax	—	—	—	—	—	(1,431)	(1,431)
Net loss	—	—	—	—	(47,605)	—	(47,605)
Balance at March 31, 2019	47,563	$ 48	$ (2,185)	$ 1,008,796	$ (441,448)	$ 1,375	$ 566,586
Compensation expense for issuance of stock options to employees	—	—	—	3,180	—	—	3,180
Compensation expense for issuance of restricted stock to employees	34	—	—	1,354	—	—	1,354
Adjustments to Treasury Stock	(65)	—	1,586	(1,586)	—	—	—
Purchase of Treasury Stock	3	—	(39)	—	—	—	(39)
Other comprehensive (loss) income, net of tax	—	—	—	—	—	1,242	1,242
Net income	—	—	—	—	(27,486)	—	(27,486)
Balance at June 30, 2019	47,535	$ 48	$ (638)	$ 1,011,744	$ (468,934)	$ 2,617	$ 544,837
Compensation expense for issuance of stock options to employees	—	—	—	2,057	—	—	2,057
Compensation expense for issuance of restricted stock to employees	5	—	—	1,236	—	—	1,236
Other comprehensive (loss) income, net of tax	—	—	—	—	—	(3,253)	(3,253)
Net loss	—	—	—	—	(263,535)	—	(263,535)
Balance at September 30, 2019	47,540	$ 48	$ (638)	$ 1,015,037	$ (732,469)	$ (636)	$ 281,342

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (16,546)	$ (338,626)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Share-based compensation expense	6,512	11,494
Amortization of net premiums and discounts on investments	(28)	(1,325)
Amortization of debt discount and debt issuance costs	12,219	12,202
Depreciation and amortization expense	30,919	24,697
Asset impairment	4,131	277,561
Change in acquired contingent consideration obligation	(33,455)	(56,342)
Non-cash royalty revenue	(8,496)	(7,556)
Deferred tax provision (benefit)	8,801	(3,667)
Change in derivative liability	(40,320)	—
Gain on disposal of property and equipment	(200)	—
Changes in assets and liabilities:		
Decrease in accounts receivable	8,698	5,877
(Increase) decrease in prepaid expenses and other current assets	(16,712)	13,725
(Increase) decrease in inventory	(4,899)	1,619
Decrease in other assets	17	—
Decrease in accounts payable, accrued expenses and other current liabilities	(13,391)	(56,141)
Increase (decrease) in other non-current liabilities	296	(256)
Net cash used in operating activities	(62,454)	(116,738)
Cash flows from investing activities:		
Purchases of property and equipment	(4,074)	(76,414)
Purchases of investments	—	(171,431)
Proceeds from maturities of investments	58,415	191,342
Net cash provided by (used in) investing activities	54,341	(56,503)
Cash flows from financing activities:		
Debt issuance costs	(1,071)	—
Proceeds from issuance of common stock and option exercises	—	24
Purchase of treasury stock	—	(91)
Repayment of loans payable	(597)	(614)
Net cash used in financing activities	(1,668)	(681)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	519	(265)
Net decrease in cash, cash equivalents and restricted cash	(9,262)	(174,187)
Cash, cash equivalents and restricted cash at beginning of period	105,192	294,351
Cash, cash equivalents and restricted cash at end of period	$ 95,930	$ 120,164
Supplemental disclosure:		
Cash paid for interest	$ 6,067	$ 3,037
Cash paid for taxes	250	2,562

See accompanying Unaudited Notes to Consolidated Financial Statements

(1) Organization and Business Activities

Acorda Therapeutics, Inc. ("Acorda" or the "Company") is a biopharmaceutical company focused on developing therapies that restore function and improve the lives of people with neurological disorders.

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (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 and nine-month periods ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. When used in these notes, the terms "Acorda" or "the Company" mean Acorda Therapeutics, Inc. The December 31, 2019 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, 2019.

(2) Summary of Significant Accounting Policies

Our significant accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2019. Effective January 1, 2020, the Company adopted ASU 2016-13, "Financial Instruments – Credit Losses" (Topic 326), ASU 2018-13, "Fair Value Measurement (Topic 820), ASU 2018-15, "Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract", and, ASU 2018-18, "Collaborative Arrangements" (Topic 808). Other than the adoption of the new accounting guidance, our significant accounting policies have not changed materially from December 31, 2019.

Restricted Cash

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:

	Nine-month period ended September 30, 2020		Nine-month period ended September 30, 2019	
(In thousands)	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 62,085	$ 57,910	$ 293,564	$ 119,521
Restricted cash	12,836	13,200	532	387
Restricted cash non-current	30,270	24,819	255	256
Total Cash, cash equivalents and restricted cash per statement of cash flows	$ 105,191	$ 95,929	$ 294,351	$ 120,164

Amounts included in restricted cash represent those amounts in escrow related to the 6% semi-annual interest portion of the convertible note exchange completed in December 2019 payable within the next 12 months and those amounts required to be set aside to cover the Company's self-funded employee health insurance costs over the next 12 months. Restricted cash non-current represents those amounts in escrow related to the 6% semi-annual interest portion of the convertible note exchange completed in December 2019 payable subsequent to the next twelve months and cash collateralized standby letters of credit in connection with obligations under facility leases due to the long-term nature of the letters of credit. The 6% semi-annual interest portion of the convertible notes is payable in cash or, if permitted by the terms of the notes, stock.

Inventory

The major classes of inventory were as follows:

(In thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 3,366	$ 1,753
Work-in-progress	6,010	13,509
Finished goods	20,744	9,959
Total	$ 30,120	$ 25,221

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 United States of America is deemed to be the currency of the local country, unless otherwise determined that the United States dollar would serve as a more appropriate functional currency given the economic operations of the entity. Accordingly, the assets and liabilities of the Company's foreign subsidiary, Biotie, are translated into United States dollars using the period-end exchange rate; 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 losses and gains are recognized in the period incurred and are reported as other (expense) income, net in the statement 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, who is the chief operating decision maker. 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 with respect 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 derived from the sales of Inbrija and Ampyra in the U.S. for the three and nine-month periods ended September 30, 2020 and 2019.

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 indefinite lived intangible assets not subject to amortization and property plant and equipment, may warrant revision or that the carrying value of the assets may be impaired. 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, results of clinical trials, stock price, loss of a major customer and significant negative economic trends. Based on the Company's evaluation for the three-month period ended March 31, 2020, the Company determined that its indefinite lived intangible asset BTT1023 was fully impaired and recorded an asset impairment in its consolidated statement of operations. The Company also determined that its finite lived intangible assets were not impaired for the three and nine-month periods ended September 30, 2020.

Liquidity

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 Financials Statements—Going* Concern" ("ASC Topic 205-40"), which requires the Company to evaluate whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that its annual and interim consolidated financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting. Determining the extent, if any, to which conditions or events raise substantial doubt about the Company's ability to continue

as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgement by management.

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

Based on our cash, cash equivalents and short-term investments at September 30, 2020, our recent net losses, and our obligations that are due within the next 12 months, including $69.0 million aggregate principal amount of our 1.75% Convertible Senior Notes due 2021 that mature on June 15, 2021, management has concluded that there is substantial doubt regarding our ability to meet our obligations within one year after the date the consolidated financial statements in this report are issued and, therefore, to continue as a going concern.

Our ability to meet our future operating requirements, repay our liabilities, 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 6.00% Convertible Senior Secured Notes due 2024, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous and which are likely to be highly dilutive. Also, 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.

Due to these uncertainties, there is substantial doubt about the Company's ability to continue as going concern. These unaudited condensed consolidated financial statements and accompanying notes have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were no subsequent events that required disclosure in these financial statements.

Accounting Pronouncements Adopted

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses" (Topic 326): Measurement of Credit Losses on Financial Instruments and subsequently amended by ASU 2019-04 and ASU 2019-05 which introduces a forward-looking approach, based on expected losses, to estimate credit losses on certain types of financial instruments, including trade receivables. This new standard amends the current guidance on the impairment of financial instruments. The ASU adds to U.S. GAAP an impairment model known as current expected credit loss (CECL) model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. The ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company adopted this guidance effective January 1, 2020. The adoption of this guidance did not have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 "Fair Value Measurement (Topic 820): "Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement." The amendment in this ASU eliminate, add and modify certain disclosure requirements for fair value measurements as part of its disclosure framework project. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public business entities will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company adopted this guidance effective January 1, 2020. The adoption of this guidance did not have a significant impact on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.” The ASU clarifies certain aspects of ASU 2015-05, “Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement,” which was issued in April 2015. Specifically, the ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license).” The ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company adopted this guidance effective January 1, 2020. The adoption of this guidance did not have an impact on the consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Collaborative arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. ASU 2018-18 clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. The Company adopted this guidance effective January 1, 2020. The adoption of this guidance did not have a significant impact on the consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes. The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

In March 2020, the FASB issued ASU 2020-03, “Codification Improvements to Financial Instruments”: The amendments in this update are to clarify, correct errors in, or make minor improvements to a variety of ASC topics. The changes in ASU 2020-03 are not expected to have a significant effect on current accounting practices. The ASU improves various financial instrument topics in the Codification to increase stakeholder awareness of the amendments and to expedite the improvement process by making the Codification easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. The ASU is effective for fiscal years beginning after December 15, 2020 with early application 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. We did not have any contract assets or any contract liabilities as of September 30, 2020 and 2019.

The following table disaggregates our revenue by major source:

(In thousands)	Three-month period ended September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Revenues:				
Net product revenues:				
Ampyra	$ 27,343	$ 39,322	$ 73,546	$ 123,579
Inbrija	5,833	4,889	14,901	9,164
Other	1,511	589	1,706	582
Total net product revenues	34,687	44,800	90,153	133,325
Milestone revenues	15,000	—	15,000	—
Royalty revenues	3,403	2,922	9,654	8,586
Total net revenues	$ 53,090	$ 47,722	$ 114,807	$ 141,911

(4) Share-based Compensation

During the three-month periods ended September 30, 2020 and 2019, the Company recognized share-based compensation expense of $2.5 million and $3.3 million, respectively. During the nine-month periods ended September 30, 2020 and 2019, the Company recognized share-based compensation expense of $6.5 million and $11.5 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2020 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 September 30, 2020 and 2019 were approximately $0.39 and $2.69, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2020 and 2019 were approximately $0.66 and $6.49, respectively.

