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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from to

Commission file number: 001-37372

Collegium Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

Virginia	**03-0416362**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
100 Technology Center Drive Stoughton, MA	**02072**
(Address of principal executive offices)	(Zip Code)

(781) 713-3699

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	COLL	The NASDAQ Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See 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 ☐ (Do not check if smaller reporting company)	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 ☒

As of April 30, 2021, there were 35,247,618 shares of Common Stock, $0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our current expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. These statements may be preceded by, followed by or include the words "aim," "anticipate," "believe," "estimate," "expect," "forecast," "intend," "outlook," "plan," "potential," "project," "projection," "seek," "may," "could," "would," "should," "can," "can have," "likely," the negatives thereof and other words and terms of similar meaning.

Forward-looking statements are inherently subject to risks, uncertainties and assumptions; they are not guarantees of performance. You should not place undue reliance on these statements. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our ability to commercialize and grow sales of our products, particularly in light of current global challenges stemming from the COVID-19 pandemic;
- our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products and any product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts with favorable terms for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P.;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and to manufacture adequate quantities of commercially salable inventory and to maintain our supply chain in the face of global challenges, such as the COVID-19 pandemic;
- our ability to effectively manage our relationships with licensors and to commercialize products that we in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our operations and business development;
- our ability to comply with the terms of our outstanding indebtedness;
- regulatory developments in the United States;
- our ability to obtain and maintain sufficient intellectual property protection for our products and any product candidates;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency ("DEA") compliance;
- the loss of key commercial, scientific or management personnel;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Quarterly Report on Form 10-Q.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Quarterly Report on Form 10-Q (including the exhibits hereto) might not occur. We undertake no obligation, and specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

These and other risks are described under the heading "Risk Factors" in this Quarterly Report on Form 10-Q. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 182,790	$ 174,116
Accounts receivable, net	93,156	83,320
Inventory	15,498	15,614
Prepaid expenses and other current assets	4,867	4,838
Total current assets	296,311	277,888
Property and equipment, net	19,760	18,988
Operating lease assets	8,209	8,391
Intangible asset, net	319,109	335,904
Restricted cash	2,547	2,547
Other noncurrent assets	129	123
Total assets	$ 646,065	$ 643,841
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 8,666	$ 10,016
Accrued expenses	16,894	24,656
Accrued rebates, returns and discounts	156,153	156,554
Current portion of term notes payable	47,705	47,495
Current portion of operating lease liabilities	750	730
Total current liabilities	230,168	239,451
Term notes payable, net of current portion	98,006	110,019
Convertible senior notes	139,286	99,575
Operating lease liabilities, net of current portion	8,570	8,765
Total liabilities	476,030	457,810
Commitments and contingencies (see Note 14)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at March 31, 2021 and December 31, 2020; issued and outstanding shares - none at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at March 31, 2021 and December 31, 2020; issued and outstanding shares - 35,203,824 at March 31, 2021 and 34,612,054 at December 31, 2020	35	35
Additional paid-in capital	482,197	519,143
Accumulated deficit	(312,197)	(333,147)
Total shareholders’ equity	170,035	186,031
Total liabilities and shareholders’ equity	$ 646,065	$ 643,841

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2021	**2020**
Product revenues, net	$ 87,721	$ 76,511
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	15,328	27,229
Intangible asset amortization	16,795	10,295
Total cost of products revenues	32,123	37,524
Gross profit	55,598	38,987
Operating expenses		
Research and development	2,930	2,666
Selling, general and administrative	31,476	31,260
Total operating expenses	34,406	33,926
Income from operations	21,192	5,061
Interest expense	(5,721)	(4,823)
Interest income	3	212
Income before income taxes	15,474	450
Benefit from income taxes	(188)	—
Net income	$ 15,662	$ 450
Earnings per share — basic	$ 0.45	$ 0.01
Weighted-average shares — basic	34,951,740	34,100,688
Earnings per share — diluted	$ 0.41	$ 0.01
Weighted-average shares — diluted	41,160,092	35,069,693

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three months ended March 31,	
	2021	2020
Operating activities		
Net income	$ 15,662	$ 450
Adjustments to reconcile net income to net cash used in operating activities:		
Amortization expense	16,795	10,295
Depreciation expense	439	198
Stock-based compensation expense	6,879	4,951
Non-cash lease expense	7	18
Non-cash interest expense for amortization of debt discount and issuance costs	919	1,336
Changes in operating assets and liabilities:		
Accounts receivable	(9,836)	(12,474)
Inventory	(400)	(6,714)
Prepaid expenses and other assets	(115)	(2,990)
Accounts payable	(1,350)	(108)
Accrued expenses	(8,029)	(15,968)
Accrued rebates, returns and discounts	(401)	14,337
Operating lease assets and liabilities	—	—
Net cash provided by (used in) operating activities	20,570	(6,669)
Investing activities		
Purchase of intangible asset	—	(366,811)
Purchases of property and equipment	(428)	(836)
Net cash used in investing activities	(428)	(367,647)
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plans	358	357
Proceeds from the exercise of stock options	4,182	4,454
Payments made for employee stock tax withholdings	(3,508)	(1,358)
Proceeds from issuance of term note, net of issuance costs of $2,200	—	192,373
Proceeds from convertible senior notes, net of issuance costs of $4,956	—	138,794
Repayment of term notes	(12,500)	—
Repayment of term loan	—	(11,500)
Net cash (used in) provided by financing activities	(11,468)	323,120
Net increase (decrease) in cash, cash equivalents and restricted cash	8,674	(51,196)
Cash, cash equivalents and restricted cash at beginning of period	176,663	170,019
Cash, cash equivalents and restricted cash at end of period	$ 185,337	$ 118,823
Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets:		
Cash and cash equivalents	$ 182,790	$ 116,178
Restricted cash	2,547	2,645
Total cash, cash equivalents and restricted cash	$ 185,337	$ 118,823
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 5,746	$ 3,456
Cash paid for income taxes	$ 418	$ —
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment in accounts payable and accrued expenses	$ 560	$ 392
Asset acquisition transaction costs in accounts payable and accrued expenses	$ —	$ 1,415
Accrued royalties discharged upon closing of asset acquisition	$ —	$ 1,145
Inventory used in the construction and installation of property and equipment	$ 516	$ 394
Term notes issuance costs in accounts payable and accrued expenses	$ —	$ 256
Convertible senior notes issuance costs in accounts payable and accrued expenses	$ —	$ 517

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, in thousands, except share and per share amounts)

1. Nature of Business

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Stoughton, Massachusetts. The Company is a specialty pharmaceutical company committed to being the leader in responsible pain management. The Company's first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the United States Food and Drug Administration (the "FDA") approved the Company's new drug application ("NDA") for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza ER.

The Company's product portfolio also includes Nucynta ER and Nucynta IR (the "Nucynta Products"). On February 6, 2020, the Company entered into an Asset Purchase Agreement with Assertio Therapeutics, Inc. ("Assertio"), pursuant to which the Company agreed to acquire from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition") that it had previously licensed pursuant to a 2017 commercialization agreement with Assertio (the "Nucynta Commercialization Agreement"). The Nucynta Acquisition included a license from Grünenthal GmbH ("Grünenthal"), pursuant to which the Company assumed all commercialization responsibilities, including sales and marketing, for the Nucynta Products. The Nucynta Acquisition was consummated on February 13, 2020 for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments as described in the Nucynta Purchase Agreement. Following the closing, the Company's prior royalty obligation to Assertio ceased and the Company's only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

The Company periodically reviews its accounting estimates in light of changes in circumstances, facts and experience. As of the date of the filing of this Quarterly Report on Form 10-Q, the COVID-19 pandemic and actions taken to contain it have impacted revenue (due to fewer new patients beginning therapy with the Company's products and adverse impact on the Company's ability to promote products due to closure or limited operations of many physicians' offices) and decreased certain operating expenses, including travel, marketing and expenses associated with participation in congresses that have been postponed. The Company believes that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease. Although travel and other restrictions have started to be lifted in certain jurisdictions, there remains substantial uncertainty as to the possibility of further surges in infections, which could lead to travel and other restrictions being re-imposed.

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to continue successfully commercializing products, changing market conditions for products and development of competing products, changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, inability to manufacture of adequate commercial inventory, inability to secure adequate supplies of active pharmaceutical ingredients, key personnel retention, protection of intellectual property, and patent infringement litigation.

The Company believes that its cash and cash equivalents at March 31, 2021, together with expected cash inflows from the commercialization of its products, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements under its current business plan for the foreseeable future.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of Collegium Pharmaceutical, Inc. (a Virginia corporation) as well as the accounts of Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, and Collegium NF, LLC (a Delaware limited liability company), organized in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial

statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete consolidated financial statements.

In the opinion of the Company's management, the accompanying unaudited Condensed Consolidated Financial Statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to fairly present the financial position of the Company as of March 31, 2021, and the results of operations and cash flows for the three months ended March 31, 2021 and 2020. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the full year.

The preparation of the Condensed Consolidated Financial Statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Estimates in the Company's consolidated financial statements include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of products, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, impairment of intangible assets and tax valuation allowances. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions. The consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "Annual Report").

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report. There have been no material changes in the Company's significant accounting policies, other than the adoption of accounting pronouncements below, as compared to the significant accounting policies described in the Annual Report.

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updated ("ASU") 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This ASU simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exceptions for contracts in an entity's own equity. Under ASU 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital. Consequently, a convertible debt instrument, such as the Company's convertible senior notes, will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments and requires additional disclosures. This guidance is required to be adopted by January 1, 2022, and early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020.

The Company elected to early adopt this guidance on January 1, 2021 using the modified retrospective method. Under this transition method, the cumulative effect of the accounting change was removing the impact of recognizing the equity component of the Company's convertible notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization). The cumulative effective of the accounting change as of January 1, 2021 was an increase to the carrying amount of the convertible notes of $39,489, a reduction to accumulated deficit of $5,288, and a reduction to additional paid-in capital of $44,777. Interest expense of the convertible senior notes will be lower as a result of adoption of this guidance and diluted net loss per share will be computed using the if-converted method for the convertible senior notes. As a result of the adoption of this guidance, interest expense was decreased by and net income was increased by $1,552 for the three months ended March 31, 2021, and diluted earnings per share was increased by $0.02 per share.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 affect a wide variety of income tax accounting standards with the objective of reducing their complexity. The new standard became effective for annual and interim periods beginning after December 15, 2020. The Company adopted this standard during the three months ended March 31, 2021 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848)*: Facilitation of the Effects of Reference Rate Reform on Financial Reporting, to ease the potential burden in accounting for reference rate reform. The amendments in ASU 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The new standard became effective immediately and may be applied prospectively to contracts and transactions through December 31, 2022. Subsequent to issuance, the FASB issued ASU 2021-01 in January 2021 to refine and clarify some its guidance on ASU 2020-04. Upon the transition of the Company's contracts and transactions to new reference rates in connection with reference rate reform, the Company will prospectively apply the standard and disclose the effect on its condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

3. Revenue from Contracts with Customers

The Company's revenue to date is from sales of the Company's products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users").

