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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, 2023

OR

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

For the transition period from to

Commission file number: 001-37372

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 ☐	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, 2023, there were 34,594,760 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 ("Quarterly Report") 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;
- our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products, 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;
- 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 ingredients for each of our products, manufacture adequate quantities of commercially salable inventory and maintain our supply chain;
- 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 business development;
- our ability to obtain regulatory approval for any product candidates we may acquire in the future;
- our ability to comply with the terms of our outstanding indebtedness;
- regulatory and legislative developments in the United States, including the adoption of opioid stewardship and similar taxes that may impact our business;
- our ability to obtain and maintain sufficient intellectual property protection for our products and any future 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;
- our customer concentration, which may adversely affect our financial condition and results of operations; and
- 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.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Quarterly Report (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. 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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 269,480	$ 173,688
Accounts receivable, net	179,127	183,119
Inventory	32,895	46,501
Prepaid expenses and other current assets	16,798	16,681
Total current assets	498,300	419,989
Property and equipment, net	18,879	19,521
Operating lease assets	6,658	6,861
Intangible assets, net	530,002	567,468
Restricted cash	2,547	2,547
Deferred tax assets	23,969	23,950
Other noncurrent assets	87	100
Goodwill	133,857	133,695
Total assets	$ 1,214,299	$ 1,174,131
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 2,992	$ 3,494
Accrued expenses	24,433	36,129
Accrued rebates, returns and discounts	200,902	230,491
Current portion of term notes payable	183,333	162,500
Current portion of operating lease liabilities	1,042	1,112
Total current liabilities	412,702	433,726
Term notes payable, net of current portion	353,769	397,578
Convertible senior notes	261,222	140,873
Operating lease liabilities, net of current portion	6,873	7,112
Total liabilities	1,034,566	979,289
Commitments and contingencies (refer to Note 15)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000; 37,816,843 issued and 34,581,020 outstanding shares at March 31, 2023 and 37,084,759 issued and 33,848,936 outstanding shares at December 31, 2022	38	37
Additional paid-in capital	540,389	538,073
Treasury stock, at cost; 3,235,823 shares at March 31, 2023 and 3,235,823 shares at December 31, 2022	(61,924)	(61,924)
Accumulated deficit	(298,770)	(281,344)
Total shareholders’ equity	179,733	194,842
Total liabilities and shareholders’ equity	$ 1,214,299	$ 1,174,131

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,	
	2023	**2022**
Product revenues, net	$ 144,767	$ 83,751
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	29,899	16,332
Intangible asset amortization	37,466	18,923
Total cost of products revenues	67,365	35,255
Gross profit	77,402	48,496
Operating expenses		
Research and development	—	3,983
Selling, general and administrative	52,775	54,528
Total operating expenses	52,775	58,511
Income (loss) from operations	24,627	(10,015)
Interest expense	(21,427)	(5,831)
Interest income	2,747	4
Loss on extinguishment of debt	(23,504)	—
Loss before income taxes	(17,557)	(15,842)
Benefit from income taxes	(131)	(2,773)
Net loss	$ (17,426)	$ (13,069)
Loss per share — basic	$ (0.51)	$ (0.39)
Weighted-average shares — basic	34,319,291	33,673,912
Loss per share — diluted	$ (0.51)	$ (0.39)
Weighted-average shares — diluted	34,319,291	33,673,912

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,	
	2023	**2022**
Operating activities		
Net loss	$ (17,426)	$ (13,069)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization expense	37,466	18,923
Depreciation expense	817	715
Deferred income taxes	(46)	(6,038)
Stock-based compensation expense	6,035	6,135
Non-cash lease expense	(105)	158
Non-cash interest expense for amortization of debt discount and issuance costs	2,287	913
Loss on extinguishment of debt	23,504	—
Changes in operating assets and liabilities:		
Accounts receivable	3,993	(5,006)
Inventory	13,606	330
Prepaid expenses and other assets	(238)	677
Accounts payable	(502)	(350)
Accrued expenses	(12,131)	(6,838)
Accrued rebates, returns and discounts	(29,589)	(21,865)
Net cash provided by (used in) operating activities	27,671	(25,315)
Investing activities		
Purchases of property and equipment	(176)	(108)
Acquisition of BDSI (net of cash acquired)	—	(572,069)
Net cash used in investing activities	(176)	(572,177)
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plan	169	203
Proceeds from the exercise of stock options	3,848	3,261
Payments made for employee stock tax withholdings	(7,736)	(3,382)
Repayment of term notes	(25,000)	—
Proceeds from term note modification	—	517,682
Proceeds from issuances of 2029 Convertible Notes, net of issuance costs of $5,846	235,654	—
Repurchase of 2026 Convertible Notes, including premium	(138,638)	—
Net cash provided by financing activities	68,297	517,764
Net increase (decrease) in cash, cash equivalents and restricted cash	95,792	(79,728)
Cash, cash equivalents and restricted cash at beginning of period	176,235	188,973
Cash, cash equivalents and restricted cash at end of period	$ 272,027	$ 109,245
Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets:		
Cash and cash equivalents	$ 269,480	$ 106,698
Restricted cash	2,547	2,547
Total cash, cash equivalents and restricted cash	$ 272,027	$ 109,245
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 19,499	$ 5,833
Cash paid for income taxes	$ 743	$ 2,114
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment in accounts payable and accrued expenses	$ —	$ 148
Note issuance costs in accounts payable and accrued expenses	$ 434	$ —

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" or "Collegium") 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's mission is to build a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. The Company's portfolio includes Xtampza ER, Nucynta ER and Nucynta IR (collectively the "Nucynta Products"), Belbuca, and Symproic.

Xtampza ER, an abuse-deterrent, oral formulation of oxycodone, was approved by the U.S. Food and Drug Administration ("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. The Company commercially launched Xtampza ER in June 2016.

The Nucynta Products are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol. 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. The Company began shipping and recognizing product sales on the Nucynta Products in January 2018 and began marketing the Nucynta Products in February 2018.

On March 22, 2022 (the "Acquisition Date"), the Company acquired BioDelivery Sciences International, Inc. ("BDSI"), a specialty pharmaceutical company working to deliver innovative therapies for individuals living with serious and debilitating chronic conditions, pursuant to an Agreement and Plan of Merger, dated as of February 14, 2022, by and among the Company, Bristol Acquisition Company Inc., the Company's wholly owned subsidiary, and BDSI (the "BDSI Acquisition"). Upon closing, the Company acquired the Belbuca and Symproic products. Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate. Symproic was approved by the FDA in March 2017 for the treatment of opioid-induced constipation ("OIC") in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. The Company began shipping and recognizing product sales related to Belbuca and Symproic in March 2022.

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, product-related litigation, 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. As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, the Company's business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, the Company expects the trends that emerged as a result of the pandemic to persist in the near to medium term.

The Company believes that its cash and cash equivalents at March 31, 2023, 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 at least one year from the date the consolidated financial statements were issued.

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) and its subsidiaries. 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, 2023, and the results of operations and cash flows for the three months ended March 31, 2023 and 2022. The results of operations for the three months ended March 31, 2023 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, 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 most recently filed annual report on Form 10-K for the fiscal year ended December 31, 2022 (the "Annual Report").

There were no changes in the Company's significant accounting policies from those described in the Company's Annual Report.

Recently Adopted Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as required by the specified effective dates.

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 wholesalers ("customers"), which in turn sell the product to pharmacies for the treatment of patients.

Revenue Recognition

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 with a customer, 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, 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.

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.

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.

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; 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.

The Company bases its estimates of variable consideration, which could include estimates of future rebates, returns, and other adjustments, on historical data and other information. Estimates include: (i) timing of the rebates and returns incurred, (ii) pricing adjustments related to rebates and returns, and (iii) the quantity of product that will be rebated or returned in the future. Significant judgment is used in determining the appropriateness of these assumptions at each reporting period.

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales. 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 wholesalers. Given that wholesalers sell the product to pharmacies, which in turn dispense the product to patients, claims can be submitted significantly after 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 future estimates, which could have an effect on earnings in the period of the adjustment.

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.

Provisions for product returns, including returns for Xtampza, the Nucynta Products, Belbuca and Symproic, are based on product-level returns rates, including processed as well as unprocessed return claims, in addition to relevant market events and other factors. Estimates of the future product returns are made at the time of revenue recognition to determine the amount of consideration to which the Company expects to be entitled (that is, excluding the products expected to be returned). At the end of each reporting period, the Company analyzes trends in returns rates and updates its assessment of variable consideration for returns to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. To the extent the Company receives amounts in excess of

what it expects to be entitled to receive due to a product return, the Company does not recognize revenue when it transfers products to customers but instead recognizes those excess amounts received as a refund liability. The Company updates the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds with the corresponding adjustments recognized as revenue (or reductions of revenue).

The Company provides the right of return to its customers for an 18-month window beginning six months prior to expiration and up until twelve months after expiration. The Company's customers short-pay an existing invoice upon notice of a product return claim. Adjustments to the preliminary short-paid claims are processed when the return claim is validated and finalized. The Company's return policy requires that product is returned and that the return is claimed within the 18-month window.

At the end of each reporting period, the Company updates the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. Variable consideration, including the risk of customer concessions, is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is subsequently resolved. In particular, resolution of the unprocessed return claims includes the risk of concession for those that are outside of the Company's return policy.

Significant judgment is required to determine the variable consideration included in the transaction price as described above. Adjustments to the estimated variable consideration included in the transaction price occurs when new information indicates that the estimate should be revised. If the value of accepted and processed claims is different than the amount estimated and included in variable consideration, then adjustments would impact product revenues, net and earnings in the period such revisions become known. The amount of variable consideration ultimately received and included in the transaction price may materially differ from the Company's estimates, resulting in additional adjustments recorded to increase or decrease product revenues, net.