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

	For the three-month period ended September 30,		For the nine-month period ended September 30,	
(In thousands)	2020	2019	2020	2019
Research and development expense	$ 555	$ 719	$ 1,418	$ 2,203
Selling, general and administrative expense	1,832	2,424	4,834	8,785
Cost of Sales	93	149	260	505
Total	$ 2,480	$ 3,292	$ 6,512	$ 11,493

A summary of share-based compensation activity for the nine-month period ended September 30, 2020 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, 2020	10,469	$ 22.96		
Granted	237	1.00		
Cancelled	(2,339)	27.41		
Exercised	—	—		
Balance at September 30, 2020	8,366	$ 21.09	6.0	$ —
Vested and expected to vest at September 30, 2020	8,342	$ 21.14	6.0	$ —
Vested and exercisable at September 30, 2020	6,482	$ 25.72	4.7	$ —

Restricted Stock and Performance Stock Unit Activity

(In thousands) Restricted Stock and Performance Stock Units	Number of Shares
Nonvested at January 1, 2020	425
Granted	—
Vested	(4)
Forfeited	(60)
Nonvested at September 30, 2020	361

Unrecognized compensation cost for unvested stock options, restricted stock awards and performance stock units as of September 30, 2020 totaled $7.8 million and is expected to be recognized over a weighted average period of approximately 1.4 years.

During the three and nine-month periods ended September 30, 2020, the Company did not make any repurchases of shares.

(5) Income (Loss) Per Share

The following table sets forth the computation of basic and diluted loss per share for the three and nine-month periods ended September 30, 2020 and 2019:

(In thousands, except per share data)	Three-month period ended September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Basic and diluted				
Net income (loss)—basic	$ 7,347	$ (263,535)	$ (16,546)	$ (338,626)
Plus: Dilutive effect of convertible notes, net of tax	1,476	—	—	—
Net income (loss)—diluted	$ 8,823	$ (263,535)	$ (16,546)	$ (338,626)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	47,705	47,511	47,704	47,491
Plus: Dilutive effect of convertible notes	118,440	—	—	—
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	166,145	47,511	47,704	47,491
Net income (loss) per share—basic	$ 0.15	$ (5.55)	$ (0.35)	$ (7.13)
Net income (loss) per share—diluted	$ 0.05	$ (5.55)	$ (0.35)	$ (7.13)

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 September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Denominator				
Stock options and restricted common shares	8,784	8,988	8,532	8,968

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 and nine-month periods ended September 30, 2020 and 2019. Additionally, for the three and nine-month periods ended September 30, 2020, the impact of our outstanding convertible notes was determined to be dilutive and anti-dilutive, respectively. As a result, for the three-month period ended September 30, 2020 the Company adjusted the

numerator amount used in the calculation of net income per diluted share to add back the interest expense associated with convertible notes of $6.8 million, which is partially offset by the derivative liability gain of $4.9 million and $0.5 tax impact. Additionally, the 118,440 million common shares required to fully convert the outstanding convertible notes were included and excluded from the denominator in the calculation of net loss per diluted share under the if converted method for the three and nine-month periods ended September 30, 2020, respectively.

(6) Income Taxes

On March 27, 2020, the CARES Act was signed into law, which enacted several tax favorable, business-related provisions. The Company reviewed the enacted provisions to determine which provisions should be considered for the three-month period ended September 30, 2020. Under the new law, the CARES Act provides that NOLs arising in a taxable year beginning after December 31, 2017, and before January 1, 2021, can be carried back to each of the five taxable years preceding the taxable year of such loss. The Company has considered the impact to the tax provision for the carryback of net operating losses to prior periods of taxable income incurred within the period allowed under the CARES Act. The result of carrying back these losses allowed the Company to realize certain deferred tax assets and a corresponding release of the valuation allowance of approximately $1.8 million. In July 2020, the Company received an income tax refund of $12.7 million including interest from the Internal Revenue Service, related to the 2019 net operating loss carryback. The Company recorded a tax receivable of $1.4 million for the anticipated 2020 net operating loss carryback claim as of September 30, 2020.

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 forfeitures, offset by the benefit of net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

For the three-month periods ended September 30, 2020 and 2019, the Company recorded a provision of $(1.5) million and $(0.02) million for income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended September 30, 2020 and 2019 were 16.6% and 0%, respectively. The variances in the effective tax rates for the three-month period ended September 30, 2020 as compared to the three-month period ended September 30, 2019 was due primarily to the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, goodwill impairment for which no tax benefit can be recognized, and the benefit recorded on the net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

For the nine-month periods ended September 30, 2020 and 2019, the Company recorded a benefit of $5.0 million and $0.5 million for income taxes, respectively. The effective income tax rates for the Company for the nine-month periods ended September 30, 2020 and 2019 were 23.1% and 0.14%, respectively. The variance in effective tax rates for the nine-month period ended September 30, 2020 as compared to the nine-month period ended September 30, 2019 was due primarily to the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, goodwill impairment for which no tax benefit can be recognized, and the benefit recorded on the net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

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

The Company’s state examination by the state of Massachusetts for the tax periods 2016 and 2017 was completed during the period ended September 30, 2020. The Company was assessed a tax of approximately $0.2 million.

The Company has ongoing state examinations in New Jersey and Minnesota which cover a range of tax periods, 2015 – 2018. There have been no proposed adjustments at this stage of the examinations.

(7) Fair Value Measurements

The following table presents information about the Company’s assets and liabilities measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 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 2 assets consist of investments in corporate bonds and commercial paper which are categorized as short-term investments for investments with original maturities between three months and one year. The Company's Level 3 liabilities represent acquired contingent consideration related to the acquisition of Civitas which are valued using a probability weighted discounted cash flow valuation approach and derivative liabilities related to conversion options for the convertible senior notes due December 2024 which are valued using a binomial model. For assets and liabilities not accounted for at fair value, the carrying values of these accounts approximates their fair values at September 30, 2020, except for the fair value of the Company's convertible senior notes due June 2021, which was approximately $55.3 million and the fair value of the Company's convertible senior notes due December 2024, which was approximately $119.3 million as of September 30, 2020. 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
September 30, 2020			
Assets Carried at Fair Value:			
Money market funds	$ 31,283	$ —	$ —
Corporate bonds	—	5,347	—
Liabilities Carried at Fair Value:			
Derivative liability - conversion option	—	—	832
Acquired contingent consideration	—	—	46,100
December 31, 2019			
Assets Carried at Fair Value:			
Money market funds	$ 2,219	$ —	$ —
Commercial paper	—	26,569	—
Corporate bonds	—	37,185	—
Liabilities Carried at Fair Value:			
Derivative liability - conversion option	—	—	59,409
Acquired contingent consideration	—	—	80,300

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 September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Acquired contingent consideration:				
Balance, beginning of period	$ 70,000	$ 162,537	$ 80,300	$ 168,000
Fair value change to contingent consideration included in the statement of operations	(23,608)	(50,942)	(33,455)	(56,342)
Royalty payments	(292)	(395)	(745)	(458)
Balance, end of period	$ 46,100	$ 111,200	$ 46,100	$ 111,200

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach based on estimated future sales expected from Inbrija (levodopa inhalation powder), an FDA approved drug for the treatment of OFF periods in Parkinson's disease. Using this approach, expected probability adjusted 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, (ii) probabilities of success, and (iii) discount periods and rate. The milestone payments ranged from $1.0 million to $22.0 million for Inbrija. The estimated revenue forecast for Inbrija is based on peak annual sales of $300 to $500 million. The discount rate used in the valuation was 20.5% for the three and nine-month periods ended September 30, 2020. 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 and nine-month periods ended September 30, 2020 and 2019, changes in the fair value of the acquired contingent consideration were primarily due to updates to certain revenue and expense forecast assumptions. Additionally, for the nine-month periods ended September 30, 2020 and 2019, changes in the fair value of the acquired contingent consideration were partially offset by a reduction in the discount rate and a reduction in the forecast periods 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-Conversion Option

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

(In thousands)	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019
Derivative Liability-Conversion Option				
Balance, beginning of period	$ 23,953	$ 32,881	$ 59,409	$ —
Fair value recognized upon issuance of Convertible Senior Notes	—	—	—	59,409
Fair value adjustment	(4,864)	(8,928)	(26,528)	—
Fair value re-classification to shareholder's equity	(18,257)	—	—	—
Balance, end of period	$ 832	$ 23,953	$ 32,881	$ 59,409

During 2019, a derivative liability was initially recorded as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024 (see Note 10). The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) share price as of the valuation date, (2) assumed timing of conversion of the Notes, (3) historical volatility of 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 as of September 30, 2020 was determined using a binomial model that calculates the fair value of the Notes with the conversion feature as compared to the fair value of the Notes without the conversion feature, with the difference representing the value of the conversion feature, or the derivative liability. There are several embedded features within the Notes which, upon issuance, did not meet the conditions for equity classification. As a result, these features were aggregated together and recorded as a derivative liability conversion option. The derivative liability conversion feature is measured at fair value on a quarterly basis and changes in the fair value will be recorded in the consolidated statement of operations. The Company received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company's common stock from 80,000,000 shares to 370,000,000 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 valuation of these conversion options was based on key assumptions including the Company's stock price of $0.58, the historical volatility rate of 113.0%, and risk-adjusted discount rate of 25.0%. 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 fair value of the derivative liability related to certain embedded conversion features that are precluded from equity classification for the nine-month period ended September 30, 2020 were determined based on key assumption including the Company's

stock price of $0.52, the historical volatility rate of 115.0%, and the risk-adjusted discount rate of 25.3%. The fair value of this conversion feature was calculated to be $0.8 million.

(8) Investments

The Company has determined that all of its investments are classified as available-for-sale. Available-for-sale debt securities are carried at fair value with interest on these investments included in interest income and are recorded based on quoted market prices. Available-for-sale investments consisted of the following at September 30, 2020 and December 31, 2019, respectively:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
September 30, 2020				
Corporate Bonds	5,341	6	-	5,347
Total Short-term investments	$ 5,341	$ 6	$ -	$ 5,347
December 31, 2019				
Commercial Paper	$ 26,550	$ 19	$ —	$ 26,569
Corporate Bonds	37,177	20	(12)	37,185
Total Short-term investments	$ 63,727	$ 39	$ (12)	$ 63,754

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately $31.3 million and $2.2 million as of September 30, 2020 and December 31, 2019, respectively. Short-term investments have original maturities of greater than 3 months but less than 1 year and amounted to approximately $5.3 million and $63.8 million as of September 30, 2020 and December 31, 2019, respectively. The aggregate fair value of short-term investments in an unrealized loss position amounted to approximately $0 and $25.5 million as of September 30, 2020 and December 31, 2019, respectively. Short-term investments at September 30, 2020 primarily consisted of high-grade commercial paper and corporate bonds. Long-term investments have original maturities of greater than 1 year. There were no investments classified as long-term at September 30, 2020 or December 31, 2019. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of September 30, 2020 as the Company does not intend to sell its investments and it is not more likely than not that the Company will be required to sell its investments prior to the recovery of its amortized cost basis.