Revenue Recognition

In accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Performance Obligations

The Company determined that performance obligations are satisfied and revenue is recognized when a customer takes control of the Company's product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable. Payment is typically received 30 to 90 days after satisfaction of the Company's performance obligations. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

Transaction Price and Variable Consideration

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The transaction price for product sales includes variable consideration related to sales deductions, including (1) rebates and incentives, including managed care rebates,

government rebates, co-pay program incentives, and sales incentives and allowances; (2) product returns, including return estimates for both Xtampza ER and the Nucynta Products; and, (3) trade allowances and chargebacks, including fees for distribution service fees, prompt pay discounts, and chargebacks. The Company will estimate the amount of variable consideration that should be included in the transaction price under the expected value method for all sales deductions other than trade allowances, which are estimated under the most likely amount method. These provisions reflect the expected amount of consideration to which the Company is entitled based on the terms of the contract. In addition, the Company made a policy election to exclude from the measurement of the transaction price all taxes that are assessed by a governmental authority that are imposed on revenue-producing transactions.

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales from the period. As the Company's rebates and incentives are based on products dispensed to patients, the Company is required to estimate the expected value of claims at the time of product delivery to distributors. Given that distributors sell the product to pharmacies, which in turn dispense the product to patients, claims can be submitted significantly later than the related sales are recognized. The Company's estimates of these claims are based on the historical experience of existing or similar programs, including current contractual and statutory requirements, specific known market events and trends, industry data, and estimated distribution channel inventory levels. Accruals and related reserves required for rebates and incentives are adjusted as new information becomes available, including actual claims. If actual results vary, the Company may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Provisions for product returns are based on product-level historical trends, as well as relevant market events and other factors. For Xtampza ER, since the product has only been commercially sold since June 2016, estimates of product returns are based on a combination of historical returns processed to date—taking into consideration the expiration date of the product upon delivery to customers—as well as forecasted customer buying patterns, shipment and prescription trends, channel inventory levels, and other specifically known market events and trends. For the Nucynta Products, estimates of product returns are primarily based on historical trends as the Nucynta Products have been commercially sold for a number of years.

Provisions for trade allowances and chargebacks are primarily based on customer-level contractual terms. Accruals and related reserves are adjusted as new information becomes available, which generally consists of actual trade allowances and chargebacks processed relating to sales recognized in the period.

The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. In general, performance obligations do not include any estimated amounts of variable consideration that are constrained. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the three months ended March 31, 2021 and 2020:

Three months ended March 31, 2021	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2020	$ 132,775	$ 23,779	$ 19,055
Provision related to current period sales	86,716	3,730	21,002
Changes in estimate related to prior period sales	(441)	—	—
Credits/payments made	(75,442)	(14,964)	(23,853)
Balance at March 31, 2021	$ 143,608	$ 12,545	$ 16,204

Three months ended March 31, 2020	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2019	$ 129,901	$ 27,648	$ 14,020
Provision related to current period sales	83,573	3,406	18,770
Changes in estimate related to prior period sales	1,131	—	49
Credits/payments made	(73,075)	(698)	(18,625)
Balance at March 31, 2020	$ 141,530	$ 30,356	$ 14,214

(1) Provisions for rebates and incentives includes managed care rebates, government rebates and co-pay program incentives. Provisions for rebates and incentives are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Consolidated Condensed Balance Sheets.
(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.
(3) Provisions for trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Condensed Consolidated Balance Sheets.

As of March 31, 2021, the Company did not have any transaction price allocated to remaining performance obligations and any costs to obtain contracts with customers, including pre-contract costs and set up costs, were immaterial.

Disaggregation of Revenue

The Company disaggregates its product revenue, net from contracts with customers, into the categories included in the table below. These categories depict how the nature, timing and uncertainty of revenue and cash flows are affected by economic factors:

	Three months ended March 31,	
	2021	2020
Xtampza ER	$ 35,409	$ 31,507
Nucynta Products[1]	52,312	45,004
Total product revenues, net	$ 87,721	$ 76,511

(1) For the three months ended March 31, 2021, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $30,526 and $21,786, respectively. For the three months ended March 31, 2020, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $27,970 and $17,034, respectively.

4. License Agreements

The Company periodically enters into license agreements to develop and commercialize its products. As of December 31, 2019, the Company's only license agreement was the Nucynta Commercialization Agreement. Upon the closing of the Nucynta Acquisition in February 2020, the Nucynta Commercialization Agreement was effectively terminated. Prior to the Nucynta Acquisition, the Company was conditionally obligated to make royalty payments to Assertio conditional

upon net sales and based on the following royalty structure for the period between January 1, 2019 and December 31, 2021:

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $210,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

Upon the closing of the Nucynta Acquisition, the Nucynta Commercialization Agreement was effectively terminated and the Company's royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company no longer pays royalties to Assertio and the Company's only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

The assets acquired, liabilities assumed, and equity interests issued by the Company in connection with the Nucynta Commercialization Agreement are further described in Note 8.

5. Earnings Per Share

Basic earnings per share is calculated by dividing the net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing the net income by the weighted average number of shares of common stock, plus potentially dilutive securities outstanding for the period, as determined in accordance with the treasury stock or if-converted accounting method. Potentially dilutive securities outstanding include stock options, unvested restricted stock units, performance share units, warrants, and shares related to the convertible senior notes, but are only included to the extent that their addition is dilutive.

The following table presents the computations of basic and dilutive earnings per common share:

	Three months ended March 31,	
	2021	**2020**
Numerator:		
Net income	$ 15,662	$ 450
Adjust for interest expense recognized on convertible senior notes:	1,165	—
Net income - diluted	$ 16,827	$ 450
Denominator:		
Weighted-average shares outstanding — basic	34,951,740	34,100,688
Effect of dilutive securities:		
Stock options	663,921	553,197
Restricted stock units	404,646	305,341
Performance share units	5,201	8,141
Employee stock purchase plan	9,693	29,681
Warrants	199,757	72,645
Convertible senior notes	4,925,134	—
Weighted average shares outstanding — diluted	41,160,092	35,069,693
Earnings per share — basic	$ 0.45	$ 0.01
Earnings per share — diluted	$ 0.41	$ 0.01

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 in cash, shares or a combination of the two. Since the Company intends to settle the principal amount of the convertible senior notes in cash, the Company used the treasury stock method for determining the potential dilution in the diluted earnings per share computation for the three months ended March 31, 2020. Effective for the three months ended March 31, 2021, the Company uses the if-converted method for the convertible senior notes as a result of the adoption of ASU 2020-06, as described in Recent Adopted Accounting Pronouncements above.

The following table presents dilutive securities excluded from the calculation of diluted earnings per share due to their anti-dilutive effect:

	Three months ended March 31,	
	2021	2020
Stock options	1,539,731	2,262,400
Restricted stock units	671,854	57,834
Performance share units	416,820	267,498
Convertible senior notes	—	4,925,134

For performance share units, these securities were excluded from the calculation of diluted earnings per share as the performance-based or market-based vesting conditions were not met as of the end of the reporting period. For all other securities, these securities were excluded from the calculation of diluted earnings per share as their inclusion would have had an anti-dilutive effect.

6. Fair Value of Financial Instruments

Disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for financial instruments with respect to which it is practicable to estimate that value. Fair value measurements and disclosures describe the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, as follows:

Level 1 inputs: Quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2 inputs: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the three months ended March 31, 2021 and 2020.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at March 31, 2021 and December 31, 2020:

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2021				
Money market funds, included in cash equivalents	$ 45,072	$ 45,072	$ —	$ —
December 31, 2020				
Money market funds, included in cash equivalents	$ 45,069	$ 45,069	$ —	$ —

As of March 31, 2021, the convertible senior notes had a fair value of approximately $158,234 and a net carrying value of $139,286. The fair value of the Company's convertible senior notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation.

The fair value of the Company's term notes fall into the Level 2 category within the fair value level hierarchy and the fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals.

As of March 31, 2021, and December 31, 2020, the carrying amounts of the cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, accrued rebates, returns and discounts, and term notes payable reasonably approximated their estimated fair values.

7. Inventory

Inventory as of March 31, 2021 and December 31, 2020 consisted of the following:

	As of March 31, 2021	As of December 31, 2020
Raw materials	$ 5,011	$ 3,514
Work in process	802	1,096
Finished goods	9,685	11,004
Total inventory	$ 15,498	$ 15,614

The aggregate charges related to excess inventory for the three months ended March 31, 2021 and 2020 were immaterial. These expenses were recorded as a component of cost of product revenues. During the three months ended March 31, 2021 and 2020, inventory used in the construction and installation of property and equipment was $516 and $394, respectively.

8. Intangible Asset

As of March 31, 2021 and December 31, 2020, the Company's only intangible asset (the "Nucynta Intangible Asset") is related to the Nucynta Acquisition and Nucynta Commercialization Agreement. The gross carrying amount and accumulated amortization of the Nucynta Intangible Asset were as follows:

	As of March 31, 2021	As of December 31, 2020
Gross carrying amount	$ 521,170	$ 521,170
Accumulated amortization	(202,061)	(185,266)
Intangible asset, net	$ 319,109	$ 335,904

Nucynta Acquisition

In February 2020, the Company entered into the Nucynta Purchase Agreement with Assertio, pursuant to which the Company acquired certain intellectual property and manufacturing rights related to the Nucynta Products, including U.S. commercialization rights, U.S. manufacturing rights, and inventory, for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments. The Company also agreed to assume certain regulatory and supply chain contracts, and obligations related to Nucynta Products (see Note 4). In February 2020, the Company entered into a loan agreement (see Note 10) and issued convertible senior notes (see Note 11) to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The consideration transferred in the asset acquisition was measured at cost, including transaction costs, assets transferred by the Company, and royalty obligations discharged by the seller. The table below represents the costs accumulated to

acquire the commercial rights for the Nucynta Products based on the terms of the Nucynta Purchase Agreement, as amended:

Acquisition consideration:		
Base purchase price	$	375,000
Cash paid for inventory		6,030
Transaction costs		6,297
Reduction for 2020 cash transferred to Assertio under the prior Nucynta Commercialization Agreement[(1)]		(13,071)
Reduction for accrued royalty obligation discharged upon closing[(1)]		(1,145)
Total acquisition consideration:	$	373,111

(1) Represents $14,216 total reduction to the base purchase price comprising of $13,071 of cash payments transferred to Assertio under the prior Nucynta Commercialization Agreement as well as a reduction for discharged pre-acquisition accrued royalties based on sales from January 1, 2020 through closing.