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the three months ended March 31, 2023 and 2022:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2022	$ 156,937	$ 73,554	$ 22,058
Provision related to current period sales	92,871	10,166	34,921
Changes in estimate related to prior period sales	36	571	92
Credits/payments made	(122,852)	(10,381)	(32,563)
Balance at March 31, 2023	$ 126,992	$ 73,910	$ 24,508

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2021	$ 142,379	$ 54,617	$ 13,226
Acquired from BDSI	34,158	18,187	7,575
Provision related to current period sales	95,413	7,072	22,612
Changes in estimate related to prior period sales	(514)	—	(37)
Credits/payments made	(118,937)	(4,899)	(22,001)
Balance at March 31, 2022	$ 152,499	$ 74,977	$ 21,375

(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 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 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 Consolidated Balance Sheets.

As of March 31, 2023, 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 discloses disaggregated revenue from contracts with customers into categories that depict how the nature, amount, timing, and uncertainty of revenue and cash flows are affected by economic factors. When selecting the type of category to use to disaggregate revenue, the Company considers how information about the Company's revenue has been presented for other purposes as well as what information is regularly reviewed and used for evaluating financial performance. As such, the Company disaggregates its product revenues, net from contracts with customers by product, as disclosed in the table below.

	Three Months Ended March 31,	
	2023	**2022**
Xtampza ER	$ 47,869	$ 31,518
Belbuca	44,212	3,310
Nucynta IR	27,899	29,335
Nucynta ER	21,136	19,263
Symproic	3,651	300
Other	—	25
Total product revenues, net	$ 144,767	$ 83,751

The Company began recognizing revenue from net product sales of Belbuca and Symproic following the Acquisition Date (refer to Note 4, *Acquisitions*).

4. Acquisitions

On March 22, 2022, the Company closed the BDSI Acquisition, with BDSI surviving as a wholly owned subsidiary of the Company. The BDSI Acquisition was completed to leverage the Company's existing sales force and other operations to commercialize additional products that are typically marketed to similar physicians and to develop other synergies. The Company obtained control through the acquisition of shares in an all-cash transaction which closed on March 22, 2022.

The total consideration paid for the BDSI acquisition was approximately $669,431 consisting of the following (in thousands, except per share amounts):

Fair Value of Purchase Price Consideration	**Amount**
Fair value of purchase price consideration paid at closing:	
Cash consideration for all outstanding shares of BDSI's common and preferred stock (103,235,298 shares acquired at $5.60 per share)	$ 578,118
Cash consideration paid to settle RSUs and in-the-money options	28,309
Cash paid to settle BDSI debt	63,004
Total purchase consideration	$ 669,431

The Company has accounted for the BDSI Acquisition as a business combination and, accordingly, has included the assets acquired, liabilities assumed and results of operations in its financial statements following the Acquisition Date.

The final allocation of the consideration transferred to the assets acquired and liabilities assumed has been completed. During the three months ended March 31, 2023, the Company recorded measurement period adjustments to increase accrued expenses by $134 and deferred tax liabilities by $28, with a corresponding increase to goodwill of $162.

The following tables set forth the final allocation of the BDSI Acquisition purchase price to the estimated fair value of the net assets acquired at the Acquisition Date:

	Amounts Recognized at the Acquisition Date
Assets Acquired	
Cash and cash equivalents	$ 97,362
Accounts receivable	55,495
Inventory	77,382
Prepaid expenses and other current assets	6,125
Property and equipment	1,242
Operating lease assets	481
Intangible assets	435,000
Total assets	$ 673,087
Liabilities Assumed	
Accounts payable	$ 12
Accrued expenses	18,249
Accrued rebates, returns and discounts	56,261
Operating lease liabilities	481
Deferred tax liabilities	62,510
Total liabilities	$ 137,513
Total identifiable net assets acquired	535,574
Goodwill	133,857
Total consideration transferred	$ 669,431

The valuation of the acquired intangible assets is inherently subjective and relies on significant unobservable inputs. The Company used an income approach to value the $435,000 of intangible assets. The valuation for each of these intangible assets was based on estimated projections of expected cash flows to be generated by the assets, discounted to the present value at discount rates commensurate with risk. The Company amortizes the identifiable intangible assets on a straight-line basis over their respective useful lives (refer to Note 9, *Goodwill and Intangible Assets*). In addition, the acquired inventory was recognized at its acquisition-date fair value, which resulted in an increase of $54,700 compared to its preacquisition book value.

The excess of the purchase price over the fair value of identifiable net assets acquired represents goodwill. This goodwill is primarily attributable to synergies of merging operations. The acquired goodwill is not deductible for tax purposes.

5. License Agreements

Shionogi license and supply agreement

Prior to the BDSI Acquisition, BDSI and Shionogi Inc. (“Shionogi”) entered into an exclusive license agreement (the “Shionogi License Agreement”) for the commercialization of Symproic in the United States including Puerto Rico (the “Shionogi Territory”) for opioid-induced constipation in adult patients with chronic non-cancer pain (the “Shionogi Field”).

Pursuant to the terms of the Shionogi License Agreement, tiered royalty payments on net sales of Symproic in the Shionogi Territory are payable quarterly based on a royalty rate that ranges from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third-party licensor of Shionogi) based on volume of net sales and whether Symproic is being sold as an authorized generic. Unless earlier terminated, the Shionogi License Agreement will continue in effect until the expiration of the royalty obligations, as defined therein. Upon expiration of the Shionogi License Agreement, all licenses granted for Symproic in the Shionogi Field and in the Shionogi Territory survive and become fully-paid, royalty-free, perpetual and irrevocable.

BDSI and Shionogi also had entered into a supply agreement under which Shionogi will supply Symproic at cost plus an agreed upon markup. In the event that Symproic is sourced from a third-party supplier, Shionogi would continue to supply naldemedine tosylate for use in Symproic manufacturing at cost plus such agreed upon markup for the duration of the Shionogi License Agreement.

6. Earnings Per Share

Basic earnings per share is calculated by dividing the net income or loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted earnings per share is computed by dividing the net income or loss 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, if-converted, or contingently issuable accounting methods, depending on the nature of the security. For purposes of the diluted earnings per share calculation, stock options, restricted stock units ("RSUs"), performance share units ("PSUs"), and shares potentially issuable in connection with the Company's employee stock purchase plan and convertible senior notes are considered potentially dilutive securities and included to the extent that their addition is not anti-dilutive.

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

	Three Months Ended March 31,	
	2023	**2022**
Numerator:		
Net loss	$ (17,426)	$ (13,069)
Adjustment for interest expense recognized on convertible senior notes:	—	—
Net loss - diluted	$ (17,426)	$ (13,069)
Denominator:		
Weighted-average shares outstanding — basic	34,319,291	33,673,912
Effect of dilutive securities:		
Stock options	—	—
Restricted stock units	—	—
Performance share units	—	—
Employee stock purchase plan	—	—
Warrants	—	—
Convertible senior notes	—	—
Weighted average shares outstanding — diluted	34,319,291	33,673,912
Loss per share — basic	$ (0.51)	$ (0.39)
Loss per share — diluted	$ (0.51)	$ (0.39)

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 and 2029 in cash, shares or a combination of the two. The Company uses the if-converted method for the convertible senior notes.

The following table presents dilutive securities excluded from the calculation of diluted earnings per share:

	Three Months Ended March 31,	
	2023	**2022**
Stock options	1,443,996	2,401,110
Restricted stock units	2,455,919	2,039,179
Performance share units	503,880	484,292
Warrants	—	1,041,667
Convertible senior notes	7,509,104	4,925,134

For PSUs, 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. All other securities presented in the table above were excluded from the calculation of diluted earnings per share as their inclusion would have had an antidilutive effect.

7. 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, 2023 and 2022.

The following table presents the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at March 31, 2023 and December 31, 2022:

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2023				
Money market funds, included in cash equivalents	$ 122,554	$ 122,554	$ —	$ —
December 31, 2022				
Money market funds, included in cash equivalents	$ 172,590	$ 172,590	$ —	$ —

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis using quoted market prices. Accordingly, these securities are categorized as Level 1.

Assets and Liabilities Not Carried at Fair Value

As of March 31, 2023, the fair value of the Company's 2.625% convertible senior notes due in 2026 was $28,656 and the fair value of the Company's 2.875% convertible senior notes due in 2029 was $216,505, which were estimated utilizing market quotations, and are considered Level 2.

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, 2023, the outstanding principal balance of the term notes of $550,000 reasonably approximated the estimated fair value.

As of March 31, 2023, and December 31, 2022, the carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, and accrued rebates, returns and discounts reasonably approximated their estimated fair values.

8. Inventory

Inventory as of March 31, 2023 and December 31, 2022 consisted of the following:

	March 31, 2023	December 31, 2022
Raw materials	$ 5,831	$ 5,600
Work in process	13,347	24,672
Finished goods	13,717	16,229
Total inventory	$ 32,895	$ 46,501

The aggregate charges related to excess and obsolete inventory for the three months ended March 31, 2023 was $906. These expenses were recorded as a component of cost of product revenues. The aggregate charges related to excess and obsolete inventory for the three months ended March 31, 2022 were immaterial.

9. Goodwill and Intangible Assets

The following tables summarizes the changes in the carrying amount of goodwill:

	Amount
Balance at December 31, 2022	$ 133,695
Goodwill resulting from acquisitions	—
Measurement period adjustments from BDSI Acquisition	162
Balance at March 31, 2023	$ 133,857

The Company's goodwill resulted from the BDSI Acquisition. During the three months ended March 31, 2023, goodwill increased by $162 due to measurement period adjustments associated with the BDSI Acquisition. Refer to Note 4, *Acquisitions*.