Unrealized holding gains and losses, which relate to debt instruments, are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding gains on available-for-sale investments during the nine-month period ended September 30, 2020, were as follows (in thousands):

(In thousands)	Net Unrealized Gains (Losses) on Marketable Securities
Balance at December 31, 2019	$ 27
Other comprehensive income before reclassifications:	
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive loss	(21)
Balance at September 30, 2020	$ 6

(9) Liability Related to Sale of Future Royalties

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP (“Royalty Agreement”). In exchange for the payment of $40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the License and Collaboration Agreement between the Company and

Biogen, up to an agreed upon threshold of royalties. When this threshold is met, if ever, the Fampyra royalties will revert back to the Company and the Company will continue to receive the Fampyra royalties from Biogen until the revenue stream ends. The transaction does not include potential future milestones to be paid.

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

The following table shows the activity within the liability account for September 30, 2020 and December 31, 2019, respectively:

(In thousands)	Nine-month period ended September 30, 2020	Twelve-month period ended December 31, 2019
Liability related to sale of future royalties - beginning balance	$ 24,401	$ 30,716
Deferred transaction costs recognized	318	639
Non-cash royalty revenue payable to HCRP	(8,496)	(10,271)
Non-cash interest expense recognized	1,548	3,317
Liability related to sale of future royalties - ending balance	$ 17,771	$ 24,401

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

The 2024 Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among the Company, its wholly owned subsidiary, Civitas Therapeutics, Inc. (along with any domestic subsidiaries acquired or formed after the date of issuance, the "Guarantors"), and Wilmington Trust, National Association, as trustee and collateral agent (the "Indenture"). The 2024 Notes are senior obligations of the Company and the Guarantors, secured by a first priority security interest in substantially all of the assets of the Company and the Guarantors, subject to certain exceptions described in the Security Agreement, dated as of December 23, 2019, between the grantors party thereto and Wilmington Trust, National Association, as collateral agent (the "Security Agreement").

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

The 2024 Notes will be convertible at the option of the holder into shares of common stock of the Company at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion rate for the 2024 Notes is 285.7142 shares of the Company's common stock per $1,000 principal amount of 2024 Notes, representing an initial conversion price of approximately $3.50 per share of common stock. The conversion rate is subject to adjustment in certain circumstances as described in the Indenture.

The Company may elect to settle conversions of the 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 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 Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

Subject to a number of exceptions and qualifications, the Indenture restricts the ability of the Company and certain of its subsidiaries to, among other things, (i) pay dividends or make other payments or distributions on their capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) make certain investments, (iii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, which includes, among other items, indebtedness incurred to refinance the 2021 Notes, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell of all or substantially all of their assets. The Indenture also requires the Company to make an offer to repurchase the 2024 Notes upon the occurrence of certain asset sales.

The Indenture provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the 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 Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the Indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by the Company to make required payments under other indebtedness of the Company or certain subsidiaries having an outstanding principal amount of $30.0 million or more, (vii) failure by the Company or certain subsidiaries to pay final judgments aggregating in excess of $30.0 million, (viii) certain events of bankruptcy or insolvency and (ix) the commercial launch in the United States of a product determined by the U.S. FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to the Company, all outstanding 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 2021 Notes received by the Company in the Exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, $69.0 million of the 2021 Notes remained outstanding.

The Company determined that the exchange of the 2021 Notes for 2024 Notes qualified for a debt extinguishment and recognized a gain on extinguishment of $55.1 million for the year ended December 31, 2019, representing the difference between the fair value of the liability component immediately before the exchange and the carrying value of the debt. The Company recorded an adjustment of $38.4 million to additional paid-in capital to adjust the equity component of 2021 Notes in connection with the extinguishment.

The Company assessed all terms and features of the 2024 Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the 2024 Notes, including the conversion, put and call features. The Company concluded the conversion feature required bifurcation as a derivative. The fair value of the conversion feature derivative was determined based on the difference between the fair value of the 2024 Notes with the conversion option and the fair value of the 2024 Notes without the conversion option 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 Notes on the closing date, or December 24, 2019. There are several embedded features within the Notes which, upon issuance, did not meet the conditions for equity classification. As a result, these features were aggregated together and recorded as the derivative liability conversion option. The conversion feature is measured at fair value on a quarterly basis and changes in the fair value of the conversion feature for the period will be recognized in the consolidated statements of operations. The Company performed a valuation of the derivative liability for the period ended September 30, 2020 and determined that the fair value of the derivative liability was $19.1 million representing a change of $4.9 million that is recognized in the consolidated statement of operations for the three-month period ended September 30, 2020.

The Company received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company's common stock from 80,000,000 shares to 370,000,000 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 for the period ended September 30, 2020 and determined the fair value 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 $0.8 million as of September 30, 2020.

The outstanding New Note balance as of September 30, 2020 and December 31, 2019 consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019
Liability component:		
Principal	207,000	$ 207,000
Less: debt discount and debt issuance costs, net	(72,378)	(80,028)
Net carrying amount	$ 134,622	$ 126,972
Equity component	$ 18,257	$ —
Derivative liability-conversion option	$ 832	$ 59,409

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 derivative conversion feature at issuance, is being amortized using the effective interest method through December 1, 2024. For the three and nine-month periods ended September 30, 2020, the Company recognized $6.0 million and $17.5 million, respectively, of interest expense related to the 2024 Notes at the effective interest rate of 18.1%. The fair value of the Company's 2024 Notes was approximately $119.3 million as of September 30, 2020.

In connection with the issuance of the 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 Notes for the three and nine-month periods ended September 30, 2020:

(In thousands)	Three-month period ended September 30, 2020	Nine-month period ended September 30, 2020
Contractual interest expense	$ 3,105	$ 9,315
Amortization of debt issuance costs	204	585
Amortization of debt discount	2,663	7,647
Total interest expense	$ 5,972	$ 17,547

Convertible Senior Notes Due 2021

On June 17, 2014, the Company issued $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the 2021 Notes) in an underwritten public offering. The net proceeds from the offering were $337.5 million after deducting the Underwriter's discount and offering expenses paid by the Company. On December 24, 2019, the Company completed the private exchange of $276.0 million aggregate principal amount of its outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the "2024 Notes") and cash. The 2021 Notes received by the Company in the exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the exchange, $69.0 million of the 2021 Notes remained outstanding.

The 2021 Notes are convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, under certain circumstances as outlined in the indenture, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per $1,000 principal amount of the 2021 Notes (representing an initial conversion price of approximately $42.56 per share).

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

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

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their 2021 Notes in principal amounts of $1,000 or an integral multiple thereof. The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2021 Notes by notice to the Company and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2021 Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the 2021 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2021 Notes.

The 2021 Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The 2021 Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

In accounting for the issuance of the 2021 Notes, the Company separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2021 Notes as a whole. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The outstanding note balance as of September 30, 2020 and December 31, 2019 consisted of the following:

(In thousands)	**September 30, 2020**	**December 31, 2019**
Liability component:		
Principal	69,000	$ 69,000
Less: debt discount and debt issuance costs, net	(1,581)	(3,198)
Net carrying amount	$ 67,419	$ 65,802
Equity component	$ 22,791	$ 22,791

In connection with the issuance of the 2021 Notes, the Company incurred approximately $7.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability

and equity components based on the allocation of the proceeds. Of the total $7.5 million of debt issuance costs, $1.3 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $6.2 million were allocated to the liability component and recorded as a reduction in the carrying amount of the debt liability on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the 2021 Notes using the effective interest method.

As of September 30, 2020, the remaining contractual life of the 2021 Notes is approximately 9 months. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through September 30, 2020. The fair value of the Company's 2021 Notes was approximately $55.3 million as of September 30, 2020.

The following table sets forth total interest expense recognized related to the 2021 Notes for the three and nine-month periods ended September 30, 2020 and 2019:

(In thousands)	Three-month period ended September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Contractual interest expense	$ 302	$ 1,509	$ 906	$ 4,528
Amortization of debt issuance costs	50	241	150	713
Amortization of debt discount	495	2,360	1,467	6,997
Total interest expense	$ 847	$ 4,110	$ 2,523	$ 12,238

(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 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.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred, if any. Our leases have remaining lease terms of 2 years to 7 years, some of which include options to extend the lease term for up to 15 years, and some of which include options to terminate the lease within 2 years.

Operating Leases

We lease certain office space, manufacturing and warehouse space under arrangements classified as leases under ASC 842. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for these leases on a straight-line basis over the lease term. Most leases include one or more options to renew, with renewal options ranging from 5 to 15 years. The exercise of lease renewal options is at our sole discretion. One of our leases also includes an option to early terminate the lease within 2 years.

Ardsley, New York

In June 2011, the Company entered into a 15-year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. In 2014, the Company exercised its option to expand into an additional 25,405 square feet of office space, which the Company occupied in January 2015. The Company has options to extend the term of the lease for three additional five-year periods, and the Company has an option to terminate the lease after 10 years subject to payment of an early termination fee. The Company's extension and early termination rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that the Company not be in default under the lease.

The Ardsley lease provides for monthly payments of rent during the lease term. These payments consist of base rent, which takes into account the costs of the facility improvements funded by the facility owner prior to the Company's occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges.

Chelsea, Massachusetts

Through our Civitas subsidiary, we lease a manufacturing facility in Chelsea, Massachusetts which we use to manufacture Inbrija. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas leases this facility from North River Everett Ave, LLC pursuant to a lease with a term that expires on December 31, 2025, and Civitas has two additional extension options of five years each.

In 2017, the Company's Civitas subsidiary amended its existing Chelsea, Massachusetts lease. The amendment added expansion property located in Chelsea, Massachusetts next to the existing facility. The additional property includes land being used for parking and a free-standing warehouse building on the same site.

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

Additional Facilities

In October 2016, we entered into a 10-year lease agreement with a term commencing January 1, 2017, for approximately 26,000 square feet of lab and office space in Waltham, MA. The lease provides for monthly rental payments over the lease term.

Our leases have remaining lease terms of 2 years to 7 years, which assumes exercise of the early termination of our Ardsley, NY lease. We do not include any renewal options in our lease terms when calculating our lease liabilities as we are not reasonably certain that we will exercise these options. When calculating the lease liability, we assume exercise of the Ardsley early termination option. The weighted-average remaining lease term for our operating leases was 3.9 years at September 30, 2020. The weighted-average discount rate was 7.14% at September 30, 2020.