The Company then allocated the consideration transferred to the individual assets acquired on a relative fair value basis as summarized in the table below:

Assets acquired:		
Nucynta Intangible Asset	$	367,081
Inventory		6,030
Total consideration allocated to assets acquired:	$	373,111

The Company concluded that the consideration allocable to the Nucynta Intangible Asset for the additional intellectual property and manufacturing rights it acquired as part of the Nucynta Acquisition were incremental costs associated with the pre-existing intangible asset from the former Nucynta Commercialization Agreement, as such costs result in probable future economic benefits. Specifically, the additional intellectual property rights acquired in the Nucynta Acquisition enable the Company to eliminate royalty obligations otherwise payable to Assertio under the former Nucynta Commercialization Agreement.

Effective February 13, 2020, upon the closing of the Nucynta Acquisition, the Nucynta Commercialization Agreement was effectively terminated and the Company's royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company no longer pay royalties to Assertio and the Company's only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

A summary of the gross carrying amount, accumulated amortization, and net book value of the Nucynta Intangible Asset is as follows:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Balance as of December 31, 2019	$ 154,089	$ (124,586)	$ 29,503
Amortization expense through Nucynta Acquisition	—	(1,754)	(1,754)
Additional cost incurred from Nucynta Acquisition	367,081	—	367,081
Amortization expense from Nucynta Acquisition through period end	—	(58,926)	(58,926)
Balance as of December 31, 2020	$ 521,170	$ (185,266)	$ 335,904
Amortization expense	—	(16,795)	(16,795)
Balance as of March 31, 2021	$ 521,170	$ (202,061)	$ 319,109

Amortization

The Company has been amortizing the Nucynta Intangible Asset over its useful life, which is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The Company had initially determined that the useful life for the intangible asset was approximately 4.0 years from the closing date of the Nucynta Commercialization Agreement, January 9, 2018 on the basis of the majority of the cash flows expected to be realized for

future product sales under the Nucynta Commercialization Agreement. The Nucynta Acquisition significantly impacted the timing and amount of future cash inflows from the sales of the Nucynta Products, and, therefore, the Company considered it to be a triggering event to remeasure the expected useful life of the Nucynta Intangible Asset. The Company determined that the useful life for the Nucynta Intangible Asset was approximately 5.9 years from the Closing Date of the Nucynta Acquisition and accordingly, the intangible asset is amortized prospectively over its revised useful life. The Company recognizes amortization expense as a component of cost of product revenues in the Condensed Consolidated Statement of Operations on a straight-line basis over its useful life as it approximates the period of economic benefits expected to be realized from future cash inflows from sales of the Nucynta Products.

The following table presents amortization expense recognized for the three months ended March 31, 2021 and 2020:

	Three months ended March 31,	
	2021	2020
Nucynta amortization expense included in cost of product revenues	$ 16,795	$ 10,295

As of March 31, 2021, the remaining amortization period is approximately 4.8 years and is expected to be recognized in the following periods:

Years ended December 31,	Amortization Expense
2021	$ 50,386
2022	67,181
2023	67,181
2024	67,181
2025	67,180
Remaining amortization expense:	$ 319,109

9. Accrued Expenses

Accrued expenses as of March 31, 2021 and December 31, 2020 consisted of the following:

	As of March 31, 2021	As of December 31, 2020
Accrued royalties	$ 7,324	$ 12,954
Accrued product taxes and fees	2,051	1,817
Accrued payroll and related benefits	1,931	892
Accrued incentive compensation	1,550	1,417
Accrued sales and marketing	1,378	261
Accrued bonuses	1,011	4,571
Accrued audit and legal	599	445
Accrued interest	472	1,415
Accrued other operating costs	578	884
Total accrued expenses	$ 16,894	$ 24,656

10. Term Notes Payable

Pharmakon Term Notes

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, the Company, together with its subsidiary, Collegium Securities Corporation, entered into a Loan Agreement (the “Loan Agreement”) with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively “Pharmakon”). The Loan Agreement provides for a $200,000 secured term loan (the “term notes”), the

proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement. On February 13, 2020 (the "Closing Date"), the Company received the $200,000 proceeds from the term notes.

The term notes bear interest at a rate based upon the three-month LIBOR rate, subject to a LIBOR floor of 2.0%, plus a margin of 7.5% per annum, payable quarterly in arrears. The Company is required to repay the term notes by making equal quarterly payments of principal beginning in the first quarter immediately following the third month anniversary of the Closing Date. The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the Closing Date and is guaranteed by the Company's material domestic subsidiaries and also secured by substantially all of the Company's material assets. On the Closing Date, the Company paid to Pharmakon a facility fee equal to 2.50% of the aggregate principal amount of the term notes, or $5,000, in addition to $427 of other expenses incurred by Pharmakon and reimbursed by the Company (together, the "discount"). Net proceeds of $194,573 were transferred to Assertio by the Company as agent in partial satisfaction of the Nucynta Purchase Agreement. In addition, the Company capitalized $2,456 of term notes issuance costs, related to legal and advisory fees.

Except with respect to certain prepayments made with the proceeds from new equity issuances as described below, the Loan Agreement permits voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium is equal to 3.00% of the principal amount being prepaid prior to the second-year anniversary of the Closing Date, 2.00% of the principal amount being prepaid on or after the second-year anniversary, but on or prior to the third-year anniversary, of the Closing Date, and 1.00% of the principal amount being prepaid on or after the third-year anniversary of the Closing Date, but prior to the fourth-year anniversary of the Closing Date. The Loan Agreement also includes a make-whole premium if there is a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default on or prior to the second-year anniversary of the Closing Date in an amount equal to foregone interest from the date of prepayment through the second-year anniversary of the Closing Date. A change of control triggers a mandatory prepayment of the term notes.

The Loan Agreement also permits single voluntary prepayments of the Loan Agreement of less than or equal to $50,000 made solely from the proceeds of an equity issuance by the Company. If equity prepayment occurs prior to the second-year anniversary of the Closing Date, a prepayment premium of 5.00% would apply, with no make-whole premium.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require the Company to maintain $200,000 in annual net sales and covenants that limit the Company's ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business, restrictions which limit the Company's ability to pay dividends and restrictions of net assets of subsidiaries. The Loan Agreement also contains customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for Pharmakon following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. Under certain circumstances, a default interest rate will apply on outstanding obligations during the occurrence and continuance of an event of default.

During the three months ended March 31, 2021 and 2020, the Company recognized interest expense of $4,556 and $2,986, respectively, related to the term notes.

As of March 31, 2021, principal repayments under the term notes are estimated to be paid as follows:

Years ended December 31,	**Principal Payments**
2021	$ 37,500
2022	50,000
2023	50,000
2024	12,500
Total before unamortized discount and issuance costs	$ 150,000
Less: unamortized discount and issuance costs	(4,289)
Total term notes	$ 145,711

Silicon Valley Bank Term Loan Facility

From August 2012 until January 2020, the Company maintained a term loan facility with Silicon Valley Bank ("SVB"), which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan ("Consent and Amendment"), the Company had a term loan facility in an amount of $11,500, which replaced the Company's previously existing term loan facility. The proceeds of the Consent and Amendment were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan.

The Consent and Amendment bore interest at a rate per annum of 0.75% above the prime rate (as defined in the Consent and Amendment). The Company was eligible to repay the Consent and Amendment in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in January 2020.

In January 2020, the Company prepaid the outstanding principal and accrued interest on the Consent and Amendment along with the required prepayment fees. The loss on extinguishment of the term loan was immaterial and was recorded as a component of interest expense.

11. Convertible Senior Notes

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "convertible notes") in the aggregate principal amount of $143,750, in a public offering registered under the Securities Act of 1933, as amended. The convertible notes were issued in connection with funding the Nucynta Acquisition, and the proceeds of the convertible notes were used to finance a portion of the purchase price payable pursuant to the Nucynta Purchase Agreement. Some of the Company's existing investors participated in the convertible notes offering.

The Company may, at its option, settle the convertible notes in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock. Accordingly, the Company separately accounted for the liability component (the "Liability Component") and the embedded derivative conversion option (the "Equity Component") of the convertible notes by allocating the proceeds between the Liability Component and the Equity Component. In connection with the issuance of the convertible notes, the Company incurred approximately $5,473 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs between the Liability Component and the Equity Component based on the allocation of the proceeds. Of the total debt issuance costs, $1,773 was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $3,700 was allocated to the Liability Component and recorded as a debt discount of the convertible notes. The portion allocated to the Liability Component is amortized to interest expense using the effective interest method over six years.

Prior to the adoption of ASU 2020-06 on January 1, 2021, the initial carrying amount of the Liability Component of $97,200 was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible borrowing rate for similar debt. The Equity Component of the Notes of $46,550 was recognized as a debt discount. The excess of the principal amount of the Liability Component over its carrying amount was amortized to interest expense using the effective interest method over six years.

Subsequent to the adoption of ASU 2020-06 on January 1, 2021, which the Company elected to adopt using the modified retrospective method, the Company removed the impact of recognizing the Equity Component of the senior convertible notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization). The cumulative effective of the accounting change as of January 1, 2021 was an increase to the carrying amount of the convertible notes of $39,489, a reduction to accumulated deficit of $5,288, and a reduction to additional paid-in capital of $44,777.

The convertible notes are the Company's senior unsecured obligations and bear interest at a rate of 2.625% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on

the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, 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. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. The initial conversion rate is 34.2618 shares of common stock per $1 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the convertible notes may convert all or any portion of their convertible notes, in multiples of $1 principal amount, at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2020, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
(2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the "trading price" per $1 principal amount of the Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day;
(3) upon the occurrence of certain corporate events or distributions on the Company's common stock;
(4) if the Company calls the convertible notes for redemption; or
(5) at any time from, and including, August 15, 2025 until the close of business on the scheduled trading day immediately before the maturity date.

As of March 31, 2021, none of the above circumstances had occurred and as such, the convertible notes could not have been converted.

The Company may not redeem the convertible notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the convertible notes, in whole and not in part, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on:

(1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and
(2) the trading day immediately before the date the Company sends such notice.

Calling any convertible note for redemption will constitute a make-whole fundamental change with respect to that convertible note, in which case the conversion rate applicable to the conversion of that convertible note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The convertible notes have customary default provisions, including (i) a default in the payment when due (whether at maturity, upon redemption or repurchase upon fundamental change or otherwise) of the principal of, or the redemption price or fundamental change repurchase price for, any note; (ii) a default for 30 days in the payment when due of interest on any note; (iii) a default in the Company's obligation to convert a note in accordance with the indenture; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) certain payment or other defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $20,000; and (vi) certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

As of March 31, 2021, the convertible notes outstanding consisted of the following:

Principal	$	143,750
Less: unamortized issuance costs		(4,464)
Net carrying amount	$	139,286

The Company determined the expected life of the convertible notes was equal to its six-year term. Subsequent to the adoption of ASU 2020-06, the effective interest rate on the convertible notes was 3.26%. As of March 31, 2021, the if-converted value did not exceed the remaining principal amount of the convertible notes.