The following table sets forth the cost, accumulated amortization, and carrying amount of intangible assets as of March 31, 2023 and December 31, 2022:

	Amortization Period (Years)	March 31, 2023			December 31, 2022		
		Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Belbuca	4.8	$ 360,000	$ (77,277)	$ 282,723	$ 360,000	$ (58,428)	$ 301,572
Nucynta Products	8.0	521,170	(336,424)	184,746	521,170	(319,628)	201,542
Symproic	9.6	70,000	(7,467)	62,533	70,000	(5,646)	64,354
Elyxyb	—	—	—	—	5,000	(5,000)	—
Total intangibles		$ 951,170	$ (421,168)	$ 530,002	$ 956,170	$ (388,702)	$ 567,468

The following table presents amortization expense recognized in cost of product revenues for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
Belbuca	$ 18,849	$ 1,937
Nucynta Products	16,796	16,795
Symproic	1,821	182
Elyxyb	—	9
Total amortization expense	$ 37,466	$ 18,923

As of March 31, 2023, the remaining amortization expense expected to be recognized is as follows:

Years ended December 31,	Belbuca	Nucynta Products	Symproic	Total
2023	$ 56,544	$ 50,385	$ 5,464	$ 112,393
2024	75,393	67,181	7,285	149,859
2025	75,393	67,180	7,285	149,858
2026	75,393	—	7,285	82,678
2027	—	—	7,285	7,285
Thereafter	—	—	27,929	27,929
Remaining amortization expense	$ 282,723	$ 184,746	$ 62,533	$ 530,002

10. Accrued Expenses

Accrued expenses as of March 31, 2023 and December 31, 2022 consisted of the following:

	March 31, 2023	December 31, 2022
Accrued royalties	$ 7,726	$ 13,770
Accrued product taxes and fees	4,821	4,352
Accrued audit and legal	2,283	1,957
Accrued incentive compensation	1,486	2,130
Accrued bonuses	1,333	1,507
Accrued sales and marketing	1,225	6,347
Accrued interest	1,051	1,410
Accrued payroll and related benefits	843	1,208
Accrued other operating costs	3,665	3,448
Total accrued expenses	$ 24,433	$ 36,129

11. Term Notes Payable

2022 Term Loan

On March 22, 2022, in connection with the closing of the BDSI Acquisition, the Company entered into an Amended and Restated Loan Agreement by and among the Company, and BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon") (the "2022 Loan Agreement"). The 2022 Loan Agreement provided for a $650,000 secured term loan (the "2022 Term Loan"), the proceeds of which were used to repay the Company's existing term notes and fund a portion of the consideration to be paid to complete the BDSI Acquisition. The 2022 Loan Agreement was accounted for as a debt modification and transaction fees of $173 were expensed. In connection with the 2022 Loan Agreement, the Company paid loan commitment and other fees to the lender of $19,818, which together with preexisting debt issuance costs and note discounts of $2,049 will be amortized over the term of the loan using the effective interest rate.

The 2022 Term Loan will mature on the 48-month anniversary of the closing of the BDSI Acquisition and is guaranteed by the Company's material domestic subsidiaries. The 2022 Term Loan is also secured by substantially all of the assets of the Company and its material domestic subsidiaries. The 2022 Term Loan bears interest at a rate based upon the London Interbank Offered Rate ("LIBOR") (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. As of March 31, 2023, the interest rate was 12.3%. The Company paid $100,000 in principal payments under the 2022 Term Loan during the first year and the remaining $550,000 balance is required to be paid in equal quarterly installments over the remaining three years.

The 2022 Loan Agreement permits voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium is equal to 2.00% of the principal amount being prepaid prior to the second-year anniversary of the closing date, or 1.00% of the principal amount being prepaid on or after the second-year anniversary of the closing date. The 2022 Loan Agreement also includes a make-whole premium in the event of a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default (as defined in the 2022 Loan Agreement) on or

prior to the second-year anniversary of the closing date, in each case 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 also triggers a mandatory prepayment of the 2022 Term Loan.

The 2022 Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, 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. Failure to comply with these covenants would constitute an Event of Default under the 2022 Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The 2022 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 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement.

During the three months ended March 31, 2023 and 2022, the Company recognized interest expense of $19,679 and $1,823, respectively, related to the 2022 Term Loan.

As of March 31, 2023, future required principal repayments under the 2022 Term Loan are as follows:

Years ended December 31,	**Principal Payments**
2023	$ 137,500
2024	183,333
2025	183,333
2026	45,834
Total before unamortized discount and issuance costs	$ 550,000
Less: unamortized discount and issuance costs	(12,898)
Term notes carrying value	$ 537,102

12. Convertible Senior Notes

2026 Convertible Notes

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "2026 Convertible Notes") in the aggregate principal amount of $143,750, in a public offering registered under the Securities Act of 1933, as amended. The 2026 Convertible Notes were issued in connection with funding the acquisition of the Nucynta Products. Some of the Company's existing investors participated in the 2026 Convertible Notes offering. In connection with the issuance of the 2026 Convertible Notes, the Company incurred approximately $5,473 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees.

The 2026 Convertible Notes are 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 2026 Convertible 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 2026 Convertible 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 2026 Convertible Notes may convert all or any portion of their 2026 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 2026 Convertible 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 2026 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, 2023, none of the above circumstances had occurred and as such, the 2026 Convertible Notes could not have been converted.

The Company did not have the right to redeem the 2026 Convertible Notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the 2026 Convertible Notes, in whole and not in part, at a cash redemption price equal to the principal amount of the 2026 Convertible 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 2026 Convertible Notes for redemption will constitute a make-whole fundamental change, in which case the conversion rate applicable to the conversion of any 2026 Convertible Notes, if converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The 2026 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, if such default is not cured within 3 calendar days after its occurrence; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) a default in any of the Company's other obligations or agreements under the indenture that are not cured or waived within 60 days after notice to the Company; (vi) certain payment 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 or other defaults by the Company or certain subsidiaries with respect to such indebtedness that result in the acceleration of such indebtedness; (vii) default upon the occurrence of one or more final judgments being rendered against the Company or any of the Company's significant subsidiaries for the payment of at least $20,000; and (viii) certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

Repurchase of a Portion of the 2026 Convertible Notes

Contemporaneously with the offering of the 2029 Convertible Notes (as defined below), the Company entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117,400 aggregate principal amount of the 2026 Convertible Notes for an aggregate of $140,100 of cash, which includes accrued and unpaid interest on the 2026 Convertible Notes to be repurchased. This transaction involved a contemporaneous exchange of cash between the Company and holders of the 2026 Convertible Notes participating in the issuance of the 2029 Convertible Notes. Accordingly, the Company evaluated the transaction for modification or extinguishment accounting in accordance with *Accounting Standards Codification* (*"ASC") 470-50, Debt – Modifications and Extinguishments* on a creditor-by creditor basis depending on whether the exchange was determined to have substantially different terms. The repurchase of the 2026 Convertible Notes and issuance of the 2029 Convertible Notes were deemed to have substantially different terms based on the present value of the cash flows immediately prior to and after the exchange. Therefore, the repurchase of the 2026 Convertible Notes was accounted for as a debt extinguishment. The Company recorded a $23,504 loss on early extinguishment of debt on the Condensed Consolidated Statements of Operations for the three months ending March 31, 2023, which includes the recognition of previously deferred financing

costs of $2,264. After giving effect to the repurchase, the total remaining principal amount outstanding under the 2026 Convertible Notes as of March 31, 2023 was $26,350.

2029 Convertible Notes

On February 10, 2023, the Company issued 2.875% convertible senior notes due in 2029 (the "2029 Convertible Notes") in the aggregate principal amount of $241,500, in a private offering to qualified institutional buyers pursuant to Section 4(a)(2) and Rule 144A under the Securities Act of 1933, as amended. The 2029 Convertible Notes were issued to finance the concurrent repurchase of a portion of the 2026 Convertible Notes, and the remainder of the net proceeds may be used for general corporate purposes. In connection with the issuance of the 2029 Convertible Notes, the Company incurred approximately $6,280 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees.

The 2029 Convertible Notes are senior, unsecured obligations and bear interest at a rate of 2.875% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2023. The 2029 Convertible Notes will mature on February 15, 2029, unless earlier repurchased, redeemed or converted. Before November 15, 2028, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after November 15, 2028, 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 initial conversion rate is 27.3553 shares of common stock per $1 principal amount of 2029 Convertible Notes, which represents an initial conversion price of approximately $36.56 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the 2029 Convertible Notes may convert all or any portion of their 2029 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 June 30, 2023, 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 2029 Convertible 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 any or all of the 2029 Convertible Notes for redemption, but only with respect to the 2029 Convertible Notes called for redemption; or
(5) at any time from, and including, November 15, 2028 until the close of business on the scheduled trading day immediately before the maturity date.

As of March 31, 2023, none of the above circumstances had occurred and as such, the 2029 Convertible Notes could not have been converted.

The Company may not redeem the 2029 Convertible Notes prior to February 17, 2026. On or after February 17, 2026 and on or before the 40th scheduled trading day before the maturity date, the Company may redeem the 2029 Convertible Notes, in whole or in part, at a cash redemption price equal to the principal amount of the 2029 Convertible 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.

However, the Company may not redeem less than all of the outstanding 2029 Convertible Notes unless at least $75,000 aggregate principal amount of the 2029 Convertible Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice.

Calling any 2029 Convertible Note for redemption will constitute a make-whole fundamental change with respect to that 2029 Convertible Note, in which case the conversion rate applicable to the conversion of that 2029 Convertible Note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The 2029 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, if such default is not cured within 3 business days after its occurrence; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) a default in any of the Company's other obligations or agreements under the indenture that are not cured or waived within 60 days after notice to the Company; (vi) certain payment defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $30,000 or other defaults by the Company or certain subsidiaries with respect to such indebtedness that result in the acceleration of such indebtedness; (vii) default upon the occurrence of one or more final judgments being rendered against the Company or any of the Company's significant subsidiaries for the payment of at least $30,000; and (xiii) upon the occurrence of certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

The 2026 Convertible Notes and 2029 Convertible Notes (together, the "Convertible Notes") are classified on the Condensed Consolidated Balance Sheets as of March 31, 2023, as convertible senior notes.