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

(In thousands)	Balance Sheet Classification	September 30, 2020	September 30, 2019
Right-of-use assets	Right of use assets	$ 19,805	$ 24,675
Current lease liabilities	Current portion of lease liabilities	7,893	7,696
Non-current lease liabilities	Non-current portion of lease liabilities	18,747	24,393

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

(In thousands)	Three-month period ended September 30, 2020	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Operating lease cost	$ 1,775	$ 1,776	$ 5,572	$ 5,293
Variable lease cost	1,052	1,119	2,687	3,544
Short-term lease cost	443	440	1,248	1,094
Total lease cost	$ 3,270	$ 3,335	$ 9,507	$ 9,931

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

(In thousands)		
2020 (excluding the nine months ended September 30, 2020)	$	1,951
2021		7,944
2022		10,024
2023		3,097
2024		3,184
Later years		4,594
Total lease payments		30,794
Less: Imputed interest		(4,155)
Present value of lease liabilities	$	26,639

Supplemental cash flow information related to our operating leases are as follows:

(In thousands)	Nine-month period ended September 30, 2020	Nine-month period ended September 30, 2019
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	$ 5,818	$ 5,605
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 770

(12) Commitments and Contingencies

The Company has a dispute with another party which has asserted a claim related to royalties on sales of Ampyra (which lost exclusivity in July 2018). While the Company is unable to determine the ultimate outcome of the dispute, and believes it has valid defenses and intends to defend itself vigorously, the Company determined that it is probable that the Company may incur a liability related to the dispute which the Company estimated could be $2 million, inclusive of its legal costs. The Company recorded a liability of $2 million in the three-month period ended September 30, 2020 related to the dispute, however, the Company notes that depending upon the ultimate outcome of the dispute, the potential liability could be more or less than the amount recorded.

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

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.

Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 96% of commercial health insurance plan and approximately 25% of Medicare plan lives. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods. We project peak U.S. annual net revenue of Inbrija to be in the range of $300 to $500 million.

In September 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

We were previously engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, which was upheld on appeal in September 2018, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that have been marketed since we lost our appeal of the District Court decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

In 2019, we announced a corporate restructuring to reduce costs and focus our resources on the commercial launch of Inbrija, which is our key strategic priority for 2020. We are continuing our efforts to manage our cost structure, such as by identifying potential operating efficiencies and opportunities to convert fixed costs into variable costs. One of our key initiatives is to monetize the excess capacity of our Chelsea manufacturing facility, which we believe could offset expenses and reduce our cost of goods for Inbrija.

In December 2019, we announced the successful completion of a private exchange of $276 million of our convertible senior notes due in 2021 in exchange for a combination of approximately $207 million aggregate principal amount of newly-issued convertible senior secured notes due 2024 and $55.2 million in cash. The convertible senior secured notes have a conversion price of approximately $3.50 per share. As a result of the exchange, approximately $69 million of convertible senior notes due in 2021, with a conversion price of $42.56, remain outstanding. Addressing the remaining portion of the convertible notes due 2021 is a top priority in addition to our focus on the Inbrija launch. More information about the terms and conditions of the 2021 and 2024 convertible notes is set forth in Note 10 to our Consolidated Financial Statements in included in this report as well as in *Financing Arrangements* below.

On July 13, 2020, we received a U.S. income tax refund from the Internal Revenue Service of approximately $12.4 million plus interest of $0.3 million, pursuant to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). Under the CARES Act, among other things, net operating losses arising in a taxable year beginning after December 31, 2017, and before January 1, 2021, can be carried back to the preceding five years to apply against taxable income reported in such

years. Pursuant to this provision of the CARES Act, the Company was eligible to carry back 2019 net operating losses to tax years 2017 and 2018, resulting in the refund.

As of September 30, 2020, we had cash, cash equivalents, short-term investments and restricted cash of approximately $101.3 million. Restricted cash includes $37.3 million in escrow related to the 6% semi-annual interest portion of the convertible senior secured notes due 2024. As further described below under *Financing Arrangements*, if we are permitted under the notes indenture and we elect to pay interest due in stock, the cash equivalent will be released from escrow.

On October 30, 2020, we received a $15 million milestone payment from Biogen International GmbH under our license and collaboration with Biogen. Biogen markets Ampyra outside the U.S. as Fampyra. We became entitled to the milestone payment based on Biogen's ex-U.S. net sales of Fampyra exceeding $100 million over the four consecutive quarters ending with the third quarter of 2020. This payment was recorded as milestone revenue in the third quarter, but is not included in our third quarter-end cash balance because it was received in October 2020. We will retain approximately $14 million of the milestone payment net of our payment obligations to another party.

COVID-19 Pandemic

Our business and financial condition have been impacted by, and are subject to risks resulting from, the COVID-19 (novel coronavirus) pandemic. The COVID-19 pandemic has already caused significant disruptions in the healthcare industry. The duration of the pandemic is difficult to predict, and it is likely to have ongoing impacts as it continues. The travel restrictions, "shelter in place" orders, quarantine policies, and general concerns about the spread of COVID-19 have disrupted the delivery of healthcare to patients, for example making it more difficult for some patients to visit with their physician and obtain pharmaceutical prescriptions. Also, healthcare office staffing shortages may delay the administrative work, and particularly insurance-related documentation, needed to obtain reimbursement for prescriptions. We believe these factors contributed to decreases in new Inbrija prescriptions during 2020. For example, we experienced a decrease in new Inbrija prescriptions late in the first quarter and during part of the second quarter, followed by a period of new prescription growth through July, and then another period of decrease in August and September. We have seen a resumed upward trajectory in new prescriptions since late September, but the ongoing impact of the COVID-19 pandemic on prescriptions is uncertain.

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

Inbrija (levodopa inhalation powder)/Parkinson's Disease

Inbrija (levodopa inhalation powder) is the first and only inhaled levodopa, or L-dopa, for intermittent treatment of OFF episodes, also known as OFF periods, in people with Parkinson's disease treated with carbidopa/levodopa regimen. Our New Drug Application, or NDA, for Inbrija was approved by the U.S. Food and Drug Administration, or FDA, on December 21, 2018. The approval is for a single dose of 84 mg (administered as two capsules), which may be taken up to five times per day. Inbrija became commercially available in the U.S. on February 28, 2019. Currently, Inbrija is available in the U.S. without the need for a medical exception for approximately 96% of commercial health insurance plan and approximately 25% of Medicare plan lives. Net revenue for Inbrija was $5.8 million for the quarter ended September 30, 2020 and $4.9 million for the quarter ended September 30, 2019. We project peak U.S. annual net revenue of Inbrija to be in the range of $300 to $500 million.

In September 2019, we announced that the European Commission, or EC, approved our Marketing Authorization Application, or MAA, for Inbrija. The approved dose is 66 mg (administered as two capsules) up to five times per day (per European Union, or EU, convention, this reflects emitted dose and is equivalent to the 84 mg labelled dose in the U.S.). Under the MAA, Inbrija is indicated in the EU for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor. The MAA approved Inbrija for

use in what were then the 27 countries of the EU, as well as Iceland, Norway and Liechtenstein. Following the ratification of the Withdrawal Agreement between the United Kingdom and the EU, the UK left the EU on January 31, 2020. However, this EU marketing authorization remains valid in the UK during a transitional period that will end on December 31, 2020. After that date, we expect that EU law will cease to apply in and to the UK. The EU and the UK are currently negotiating a trade agreement, which would govern their future relationship after the end of the transitional period. It is currently unclear whether the parties can reach an agreement before December 31, 2020 and whether that agreement would also cover the regulation of medicinal products. Separately, the UK has indicated that it intends to convert all valid EU marketing authorizations automatically into national marketing authorizations, unless the marketing authorization holder objects. We are in discussions with potential partners regarding the distribution of Inbrija outside of the U.S., with potential partners in Europe and Japan.

Inbrija is marketed in the U.S. through our own specialty sales force and commercial infrastructure, and is distributed in the U.S. primarily through a network of specialty pharmacies, which deliver the medication to patients by mail, and ASD Specialty Healthcare, Inc. (an AmeriSource Bergen affiliate). We are in the process of transitioning from the network of several specialty pharmacies to a single specialty pharmacy for U.S. sales of Inbrija, which we believe has potential benefits to patients and our business. Our neuro-specialty sales and marketing team includes our own sales representatives as well as established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Market Access Account Directors who provide information to payers and physicians on our marketed products; and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives. Our sales representatives, which we are supplementing with contract sales representatives, are targeting approximately 5,000 healthcare providers, currently focusing on a priority list of approximately 2,000 physicians who are high volume prescribers of levodopa/carbidopa. Our Inbrija launch activities were initially focused on physician awareness and market access. We are maintaining these efforts while increasing focus on patient awareness, education and training.

We have established Prescription Support Services for Inbrija, which we sometimes refer to as the Inbrija hub. Prescription Support Services is designed to help patients navigate their insurance coverage and offer reimbursement support services, when appropriate. Services fall into one of these four categories: insurance verification, to research patient insurance benefits and confirm insurance coverage; prior authorization support, to identify prior authorization requirements; appeals support; and assistance identifying which specialty pharmacy a patient will utilize based on their insurance coverage. For patients that may need assistance paying for their medication, Prescription Support Services offers several support options, including: a program that provides no cost medication to patients who meet specific program eligibility requirements; co-pay support, which may help commercially insured (non-government funded) patients lower their out-of-pocket costs; and a bridge program, for federally-insured patients who experience a delay in coverage determination. We have implemented a no-cost sample program, available at physician offices, to enable patients and their physicians to assess the value of Inbrija before the patient incurs out-of-pocket co-pay or co-insurance costs. In addition, we have implemented a free trial program, available through the Inbrija hub, for commercially insured patients who cannot access the free samples because of offices and institutions that have policies that prohibit samples.

Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. The standard baseline treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects. As Parkinson's progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson's symptoms that result from low levels of dopamine between doses of oral carbidopa/levodopa. OFF periods are often highly disruptive to people with Parkinson's. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40% of people with Parkinson's in the U.S. experience OFF periods.

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

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

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

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

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

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

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

Ampyra

Ampyra was approved by the FDA in January 2010 to improve walking in adults with multiple sclerosis. To our knowledge, Ampyra is the first drug approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Net revenue for Ampyra was $27.3 million for the quarter ended September 30, 2020 and $39.3 million for the quarter ended September 30, 2019.

We were previously engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, which was upheld on appeal in September 2018, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that have been marketed since we lost our appeal of the District Court decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH, or Biogen, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on net sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. In October 2020, we received a $15 million milestone payment from Biogen based on ex-U.S. net sales exceeding $100 million over the four consecutive quarters ending with the third quarter of 2020. This payment was recorded as milestone revenue in the third quarter, but is not included in our third quarter-end cash balance because it was received in October 2020. We will retain approximately $14 million of the milestone payment net of our payment obligations to another party. In November 2017, we announced a $40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. Until this threshold is met, if ever, we will not receive Fampyra royalties although we retained the right to receive any potential future milestone payments, including the milestone payment described above. The HCRP

transaction is accounted for as a liability, as described in Note 9 to our Consolidated Financial Statements included in this report.