The following table presents the total interest expense recognized related to the convertible notes during the three months ended March 31, 2021 and 2020:

	Three months ended March 31,	
	2021	2020
Contractual interest expense	$ 943	$ 503
Amortization of debt discount	—	818
Amortization of debt issuance costs	222	65
Total interest expense	$ 1,165	$ 1,386

As of March 31, 2021, the future minimum payments on the convertible notes were as follows:

Years ended December 31,	Future Minimum Payments
2021	$ 1,887
2022	3,773
2023	3,773
2024	3,773
2025	3,773
Thereafter	145,638
Total minimum payments	$ 162,617
Less: interest	(18,867)
Less: unamortized issuance costs	(4,464)
Convertible senior notes	$ 139,286

12. Equity

The changes in shareholders' equity for three months ended March 31, 2021 were as follows:

	Common Stock		Additional Paid- In	Accumulated	Total Shareholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance, December 31, 2020	34,612,054	$ 35	$ 519,143	$ (333,147)	$ 186,031
Cumulative effect adjustment for adoption of ASU 2020-06	—	—	(44,777)	5,288	(39,489)
Exercise of common stock options	289,164	—	4,102	—	4,102
Issuance for employee stock purchase plan	24,630	—	358	—	358
Vesting of restricted stock units ("RSUs") and performance share units ("PSUs")	413,538	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(135,562)	—	(3,508)	—	(3,508)
Stock-based compensation	—	—	6,879	—	6,879
Net income	—	—	—	15,662	15,662
Balance, March 31, 2021	35,203,824	$ 35	$ 482,197	$ (312,197)	$ 170,035

The changes in shareholders' equity for three months ended March 31, 2020 were as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2019	33,678,840	$ 34	$ 447,297	$ (359,899)	$ 87,432
Exercise of common stock options	455,573	—	4,454	—	4,454
Issuance for employee stock purchase plan	39,411	—	357	—	357
Vesting of RSUs	195,280	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(63,064)	—	(1,358)	—	(1,358)
Stock-based compensation	—	—	4,951	—	4,951
Equity component of 2020 Convertible Notes, net of issuance costs of $1,773	—	—	44,777	—	44,777
Net income	—	—	—	450	450
Balance, March 31, 2020	34,306,040	$ 34	$ 500,478	$ (359,449)	$ 141,063

Common Stock

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the Company's board of directors ("Board of Directors") prior to January 1st). As of March 31, 2021, there were 768,668 shares of common stock available for issuance pursuant to the Plan. The Plan provides for granting of both Internal Revenue Service qualified incentive stock options and non-qualified options, restricted stock awards, restricted stock units and performance stock units. The Company's qualified incentive stock options, non-qualified options and restricted stock units generally vest ratably over a four-year period of service. The stock options generally have a ten-year contractual life and, upon termination, vested options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately upon termination. Refer to Note 13, *Stock-based Compensation*, for more information.

Warrants

As of March 31, 2021, the warrant issued to Assertio in November 2018 was the Company's only outstanding warrant. In connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The terms of the warrant are fixed, with the exception of customary adjustments for changes in the Company's capitalization. The warrant may only be settled with the issuance of shares of common stock upon exercise and will expire in November 2022. The Company has recorded the relative fair value of the warrant as a component of equity interest issued by the Company as consideration transferred in the cost accumulation model for the asset acquisition. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. The Company concluded that the warrant met the definition of an equity instrument and was recorded as a component of additional paid-in capital in the Company's Condensed Consolidated Balance Sheet as of the issuance date.

13. Stock-based Compensation

Performance Share Units, Restricted Stock Units and Stock Options

Performance Share Units

The Company periodically grants PSUs to certain members of the Company's senior management team. PSUs vest subject to the satisfaction of annual and cumulative performance and/or market conditions established by the Compensation Committee.

A summary of the Company's PSU activity for the three months ended March 31, 2021 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2020	283,223	$ 24.26
Granted	213,180	35.12
Vested	(60,990)	22.45
Forfeited	—	—
Performance adjustment	(12,609)	21.80
Outstanding at March 31, 2021	422,804	$ 30.07

The number of PSUs granted represents the target number of shares of common stock that may be earned, however, the actual number of shares earned may vary based on the satisfaction of performance criteria. The weighted-average grant date fair value of PSUs granted for the three months ended March 31, 2021 and 2020 was $35.12 and $28.49, respectively.

Restricted Stock Units

The Company granted RSUs to employees for the three months ended March 31, 2021. The Company's RSUs generally vest ratably over a four-year period of service. A summary of the Company's RSU activity for the three months ended March 31, 2021 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2020	1,242,387	$ 19.42
Granted	1,163,664	24.43
Vested	(352,548)	19.42
Forfeited	(14,968)	21.35
Outstanding at March 31, 2021	2,038,535	$ 22.27

The weighted-average grant date fair value per share of RSUs granted for the three months ended March 31, 2021 and 2020 was $24.43 and $21.34, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the three months ended March 31, 2021 and 2020 was $9,116 and $4,204, respectively.

Stock Options

A summary of the Company's stock option activity for the three months ended March 31, 2021 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	3,860,481	$ 17.78	7.2	$ 13,011
Granted	63,000	19.97		
Exercised	(289,164)	14.18		
Cancelled	(25,491)	19.30		
Outstanding at March 31, 2021	3,608,826	$ 18.09	7.0	$ 20,895
Exercisable at March 31, 2021	2,353,069	$ 17.57	6.3	$ 14,949

The weighted average assumptions used in the Black Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Three months ended March 31,	
	2021	2020
Risk-free interest rate	0.5 %	1.5 %
Volatility	68.3 %	65.5 %
Expected term (years)	6.0	6.1
Expected dividend yield	— %	— %

The weighted-average grant date fair value per share of stock options granted for the three months ended March 31, 2021 and 2020 was $12.08 and $12.86, respectively.

Employee Stock Purchase Plan

The Company's 2015 Employee Stock Purchase Plan allows employees to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. During the three months ended March 31, 2021, 24,630 shares of common stock were purchased for total proceeds of $358. The expense for the three months ended March 31, 2021 and 2020 was $72 and $79, respectively.

Stock-based Compensation Expense

A summary of the Company's stock-based compensation expense was allocated as follows:

	Three months ended March 31,	
	2021	2020
Research and development	$ 1,217	$ 770
Selling, general and administrative	5,662	4,181
Total stock-based compensation expense	$ 6,879	$ 4,951

At March 31, 2021, there was approximately $63,922 of unrecognized compensation expense related to unvested options, restricted stock units and performance stock units, which is expected to be recognized as expense over a weighted average period of approximately 2.9 years.

14. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may face legal claims or actions in the normal course of business. Except as disclosed below, the Company is not currently a party to any litigation and, accordingly, does not have any amounts recorded for any litigation related matters.

Xtampza ER Litigation

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Orange Book, in this case OxyContin. The 505(b)(2) process requires that the Company certify to the FDA that the Company does not infringe any of the patents listed for OxyContin in the Orange Book, or that the patents are invalid. The process also requires that the Company notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA, and any other Orange Book-listed patent owners that it has made such a certification. On February 11, 2015, the Company made the required certification documenting why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin, five of which have been invalidated in court proceedings, and provided the required notice to Purdue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

In response to these actions, Purdue sued the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After the Company filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in the Company's favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, the Company was able to obtain final approval for Xtampza ER and launch the product commercially.

Purdue subsequently filed two follow-on lawsuits asserting infringement of two patents that had been late-listed in the Orange Book and therefore could not trigger any stay of FDA approval: Purdue filed suit asserting infringement of Patent No. 9,073,933 in November 2015, and asserted infringement of Patent No. 9,522,919 in April 2017. In addition, Purdue filed suit on two patents that had not been listed in the Orange Book, filing suit in June 2016 asserting infringement of Patent No. 9,155,717 and in September 2017, asserting infringement of Patent No. 9,693,961.

On March 13, 2018, the Company filed a Petition for Post-Grant Review ("PGR") of the ′961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. The PTAB held oral argument on the proceedings on July 10, 2019 and was scheduled to issue a decision on the patentability of the ′961 patent by no later than October 4, 2019. On September 15, 2019, Purdue commenced a voluntary case under chapter 11 of title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. On September 24, 2019, Purdue gave the PTAB notice of its bankruptcy filing and sought the imposition of an automatic stay of the PGR proceedings. On October 2, 2019, the PTAB extended the one-year period for issuing its decision by up to six months.

In October 2017, and in response to the filing of the Company's Supplemental NDA ("sNDA") seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patent. The Company filed a motion to dismiss that action, and the Court granted its motion on January 16, 2018.

On April 9, 2021, Purdue filed another follow-on lawsuit asserting infringement of U.S. Patent No. 10,407,434, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval.

A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment that the Company filed. Specifically, the Court ruled that the Xtampza ER formulation does not infringe the ′497 and ′717 patents. On September 18, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. On September 20, 2019, the matter was stayed pending further order of the Court.

On September 1, 2020, the Bankruptcy Court entered an Order Granting Motions for Relief from the Automatic Stay, lifting the automatic stays in both the District of Massachusetts and PTAB proceedings. The Company appealed the Bankruptcy Court's Order, in part, and that appeal is stayed, on consent by Purdue, pending the outcome of the PTAB proceedings and any appeal thereto. On September 11, 2020, Purdue filed a motion to terminate the PTAB action on the basis that those proceedings had gone beyond the 18-month statutory period. The Company opposed Purdue's motion and the parties are awaiting the PTAB's decision.

On April 2, 2021, the Court granted Purdue's Motion to Lift the Stay in the District of Massachusetts that was entered following Purdue's Notice of Bankruptcy. The Court set a October 5, 2021 claim construction hearing for the ′961 patent and the ′434 patent. Fact discovery is set to close on March 11, 2022. Depositions of expert witnesses must conclude by May 17, 2022. The court has not set a deadline for dispositive motions or trial.

The suits that remain pending, which assert infringement of the ′933, the ′919, the ′434, and the ′961 patents, were consolidated by the District of Massachusetts. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the Company's products accused of infringement. The Company has denied all claims and has requested a judgment that the remaining asserted patents are invalid and/or not infringed; the Company is also seeking a judgment that the case is exceptional and has requested an award of the Company's attorneys' fees for defending the case.

The Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against the Company in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate-release and extended-release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, the Company filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of the Company's affirmative defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings related to patent exhaustion and any discovery related to that Motion. Also, on December 10, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. On June 18, 2019, the Court heard oral argument on the Company's Rule 12(c) Motion for Judgment on the Pleadings. On June 19, 2019, the Court issued an order stating that "judgment in Collegium's favor is warranted under the doctrine of patent exhaustion to the extent Collegium's alleged infringing activities resulted from sales that fall within the scope of that covenant." The Court explained, however, that based on the current record, it was not possible "to determine whether title of the Nucynta Products was transferred to Collegium" from sales authorized by Purdue's covenant not to sue. The Court ordered discovery on this issue and the case remained "stayed with the exception of discovery and briefing on and resolution of the Company's anticipated motion for summary judgment based on patent exhaustion."

On September 19, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. The Nucynta litigation is subject to the automatic bankruptcy stay.

Pending resolution of the bankruptcy action, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Teva Litigation

Presently, the Company has nineteen patents listed in the FDA Orange Book as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729; 10,188,644; 10,525,052; 10,525,053; 10,646,485; and 10,668,060 (the "Orange Book Patents").

Teva filed an ANDA seeking FDA approval to market generic extended-release oxycodone capsule products (the "proposed ANDA products"). Teva also filed certifications with the FDA that its proposed ANDA products will not infringe the Orange Book Patents and/or that the Orange Book Patents are invalid. Teva sent the Company a Notice Letter indicating that it had made such certification to the FDA.

On February 22, 2018—within the 45-day period that gives the Company a 30-month stay of FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the twelve Orange Book Patents that were listed at that time. Teva responded to the complaint on May 14, 2018, denying infringement by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on June 4, 2018.

The Company listed two additional patents in the Orange Book in 2018 and Teva amended its ANDA to include certifications to the FDA of non-infringement and invalidity with respect to those patents. Teva notified the Company of its certification and the Company filed a second lawsuit in the District of Delaware, asserting those two patents, on November 30, 2018. Teva responded to the complaint on January 11, 2019 denying infringement by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on February 1, 2019. The court consolidated the second suit with the first suit, and thus both suits are proceeding on the same schedule.

The parties briefed claim construction and the court heard argument on April 12, 2019. On September 11, 2019, the Court issued a Report and Recommendation construing two of the six terms or sets of terms that are in dispute. The remaining terms will be addressed in one or more forthcoming Report and Recommendations. Fact discovery was scheduled to close on September 20, 2019 and expert discovery was scheduled to close on January 24, 2020.

The Company listed an additional patent in the Orange Book in January 2019 and Teva amended its ANDA to include certifications to the FDA of non-infringement and invalidity with respect to that patent. Teva notified us of its certification and the Company filed a third lawsuit in the District of Delaware, asserting the additional Orange Book Patent, on May 9, 2019. Teva responded to the complaint on June 6, 2019, denying infringement by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patent. The Company answered Teva's counterclaims on June 27, 2019. The parties filed a proposed Scheduling Order, which the Court entered on September 4, 2019.

On September 20, 2019, the parties jointly agreed to stay both litigations.

The Company listed four additional patents in the Orange Book in first half of 2020, which brings the total number of Orange Book Patents for Xtampza ER to nineteen.

Teva and the Company have entered into a Settlement Agreement and License Agreement to resolve the case. On October 7, 2020, the Court entered a Consent Judgment and Order of Permanent Injunction that dismissed with prejudice all affirmative defenses, claims, and counterclaims which have or could have been raised by Teva. The Order states that Teva would infringe each of the Litigated Patents by using, making, offering to sell, selling, and/or importing Teva's ANDA product in or into the United States. It further states that the Litigated Patents, and all claims contained therein, are valid and enforceable, solely with respect to the Teva ANDA and Teva ANDA Product. It further stated that, except as authorized and licensed by the Company under the License, Teva, its officers, agents, employees, affiliates, successors and all persons in active concert or participation with Teva, are permanently enjoined from using, making, offering for sale, or selling in the United States, or importing into the United States, Teva's ANDA Product and/or inducing or assisting others to use, make, offer for sale, or sell in the United States, or import into the United States, Teva's ANDA Product.

On September 29, 2020, the Company entered into a settlement agreement with Teva resolving the patent litigation in the U.S. District Court for the District of Delaware. Pursuant to the terms of the settlement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company will grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to U.S. Food and Drug Administration approval, and acceleration under certain circumstances). As a result of the settlement, Teva has agreed to a consent judgment confirming that its proposed generic products infringe upon the Company's asserted patents and that those patents are valid and enforceable with respect to Teva's proposed generic products. Additional details regarding the settlement are confidential.

Opioid Litigation

As a result of the opioid epidemic, numerous state and local governments, healthcare providers, and other entities have brought suit against manufacturers, wholesale distributors, and pharmacies alleging a variety of claims related to opioid marketing and distribution practices. In late 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered the consolidation of what were then a few hundred cases pending around the country in federal court against opioid manufacturers and distributors into a Multi-District Litigation (MDL) in the Northern District of Ohio. Currently, the Opioid MDL consists of over 2,000 opioid-related cases brought primarily by states, cities, counties, and other local entities. Generally speaking, these suits do not seek damages for injuries to individuals but rather compensation for the cost of public services needed to address the consequences of addicted communities, ranging from emergency response capabilities to rehabilitation services. The Company has been named as a defendant in a small subset of the MDL cases. Of the 21 MDL cases that have named the Company as a defendant, the allegations against it have been dismissed or withdrawn in 13 cases. In addition, the Company has been dismissed from three non-MDL cases filed in Pennsylvania and Arkansas state courts.

Eight cases that name the Company as a defendant, originally filed in three states, remain pending in the MDL:

- Virginia. On January 11, 2019, the City of Portsmouth filed a lawsuit in Virginia Circuit Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws. On October 3, 2019, the City of Portsmouth case was transferred to the MDL.
- New Jersey. On March 15, 2019, the Company was named in a lawsuit in the MDL by the City of Paterson, New Jersey. The lawsuit alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws, and seeks, generally, penalties and/or injunctive relief. On June 14, 2019, the City of Trenton filed a lawsuit in the New Jersey Superior Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws and the New Jersey Drug Dealer Liability Act. On December 18, 2019, the case was transferred to the MDL.
- Connecticut. On April 9, 2019, the City of Norwich, Connecticut and the Town of Enfield, Connecticut filed lawsuits that name the Company in Connecticut Superior Court. The lawsuits allege violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On June 28, 2019, both cases were transferred to the MDL. In October 2019, the Company was named in two additional Connecticut lawsuits: the City of Middletown and the Town of Wethersfield. These cases were both also transferred to the MDL in July 2019. Finally, on January 15, 2020, the Town of Windham, Connecticut filed a lawsuit that names the Company, among other pharmaceutical manufacturers, in Connecticut Superior Court. The lawsuit alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On March 3, 2020, the lawsuit was transferred to the MDL.

Each of the lawsuits in the MDL naming the Company seeks, generally, penalties and injunctive relief. None of the lawsuits naming the Company are designated as representative cases in the MDL, and therefore, are effectively currently stayed.

Outside of the MDL, there are several cases pending against the Company in state courts in Pennsylvania and Massachusetts:

- In Pennsylvania, six lawsuits naming the Company have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors. These include lawsuits filed between May 2018 and July 2019 on behalf of Bucks County, Clinton County, Mercer County, Warrington Township, Warminster Township, and the City of Lock Haven, each of Pennsylvania, alleging claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. None of these cases has been designated a Track One case in which discovery would commence, and therefore they are all effectively stayed at present.

- In Massachusetts, there are lawsuits by the City of Worcester, the City of Salem, the City of Framingham, the Town of Lynnfield, the City of Springfield, the City of Haverhill, the City of Gloucester, the Town of Canton, the Town of Wakefield, the City of Chicopee, the Town of Natick, the City of Cambridge and the Town of Randolph, all of which have been consolidated before the Business Litigation Session of the Superior Court. The actions allege a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. The case brought by the City of Springfield was selected to advance for the purpose of motion practice, defendants' motions to dismiss were denied on January 3, 2020. There is no trial date set for this case.

The Company disputes the allegations in these lawsuits and intends to vigorously defend these actions. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Opioid-Related Request and Subpoenas

The Company, like a number of other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing. The Company has received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, Maryland and Massachusetts. The Company is currently cooperating with each of the foregoing states in their respective investigations.

15. Income Taxes

The income tax provision for the interim periods reflects the Company's estimate of the effective tax rates expected to be applicable for the full fiscal years, adjusted for any discrete events which are recorded in the period in which they occur. The estimates are reevaluated each quarter based on the Company's estimated tax expense for the full fiscal year.

The following table presents information regarding Company's income tax expense recognized for the three months ended March 31, 2021 and 2020:

	Three months ended March 31,	
	2021	2020
Benefit from income taxes	$ (188)	$ —
Effective tax rate	(1.2%)	0.0%

The Company is subject to U.S. federal and state income taxes. For the three months ended March 31, 2021 the Company recorded a benefit from income taxes of $188 and none, respectively. The benefit from income taxes in the first quarter of 2021 was primarily related to a benefit from income taxes of $1,527 related to excess tax benefits of stock-based compensation offset by provisions for income taxes of $1,339 attributable to state income tax expense. The Company expects to record an income tax provision in the remaining quarters of 2021 that exceeds excess tax benefits from income taxes. As a result, these excess tax benefits and provisions recorded on a quarterly basis are not expected to have any effect on our annual provision for (benefit from) income taxes. For the three months ended March 31, 2021 and 2020, no federal current income tax expense was recorded as the Company has enough federal net operating losses (or "NOLs") carryover to offset taxable income. The Company has a full valuation allowance against its deferred tax assets as of March 31, 2021 and 2020 and no deferred tax expense was recorded in either period.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. The Company recorded a valuation allowance against all of its deferred tax assets as of March 31, 2021 and December 31, 2020. The Company intends to continue to maintain a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. Given the Company's current earnings and anticipated future earnings, however, the Company believes that there is a reasonable possibility that within the next 12 months, sufficient positive evidence may become available to allow the Company to reach a conclusion that a significant portion or all of the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to the provision for income taxes for the period the release is recorded. The exact timing and amount of the valuation allowance release, however, are subject to change on the basis of the level of profitability that the Company is able to actually achieve.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report on Form 10-Q, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

OVERVIEW

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our portfolio includes Xtampza ER, an abuse-deterrent, extended-release, oral formulation of oxycodone, and Nucynta ER and Nucynta IR (collectively, the "Nucynta Products"), which are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol.

Xtampza ER was approved by the FDA in April 2016 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We commercially launched Xtampza ER in June 2016.