As of March 31, 2023, the outstanding balance of the Convertible Notes consisted of the following:

	2026 Convertible Notes	2029 Convertible Notes	Total Convertible Notes
Principal	$ 26,350	$ 241,500	$ 267,850
Less: unamortized issuance costs	(484)	(6,144)	(6,628)
Net carrying amount	$ 25,866	$ 235,356	$ 261,222

The Company determined the expected life of the 2026 Convertible Notes and 2029 Convertible Notes was equal to the six-year term of each. The effective interest rate on the 2026 Convertible Notes and 2029 Convertible Notes is 3.34% and 3.28%, respectively. As of March 31, 2023, 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, 2023, and 2022:

	Three Months Ended March 31,	
	2023	2022
Contractual interest expense	$ 1,479	$ 943
Amortization of debt issuance costs	263	223
Total interest expense	$ 1,742	$ 1,166

As of March 31, 2023, the future minimum payments on the Convertible Notes were as follows:

Years ended December 31,	2026 Convertible Notes	2029 Convertible Notes	Total Convertible Notes
2023	$ 346	$ 3,568	$ 3,914
2024	692	6,943	7,635
2025	692	6,943	7,635
2026	26,696	6,943	33,639
2027	—	6,943	6,943
Thereafter	—	251,915	251,915
Total minimum payments	$ 28,426	$ 283,255	$ 311,681
Less: interest	(2,076)	(41,755)	(43,831)
Less: unamortized issuance costs	(484)	(6,144)	(6,628)
Convertible Notes carrying value	$ 25,866	$ 235,356	$ 261,222

13. Equity

The changes in shareholders' equity for the three months ended March 31, 2023 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance, December 31, 2022	37,084,759	$ 37	$ 538,073	(3,235,823)	$ (61,924)	$ (281,344)	$ 194,842
Exercise of common stock options	234,132	—	3,848	—	—	—	3,848
Issuance for employee stock purchase plan	11,329	—	169	—	—	—	169
Vesting of RSUs and PSUs	775,904	1	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(289,281)	—	(7,736)	—	—	—	(7,736)
Stock-based compensation	—	—	6,035	—	—	—	6,035
Net loss	—	—	—	—	—	(17,426)	(17,426)
Balance, March 31, 2023	37,816,843	$ 38	$ 540,389	(3,235,823)	$ (61,924)	$ (298,770)	$ 179,733

The changes in shareholders' equity for the three months ended March 31, 2022 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance, December 31, 2021	35,806,119	$ 36	$ 502,095	(2,150,717)	$ (42,861)	$ (256,342)	$ 202,928
Exercise of common stock options	190,074	—	3,261	—	—	—	3,261
Issuance for employee stock purchase plan	13,421	—	203	—	—	—	203
Vesting of RSUs and PSUs	563,050	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(191,667)	—	(3,382)	—	—	—	(3,382)
Share repurchases	—	—	5,000	(307,132)	(5,000)	—	—
Stock-based compensation	—	—	6,135	—	—	—	6,135
Net loss	—	—	—	—	—	(13,069)	(13,069)
Balance, March 31, 2022	36,380,997	$ 36	$ 513,312	(2,457,849)	$ (47,861)	$ (269,411)	$ 196,076

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, 2023, there were 1,983,955 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 for three months following the termination date, while unvested options are forfeited immediately upon termination. Refer to Note 14, *Stock-based Compensation*, for more information.

Share Repurchases

In August 2021, the Board of Directors authorized a share repurchase program to repurchase up to $100,000 of outstanding shares of the Company's common stock at any time or times through December 31, 2022 (the "Prior Repurchase Program"). The Prior Repurchase Program permitted the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. Shares repurchased under the Prior Repurchase Program were returned to the Company's pool of authorized but unissued shares available for reissuance. The timing and amount of any such repurchases were determined based on share price, market conditions, legal requirements, and other relevant factors.

Through December 31, 2022, the Company repurchased 3,235,823 shares at a weighted-average price of $19.14 per share for a total of $61,924 under the Prior Repurchase Program and the cost of repurchased shares were recorded as treasury stock in the Consolidated Balance Sheet. The Prior Repurchase Program expired on December 31, 2022.

In January 2023, the Board of Directors authorized a share repurchase program to repurchase up to $100,000 of the Company's common stock through December 31, 2023 (the "2023 Repurchase Program"). The 2023 Repurchase Program permits the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. The timing and amount of any shares purchased on the open market will be determined based on the Company's evaluation of the market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund the 2023 Repurchase Program.

As of March 31, 2023, the Company has not yet repurchased shares under the 2023 Repurchase Program. Thus, $100,000 remained available for share repurchases under the 2023 Repurchase Program as of March 31, 2023.

14. Stock-based Compensation

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 Company's Compensation Committee.

A summary of the Company's PSU activity for the three months ended March 31, 2023 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	447,770	$ 28.71
Granted	216,500	38.71
Vested	(223,170)	27.99
Forfeited	—	—
Performance adjustment	62,780	27.14
Outstanding at March 31, 2023	503,880	$ 33.13

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, 2023, and 2022 was $38.71 and $24.12, respectively.

Restricted Stock Units

The Company granted RSUs to employees during the three months ended March 31, 2023. 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, 2023 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	2,047,571	$ 19.67
Granted	1,093,296	26.82
Vested	(552,734)	20.42
Forfeited	(132,214)	21.66
Outstanding at March 31, 2023	2,455,919	$ 22.58

The weighted-average grant date fair value per share of RSUs granted for the three months ended March 31, 2023 and 2022 was $26.82 and $17.68, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the three months ended March 31, 2023, and 2022 was $14,779 and $8,001, respectively.

Stock Options

A summary of the Company's stock option activity for the three months ended March 31, 2023 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, 2022	1,683,805	$ 18.84	5.5	$ 7,953
Exercised	(234,132)	16.36		
Cancelled	(5,677)	20.01		
Outstanding at March 31, 2023	1,443,996	$ 19.24	5.0	$ 7,074
Exercisable at March 31, 2023	1,358,588	$ 19.20	4.9	$ 6,730

There were no stock options granted during the three months ended March 31, 2023 and 2022.

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, 2023, 11,329 shares of common stock were purchased for total proceeds of $169. The expense for the three months ended March 31, 2023 and 2022 was $46 and $32, respectively.

Stock-based Compensation Expense

A summary of the allocation of the Company's stock-based compensation expense for the three months ended March 31, 2023 and 2022 is as follows:

	Three Months Ended March 31,	
	2023	2022
Research and development	$ —	$ 1,591
Selling, general and administrative	6,035	4,544
Total stock-based compensation expense	$ 6,035	$ 6,135

At March 31, 2023, there was approximately $61,072 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.

15. 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 material litigation and, accordingly, does not have any other amounts recorded for any litigation related matters.

Xtampza ER Litigation

The Company filed the New Drug Application ("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 New Drug Application ("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.

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 any appeal of the PTAB proceedings. 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. On November 19, 2021, the PTAB (i) denied Purdue's motion to terminate the PGR and (ii) issued its Final Written Decision, finding that claims 1-17 of the ′961 patent were invalid for lack of written description and anticipation. On December 17, 2021, Purdue filed a Request for Director Review. That request was denied on February 7, 2022. On February 16, 2022, Purdue filed a Federal Circuit notice of appeal. On April 12, 2022, the Company filed a Motion to Dismiss the Appeal as Untimely. On May 20, 2022, the Federal Circuit denied the Motion to Dismiss and directed the parties to address jurisdiction during merits briefing.

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. 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. The Company responded to Purdue's complaint asserting the ′434 patent with a motion to dismiss. On May 21, 2021, and in response to the Company's motion to dismiss, Purdue filed an amended complaint asserting the ′434 patent. The Company renewed its motion to dismiss on June 4, 2021, arguing: (i) Purdue cannot, as a matter of law, state a claim for infringement under § 271(e)(2)(A); (ii) Purdue cannot, as a matter of law, state a claim for product-by-process infringement under §271(g); and (iii) Purdue has not alleged facts sufficient to support any indirect infringement theory under §271(b) or (c). The Court held a hearing on the Company's motion to dismiss on October 13, 2021, and the motion is pending before the Court.

Like the prior follow-on lawsuits, the ′434 patent litigation was consolidated into the lead case and a scheduling order was entered. On October 5, 2021, the Court held a claim construction hearing for the ′961 patent and the ′434 patent. On February 10, 2023, the Court set (i) the fact discovery deadline for August 2, 2023; and (ii) expert witness depositions to conclude by November 22, 2023. The Court has not set a deadline for dispositive motions or trial.

The remaining patents-in-suit in the lead consolidated action in the District of Massachusetts are the ′933, ′919, ′434, and ′961 patents. The parties agreed, however, that litigation concerning the ′961 patent is stayed pending resolution of Purdue's Federal Circuit appeal of the PTAB decision invalidating the claims of the ′961 patent. Purdue has made a demand for monetary relief, and 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.

Litigation Related to the BDSI Acquisition

On February 25, 2022, in connection with the BDSI Acquisition, a purported individual stockholder of BDSI filed a complaint in the United States District Court for the Southern District of New York, captioned *Stein v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01600, naming as defendants BDSI and each member of its Board of Directors as of the date of the Merger Agreement ("*Stein* Action"). On February 28, 2022, two additional cases were filed by purported individual stockholders of BDSI in the same court, captioned *Sanford v. BioDelivery Sciences International, Inc., et al*., No. 1:22-cv-01676 ("*Sanford* Action"), and *Higley v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01658 ("*Higley* Action"). On March 2, 2022 and March 5, 2022, two additional cases were filed by purported individual stockholders of BDSI in the United States District Court for the Eastern District of New York, captioned *Justice II v. BioDelivery Sciences International, Inc., et al*., No. 1:22-cv-01145 ("*Justice* Action") and *Zomber v. BioDelivery Sciences International, Inc., et al*., No. 1:22-cv-01220 ("*Zomber* Action"; together with the *Stein*, *Sanford*, *Higley*, and *Justice* Actions, the "Actions"). The Actions and any similar subsequently filed cases involving BDSI, its officers or Board of Directors, or any committee thereof, and/or any of the Company's officers or directors relating directly or indirectly to the Merger Agreement, the BDSI Acquisition or any related transaction, are referred to as the "Merger Litigations."