Ampyra Patent Update

Six issued Ampyra patents have been listed in the Orange Book. The five initial Orange Book-listed patents have been the subject of litigation with certain generic drug manufacturers, as described above. In connection with the litigation, our Orange Book-listed patent that expired on July 30, 2018, was upheld, but four other Ampyra patents set to expire between 2025 and 2027 were invalidated. At our request, these four patents have been delisted from the Orange Book. The sixth Orange Book-listed patent (U.S. Patent No. 9,918,973), set to expire in 2024, was more recently issued and was not involved in the litigation. At our request, this patent has also been delisted from the Orange Book. We note that this patent did not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that were involved in the patent litigation described in this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmBH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmBH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmBH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. In February 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We appealed the decision. In the Appeal Hearings in September 2019, the European Technical Board of Appeals upheld claims covering Fampyra in both the EP 1732548 patent and the EP 2377536 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. In June 2019, the EPO granted EP 2460521, which is a divisional of the EP 2377536 patent. In November 2019, we filed a request withdrawing our approval of the text on which EP 2460521 was granted, resulting in termination of the patent. Nullity actions have been filed in Germany against both of the German national patents derived from EP 1732548 and EP 2377536 by ratiopharm GmbH, a generic manufacturer affiliated with Teva. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

ARCUS Product Development

We have been exploring opportunities for other proprietary products in which inhaled delivery of medicine using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients. We believe there are potential opportunities with central nervous system, or CNS, as well as non-CNS, disorders.

Our ARCUS development has been focused on a program for acute treatment of migraine. Existing oral therapies for migraine can be associated with slow onset of action and gastrointestinal challenges. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. We have been evaluating therapeutic candidates for their suitability to move forward with this program. Due to the restructuring described above and associated cost-cutting measures, we have deferred consideration of further investment into potential new ARCUS applications in migraine pending additional progress with the Inbrija commercial launch in the U.S.

In July 2015, the Bill & Melinda Gates Foundation awarded us a grant to support the development of a formulation and delivery system for a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome, or nRDS. In collaboration with the Massachusetts Institute of Technology, we developed a formulation and delivery device based on our proprietary ARCUS drug delivery technology. nRDS is a condition affecting prematurely born infants in which their lungs are underdeveloped and thus lack a sufficient amount of lung surfactant. It can be fatal, or lead to severe, chronic health issues caused by a lack of oxygen getting to the baby's brain and other organs. Delivering liquid surfactant to the lungs via intubation is the standard of care. We believe that our formulation and delivery system may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. Based on recent achievement of pre-clinical proof of concept, the foundation has expanded the funding to include pre-IND development, including an additional grant of approximately $2.08 million in 2020 to continue this work. This program is not aimed at developing a commercial product, but our work on this program (funding for which has not been impacted by the

restructuring) could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

Other Research and Development Programs

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

Financial Guidance for 2020

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

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

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

Results of Operations

Three-Month Period Ended September 30, 2020 Compared to September 30, 2019

Net Product Revenues

Inbrija

We recognize product sales of Inbrija following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Inbrija of $5.8 million and $4.9 million for the three-month periods ended September 30, 2020 and 2019, respectively, an increase of $0.9 million or 18.4%. The net revenue increase is due primarily to an increase in sales activity in the three-month period ended September 30, 2020 of $1.4 million compared to the three-month period ended September 30, 2019, partially offset by discount and allowance adjustments of $0.5 million.

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers. We recognized net revenue from the sale of Ampyra of $27.3 million and $39.3 million for the three-month periods ended September 30, 2020 and 2019, respectively, a decrease of $12.0 million, or 30.5%. The net revenue decrease is due primarily to a decrease in net volume of $15.3 million, partially offset by net price increase and discount and allowance adjustments of $4.8 million. Net revenue from sales of Ampyra decreased for the three-month period ended September 30, 2020 compared to the three-month period ended September 30, 2019 due to the entry of generic versions of Ampyra as a result of the invalidation of certain of our Ampyra patents in 2017.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, returns and discounts. Discounts and allowances are recorded following shipment of our products to our customers. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

Other Product Revenues

We recognized net revenue from the sale of other products of $1.5 million for the three-month period ended September 30, 2020 as compared to $0.6 million for the three-month period ended September 30, 2019, an increase of $0.9 million, or 150%.

Milestone Revenue

We recognized $15 million and $0 million in milestone revenue for the three-month periods ended September 30, 2020 and 2019, respectively. The increase is due to the $15 million milestone payment earned in the three-month period ended September 30, 2020 and received from Biogen in October 2020 based on ex-U.S. Fampyra net sales exceeding $100 million over a period of four consecutive quarters ending with the third quarter of 2020. We will retain approximately $14 million of the milestone payment net of our payment obligations to another party.

Royalty Revenue

We recognized $3.4 million and $2.9 million in royalty revenue for the three-month periods ended September 30, 2020 and 2019, respectively, an increase of $0.5 million, or 17.2%.

Cost of Sales

We recorded cost of sales of $12.2 million for the three-month period ended September 30, 2020 as compared to $8.0 million for the three-month period ended September 30, 2019. Cost of sales for the three-month period ended September 30, 2020 consisted primarily of $8.8 million in inventory costs related to recognized revenues and $3.3 million in royalty fees based on net product shipments. Cost of sales for the three-month period ended September 30, 2019 consisted primarily of $7.2 million in inventory costs related to recognized revenues and $0.2 million in royalty fees based on net product shipments and $0.5 million for costs related to sales of the authorized generic version of Ampyra. Cost of sales for inventory manufactured pre-launch for Inbrija was not recorded for the three-month period ended September 30, 2019, since the inventory manufactured prior to the FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses in 2018.

Amortization of intangibles

We recorded amortization of intangible asset related to Inbrija of $7.7 million for the three-month periods ended September 30, 2020 and 2019.

Research and Development

Research and development expenses for the three-month period ended September 30, 2020 were $5.7 million as compared to $16.1 million for the three-month period ended September 30, 2019, a decrease of approximately $10.4 million, or 64.6%. The decrease was due primarily to reductions in Civitas spending of $7.2 million due to the commercialization of Inbrija in the first quarter of 2019, decreased spending on supply chain expansion, reductions in Ardsley spending of $3.1 million due to a continuing shift away from development activities related to earlier stage programs due to the Company's focus on the Inbrija launch, partially offset by a reduction of $0.1 million in third party credits received related to program cancellations for Biotie that were recognized in the prior year.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2020 were $21.9 million compared to $27.5 million for the three-month period ended September 30, 2019, a decrease of approximately $5.6 million, or 20.4%. The decrease was primarily due to a decrease in Inbrija spending of $0.6 million, a decrease in overall salaries and benefit costs of $3.1 million, and a decrease in Ampyra marketing related spending of $1.9 million.

General and administrative expenses for the three-month period ended September 30, 2020 were $18.1 million compared to $21.2 million for the three-month period ended September 30, 2019, a decrease of approximately $3.1 million, or 14.6%. The decrease was primarily due to a decrease in overall salaries and benefit costs of $2.2 million and a decrease in Civitas launch spending of $0.5 million, partially offset by an increase in other departmental spending of $0.3 million.

Goodwill Impairment

We recognized a goodwill impairment charge of $277.6 million in the three-month period ended September 30, 2019. During the third quarter of 2019, we experienced a significant decline in our stock price that reduced the market capitalization below the carrying value of the Company. We performed a quantitative assessment and after completing the assessment during the third quarter of 2019, we concluded that the carrying value of the Company exceeded its estimated fair value as of September 30, 2019 and therefore, the goodwill was fully impaired.

Change in Fair Value of Derivative Liability

A derivative liability was recorded in December 2019 as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024. The derivative liability is measured at fair value on a quarterly basis and changes in the fair value are recorded in the consolidated statement of operations. We recorded income of $4.9 million due to the change in the fair value of the derivative liability for the three-month period ended September 30, 2020.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Inbrija. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of those future royalties is assessed quarterly. We recorded income pertaining to changes in the fair-value of acquired contingent consideration of $23.6 million for the three-month period ended September 30, 2020 as compared to $50.9 million for the three-month period ended September 30, 2019. The changes in the fair-value of the acquired contingent consideration were primarily due to updates to certain product revenue and expense forecast assumptions, partially offset by a reduction in the discount rate and a reduction in the forecast periods for the passage of time.

Other Expense, Net

Other expense, net was $7.2 million and $4.2 million for the three-month periods ended September 30, 2020 and 2019, respectively.

Provision for Income Taxes

On March 27, 2020, the CARES Act was signed into law, which enacted several tax favorable, business-related provisions. The Company reviewed the enacted provisions to determine which provisions should be considered for the three-month period ended September 30, 2020. Under the new law, the CARES Act provides that NOLs arising in a taxable year beginning after December 31, 2017, and before January 1, 2021, can be carried back to each of the five taxable years preceding the taxable year of such loss. The Company has considered the impact to the tax provision for the carryback of net operating losses to prior periods of taxable income incurred within the period allowed under the CARES Act. The result of carrying back these losses allowed the Company to realize certain deferred tax assets and a corresponding release of the valuation allowance of approximately $1.8 million. The Company received in July 2020, its U.S. income tax refund from the Internal Revenue Service of $12.7 million including interest, related to the 2019 net operating loss carryback. The Company recorded a tax receivable of $1.4 million for the anticipated 2020 net operating loss carryback claim as of September 30, 2020.

For the three-month periods ended September 30, 2020 and 2019, the Company recorded a provision of ($1.5) million and ($0.02) million for income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended September 30, 2020 and 2019 were 16.6% and 0%, respectively.

The variance in the effective tax rates for the three-month period ended September 30, 2020 as compared to the three-month period ended September 30, 2019 was due primarily to the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, goodwill impairment for which no tax benefit can be recognized, and the benefit recorded on the net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

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

The Company’s state examination by the state of Massachusetts for the tax periods 2016 and 2017 was completed during the period ended September 30, 2020. The Company was assessed a tax of approximately $0.2 million.

Nine-Month Period Ended September 30, 2020 Compared to September 30, 2019

Net Product Revenues

Inbrija

We recognize product sales of Inbrija following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Inbrija of $14.9 million and $9.2 million for the nine-month periods ended September 30, 2020 and September 30, 2019, respectively, an increase of $5.7 million, or 62.0%. The net revenue increase was due primarily to increased sales activity of $9.7 million, partially offset by discount and allowance adjustments of $4.0 million.