Nucynta ER is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. We initially licensed the right to commercialize the Nucynta Products in the United States through a Commercialization Agreement with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio") entered into in December 2017 (the "Nucynta Commercialization Agreement"). On February 13, 2020, we closed an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which we agreed to acquire from Assertio certain assets

related to the Nucynta Products (the "Nucynta Acquisition"), including the license from Grünenthal GmbH ("Grünenthal"), for an aggregate purchase price of $375.0 million. Upon closing, the Nucynta Commercialization Agreement was effectively terminated. Our prior royalty obligation to Assertio ceased and our only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

For the three months ended March 31, 2021, we generated $87.7 million in net revenues, comprised of $35.4 million from sales of Xtampza ER and $52.3 million from sales of the Nucynta Products.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza ER to approximately 11,000 health care professionals who write approximately 65% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 145 sales representatives and managers. We are promoting the Nucynta Products to the same health care professionals to whom we promote Xtampza ER, leveraging our existing sales organization. We have historically paid royalties to Assertio on all revenues from the sale of Nucynta Products based on certain net sales thresholds. Upon the closing of the Nucynta Acquisition and the termination of the Nucynta Commercialization Agreement (except for certain sections that survive in accordance with the Nucynta Purchase Agreement) in February 2020, our prior royalty obligation to Assertio ceased and our only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

We were historically not profitable and incurred net losses in each year since inception until 2020. We generated net income of $15.7 million in the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $312.2 million. Substantially all of our net losses resulted from costs incurred in connection with selling, general and administrative costs associated with our operations and research and development programs.

We believe that our cash and cash equivalents at March 31, 2021, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

As of the date of the filing of this Quarterly Report on Form 10-Q, we expect the COVID-19 pandemic and actions taken to contain it to impact our revenue (due to fewer new patients beginning therapy with our products and adverse impact on our ability to promote our products due to closure or limited operations of many physicians' offices) and have decreased certain operating expenses, including travel, marketing and expenses associated with participation in congresses that have been postponed. We believe that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease. Although travel and other restrictions have started to be lifted in certain jurisdictions, there remains substantial uncertainty as to the possibility of further surges in infections, which could lead to travel and other restrictions being re-imposed.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 ("Annual Report"), relate to revenue recognition and impairment of intangible assets. Estimates include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of our products, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets and tax valuation allowances. We base our estimates and assumptions on historical experience when available and on various factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or

conditions. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report.

RESULTS OF OPERATIONS

	Three months ended March 31,	
	2021	2020
	(in thousands)	
Product revenues, net	$ 87,721	$ 76,511
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	15,328	27,229
Intangible asset amortization	16,795	10,295
Total cost of products revenues	32,123	37,524
Gross profit	55,598	38,987
Operating expenses		
Research and development	2,930	2,666
Selling, general and administrative	31,476	31,260
Total operating expenses	34,406	33,926
Income from operations	21,192	5,061
Interest expense	(5,721)	(4,823)
Interest income	3	212
Income before income taxes	15,474	450
Benefit from income taxes	(188)	—
Net income	$ 15,662	$ 450

Comparison of the three months ended March 31, 2021 and March 31, 2020

Product revenues, net were $87.7 million for the three months ended March 31, 2021 (the “2021 Quarter”), compared to $76.5 million for the three months ended March 31, 2020 (the “2020 Quarter”). The $11.2 million increase was related to an increase in revenue for the Nucynta Products of $7.3 million, combined with an increase in revenue for Xtampza ER of $3.9 million. For the 2021 Quarter, Nucynta IR and ER product revenues, net were $30.5 million and $21.8 million, respectively, compared to $28.0 million and $17.0 million, respectively, for the 2020 Quarter. The increase in revenue for the Nucynta Products was primarily related to an increase from gross-to-net adjustments and price, partially offset by lower sales volume. For the 2021 Quarter, Xtampza ER product revenues, net were $35.4 million, compared to $31.5 million for the 2020 Quarter. The increase in revenue for Xtampza ER was primarily related to an increase in sales volume due to increased demand and an increase in price.

Cost of product revenues (excluding intangible asset amortization) was $15.3 million for the 2021 Quarter, compared to $27.2 million for the 2020 Quarter. The $11.9 million decrease was primarily related to a decrease in royalty expense for the Nucynta Products. In the 2020 Quarter, we recognized $14.2 million in sales-based royalty expense due to Assertio under the terms of the Nucynta Commercialization Agreement. Our sales-based royalty obligations to Assertio ceased upon closing of the Nucynta Acquisition on February 13, 2020.

Intangible asset amortization was $16.8 million for the 2021 Quarter, compared to $10.3 million for the 2020 Quarter. The $6.5 million increase was primarily related to the Nucynta Acquisition, in which $367.1 million of consideration was allocated to the existing intangible asset as incremental cost in 2020. The intangible asset is being amortized on a straight-line basis over its estimated useful life of approximately six years.

Research and development expenses were $2.9 million for the 2021 Quarter, compared to $2.7 million for the 2020 Quarter. The $264,000 increase was primarily related to an increase in salaries, wages and benefits, including stock-based compensation expense.

Selling, general and administrative expenses were $31.5 million for the 2021 Quarter, compared to $31.3 million for the 2020 Quarter. The $216,000 increase was primarily related to:

- an increase in salaries, wages and benefits, including stock-based compensation expense, of $1.3 million; and
- an increase in audit, legal and professional fees of $796,000; partially offset by

- a decrease in sales, marketing, and consulting costs of $1.5 million, primarily due to lower costs incurred in the 2021 Quarter to support the ongoing commercialization of our products; and
- a decrease in product taxes and fees of $543,000 primarily due to timing of when states enacted certain excise taxes on the sales of opioids.

Operating expenses, excluding stock-based compensation expense, were $27.5 million in the 2021 Quarter compared to $29.0 million in the 2020 Quarter. The $1.5 million decrease was primarily related to the decrease in sales, marketing, and consulting costs as described above.

Interest expense was $5.7 million for the 2021 Quarter, compared to $4.8 million in the 2020 Quarter. The $898,000 increase was primarily due to a full quarter of interest expense recognized in the 2021 Quarter associated with the term notes and convertible notes issued in connection with the Nucynta Acquisition compared to a partial quarter in the 2020 Quarter. This increase was partially offset by lower non-cash interest expense associated with the Company's senior convertible notes in the 2021 Quarter as a result of the adoption of ASU 2020-06 in the 2021 Quarter.

Interest income was $3,000 for the 2021 Quarter, compared to $212,000 in the 2020 Quarter. The $209,000 decrease was primarily due to lower interest rates in the 2021 Quarter.

Benefit from income taxes was $188,000 for the 2021 Quarter, compared to none for 2020 Quarter. The $188,000 increase was primarily due to excess tax benefits related to stock-based compensation partially offset by provisions for current state income taxes. We did not record income tax expense in 2020 Quarter due to the utilization of NOLs carried forward to offset both federal and state taxable income.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have incurred cumulative net losses and negative cash flows from operations since inception until 2020. Historically, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public offerings of common stock and convertible notes, and commercial bank debt. As of December 31, 2020, we had $174.1 million in cash and cash equivalents. As of March 31, 2021, we had $182.8 million in cash and cash equivalents.

Borrowing Arrangements and Equity Offerings

The following transactions represent the material changes in borrowing arrangements and equity offerings that were previously disclosed in our most recent Annual Report.

Pharmakon Term Notes

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, we, together with our subsidiary, Collegium Securities Corporation, entered into the Loan Agreement with BioPharma Credit PLC, as collateral agent and lender; and BioPharma Credit Investments V (Master) LP, as lender. The Loan Agreement provides for a $200.0 million secured term loan (the "term notes"), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the closing of the Nucynta Acquisition, and are guaranteed by our material domestic subsidiaries and are also secured by substantially all of our material domestic assets. The term notes will bear interest at a rate based upon LIBOR (subject to a LIBOR floor of 2.0%), plus a margin of 7.5% per annum. We are required to repay the term notes by making equal quarterly payments.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require us to maintain $200.0 million in annual net sales and covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding our ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for the

lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement.

2026 Convertible Notes

On February 13, 2020, in connection with the execution of the Nucynta Purchase Agreement, we issued 2.625% convertible senior notes due 2026 (the "convertible notes"), in the aggregate principal amount of $143.8 million, in a public offering registered under the Securities Act of 1933, as amended. The proceeds were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The convertible notes are senior, unsecured obligations and will accrue interest at a rate of 2.625% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, which began on August 15, 2020. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate is 34.2618 shares of common stock per $1,000 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price will be subject to adjustment upon the occurrence of certain events.

Silicon Valley Bank Term Loan Facility

From August 2012 until January 2020, we maintained a term loan facility with Silicon Valley Bank, which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan, we had a term loan facility in an amount of $11.5 million, which replaced our previously existing term loan facility. The proceeds were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan. In January 2020, in anticipation of consummation of the Nucynta Acquisition and related financing activities, we repaid all of our outstanding indebtedness under the amended term loan.

Cash Flows

	Three months ended March 31,	
	2021	**2020**
Net cash provided by (used in) operating activities	$ 20,570	$ (6,669)
Net cash used in investing activities	(428)	(367,647)
Net cash (used in) provided by financing activities	(11,468)	323,120
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 8,674	$ (51,196)

Operating activities. Cash provided by operating activities was $20.6 million in the 2021 Quarter, compared to cash used in operating activities of $6.7 million in 2020 Quarter. The $27.3 million increase in cash provided by operating activities was primarily due to higher net income and higher non-cash adjustments including higher intangible asset amortization related to the Nucynta Acquisition and higher stock-based compensation expense.

Investing activities. Cash used in investing activities was $428,000 in the 2021 Quarter, compared to cash used in investing activities of $367.6 million in the 2020 Quarter. The $367.2 million decrease in cash used in investing activities was primarily related to the Nucynta Acquisition, which closed in the 2020 Quarter. The remaining change is primarily related to the timing of purchases of property and equipment.

Financing activities. Cash used in financing activities was $11.5 million for the 2021 Quarter, compared to cash provided by financing activities of $323.1 million in the 2020 Quarter. The $334.6 million decrease in cash provided by financing activities was primarily related to net proceeds from the term notes of $192.4 million and issuance of the convertible notes of $138.8 million, both of which were issued in the 2020 Quarter. The remaining change is primarily related to changes in proceeds from the issuance of shares under our employee stock purchase plan and proceeds from exercises of stock options, offset by payments made for employee restricted stock tax withholdings.

Funding Requirements

We believe that our cash and cash equivalents at March 31, 2021 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Certain economic or strategic considerations may cause us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the generation of reasonable levels of revenue from products sales;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the cost of patent infringement litigation, including our litigation with Purdue, relating to Xtampza ER and the Nucynta Products, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- the timing and costs associated with manufacturing our products, for commercial sale and clinical trials; and
- the effect of competing technological and market developments.