The Merger Litigations filed to date generally allege that the Schedule 14D-9 is materially incomplete and misleading by allegedly failing to disclose purportedly material information relating to the sale process leading to the Merger, BDSI's financial projections, and the analyses performed by Moelis & Company LLC in connection with the Merger. The Merger Litigations assert violations of Section 14(e) of the Exchange Act and violations of Section 20(a) of the Exchange Act against BDSI's Board of Directors. Additionally, the *Stein*, *Higley*, *Justice*, and *Zomber* complaints assert violations of Section 14(d) of the Exchange Act and Rule 14d-9 promulgated thereunder. The Merger Litigations seek, among other things: an injunction enjoining consummation of the Merger, rescission of the Merger Agreement, a declaration that BDSI and its Board of Directors violated Sections 14(e) and 20(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, damages, costs of the action, including plaintiffs' attorneys' fees and experts' fees and expenses, and any other relief the court may deem just and proper.

In addition, on February 24, 2022, February 28, 2022, and March 7, 2022, BDSI received demand letters from three purported stockholders of BDSI seeking to inspect certain books and records of BDSI related to the Merger (collectively, the "Inspection Letters"). On March 4, 2022, March 9, 2022, and March 11, 2022, BDSI received demand letters from four purported stockholders alleging that the Schedule 14D-9 omits purportedly material information relating to the Merger (collectively, the "Demand Letters").

On April 14, 2022, plaintiff in the *Higley* Action filed a notice of voluntary dismissal of the complaint. On May 15, 2022, plaintiff in the *Zomber* Action filed a notice of voluntary dismissal of the complaint. And, on June 24, 2022, plaintiff in the *Justice* Action filed a notice of voluntary dismissal of the complaint. In the remaining *Stein* and *Sanford* Actions, on July 20, 2022, the respective Courts entered an Order for plaintiff to serve a summons and complaint by August 3, 2022. On July 28, 2022, plaintiff in the *Sanford* Action filed a partial voluntary dismissal of the individual named defendants but not BDSI from that action and filed a waiver of service as to BDSI. On October 26, 2022, plaintiff in the *Sanford* Action filed a notice of voluntary dismissal of the complaint as to Defendant BDSI as well. To date, the complaint in the *Stein* Action has not been served on, nor was service waived by, any of the named defendants in that action.

While the Company believes that the remaining Merger Litigations, Inspection Letters, and Demand Letters are without merit and that the disclosures in the Schedule 14D-9 comply fully with applicable law, solely in order to avoid the expense and distraction of litigation, BDSI previously determined to voluntarily supplement the Schedule 14D-9 with certain supplemental disclosures set forth in BDSI's Schedule 14D-9 filed with the SEC on March 11, 2022 (the "Supplemental Disclosures"). The Company and BDSI believe that the Supplemental Disclosures mooted all allegations or concerns raised in the Merger Litigations, Inspection Letters, and Demand Letters.

As set forth in the Supplemental Disclosures, nothing therein shall be deemed an admission of the legal necessity or materiality under applicable law of the Supplemental Disclosures. To the contrary, the Company and BDSI specifically deny all allegations that any of the Supplemental Disclosures, or any other additional disclosures, were or are required. The Company plans to defend the Merger Litigations 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.

Opioid Litigation

As a result of the opioid epidemic, numerous state and local governments, healthcare providers, and other entities 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 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. Of the 21 MDL cases that named the Company as a defendant, the allegations against it were previously dismissed or withdrawn in 13 cases as of December 31, 2021. The remaining eight MDL cases that named the Company were dismissed as of April 19, 2022. In addition, the Company had been previously dismissed from three non-MDL cases filed in Pennsylvania and Arkansas state courts.

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

- In Pennsylvania, six lawsuits naming the Company were 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 included lawsuits filed between May 2018 and July 2019, alleging claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws.

- In Massachusetts, there were lawsuits by 13 municipalities, all of which were consolidated before the Business Litigation Session of the Superior Court. The actions alleged 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.

On December 24, 2021, the Company entered into a settlement framework with Scott+Scott Attorneys at Law, LLP, the law firm representing plaintiffs in each of the 27 cases, including the 8 remaining MDL cases and 19 state court cases described above. Pursuant to the terms of the settlement framework, which were later memorialized in a final settlement

agreement, the Company agreed to pay $2,750 in exchange for the dismissal, with prejudice, of each plaintiff's lawsuit against the Company and a release of claims related to such lawsuits. The settlement agreement was executed by the Company and all 27 plaintiffs, and the amounts subject to the settlement agreement were paid. As of April 19, 2022, the Company was dismissed, with prejudice, from each of the 27 cases.

The Company entered into this settlement to efficiently resolve this litigation and does not admit any liability or acknowledge any wrongdoing in connection with the settlement agreement.

Aquestive Litigation

On October 29, 2013, Reckitt Benckiser, Inc., Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior"), and Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") (collectively, the "RB Plaintiffs") filed an action against BDSI relating to its Bunavail product in the United States District Court for the Eastern District of North Carolina ("EDNC") for alleged patent infringement. Bunavail is a drug approved for the maintenance treatment of opioid dependence. This case was dismissed, but the RB Plaintiffs subsequently filed an action against BDSI, on September 22, 2014, relating to Bunavail product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claimed that Bunavail, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 (the "'167 Patent").

On January 13, 2017, Aquestive filed a complaint in the United States District Court for the District of New Jersey alleging Belbuca infringes the '167 Patent.

On March 8, 2023, the parties filed a stipulation of dismissal. The RB Plaintiffs dismissed their claims with prejudice, and BDSI dismissed its counterclaims without prejudice. Under the terms of the settlement agreement, BDSI resolved both the Bunavail and Belbuca litigations in exchange for a one-time, lump-sum payment of $8,500 to Aquestive.

Chemo Research, S.L

On March 1, 2019, BDSI filed a complaint for patent infringement in United States District Court for the District of Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, the "Chemo Defendants"), asserting that the Chemo Defendants infringe its Orange Book-listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 ("'866 patent") and 9,655,843, ("'843 patent") both expiring in July of 2027, and U.S. Patent No. 9,901,539 ("'539 patent") expiring December of 2032 (collectively, "the BEMA patents"). This complaint follows a receipt by BDSI on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has filed with the FDA an abbreviated New Drug Application ("ANDA") containing a Paragraph IV Patent Certification, for a generic version of BELBUCA Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Because BDSI initiated a patent infringement suit asserting the patents identified in the Notice Letter within 45 days after receipt, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. On March 15, 2019, BDSI filed a complaint against the Chemo Defendants in the Federal District Court for the District of New Jersey asserting the same claims for patent infringement made in the Delaware lawsuit. On April 19, 2019, Defendants filed an answer to the Delaware complaint wherein they denied infringement of the '866, '843 and '539 patents and asserted counterclaims seeking declaratory relief concerning the alleged invalidity and non-infringement of such patents.

On April 25, 2019, BDSI voluntarily dismissed the New Jersey lawsuit given Defendants' consent to jurisdiction in Delaware.

The trial to adjudicate issues concerning the validity of the Orange Book-listed patents covering BELBUCA was held from March 1-3, 2021. Chemo did not participate in the bench trial. Instead, on February 26, 2021, Chemo agreed to be bound by the decision of the Court with respect to the validity of the BEMA patents from the March 1-3, 2021 trial with Alvogen. On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's '866 patent, which expires in 2027, and certain claims in the '539 patent, which expires in 2032, to which Chemo is bound. This holding was affirmed on appeal by the Federal Circuit on December 21, 2022. The bench trial to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents was set to commence on April 25, 2022. On March 30, 2022, the Court vacated the trial and has not yet set a new trial date.

On August 1, 2022, BDSI received a second Paragraph IV certification notice letter from Chemo indicating that Chemo has amended its ANDA to (i) withdraw its generic version of the 75 mcg and 150 mcg strengths of BELBUCA; and (ii) include its generic version of the 600 mcg and 750 mcg strengths of BELBUCA, in addition to the 300 mcg, 450 mcg, and 900 mcg strengths identified in the first Chemo Paragraph IV certification notice letter. In response, BDSI filed a complaint for patent infringement in Federal District Court for the District of Delaware. Chemo answered the complaint on December 1, 2022. The Court has not set a schedule for this litigation.

On August 24, 2022, the Court instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. On February 8, 2023, the district court denied Chemo's request for a trial date in the spring, and again instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. Chemo received a complete response letter with respect to its July 29, 2022 ANDA in April 2023.

The Company plans to litigate these cases 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.

Alvogen

On September 7, 2018, BDSI filed a complaint for patent infringement in United States District Court for the District of Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, "Alvogen"), asserting that Alvogen infringes BDSI's Orange Book-listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032 (collectively, "the BEMA patents"). This complaint followed receipt by BDSI on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because BDSI initiated a patent infringement suit asserting the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid.

The Court scheduled a bench trial to adjudicate issues concerning the validity of the BEMA patents. A three-day bench trial against Alvogen was conducted commencing on March 1, 2021.