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers. We recognized net revenue from the sale of Ampyra of $73.5 million and $123.6 million for the nine-month periods ended September 30, 2020 and 2019, respectively, a decrease of $50.1 million, or 40.5%. The net revenue decrease is due primarily to decreased net volume of $63.2 million partially offset by discount and allowance adjustments of $13.7 million. Net revenue from sales of Ampyra decreased for the nine-month period ended September 30, 2020 compared to the nine-month period ended September 30, 2019 due to the entry of generic versions of Ampyra as a result of the invalidation of certain of our Ampyra patents in 2017.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, returns and discounts. Discounts and allowances are recorded following shipment of our products Inbrija and Ampyra to our customers. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

Other Product Revenues

We recognized net revenue from the sale of other products of $1.7 million for the nine-month period ended September 30, 2020 as compared to $0.6 million for the nine-month period ended September 30, 2019.

Milestone Revenue

We recognized $15 million and $0 million in milestone revenue for the nine-month periods ended September 30, 2020 and 2019, respectively. The increase is due to the $15 million milestone payment earned in the three-month period ended September 30, 2020 and received from Biogen in October 2020 based on ex-U.S. Fampyra net sales exceeding $100 million over a period of four consecutive quarters ending with the third quarter of 2020. We will retain approximately $14 million of the milestone payment net of our payment obligations to another party.

Royalty Revenue

We recognized $9.7 million and $8.6 million in royalty revenue for the nine-month periods ended September 30, 2020 and 2019, respectively, an increase of $1.1 million, or 12.8%.

Cost of Sales

We recorded cost of sales of $22.7 million for the nine-month period ended September 30, 2020 as compared to $26.2 million for the nine-month period ended September 30, 2019. Cost of sales for the nine-month period ended September 30, 2020 consisted primarily of $18.6 million in inventory costs related to recognized revenues and $3.8 million in royalty fees based on net product shipments. Cost of sales for the nine-month period ended September 30, 2019 consisted primarily of $24.9 million in inventory costs related to recognized revenues, $0.7 million in royalty fees based on net product shipments and $0.5 million for costs related to sales of the authorized generic version of Ampyra. Cost of sales for inventory manufactured pre-launch for Inbrija was not recorded for the nine-month period ended September 30, 2019, since the inventory manufactured prior to the FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses in 2018.

Amortization of intangibles

We recorded amortization of intangible asset related to Inbrija of $23.1 million for the nine-month period ended September 30, 2020 as compared to $17.9 million related to Ampyra for the nine-month period ended September 30, 2019.

Research and Development

Research and development expenses for the nine-month period ended September 30, 2020 were $18.7 million as compared to $51.1 million for the nine-month period ended September 30, 2019, a decrease of approximately $32.4 million, or 63.4%. The decrease was due primarily to reductions in Civitas spending of $23.8 million due to the commercialization of Inbrija in the first quarter of 2019, decreased spending on supply chain expansion, reductions in Ardsley spending of $8.9 million due to a continuing shift away from development activities related to earlier stage programs due to the Company's focus on the Inbrija launch, partially offset by a reduction of $0.3 million in third party credits received related to program cancellations for Biotie that were recognized in the prior year.

Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2020 were $65.2 million compared to $86.3 million for the nine-month period ended September 30, 2019, a decrease of approximately $21.1 million, or 24.4%. The decrease was attributable primarily to a decrease in overall salaries and benefits of $10.6 million, a decrease in spending related to marketing for Ampyra of $6.6 million, and a decrease in Inbrija spending of $3.9 million.

General and administrative expenses for the nine-month period ended September 30, 2020 were $54.5 million compared to $65.3 million for the nine-month period ended September 30, 2019, a decrease of approximately $10.8 million, or 16.5%. The decrease was primarily due to a reduction in salaries and benefits related costs of $8.0 million, decreased spending related to launch activities of $1.7 million, and a decrease in other departmental spending of $0.9 million.

Change in Fair Value of Derivative Liability

A derivative liability was recorded in December 2019 as a result of the issuance of the 6.00% Convertible Senior Secured Notes due 2024. The derivative liability is measured at fair value on a quarterly basis and changes in the fair value are recorded in the consolidated statement of operations. We recorded income of $40.3 million due to the change in the fair value of the derivative liability for the nine-month period ended September 30, 2020.

Goodwill Impairment

We recognized a goodwill impairment charge of $277.6 million in the nine-month period ended September 30, 2019. During the third quarter of 2019, we experienced a significant decline in our stock price that reduced the market capitalization below the carrying value of the Company. We performed a quantitative assessment and after completing the assessment during the third quarter of 2019, we concluded that the carrying value of the Company exceeded its estimated fair value as of September 30, 2019 and therefore, the goodwill was fully impaired.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Inbrija. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded an income pertaining to changes in the fair-value of acquired contingent consideration of $33.5 million for the nine-month period ended September 30, 2020 as compared to $56.3 million for the nine-month period ended September 30, 2019. The changes in the fair-value of the acquired contingent consideration were primarily due to updates to certain product revenue and expense forecast assumptions, partially offset by a reduction in the discount rate and a reduction in the forecast periods for the passage of time.

Other Expense, Net

Other expense, net was $21.8 million for the nine-month period ended September 30, 2020 as compared to $13.0 million for the nine-month period ended September 30, 2019. The change was due primarily to an increase in amortization of debt discount expense of $6.5 million and a reduction in interest income of $2.5 million, partially offset by a gain on disposal of property and equipment of $0.2.

Benefit from Income Taxes

For the nine-month periods ended September 30, 2020 and 2019, the Company recorded a benefit of $5.0 million and a benefit of $0.5 million for income taxes, respectively. The effective income tax rates for the Company for the nine-month periods ended September 30, 2020 and 2019 were 23.1% and 0.14%, respectively. The variance in the effective tax rates for the nine-month period ended September 30, 2020 as compared to the nine-month period ended September 30, 2019 was due primarily to the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, goodwill impairment for which no tax benefit can be recognized, and the benefit recorded on the net operating loss carryback under the CARES act recorded at 21% to recover taxes paid at the previous statutory rate of 35%.

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

The Company's state examination by the state of Massachusetts for tax periods 2016 and 2017 was completed during the period ended September 30, 2020. The Company was assessed a tax of approximately $0.2 million.

Liquidity and Capital Resources

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

At September 30, 2020, we had $63.3 million of cash, cash equivalents and short-term investments, compared to $125.8 million at December 31, 2019. Our September 30, 2020 cash, cash equivalents and short-term investments balance does not include restricted cash, currently held in escrow under the terms of our convertible senior secured notes due 2024, further described below under *Financing Arrangements*, which may potentially be released from escrow if we pay interest on those notes using shares of our common stock. In addition, we have incurred net losses of $16.5 million and $273.0 million for the nine months ended September 30, 2020 and the year ended December 31, 2019, respectively.

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

- the amount of revenue generated from sales of Inbrija and Ampyra;
- our ability to manage operating expenses;
- the amount and timing of purchase price, milestone or other payments that we may owe or have a right to receive under collaboration, license, asset sale, acquisition, or other agreements or transactions; and the extent to which the terms and conditions of our convertible senior secured notes due 2024 restrict or direct our use of proceeds from such transactions;
- our ability to make required payments relating to our 2024 Notes, as defined below under *Financing Arrangements*, using shares of our common stock rather than cash;
- whether and the extent to which we can refinance our remaining 2021 Notes, as defined below under *Financing Arrangements*, with later-maturing debt, the terms and conditions of any new debt that we issue, and the extent to which we make any cash payments in connection with such a transaction;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights; and
- capital required or used for future acquisitions, 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.

Based on our cash, cash equivalents and short-term investments at September 30, 2020, our recent net losses, and our obligations that are due within the next 12 months, including $69.0 million aggregate principal amount of our 2021 Notes that mature on June 15, 2021, our management has concluded that there is substantial doubt regarding our ability to meet our obligations within one year after the date the consolidated financial statements in this report are issued and, therefore, to continue as a going concern.

Our ability to meet our future operating requirements, repay our liabilities, 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.

Due to these uncertainties, there is substantial doubt about the Company's ability to continue as going concern. These unaudited condensed consolidated financial statements and accompanying notes have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Financing Arrangements

Convertible Senior Secured Notes Due 2024

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

The 2024 Notes were issued pursuant to an Indenture, dated as of December 23, 2019, among the Company, its wholly owned subsidiary, Civitas Therapeutics, Inc. (along with any domestic subsidiaries acquired or formed after the date of issuance, the "Guarantors"), and Wilmington Trust, National Association, as trustee and collateral agent (the "Indenture"). The 2024 Notes are senior obligations of the Company and the Guarantors, secured by a first priority security interest in substantially all of the assets of the Company and the Guarantors, subject to certain exceptions described in the Security Agreement, dated as of December 23, 2019, between the grantors party thereto and Wilmington Trust, National Association, as collateral agent (the "Security Agreement").

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

The 2024 Notes will be convertible at the option of the holder into shares of common stock of the Company at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion rate for the 2024 Notes is 285.7142 shares of the Company's common stock per $1,000 principal amount of 2024 Notes, representing an initial conversion price of approximately $3.50 per share of common stock. The conversion rate is subject to adjustment in certain circumstances as described in the Indenture.

The Company may elect to settle conversions of the 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 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 Indenture) occurs, in each case, at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

Subject to a number of exceptions and qualifications, the Indenture restricts the ability of the Company and certain of its subsidiaries to, among other things, (i) pay dividends or make other payments or distributions on their capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) make certain investments, (iii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, which includes, among other items, indebtedness incurred to refinance the 2021 Notes, (iv) create liens on their assets, (v) sell their assets, (vi) enter into certain transactions with affiliates or (vii) merge, consolidate or sell of all or substantially all of their assets. The Indenture also requires the Company to make an offer to repurchase the 2024 Notes upon the occurrence of certain asset sales.

The Indenture provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest for 30 days, (ii) failure to pay the 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 Indenture and the failure continues for five business days, (iv) not issuing certain notices required by the Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the Indenture for 60 days following the receipt of a notice of non-compliance, (vi) a default or other failure by the Company to make required payments under other indebtedness of the Company or certain subsidiaries having an outstanding principal amount of $30.0 million or more, (vii) failure by the Company or certain subsidiaries to pay final judgments aggregating in excess of $30.0 million, (viii) certain events of bankruptcy or insolvency and (ix) the commercial launch in the United States of a product determined by the U.S. FDA to be bioequivalent to Inbrija. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to the Company, all outstanding 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 2021 Notes received by the Company in the Exchange have been cancelled in accordance with their terms. Accordingly, upon completion of the Exchange, $69.0 million of the 2021 Notes remained outstanding.

The Company assessed all terms and features of the 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 feature required bifurcation as a derivative. The fair value of the conversion feature derivative was determined based on the difference between the fair value of the 2024 Notes with the conversion option and the fair value of the 2024 Notes without the conversion option 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 and the offsetting amount as a debt discount as a reduction to the carrying value of the Notes on the closing date, or December 24, 2019. There are several embedded features within the Notes which, upon issuance, did not meet the conditions for equity classification. The conversion feature is measured at fair value on a quarterly basis and changes in the fair value of the conversion feature for the period will be recognized in the consolidated statements of operations. The Company performed a valuation of the derivative liability for the period ended September 30, 2020 and determined that the fair value of the derivative liability was $19.1 million representing a change of $40.3 million that is recognized in the consolidated statement of operations for the nine-month period ended September 30, 2020.