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

ADDITIONAL INFORMATION

To supplement our financial results presented on a GAAP basis, we have included information about non-GAAP adjusted EBITDA. We use this non-GAAP financial measure to understand, manage and evaluate our business as we believe it represents the performance of our core business. Because this non-GAAP financial measure is an important internal measure for us, we believe that the presentation of this non-GAAP financial measure provides analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report this non-GAAP financial measure to portray the results of our major operations prior to considering certain income statement elements. This non-GAAP financial measure should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

In our quarterly and annual reports, earnings press releases and conference calls, we discuss Adjusted EBITDA, a financial measure that is not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA represents GAAP net income adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, and stock-based compensation. Adjusted EBITDA, as used by us, may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income, which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes; and
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments.

Adjusted EBITDA was $45.3 million for the 2021 Quarter compared to $20.5 million for the 2020 Quarter. The $24.8 million increase was primarily due to higher GAAP net income of $15.2 million and higher adjustments for amortization expense of $6.5 million and stock-based compensation expense of $1.9 million.

Adjusted EBITDA for three months ended March 31, 2021 and 2020 was as follows:

	Three months ended March 31,	
	2021	**2020**
GAAP net income	$ 15,662	$ 450
Adjustments:		
Interest expense	5,721	4,823
Interest income	(3)	(212)
Benefit from income taxes	(188)	—
Depreciation	439	198
Amortization	16,795	10,295
Stock-based compensation expense	6,879	4,951
Total adjustments	$ 29,643	$ 20,055
Adjusted EBITDA	$ 45,305	$ 20,505

Adjusted EBITDA by quarter during the year ended December 31, 2020 was as follows:

	First Quarter 2020	Second Quarter 2020	Third Quarter 2020	Fourth Quarter 2020
GAAP net income	$ 450	$ 8,058	$ 11,286	$ 6,958
Adjustments:				
Interest expense	4,823	8,259	8,063	7,737
Interest income	(212)	(14)	(3)	(3)
Provision for income taxes	—	246	280	304
Depreciation	198	196	195	281
Amortization	10,295	16,795	16,795	16,795
Stock-based compensation expense	4,951	5,584	5,165	6,210
Total adjustments	$ 20,055	$ 31,066	$ 30,495	$ 31,324
Adjusted EBITDA	$ 20,505	$ 39,124	$ 41,781	$ 38,282

CONTRACTUAL OBLIGATIONS

There have been no material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

For information regarding our exposure to certain market risks, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report. There have been no significant changes in our financial instrument portfolio or market risk exposures since our fiscal year ended December 31, 2020.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth in Note 14 to our financial statements, which is incorporated herein by reference to the extent applicable, there are no other material changes from the legal proceedings previously disclosed in our Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as all other information included in this Quarterly Report on Form 10-Q, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and investors could lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products and product candidates that we may develop or acquire in the future. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

Our ability to maintain profitability depends upon our ability to realize the full commercial potential of our products and to commercialize successfully any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products depends on a number of factors, including our ability to:

- realize a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- sustain a commercial organization capable of sales, marketing and distribution for the products we sell;
- obtain coverage and adequate reimbursement from third parties, including government payors; and
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers, and to our products specifically, including FDA post-marketing requirements.

If we fail to maintain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had a federal net operating loss ("NOL") carryforward of approximately $226.8 million and state NOL carryovers of approximately $170.3 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $4.6 million, and state tax credits of approximately $1.2 million. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended. As of December 31, 2020, and December 31, 2019, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

We have outstanding indebtedness in the form of our 2.625% Convertible Senior Notes and our Loan Agreement with BioPharma, which may adversely affect our business, financial condition and results of operations.

In February 2020, in connection with the Nucynta Acquisition, we incurred (i) $143.8 million in principal amount of indebtedness in the form of 2.625% Convertible Senior Notes due in 2026 (the "Convertible Notes") and (ii) $200.0 million in secured indebtedness pursuant to our Loan Agreement with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (as amended from time to time, the "Loan

Agreement"). We may also incur additional indebtedness to meet future financing needs. Our existing and future levels of indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing shareholders as a result of issuing shares of our common stock upon conversion of the convertible notes;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital;
- increasing our vulnerability to downturns in our business, our industry or the economy in general, including any such downturn related to the impact of the COVID-19 pandemic.

Holders of our Convertible Notes will have the right to require us to repurchase our Convertible Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion of our Convertible Notes. Further, our noteholders, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. Applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion. Additionally, our Loan Agreement contains certain covenants and obligations applicable to us, including, without limitation, covenants that require us and our subsidiaries to maintain $200 million in annual net sales and covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business.

Failure to comply with covenants in the indenture governing the Convertible Notes or in the Loan Agreement would constitute an event of default under these instruments, notwithstanding our ability to meet our debt service obligations. Our failure to repurchase notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. In such event, we may not have sufficient funds to satisfy all amounts due under our other indebtedness (including the Loan Agreement) and the notes. The Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. If we fail to comply with such covenants and terms, we may be in default and the maturity of the related debt could be accelerated and become immediately due and payable. In addition, because our assets are pledged as a security under the Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets are subject to the risk of foreclosure by our lenders. Moreover, a default on indebtedness under the Loan Agreement could result in a default under the terms of the indenture governing our Convertible Notes. There is no guarantee that we would be able to satisfy our obligations if any of our indebtedness is accelerated.

Risks Related to our Products

If we cannot continue successfully commercializing Xtampza ER or the Nucynta Products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products. Our business and future success are substantially dependent on our ability to continue successfully commercializing these products.

Our ability to continue successfully commercializing Xtampza ER and the Nucynta Products will depend on many factors, including but not limited to:

- our ability to manufacture commercial quantities of Xtampza ER at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to execute sales and marketing strategies successfully and continually;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of our products;
- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments with similar indications;
- our ability to defend successfully any challenges to our intellectual property or suits asserting patent infringement relating to our products;
- the availability and quality of coverage and adequate reimbursement for our products;
- a continued acceptable safety profile of our products; and
- our ability to comply with applicable legal and regulatory requirements, including any additional manufacturing or packaging requirements that may become applicable to certain opioid products.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to continue successfully commercializing or to generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of Xtampza ER and our ability to market Xtampza ER successfully may be adversely affected.

Xtampza ER was approved with label language describing abuse-deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, "Abuse-Deterrent Opioids- Evaluation and Labeling." In November 2017, the FDA approved an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

The FDA can require changes to the product labeling for Xtampza ER or the Nucynta Products at any time which can impact our ability to generate product sales. In particular, if the FDA determines that our post-marketing data for Xtampza ER does not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrates a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims, which would have a material adverse effect on our ability to continue successfully commercializing Xtampza ER.

Xtampza ER and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.

The FDA has imposed a class-wide REMS on all IR, ER and long acting ("LA") opioid drug products (known as the Opioid Analgesic REMS). The FDA continually evaluates whether the REMS program is meeting its goal of ensuring that the benefit of these drugs continue to outweigh their risks, and whether the goals or elements of the program should be modified. If the FDA determines that additional measures are necessary, the modification of the Opioid Analgesic REMS to impose additional or more burdensome requirements could increase the costs associated with marketing our products and/or reduce the willingness of healthcare providers to prescribe our products, both which would have a material adverse effect on our ability to continue successfully commercializing, or to generate sufficient revenue from, our products.

We could fail to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations.

Xtampza ER has FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA

may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of Xtampza ER.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza ER and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any pharmaceutical product marketed in the United States, including Xtampza ER and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

Engaging in off-label promotion of our products could also subject us to false claims liability under federal and state statutes, and other litigation and/or investigations, which could lead to civil and criminal penalties and fines, and could also require us to enter into agreements that materially restrict the manner in which we promote or distribute our drug products.

In addition, after product approval, subsequent discovery of serious and unanticipated adverse events associated with the product; the emergence of other problems with the product, manufacturer or facility; or our failure to make required regulatory submissions may result in adverse regulatory actions, including withdrawal of the product from the market or the requirement to add or strengthen label warnings about the product. The failure to obtain or maintain requisite governmental approvals or the imposition of additional or stronger warnings could delay or preclude us from further developing, marketing or realizing the full commercial potential of our products.

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.

Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations.

Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

If we are unable to obtain or maintain intellectual property rights for our technologies, products or any future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.

We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope.
This litigation is expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those with whom they communicate, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time

limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Products

If we are unable to utilize our own sales and marketing capabilities successfully or enter into strategic alliances with marketing collaborators, we may not continue to be successful in commercializing our products and may be unable to generate sufficient product revenue.

Our commercial organization continues to evolve and we cannot guarantee that we will continue to be successful in marketing our products. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not remain profitable. Factors that may inhibit our efforts to continue successfully commercializing our products in the United States include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

If we are not successful in retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not preserve strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty in continuing to commercialize our products.

Additionally, our sales, marketing and distribution capabilities may be hindered as a result of the COVID-19 outbreak. In response to the outbreak and the resulting mandatory closure of non-essential businesses and imposition of “social distancing” measures recommended by U.S. public health officials, our sales personnel have transitioned partly or entirely to remote work. The safety and well-being of our employees is our highest priority and we expect to maintain mitigating measures until such time as mandated closures are lifted and public health officials change their recommendations, and we have, and will continue to, equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations, whether in person or from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to continue successfully commercializing our products. The travel restrictions and “social distancing” recommendations resulting from the spread of COVID-19 have impacted our sales professionals’ ability to travel to and meet with customers in person. The outbreak has also prompted healthcare providers to limit our and our wholesalers’ and distributors’ access to physicians and other key healthcare personnel, which may inhibit our and our customers’ ability to meet existing, or generate new, demand for our products. If we are unable to successfully commercialize our products during the COVID-19 outbreak, our ability to generate sufficient product revenue may be adversely affected.

If the medical community, patients, and healthcare payors do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Physicians and others in the medical community, patients, and healthcare payors may not accept and use our products. Acceptance and use of our products will depend on a number of factors including:

- approved indications, warnings and precautions language that may be less desirable than competitive products;
- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our products;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology;
- the availability of competitive products;
- the pricing and cost-effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products over alternative treatments;
- the convenience and ease of administration to patients of our products;
- actual and perceived availability and quality of coverage and reimbursement for our products from government

or other third-party payors;
- any negative publicity related to our products or negative or positive publicity related to our competitors' products;
- the prevalence and severity of adverse side effects;
- policy initiatives by FDA, HHS, or other federal or state agencies regarding opioids;
- our ability to comply with the Opioid Analgesic REMS; and
- the effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If our products fail to have an adequate level of acceptance by the medical community, patients, or healthcare payors, we will not be able to generate sufficient revenue to remain profitable. Since we expect to rely on sales generated by Xtampza ER and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza ER or the Nucynta Products to maintain market acceptance would harm our business prospects.