On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's ′866 patent, which expires in 2027, and certain claims in the ′539 patent, which expires in 2032. Alvogen conceded infringement of those claims prior to the trial. The Court entered final judgment on January 21, 2022. The final judgment entered in this case upholding the validity of claims of the ′866 and ′539 Orange Book-listed patents extends the effective date of any final approval by the FDA of Alvogen's ANDA until December 21, 2032, which is the expiration date of the ′539 patent, and enjoins Alvogen and those acting in concert with Alvogen from commercially manufacturing, using, selling, or offering for sale Alvogen's ANDA products until December 21, 2032. Alvogen filed a motion to stay certain provisions of the final judgment in the Court. BDSI filed an opposition to Alvogen's request for a stay. The Court retained jurisdiction to decide BDSI's motion for contempt, which was filed on September 21, 2021.

Alvogen filed a notice of appeal to the Federal Circuit seeking to reverse the Court's final judgment entered on January 21, 2022. Separately, BDSI filed a cross-appeal to the Federal Circuit seeking to reverse the Court's opinion that claims 3 and 10 of the ′866 patent and claims 8, 9 and 20 of the ′843 patent are invalid and thus Alvogen is not liable for infringement of those claims, as well as any other ruling decided adversely to BDSI. On November 1, 2022, the Federal Circuit held oral argument on the parties' appeal and issued its decision on December 21, 2022. In that decision, the Federal Circuit affirmed the district court judgment that certain claims of the ′866 and ′539 patent were not invalid as obvious. The Federal Circuit also vacated the district court's judgment that certain claims of the ′866 and ′843 patent were invalid as obvious and remanded to the district court for further proceedings. The mandate issued on February 10, 2023.

As it has done in the past, the Company intends to vigorously defend its intellectual property against assertions of invalidity or non-infringement.

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.

On December 16, 2021, the Company entered into an Assurance of Discontinuance with the Massachusetts Attorney General (the "AoD"). The Company is currently cooperating with each of the remaining states in their respective investigations.

16. Income Taxes

The Company is subject to U.S. federal and state income taxes. The income tax provision for interim periods reflects the Company's estimate of the annual effective tax rate expected to be applicable for the full fiscal year, adjusted for any discrete events which are recorded in the period in which they occur.

The following table presents information regarding the Company's income tax benefit recognized for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	**2022**
Benefit from income taxes	$ (131)	$ (2,773)
Effective tax rate	0.7%	17.5%

The benefit from income taxes in the three months ended March 31, 2023 reflects the tax benefit of the current year loss. The tax benefit for the three months ended March 31, 2023 was impacted by discrete nondeductible costs associated with the debt extinguishment, partially offset by excess tax benefits related to stock compensation. The tax benefit for the three months ended March 31, 2022 was significantly impacted by discrete nondeductible transaction costs and partially offset by excess tax benefits related to stock compensation.

The Company provides a valuation allowance when it is more likely than not that deferred tax assets will not be realized. In determining the extent to which a valuation allowance for deferred tax assets is required, the Company evaluates all available evidence including projections of future taxable income, carry back opportunities, reversal of certain deferred tax liabilities, and other tax planning strategies. The Company has maintained a valuation allowance on the portion of its deferred tax assets that are not more likely than not to be realized due to tax limitation or other conditions as of March 31, 2023.

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 condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report, and in conjunction with management's discussion and analysis and our audited consolidated financial statements included in our Annual Report. 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, 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 building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. We commercialize our pain portfolio, consisting of Xtampza ER, Nucynta ER and Nucynta IR (collectively the "Nucynta Products"), Belbuca, and Symproic, in the United States.

Xtampza ER, an abuse-deterrent, oral formulation of oxycodone, 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.

The Nucynta Products are extended-release and immediate-release formulations of tapentadol. 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 in January 2018 and began marketing the Nucynta Products in February 2018.

On March 22, 2022, we acquired BDSI, a specialty pharmaceutical company working to deliver innovative therapies for individuals living with serious and debilitating chronic conditions. Upon closing of the BDSI Acquisition, we acquired the Belbuca and Symproic products. Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate. Symproic was approved by the FDA in March 2017 for the treatment of opioid-induced constipation (“OIC”) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. We began shipping and recognizing product sales related to Belbuca and Symproic in March 2022.

We believe the addition of Belbuca and Symproic to our portfolio strategically aligns with our mission to build a leading, diversified specialty pharmaceutical company committed to improving the lives of people suffering from serious medical conditions.

Outlook

The BDSI Acquisition diversified and expanded our business by adding Belbuca and Symproic to our highly differentiated pain portfolio. We expect the addition of these products to continue to strengthen our financial position through increased revenue scale and accelerated cash flow generation. While we incurred significant transaction costs and other acquisition related expenses to complete the BDSI Acquisition and to integrate BDSI’s operations, we do not expect to incur additional acquisition related expenses related to the BDSI Acquisition moving forward. In addition, we expect the step-up basis in inventory to impact our results of operations until all acquired inventory is sold, which we expect to occur within 12 to 18 months following the date of the BDSI Acquisition.

We believe that our cash and cash equivalents at March 31, 2023, 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 the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term.

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. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our consolidated financial statements, refer to our Annual Report.

There were no changes in our critical accounting policies from those described in our Annual Report.

RESULTS OF OPERATIONS

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Product revenues, net	$ 144,767	$ 83,751
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	29,899	16,332
Intangible asset amortization	37,466	18,923
Total cost of products revenues	67,365	35,255
Gross profit	77,402	48,496
Operating expenses		
Research and development	—	3,983
Selling, general and administrative	52,775	54,528
Total operating expenses	52,775	58,511
Income (loss) from operations	24,627	(10,015)
Interest expense	(21,427)	(5,831)
Interest income	2,747	4
Loss on extinguishment of debt	(23,504)	—
Loss before income taxes	(17,557)	(15,842)
Benefit from income taxes	(131)	(2,773)
Net loss	$ (17,426)	$ (13,069)

Comparison of the three months ended March 31, 2023 and March 31, 2022

Product revenues, net

Product revenues, net were $144.8 million for the three months ended March 31, 2023 (the “2023 Quarter”), compared to $83.8 million for the three months ended March 31, 2022 (the “2022 Quarter”). The $61.0 million increase is due to increases in revenue for products acquired from BDSI of $44.2 million, including $40.9 million for Belbuca, as well as increases in revenue for Xtampza ER of $16.4 million and the Nucynta Products of $0.4 million.

The increase in revenue for products acquired from BDSI was due to a full quarter of revenue in the 2023 Quarter, compared to a partial quarter of revenue in the 2022 Quarter due to the March 22, 2022 date of the BDSI Acquisition.

The increase in revenue for Xtampza ER of $16.4 million is primarily due to an increase in gross price and lower gross-to-net adjustments primarily related to provisions for rebates, partially offset by decreased sales volume and higher gross-to-net adjustments related to provisions for returns.

The increase in revenue for the Nucynta Products of $0.4 million is primarily due to an increase in gross price and lower gross-to-net adjustments primarily related to provisions for rebates, partially offset by decreased sales volume and higher gross-to-net adjustments related to provisions for returns.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $29.9 million for the 2023 Quarter, compared to $16.3 million for the 2022 Quarter. The $13.6 million increase was primarily related to the step-up basis in inventory acquired from BDSI which resulted in higher cost of product revenues of $10.2 million when sold in the 2023 Quarter, combined with an increase in royalties and cost of product revenues for products acquired from BDSI due to a full quarter of revenue in the 2023 Quarter compared to a partial quarter in the 2022 Quarter. This increase was partially offset by lower cost of product revenues primarily due to lower sales volume for Xtampza and the Nucynta Products.

Intangible asset amortization was $37.5 million for the 2023 Quarter, compared to $18.9 million for the 2022 Quarter. The $18.6 million increase in intangible asset amortization was due to a full quarter of amortization expense recognized related to the intangible assets acquired from BDSI, in which $435.0 million of consideration was allocated to our

acquired intangible assets, Belbuca, Symproic, and Elyxyb, compared to a partial quarter of amortization expense in the 2022 Quarter. The intangible assets are amortized on a straight-line basis over the respective estimated useful lives.

Operating Expenses

We did not recognize research and development expenses in the 2023 Quarter, compared to $4.0 million recognized in the 2022 Quarter. The $4.0 million decrease was due to redirection of resources from research and development activities during 2022 as we shifted our focus to supporting our commercial products rather than research and development.

Selling, general and administrative expenses were $52.8 million for the 2023 Quarter, compared to $54.5 million for the 2022 Quarter. The $1.7 million decrease was primarily related to:

- a decrease in acquisition related expenses classified as selling, general and administrative of $26.5 million; partially offset by
- an increase in audit and legal expenses of $9.4 million, primarily due to an $8.5 million litigation settlement;
- an increase in salaries, wages, and benefits of $7.3 million;
- an increase in sales and marketing expenses of $4.1 million, primarily due to the timing of marketing efforts;
- an increase in regulatory expenses of $2.0 million, primarily due to a full quarter of expenses incurred related to products acquired from BDSI; and
- an increase in trainings, conferences, and meetings expenses of $1.4 million primarily due to certain annual internal meetings being resumed for the first time in the 2023 Quarter since the onset of the COVID-19 pandemic.

Interest expense and Interest income

Interest expense was $21.4 million for the 2023 Quarter, compared to $5.8 million for the 2022 Quarter. The $15.6 million increase was primarily due to the 2022 Term Loan that we entered into in connection with the BDSI Acquisition, which substantially increased our indebtedness, along with higher interest rates impacting our variable rate term loan debt.

Interest income was $2.7 million for the 2023 Quarter, compared to $4,000 for the 2022 Quarter. The $2.7 million increase was primarily due to an increase in interest rates earned on money market funds and a higher overall balance invested in money market funds in the 2023 Quarter compared to the 2022 Quarter.