The Company received stockholder approval on August 28, 2020 to increase the number of authorized shares of the Company’s common stock from 80,000,000 shares to 370,000,000 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 for the period ended September 30, 2020 and determined the fair value 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 $0.8 million as of September 30, 2020.

The outstanding 2024 Note balance as of September 30, 2020 consisted of the following:

(In thousands)	September 30, 2020
Liability component:	
Principal	$ 207,000
Less: debt discount and debt issuance costs, net	(72,378)
Net carrying amount	$ 134,622
Equity component	$ 18,257

Convertible Senior Notes Due 2021

In June 2014, the Company entered into an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC (the "Underwriter") relating to the issuance by the Company of $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the "2021 Notes") in an underwritten public offering pursuant to the Company's Registration Statement on Form S-3 (the "Registration Statement") and a related preliminary and final prospectus supplement, filed with the SEC (the "Offering"). The principal amount of the 2021 Notes included $45 million aggregate principal amount of an underwriter option, which was exercised in full. The net proceeds from the offering, after deducting the Underwriter's discount and the offering expenses paid by the Company, were approximately $337.5 million. On December 24, 2019, the Company completed the private exchange of $276.0 million aggregate principal amount of its outstanding 2021 Notes for a combination of newly-issued 6.00% Convertible Senior Secured Notes due 2024 (the "2024 Notes") and cash. The 2021 Notes received by the Company in the exchange have been cancelled in accordance with their terms. As a result, upon completion of the exchange, $69.0 million of the 2021 Notes remained outstanding.

The 2021 Notes are governed by the terms of an indenture, dated as of June 23, 2014 (the "Base Indenture") and the first supplemental indenture, dated as of June 23, 2014 (the "Supplemental Indenture," and together with the Base Indenture, the "Indenture"), each between the Company and Wilmington Trust, National Association, as trustee (the "Trustee"). The 2021 Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per $1,000 principal amount of 2021 Notes (representing an initial conversion price of approximately $42.56 per share), only in the following circumstances and to the following extent: (1) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of 2021 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (2) during any calendar quarter commencing after the calendar quarter ending on September 30, 2014 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (3) if the Company calls any or all of the 2021 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; (4) upon the occurrence of specified events described in the Indenture; and (5) at any time on or after December 15, 2020 through the second scheduled trading day immediately preceding the maturity date.

The Company may redeem for cash all or part of the 2021 Notes, at the Company's option, after June 20, 2017 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending within five trading days prior to the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2021 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

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

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their 2021 Notes in principal amounts of $1,000 or an integral multiple thereof. The fundamental change repurchase price will be equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its 2021 Notes in connection with

such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2021 Notes by notice to the Company and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2021 Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the 2021 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2021 Notes.

The 2021 Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The 2021 Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

In accounting for the issuance of the 2021 Notes, the Company separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2021 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the seven-year term of the 2021 Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

Our outstanding 2021 Note balances as of September 30, 2020 consisted of the following:

(In thousands)	September 30, 2020
Liability component:	
Principal	$ 69,000
Less: debt discount and debt issuance costs, net	(1,581)
Net carrying amount	$ 67,419
Equity component	$ 22,791

Non-Convertible Capital Loans

Non-convertible capital loans were granted by Business Finland (formerly Tekes), with an adjusted acquisition-date fair value of $20.5 million (€18.2 million) and a carrying value of $27.0 million as of September 30, 2020. The loans are composed of fourteen non-convertible loans. The loans bear interest based on the greater of 3% or the base rate set by Finland's Ministry of Finance minus one (1) percentage point. The maturity dates for these loans range from eight to ten years from the date of issuance, however, according to certain terms and conditions of the loans, the Company may repay the principal and accrued and unpaid interest of the loans only when the consolidated retained earnings of Biotie is sufficient to fully repay the loans.

Research and Development Loans

Research and Development Loans ("R&D Loans") were granted by Business Finland with an acquisition-date fair value of $2.9 million (€2.6 million) and a carrying value of $0.6 million as of September 30, 2020. The R&D Loans bear interest based on the greater of 1% or the base rate set by Finland's Ministry of Finance minus three (3) percentage points. The repayment of these loans began in January 2017. The loan principal is paid in equal annual installments over a 5 year period, ending January 2021.

Cash, Cash Equivalents and Investments

At September 30, 2020, cash, cash equivalents and short-term investments were approximately $63.3 million, as compared to $125.8 million at December 31, 2019. Our cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of investments in a Treasury money market fund. Our short term investments consist of high-grade corporate debt securities, commercial paper and U.S. government securities with original maturities of twelve months or less at date of purchase. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. Our September 30, 2020 cash, cash equivalents and short-term investments balance does not include restricted cash, currently held in escrow under the terms of our convertible senior secured notes due 2024, further described above under *Financing Arrangements*, which may potentially be released from escrow if we pay interest on those notes using shares of our common stock.

Net Cash Used in Operations

Net cash used in operations was $62.5 million for the nine-month period ending September 30, 2020. Cash used by operations for the nine-month period ended September 30, 2020 was primarily due to net loss of $16.5 million, a change in the derivative liability of $40.3 million, an increase in prepaid expenses and other assets of $16.7 million, a decrease in accounts payable, accrued expenses and other current liabilities of $13.4 million, a change in acquired contingent consideration liability of $33.5 million and non-cash royalty revenue of $8.5 million. This was partially offset by depreciation and amortization of $30.9 million, a decrease in accounts receivable of $8.7 million, a deferred tax provision of $8.8 million, amortization of debt discount and debt issuance costs of $12.2 million, and share based compensation expense of $6.5 million.

Net Cash Provided by Investing

Net cash provided by investing activities for the nine-month period ended September 30, 2020 was $54.3 million, which was due primarily to proceeds from maturity of investments of $58.4 million, partially offset by purchases of property and equipment of $4.1 million.

Net Cash Used in Financing

Net cash used in financing activities for the nine-month period ended September 30, 2020 was $1.7 million, which was primarily due to the repayment of loans payable of $0.6 million and debt issuance costs of $1.1 million.

Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our material outstanding contractual commitments is included in Note 14 of our Annual report on Form 10-K for the year ended December 31, 2019. 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 R&D activities and in the commercialization of products. The amount and timing of any of the foregoing payments are not known due to the uncertainty surrounding the successful research, development and commercialization of the products. During the nine-month period ended September 30, 2020, commitments related to the purchase of inventory decreased as compared to December 31, 2019. As of September 30, 2020, we have inventory-related purchase commitments totaling approximately $2.5 million.

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, 2019. Effective January 1, 2020, the Company adopted ASU 2016-13, “Financial Instruments – Credit Losses” (Topic 326), ASU 2018-13, “Fair Value Measurement (Topic 820), ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract”, and, ASU 2018-18, “Collaborative Arrangements” (Topic 808). Other than the adoption of the new accounting guidance, our significant accounting policies have not changed materially from December 31, 2019.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term investments, accounts receivable, convertible notes payable, senior notes, liability related to the sale of future royalties, and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying values at September 30, 2020, except for the fair value of the Company's convertible senior notes due 2021, which was approximately $55.3 million as of September 30, 2020, and the Company's convertible senior secured notes due 2024, which was approximately $119.3 million as of September 30, 2020.

We have cash equivalents and short-term investments at September 30, 2020, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds, high-grade corporate bonds, and commercial paper, the carrying value of our cash equivalents and short-term investments approximate their fair value at September 30, 2020. At September 30, 2020, we held $63.3 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 2.2%. This amount excludes the restricted cash held in escrow related to the 6% semi-annual interest payments due on the convertible senior secured notes due 2024.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe there is any material market risk exposure with respect to derivative or other financial instruments.

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 third quarter of 2020, the period covered by this report. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief, Business Operations and Principal Accounting Officer. Based on that evaluation, these officers have concluded that, as of September 30, 2020, our disclosure controls and procedures were effective to achieve their stated purpose.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules, regulations, and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief, Business Operations and Principal Accounting Officer, as appropriate, to allow timely decisions regarding disclosure.

Change in internal control over financial reporting

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our Chief Executive Officer and Chief, Business Operations and Principal Accounting Officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended September 30, 2020, 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. 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.

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, 2019, 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 or future results. 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.

Following is the restated text of certain risk factors to report changes since our publication of risk factors in our 2019 Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for the first and second quarters of 2020.

Our ability to continue as a going concern is dependent on a significant amount of cash required to operate our business and service our debt, as well as our ability to obtain additional funding in the future; we may not have sufficient cash flow from our business to continue to sufficiently fund our operations and pay our substantial debt, including the remainder of our convertible senior notes that mature in June 2021.

We will need to expend substantial resources for commercialization of our marketed products, including costs associated with the commercialization of Inbrija. In addition, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including our convertible senior secured notes due 2024 and the remaining portion of our convertible senior notes that matures in June 2021, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to support our operations and service our debt and make necessary capital expenditures. Also, our research and development programs will not generate any revenues for the foreseeable future, if ever, because they are all in early stages, pharmaceutical development is subject to numerous risks including those described elsewhere in these risk factors, and generally we have discontinued funding our research and development pending additional progress with the Inbrija commercial launch in the U.S. As a result of these conditions, we have concluded that there is substantial doubt about our ability to meet our obligations within one year after the date the consolidated financial statements in this third quarter report are issued and, therefore, to continue as a going concern.

Our ability to meet our future operating requirements, repay our liabilities, 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 will be required to adopt one or more alternatives, subject to the restrictions contained in the indenture governing our convertible senior secured notes due 2024, such as further reducing expenses, selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous and 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. Furthermore, a determination that there is substantial doubt about a company's ability to continue as a going concern is generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result of these factors, we may not be able to engage in any of the alternative activities, or engage in such activities on desirable terms, which could harm our business, financial condition and results of operations, as well as result in a default on our debt obligations. If we are unable to take these actions, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether.

The commercial success of Inbrija (levodopa inhalation powder) and any other future products are highly dependent on market acceptance among physicians, patients and the medical community, adequate reimbursement by government and other third-party payers, and other factors.