Our products contain, and our future product candidates may contain, controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies.

Our products contain, and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. In light of the COVID-19 public health emergency, the DEA now allows the issuance of a prescription for a controlled substance after examination of a patient through telemedicine technology as an in-person examination may not be possible.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. For more information, see the section in our Annual Report entitled "Business—Government Regulation—DEA and Opioid Regulation." We may not be able to obtain sufficient quantities of these controlled substances in order to meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from developing and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances.

Current and future legislation may increase the difficulty and cost for us to continue to commercialize our products and may reduce the prices we are able to obtain for our products.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect

our ability to profitably sell our products for which we obtain marketing approval. For example, several states, including New York, have recently imposed taxes or fees on the sale of opioids. Other states could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations.

California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the effect this legislation will have on our business. Laws intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing of our products may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may subject us to more stringent product labeling and post-marketing testing and other requirements.

Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products.

Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels and tiers of preference based on the perceived value and innovation of a given product. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications and establishing administrative hurdles that incentivize use of generic and/or lower cost products first. Increasingly, third-party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that high-quality coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to expand and maintain coverage and profitable reimbursement rates from both government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to continue to commercialize our products and our overall financial condition.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to continue to commercialize our products and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act, and the Affordable Care Act has also been subject to challenges in the courts. See the section in our Annual Report entitled “Business—Government Regulation—Healthcare Reform.”

Further changes to and under the Affordable Care Act remain possible, although the new Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue and maintain profitability.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory and enforcement efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business.

Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to continue to commercialize our products.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of people who abuse drugs to discover previously unknown ways to abuse opioid drugs, including Xtampza ER and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products, decrease the revenues we are able to generate from their sale and adversely impact external investor perceptions of our business. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use, including the Comprehensive Addiction and Recovery Act and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. These laws are described in more detail under the caption “Business— Governmental Regulation — DEA and Opioid Regulation.”

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a “listed

drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In November 2017, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In the second half of 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

If the third-party manufacturers of Xtampza ER or the Nucynta Products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated facility at our third-party manufacturer's site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business.

We do not own any manufacturing facilities in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility and do not have the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our products. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products and we control only certain aspects of their activities.

In 2020, we completed the build-out of a dedicated manufacturing suite at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This dedicated facility requires the maintenance of regulatory approvals and other costs, all of which we will need to absorb. We cannot guarantee that we will be able to leverage the dedicated manufacturing suite in a profitable manner. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and the future manufacturer of Nucynta ER, exposes us to the following risks, any of which could impact commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products including the ongoing COVID-19 pandemic, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.
- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or deliver the dedicated facility according to the currently agreed timeline.
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products, before we may use the alternative manufacturer to

produce commercial supplies.
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully.
- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture our products could adversely affect our ability to continue to commercialize the product, which could in turn adversely affect our results of operations and financial condition. Certain components of Xtampza ER are naturally derived products, for which we rely on sole suppliers. The inability of any of our raw material suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our product. Furthermore, the quota procurement process limits the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to execute a business strategy that builds appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that our products to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Any stock out, or failure to obtain sufficient supplies of any of our products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of our products, could adversely affect our ability to commercialize such products, which could in turn adversely affect our results of operations and financial condition.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of our products, any production problems with our supplier could have a material adverse effect on us.

We presently depend upon a single supplier for the active pharmaceutical ingredient for Xtampza ER (oxycodone base) and the Nucynta Products (tapentadol), and we contract with this supplier for commercial supply to manufacture our products. Further, our sole supplier also supplies our primary competitor in the extended-release oxycodone space, Purdue. Although we have identified an alternate source for oxycodone base for Xtampza ER, it would be time-consuming and costly to qualify this source. Any changes that our supplier makes to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our supplier were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of disruptions in personnel or the global supply chain resulting from the COVID-19 outbreak), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply.

In our current commercial manufacturing operations, and as we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors, that loss may materially adversely affect our financial condition and results of operations.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented 36%, 31% and 30% of our product shipments for the three months ended March 31, 2021. Our loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases, a significant disruption to transportation infrastructure or other means of distribution of our products, including as a result of the ongoing COVID-19 outbreak, could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.

Our products are subject to a comprehensive regulatory scheme, including post-marketing requirements ("PMRs") to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.

We have relied upon and plan to continue to rely upon contract research organizations ("CROs") to monitor and manage data for any non-clinical and clinical programs that we may conduct, including the OPC PMR studies discussed above. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing the activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products would have an adverse impact on our commercial efforts.

Risks Related to Our Business and Strategy

Our business may be adversely affected by the COVID-19 pandemic.

The outbreak and any preventative or protective actions that we, our manufacturers, suppliers, licensors and other collaborators or governmental authorities may take with respect to the COVID-19 pandemic have disrupted and may

continue to disrupt our business and the U.S. and global economies as a whole. The COVID-19 pandemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to a substantial percentage of personnel contracting the virus or due to shutdowns that have been or may be requested or mandated by governmental authorities. The full extent to which the COVID-19 pandemic will affect the U.S. and global economies is unknown.

The COVID-19 pandemic has, and will likely continue to have, a substantial impact on the delivery of healthcare services in the United States. Healthcare providers have reduced staffing and limited access for non-patients, including our sales professionals. In addition, as discussed above, travel restrictions due to COVID-19 have impacted our sales professionals' ability to travel to customers, which has had, and will continue to have, a negative impact on our sales and the market penetration of our products. Moreover, the spread of COVID-19 has had, and may continue to have, an impact on the number of patients seeking and receiving treatment for conditions that might otherwise result in the prescription of our products, as patients increasingly make efforts to avoid or postpone seeking non-essential medical care and hospitals cancel elective surgeries due to the COVID-19 pandemic. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

The extent to which the COVID-19 pandemic continues to impact our results of operation will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the rate and manner in which it spreads, the duration of the pandemic, travel restrictions imposed by the United States and other countries, business closures or business disruption in the United States and other countries, a reduction in time spent out of home and the actions taken throughout the world, including in our markets, to contain COVID-19 or treat its impact. Although travel and other restrictions have started to be lifted in certain jurisdictions, there remains substantial uncertainty as to the possibility of further surges in infections, which could lead to travel and other restrictions being re-imposed. These actions could have a material adverse impact on our business, financial condition and results of operations, and we will continue to monitor the effects of the COVID-19 pandemic closely.

Litigation or regulatory action regarding opioid medications could negatively affect our business.

Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States. These lawsuits generally contend that we have engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. Plaintiffs seek a variety of remedies, including abatement, restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. In some of the lawsuits, the plaintiffs have alleged joint and several liability among the defendants, meaning that any given defendant may be found liable for the activities of other defendants. None of the complaints specify the exact amount of damages at issue. These cases are generally in early stages of litigation.

In addition, certain governmental and regulatory agencies are focused on the abuse of opioid medications, a concern we share, and we have received Civil Investigative Demands or subpoenas from four state attorneys general investigating our sales and marketing of opioids and seeking documents relating to the manufacture, marketing and sale of opioid medications. We are cooperating fully in these investigations. Managing litigation and responding to governmental investigations is costly and may involve a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve injunctive relief or substantial monetary penalties, either or both of which could have a material adverse effect on our reputation, business, results of operations and cash flows.

We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do.

The competition in the pain and opioid market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our products compete with oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, BioDelivery Sciences, Endo, Mallinckrodt, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we

are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do.

Our competitors have developed or may be in the process of developing technologies that are, or in the future may be, the basis for competitive products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings. The widespread acceptance of currently available therapies with which our products compete may limit market acceptance of our products. Oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance.

Commercial sales of our products, and clinical trials of our products and any future product candidates, may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.

We currently carry product liability insurance. Product liability claims may be brought against us by patients; clinical trial participants; healthcare providers; or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may cause us to incur significant costs to defend the litigation.

Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval.
Even though we do not and will not control referrals of healthcare services or bill Medicare, Medicaid or other third-party payors directly, we may provide reimbursement guidance and support regarding our products to our customers and patients. Federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic (such as the ongoing COVID-19 pandemic) or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it might become difficult or, in certain cases, impossible for us to continue our business, and any disruption could last for a substantial period of time.

The disaster recovery and business continuity plans we have in place, and the technology that we may rely upon to implement such plans, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition and results of operation.

Risks Related to Our Common Stock

The price of our common stock may be volatile and you may lose all or part of your investment.

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these Risk Factors, some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks, or any of a broad range of other risks discussed in this report, could have a material adverse effect on the market price of our common stock.

We are subject to anti-takeover provisions in our second amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders.

Certain provisions of Virginia law, the state in which we are incorporated, and our second amended and restated articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our Board of Directors or management or elect new directors to our Board of Directors.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to report our financial condition, results of operations or cash flows accurately, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. Further, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to capital markets.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Moreover, the exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

As of March 31, 2021, there were outstanding options to purchase an aggregate of 3,608,826 shares of our common stock at a weighted average exercise price of $18.09 per share, of which options to purchase 2,353,069 shares of our common stock were then exercisable. In addition, as of March 31, 2021, we had an outstanding warrant to purchase

1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

RECENT SALES OF UNREGISTERED SECURITIES

There were no unregistered sales of equity securities during the period covered by this Quarterly Report on Form 10-Q.

PURCHASE OF EQUITY SECURITIES

The following table sets forth purchases of our common stock for the three months ended March 31, 2021:

Period	(a) Total number of shares purchased [1]	(b) Average Price Paid per Share	(c) Total number of shares purchased as part of publicly announced plans or programs	(d) Maximum number of shares that may yet be purchased under the plans or programs
January 1, 2021 through January 31, 2021	1,791	$ 20.48	—	—
February 1, 2021 through February 28, 2021	132,853	$ 25.95	—	—
March 1, 2021 through March 31, 2021	918	$ 24.70	—	—
Total	135,562	$ 25.87	—	—

(1) All of the shares were transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
31.1	Certification of Chief Executive Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
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 as Inline XBRL and contained 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.

COLLEGIUM PHARMACEUTICAL, INC.

Date: May 6, 2021

By: /s/ JOSEPH CIAFFONI
Joseph Ciaffoni
Chief Executive Officer
(Principal executive officer)

Date: May 6, 2021

By: /s/ PAUL BRANNELLY
Paul Brannelly
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Ciaffoni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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 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 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.

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: May 6, 2021

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Brannelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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 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 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.

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: May 6, 2021

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 Collegium Pharmaceutical, Inc. (the "Company") for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: May 6, 2021

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 Collegium Pharmaceutical, Inc. (the "Company") for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: May 6, 2021