Taxes

Benefit from income taxes was $131,000 for the 2023 Quarter, compared to $2.8 million for the 2022 Quarter. The tax benefit for the three months ended March 31, 2023 was impacted by discrete nondeductible costs associated with the debt extinguishment, partially offset by excess tax benefits related to stock compensation. The tax benefit for the three months ended March 31, 2022 was significantly impacted by discrete nondeductible transaction costs and partially offset by excess tax benefits related to stock compensation.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have incurred cumulative net losses and negative cash flows from operations since inception until 2020. In the three months ended March 31, 2023, we also incurred a net loss. Historically, we have funded our operations primarily through the private placements and/or public offerings of our preferred stock, common stock, and convertible notes, and commercial bank debt. We are primarily dependent on the commercial success of Belbuca, Xtampza, and the Nucynta Products. In March 2022, our debt balance increased significantly as we modified our 2020 Term Loan with Pharmakon to an increased principal balance of $650.0 million to fund a portion of the consideration paid to complete the BDSI Acquisition. We paid $100.0 million in principal payments during the first year of the 2022 Term Loan. The remaining $550.0 million balance is required to be paid in equal quarterly installments over the remaining three years of the term note. As of March 31, 2023, the outstanding principal balance of the 2022 Term Loan was $550.0 million, of which $183.3 million in principal payments are due within the next 12 months. As of March 31, 2023, the outstanding principal

balance of our 2026 Convertible Notes and 2029 Convertible Notes was $26.4 million and $241.5 million, respectively. The outstanding principal balance of the 2026 Convertible Notes and 2029 Convertible Notes is not due until 2026 and 2029, respectively. As of March 31, 2023, and December 31, 2022, we had $269.5 million and $173.7 million in cash and cash equivalents, respectively.

We believe that our cash and cash equivalents at March 31, 2023, together with expected cash inflows from operations, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Borrowing Arrangements and Equity Offerings

The following transactions represent the material borrowing arrangements and equity offerings.

2022 Term Loan

On March 22, 2022, in connection with the closing of the BDSI Acquisition, we entered into an Amended and Restated Loan Agreement by and among us, and BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon") (the "2022 Loan Agreement"). The 2022 Loan Agreement provided for the $650.0 million secured 2022 Term Loan, the proceeds of which were used to repay our existing term notes and fund a portion of the consideration to be paid to complete the BDSI Acquisition. The 2022 Loan Agreement was accounted for as a debt modification and transaction fees of $173,000 were expensed. In connection with the 2022 Loan Agreement, we paid loan commitment and other fees to the lender of $19.8 million, which together with preexisting debt issuance costs and note discounts of $2.0 million will be amortized over the term of the loan using the effective interest rate.

The 2022 Term Loan will mature on the 48-month anniversary of the closing of the BDSI Acquisition and is guaranteed by our material domestic subsidiaries. The 2022 Term Loan is also secured by substantially all of our assets and those of our material domestic subsidiaries. The 2022 Term Loan bears interest at a rate based upon the London Interbank Offered Rate ("LIBOR") (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. As of March 31, 2023, the interest rate was 13.9%. We paid $100.0 million in principal payments under the 2022 Term Loan during the first year and the remaining $550.0 million balance is required to be paid in equal quarterly installments over the remaining three years. The outstanding principal balance for the 2022 Term Loan as of March 31, 2023 is $550.0 million, including $183.3 million of obligations due in the next twelve months.

The 2022 Loan Agreement permits voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium is equal to 2.00% of the principal amount being prepaid prior to the second-year anniversary of the closing date, or 1.00% of the principal amount being prepaid on or after the second-year anniversary of the closing date. The 2022 Loan Agreement also includes a make-whole premium in the event of a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default (as defined in the 2022 Loan Agreement) on or prior to the second-year anniversary of the closing date, in each case 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 also triggers a mandatory prepayment of the 2022 Term Loan.

The 2022 Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, 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 2022 Loan Agreement, notwithstanding our ability to meet our debt service obligations. The 2022 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 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement. As of March 31, 2023, we were in compliance with all of our covenants.

2026 Convertible Notes

On February 13, 2020, we issued 2.625% convertible senior notes due in 2026 (the "2026 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 2026 Convertible Notes were issued in connection with funding the acquisition of the Nucynta Products. Some of our existing investors participated in the convertible notes offering.

The 2026 Convertible Notes are senior, unsecured obligations and accrue interest at a rate of 2.625% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. 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.

Contemporaneously with the offering of the 2029 Convertible Notes (as defined below), we entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117.4 million aggregate principal amount of the 2026 Convertible Notes for an aggregate of $140.1 million of cash, which includes accrued and unpaid interest on the 2026 Convertible Notes to be repurchased. After giving effect to the repurchase, the outstanding principal balance of the 2026 Convertible Notes as of March 31, 2023 is $26.4 million. There are no principal repayment obligations due within the next 12 months.

2029 Convertible Notes

On February 10, 2023, we issued 2.875% convertible senior notes due in 2029 (the “2029 Convertible Notes”) in the aggregate principal amount of $241.5 million, in a private offering to qualified institutional buyers pursuant to Section 4(a)(2) and Rule 144A under the Securities Act of 1933, as amended. The 2029 Convertible Notes were issued to finance the concurrent repurchase of a portion of the 2026 Convertible Notes, and the remainder of the net proceeds may be used for general corporate purposes.

The 2029 Convertible Notes are senior, unsecured obligations and accrue interest at a rate of 2.875% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. The 2029 Convertible Notes will mature on February 15, 2029, unless earlier repurchased, redeemed or converted. Before November 15, 2028, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after November 15, 2028, 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 27.3553 shares of common stock per $1,000 principal amount of notes, which represents an initial conversion price of approximately $36.56 per share of common stock. The conversion rate and conversion price will be subject to adjustment upon the occurrence of certain events. The outstanding principal balance of the 2029 Convertible Notes as of March 31, 2023 is $241.5 million. There are no principal repayment obligations due within the next 12 months.

Cash Flows

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in) operating activities	$ 27,671	$ (25,315)
Net cash used in investing activities	(176)	(572,177)
Net cash provided by financing activities	68,297	517,764
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 95,792	$ (79,728)

Operating activities. Cash provided by operating activities was $27.7 million for the 2023 Quarter, compared to cash used in operating activities of $25.3 million for the 2022 Quarter. The $53.0 million increase was primarily due to the increase in cash flow from operating results, which reflects operating earnings, after adjustment for non-cash items that are included in net loss, including higher intangible asset amortization as a result of the BDSI Acquisition and

recognition of a loss on extinguishment of debt in connection with the repurchase of a portion of our 2026 Convertible Notes.

Investing activities. Cash used in investing activities was $176,000 for the 2023 Quarter, compared to $572.2 million for the 2022 Quarter. The $572.0 million decrease was primarily due to the use of $572.1 million for the BDSI Acquisition, net of cash acquired, which closed in the 2022 Quarter.

Financing activities. Cash provided by financing activities was $68.3 million for the 2023 Quarter, compared to $517.8 million for the 2022 Quarter. The $449.5 million decrease was primarily due to the repayment of the outstanding balance of the 2020 Term Loan and establishment of the 2022 Term Loan in connection with the BDSI Acquisition, which was accounted for as a debt modification and resulted in $517.7 million in proceeds from the term note modification in the 2022 Quarter, partially offset by the repurchase of a portion of our 2026 Convertibles Notes and issuance of our 2029 Convertible Notes which resulted in net proceeds of $97.0 million in the 2023 Quarter.

Funding Requirements

We believe that our cash and cash equivalents as of March 31, 2023, together with expected cash inflows from operations, 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 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 additional indebtedness, we could become subject to additional 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. In addition, adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could affect our ability to access additional funding. 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, 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 certain non-GAAP financial measures. We use these non-GAAP financial measures to understand, manage and evaluate our business as we

believe they provide additional information on the performance of our business. We believe that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide 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 these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, 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 these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial measures 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 may discuss the following financial measures that are not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income (loss) adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. 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 (loss), 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;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, and miscellaneous other acquisition related expenses incurred;
- we exclude recognition of the step-up basis in inventory from acquisitions (i.e., the adjustment to record inventory from historic cost to fair value at acquisition) as the adjustment does not reflect the ongoing expense associated with sale of our products as part of our underlying business; and

- we exclude losses on extinguishments of debt as these expenses are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis.

Adjusted EBITDA for the three months ended March 31, 2023 and 2022 was as follows:

	Three Months Ended March 31,	
	2023	2022
GAAP net loss	$ (17,426)	$ (13,069)
Adjustments:		
Interest expense	21,427	5,831
Interest income	(2,747)	(4)
Loss on extinguishment of debt	23,504	—
Benefit from income taxes	(131)	(2,773)
Depreciation	817	715
Amortization	37,466	18,923
Stock-based compensation expense	6,035	6,135
Litigation settlements	8,500	—
Acquisition related expenses	—	27,167
Recognition of step-up basis in inventory	10,170	603
Total adjustments	$ 105,041	$ 56,597
Adjusted EBITDA	$ 87,615	$ 43,528

Adjusted EBITDA was $87.6 million for the 2023 Quarter compared to $43.5 million for the 2022 Quarter. The $44.1 million increase was primarily due to higher revenue due to a full quarter of revenue from products acquired from BDSI, partially offset by higher adjusted operating expenses.

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.

Adjusted operating expenses for the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,	
	2023	2022
GAAP operating expenses	$ 52,775	$ 58,511
Adjustments:		
Stock-based compensation	6,035	6,135
Litigation settlements	8,500	—
Acquisition related expenses	—	27,167
Total adjustments	$ 14,535	$ 33,302
Adjusted operating expenses	$ 38,240	$ 25,209

Adjusted operating expenses were $38.2 million in the 2023 Quarter compared to $25.2 million in the 2022 Quarter. The $13.0 million increase was primarily driven by higher selling, general and administrative expenses including:

- an increase in salaries, wages, and benefits (excluding stock-based compensation) of $7.4 million;
- an increase in sales and marketing expenses of $4.1 million, primarily due to the timing of marketing efforts;
- an increase in regulatory expenses of $2.0 million, primarily due to a full quarter of expenses incurred related to products acquired from BDSI; and
- an increase in trainings, conferences, and meetings expenses of $1.4 million primarily due to certain annual internal meetings being resumed for the first time in the 2023 Quarter since the onset of the COVID-19 pandemic.