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

- *Market Access*: Physicians may be discouraged from prescribing our products and/or patients may not fill or refill prescriptions for our products because of the reimbursement policies of third-party payers such as commercial insurance companies and government and government-sponsored payers such as Medicare. Our sales may suffer if Inbrija or other products are not listed on the preferred drug lists of third party payers, or if Inbrija or other products are on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies. Preconditions or other reimbursement limitations imposed by third party payers may discourage physicians from prescribing Inbrija or other products because of the time and effort that may be needed by the prescribing physician to overcome these hurdles. Even if physicians prescribe Inbrija or another product, patients may not fill or refill the prescription if their out-of-pocket cost is too high, for example because of inadequate or lack of reimbursement from their insurance company or Medicare.
- *Safety and Efficacy*: Physicians may not prescribe our products if they do not consider our products as safe and effective for their labelled indication, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Inbrija or our future products that we may develop are meaningful for patients or, even if they do believe there is a potential benefit, they may stage or delay the use of Inbrija with patients or patient groups to evaluate patient feedback or for other reasons.
- *Side Effects*: Market acceptance of Inbrija or another product may be impeded by the occurrence of any side effects, adverse reactions, customer complaints or misuse (or any unfavorable publicity relating thereto) stemming from the use of the product or identified in ongoing or future studies. As further described in our other published risk factors, FDA and EU-approved product labeling for Inbrija includes limitations, warnings and precautions, which may harm its market acceptance. For example, the Inbrija product label identifies cough as one of the most common adverse reactions observed in our clinical trials, and the risk of cough may discourage some patients from taking Inbrija, and the actual occurrence of cough has led some patients to discontinue Inbrija. Also, in the third quarter of 2020, we updated the Inbrija U.S. and EU-approved labels to add “sensation of choking immediately following administration” as a potential adverse reaction.
- *Competition*: The market for Inbrija may be adversely affected by the development of products that compete with or are an alternative to Inbrija or any future products that we may develop, the timing of market entry for competing or alternative products, the perceived advantages of competing or alternative therapies over our products, and the pricing of (and reimbursement available for) our products as compared to the pricing of (and reimbursement available for) competing or alternative products. For example, Sunovion Pharmaceuticals Inc. has developed a sublingual, or under the tongue, formulation of apomorphine branded as Kynmobi that we expect to be competitive with Inbrija. Sunovion received FDA approval for Kynmobi in May 2020 for the acute, intermittent treatment of OFF episodes, and Kynmobi became available in the U.S. in September 2020.
- *Intellectual Property*: The loss of intellectual property protection for our products would enable generic competition.

Also, in the U.S., the federal government provides funding for comparative effectiveness research, which may compare our products with other treatments and may result in published findings that would, in turn, discourage use of our products by physicians and payments for our products by payers. Similar research is funded in other countries, including in some countries in Europe.

The failure of any of our products or product candidates, once approved, to achieve market acceptance would limit our ability to generate revenue and would harm our results of operations and could adversely affect our future prospects. If market acceptance of our products in the U.S., EU, or other countries does not meet expectations, our revenues or royalties from product sales would suffer and this could cause our stock price to decline or could otherwise adversely affect our stock

price.

The identification of new side effects from Inbrija (levodopa inhalation powder) or any other marketed drug products, or side effects from those products that are more frequent or severe than in the past, would harm our business and could lead to a significant decrease in sales or to the withdrawal of marketing approval in the U.S. and/or in other jurisdictions.

Based on our clinical trials, the most common adverse reactions with Inbrija (at least 5% and greater than placebo) include cough, upper respiratory tract infection, nausea and discolored sputum. We constantly monitor Inbrija adverse event reports for signals regarding potential additional adverse events.

If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for Inbrija or any products perceived to be similar to Inbrija, then in any of these circumstances:

- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;
- we may be required to make product label changes; for example, in September 2020, we updated the Inbrija label to add "sensation of choking immediately following administration" as a potential adverse reaction;
- healthcare practitioners, regulatory authorities, third party payers or patients may perceive or conclude that the risks associated with use of Inbrija outweigh the benefits, which could cause regulatory authorities such as the FDA or authorities in the EU to seek to suspend, vary or revoke Inbrija's regulatory approvals or impact the availability of adequate reimbursement by third-party payers or reimbursement authorities;
- we may be required to reformulate the product, conduct additional preclinical or clinical studies, or make changes in labeling or changes to or re-approvals of manufacturing facilities;
- regulatory authorities such as the FDA or those in the EU may take additional risk mitigation measures, such as imposing a risk evaluation and mitigation strategy (in the U.S.) or requiring an updated risk mitigation plan, detailing additional requirements to be fulfilled to manage risks (in the EU);
- our reputation in the marketplace may suffer; and
- government investigations and lawsuits, including class action suits, may be brought against us.

The above occurrences could impair our business by harming or possibly preventing sales of Inbrija, causing sales to fall below projections, and increasing our expenses.

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

A specialty pharmacy is a pharmacy that specializes in the dispensing of injectable, infused or certain other medications typically for complex or chronic conditions, including Parkinson's disease and multiple sclerosis, which often require a high level of patient education and ongoing management. Most of our Inbrija and Ampyra sales are sold through specialty pharmacies, and sales of these products are highly dependent on the performance of these specialty pharmacies.

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

- do not provide us with accurate or timely information regarding their inventories or the number of patients who are using Inbrija or Ampyra;
- fail to provide timely and accurate information regarding product adverse events or product complaints;
- fail to properly administer copay mitigation programs;
- do not effectively dispense or support Inbrija or Ampyra;
- reduce their efforts or discontinue dispensing or supporting Inbrija or Ampyra;

- do not devote the resources necessary to dispense Inbrija or Ampyra in a manner that meets patient needs;
- are unable to satisfy financial obligations to us or others; or
- lose the required licenses to distribute drugs; or cease operations.

If our specialty pharmacies do not fulfill their contractual obligations to us or fail to adequately dispense our products and deliver customer support, our product sales and business could be harmed or we could be subject to legal or regulatory liabilities or sanctions. Also, for U.S. sales of Inbrija, we are in the process of transitioning from a network of several specialty pharmacies to a single specialty pharmacy. While we believe this change has potential benefits to patients and our business, reliance on a single specialty pharmacy also potentially increases the risks described above because we would not have a backup specialty pharmacy to dispense Inbrija and provide related services if an issue arises with the single specialty pharmacy. We expect that it would take a significant amount of time if we were required to change from the single specialty pharmacy.

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

If our competitors develop and market products that are more effective, safer or more convenient than our approved products, or obtain marketing approval before we obtain approval of future products, our commercial opportunity will be reduced or eliminated.

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological conditions, including Parkinson's disease, or PD, and multiple sclerosis, or MS.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our approved or proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would harm our ability to generate revenues and recover the substantial development costs we have incurred and will continue to incur.

Our products may be subject to competition from lower-priced versions of such products and competing products imported into the U.S. from Canada, Mexico and other countries where there are government price controls or other market dynamics that cause the products to be priced lower.

Inbrija (levodopa inhalation powder)/Parkinson's Disease. Inbrija competes against other therapies approved for intermittent, or as needed, use that aim to specifically address Parkinson's disease symptoms. Apokyn, an injectable formulation of apomorphine, is approved for the treatment of OFF periods, also known as OFF episodes. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Sunovion Pharmaceuticals Inc. has developed a sublingual, or under the tongue, formulation of apomorphine branded as Kynmobi that we expect to be competitive with Inbrija. Sunovion received FDA approval for Kynmobi in May 2020 for the acute, intermittent treatment of OFF episodes, and Kynmobi became available in the U.S. in September 2020.

The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and the amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. Inbrija may face competition from therapies that can limit the occurrence of OFF periods. Approaches to achieve consistent levodopa plasma concentrations include new formulations of carbidopa/levodopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of levodopa. Amneal Pharmaceuticals, Inc. (formerly Impax Laboratories) markets RYTARY, an extended-release formulation of oral carbidopa/levodopa, and extended release formulations of oral and patch carbidopa/levodopa are being developed by others including Intec Pharma and Mitsubishi Tanabe Pharma Corporation. Also, Abbvie Inc. has developed a continuous administration of a gel-containing levodopa through a tube that is surgically implanted into the intestine. This therapy, known as Duopa, has been approved by the FDA and is approved in the EU.

One or more of our competitors may utilize their expertise in pulmonary delivery of drugs to develop and obtain

approval for pulmonary delivery products that may compete with Inbrija and any other of our other ARCUS drug delivery technology product candidates. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., MannKind Corporation, Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc and Novartis AG, among others. If approved, our product candidates may face competition in the target commercial areas for these pulmonary delivery products. Also, we are aware that at least one company, Impel Neuropharma, is developing intranasally delivered levodopa therapies which, if approved, might compete with Inbrija.

Ampyra/MS. Ampyra has become subject to competition from generic drug manufacturers. We were previously engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit, or the Federal Circuit, which issued a ruling in September 2018 upholding the District Court's decision (the "Appellate Decision"). In January 2019, the Federal Circuit denied our petition for rehearing en banc. In October 2019, the U.S. Supreme Court denied our petition for certiorari requesting review of the case. We have experienced a significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. Additional manufacturers may market generic versions of Ampyra, and we expect our Ampyra sales will continue to decline over time.

Current disease management approaches to MS are classified either as relapse management, disease course management, or symptom management approaches. For relapse management, the majority of neurologists treat sudden and severe relapses with a four-day course of intravenous high-dose corticosteroids. Many of these corticosteroids are available generically. For disease course management, there are a number of FDA-approved MS therapies that seek to modify the immune system. These treatments attempt to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS, though their precise mechanisms of action are not known. These products include Avonex, Tysabri, Plegridy and Tecfidera from Biogen, Betaseron from Bayer AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Merck Serono, Gilenya and Extavia from Novartis AG, Aubagio and Lemtrada from Genzyme Corporation (a Sanofi company), Glatopa from Sandoz International GmbH (a Novartis AG company), Zinbryta from Biogen and AbbieVie, and Rituxan from F. Hoffman-La Roche AG.

Several biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS. Other companies also have products in clinical development, including products approved for other indications in MS, to address improvement of walking ability in people with MS. Furthermore, several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates. In addition, in certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra and generic versions of Ampyra are commercially available.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006.
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation dated August 31, 2020. Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed August 31, 2020.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101).

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
Date: November 6, 2020

By: /s/ DAVID LAWRENCE
David Lawrence
Chief, Business Operations and Principal Accounting Officer
Date: November 6, 2020

EXHIBIT 31.1

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

I, Ron Cohen, certify that:

1. I have reviewed this 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: November 6, 2020

/s/ Ron Cohen

Ron Cohen
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, David Lawrence, 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: November 6, 2020

/s/ David Lawrence

David Lawrence
Chief, Business Operations and Principal Accounting Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2020, 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)
November 6, 2020

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

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lawrence, Chief, Business Operations and Principal Accounting Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ DAVID LAWRENCE
DAVID LAWRENCE
Chief, Business Operations and
Principal Accounting Officer
(Principal Financial Officer)
November 6, 2020

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