Adjusted Net Income and Adjusted Earnings Per Share

Adjusted net income is a non-GAAP financial measure that represents GAAP net income (loss) adjusted to exclude significant income and expense items that are non-cash or not indicative of ongoing operations, including consideration of the tax effect of the adjustments. Adjusted earnings per share is a non-GAAP financial measure that represents adjusted net income per share. Adjusted weighted-average shares - diluted is calculated in accordance with the treasury stock, if-converted, or contingently issuable accounting methods, depending on the nature of the security.

Adjusted net income and adjusted earnings per share for the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,	
	2023	**2022**
GAAP net loss	$ (17,426)	$ (13,069)
Adjustments:		
Non-cash interest expense	2,287	913
Loss on extinguishment of debt	23,504	—
Amortization	37,466	18,923
Stock-based compensation expense	6,035	6,135
Litigation settlements	8,500	—
Acquisition related expenses	—	27,167
Recognition of step-up basis in inventory	10,170	603
Income tax effect of above adjustments (1)	(18,874)	(13,671)
Total adjustments	$ 69,088	$ 40,070
Non-GAAP adjusted net income	$ 51,662	$ 27,001
Adjusted weighted-average shares — diluted (2)	40,196,015	39,241,622
Adjusted earnings per share (2)	$ 1.32	$ 0.71

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate for the three months ended March 31, 2023 and 2022 of 26.8% and 26%, respectively, to the items that have a tax effect. As such, the non-GAAP effective tax rates for the three months ended March 31, 2023 and 2022 were 21.5% and 25.4%, respectively.

(2) Adjusted weighted-average shares - diluted were calculated using the “if-converted” method for the Convertible Notes in accordance with ASC 260, *Earnings per Share*. As such, for the three months ended March 31, 2023 and 2022 adjusted earnings per share includes 4,646,372 shares and 4,925,134 shares, respectively, related to the assumed conversion of the Convertible Notes and the associated cash interest expense added-back to non-GAAP adjusted net income. In addition, for the three months ended March 31, 2023 and 2022, adjusted earnings per share also includes other potentially dilutive securities to the extent that they are not antidilutive given that non-GAAP adjusted net income was in an income position.

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 from our most recently filed Annual Report.

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 most recently filed Annual Report, other than from the increased borrowings under our 2029 Convertible Notes which are not indexed to LIBOR.

Our primary exposure to market risk is interest rate sensitivity in connection with our money market funds and the 2022 Term Loan.

As of March 31, 2023, our cash and cash equivalents included money market funds of $122.6 million. Our money market funds are short-term highly liquid investments, however, due to the short-term duration and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

The 2022 Term Loan has an underlying rate that is indexed to the 3-month LIBOR rate (subject to a floor of 1.20%), plus a margin of 7.5% per annum. Based on the outstanding principal amount of the 2022 Term Loan as of March 31, 2023 of $550.0 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately $5.5 million.

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, 2023. 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, 2023, 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 that have materially affected, or are 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 15, *Commitments and Contingencies*, 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 most recently filed annual report on Form 10-K for the fiscal year ended December 31, 2022 (the "Annual Report").

Item 1A. Risk Factors

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following principal risk factors that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below:

- Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products and future product candidates, if approved, that we may develop or acquire in the future;
- We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations;
- Adverse developments affecting the financial services industry could adversely affect our business, financial condition, or results of operations;
- If we cannot continue successfully commercializing our products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline;
- Despite receiving approval by the U.S. Food and Drug Administration ("FDA"), additional data may emerge that could change the FDA's position on the product labeling of any of our products, including our abuse-deterrent claims with respect to Xtampza ER, and our ability to market our products successfully may be adversely affected;
- Xtampza ER, Nucynta ER and Nucynta IR (collectively the "Nucynta Products"), and Belbuca are subject to mandatory Risk Evaluation and Mitigation Strategy ("REMS") programs, which could increase the cost, burden and liability associated with the commercialization of these products;
- Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions;
- Unfavorable outcomes in intellectual property litigation could be costly and potentially limit our ability to commercialize 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 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;
- 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;
- 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;
- 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;
- 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;
- 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;

- 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;
- 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;
- If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline;
- If the third-party manufacturers of our products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated manufacturing suite 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;
- Because we currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us;
- We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors or their distribution network is disrupted, our financial condition and results of operations may be adversely affected;
- 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;
- We may not realize all of the anticipated benefits from future acquisitions, and we may be unable to successfully integrate future acquisitions;
- Our business has been, and may continue to be, adversely affected by certain events or circumstances outside our control, including the effects of the COVID-19 pandemic and geopolitical turmoil;
- Litigation or regulatory action regarding opioid medications could negatively affect our business;
- 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;
- Commercial sales of our products, and clinical trials of any future product candidates we may develop or acquire, 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;
- 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; and
- The price of our common stock may be volatile and you may lose all or part of your investment.

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 future product candidates, if approved, 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 future product candidates, if approved, 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, 2022, we had a U.S. federal net operating loss ("NOL") carryforward of approximately $229.8 million and state NOL carryovers of approximately $252.6 million. The U.S. federal and state NOL carryforwards expire at various dates through 2037. Federal NOLs and certain state NOLs incurred in 2018 and onward have an indefinite expiration under the Tax Cuts and Jobs Act of 2017 and applicable state statutes. We also had U.S. federal tax credits of approximately $4.2 million, and state tax credits of approximately $0.8 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 ("IRC 382").

In 2021, we completed a study to assess the impact of ownership changes, if any, on our ability to use our NOL and tax credit carryovers as defined under IRC 382 (the "IRC 382 Study"). As a result of the study, we concluded that there were ownership changes that occurred during the years 2006, 2012 and 2015 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses.

As part of the acquisition of BioDelivery Sciences International, Inc. (the "BDSI Acquisition"), we acquired an estimated $234.7 million of federal NOL carryovers which are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under IRC 382. We performed an IRC 382 study following the BDSI Acquisition in 2022 and concluded that there were ownership changes that occurred during the years 2006 and 2022 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses. Refer to Note 16, *Income Taxes*, for more information.

We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations.

In March 2022, we entered into a $650.0 million secured term loan (the "2022 Term Loan") pursuant to our Amended and Restated 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 "2022 Loan Agreement"), of which $550.0 million in principal was outstanding as of March 31, 2023. In addition, we have $26.4 million in 2.625% Convertible Senior Notes due in 2026 (the "2026 Convertible Notes") and $241.5 million in 2.875% Convertible Senior Notes due 2029 (the "2029 Convertible Notes" and, together with the 2026 Convertible Notes, the "Convertible Notes"). 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, and among other things:

- requiring the dedication of a substantial portion of our cash flows 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;
- exposing us to the risk of increased interest rates as certain of our borrowings, including the 2022 Term Loan, are at variable rates of interest;
- 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; and

- 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, 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, and any failure by us to repurchase notes or to pay the cash amounts due upon the conversion when required would constitute a default under the indenture.

Additionally, the indentures governing the Convertible Notes and our 2022 Loan Agreement contain certain covenants and obligations applicable to us, including, without limitation, 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, which could limit our ability to capitalize on business opportunities that may arise or otherwise place us at a competitive disadvantage relative to our competitors.

Failure to comply with covenants in the indentures governing the Convertible Notes or in the 2022 Loan Agreement would constitute an event of default under those instruments, notwithstanding our ability to meet our debt service obligations. A default under the indentures or a fundamental change could also result in a default under one or more of the 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 that would become due. The 2022 Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement. In addition, because our assets are pledged as a security under the 2022 Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets would be subject to the risk of foreclosure by our lenders.

Further, amounts outstanding under our 2022 Loan Agreement bear interest at a rate based on LIBOR, subject to a LIBOR floor of 1.20%. LIBOR tends to fluctuate based on general short-term interest rates, rates set by the U.S. Federal Reserve and other central banks, the supply of and demand for credit in the London interbank market and general economic conditions. We have not hedged our interest rate exposure with respect to our floating rate debt. Accordingly, our interest expense for any period will fluctuate based on LIBOR and other variable interest rates, as applicable. To the extent the interest rates applicable to our floating rate debt increase, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

The Financial Conduct Authority (“FCA”), the regulatory supervisor of USD LIBOR’s administrator (“IBA”), has announced the future cessation or loss of representativeness of overnight/Spot Next, 1-month, 3-month, 6-month and 12-month USD LIBOR tenor settings. As a result, most USD tenors of LIBOR will cease on December 31, 2023. Following such date, subject to an earlier opt-in triggered by the collateral agent or us, amounts outstanding under our 2022 Loan Agreement are expected to bear interest at a rate based on the Secured Overnight Financing Rate (“SOFR”), a new index calculated by reference to short-term repurchase agreements backed by U.S. Treasury securities, in place of LIBOR. Currently, it is not possible to predict the effect of any discontinuance, modification or other reforms to LIBOR, or the establishment of alternative reference rates such as SOFR, or any other reference rate, will have on us or our borrowing costs.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition, or results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Recently, in March 2023, Silicon Valley Bank (“SVB”) was closed

by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Shortly after, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. Further, investor concerns regarding domestic or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our ability to meet our financial obligations, which could have material adverse impacts on our liquidity and our business, financial condition, or results of operations.

Risks Related to our Products

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

Our business and future success are substantially dependent on our ability to continue successfully commercializing our products, including Xtampza ER, the Nucynta Products, Belbuca and Symproic.

Our ability to continue successfully commercializing our products will depend on many factors, including but not limited to:

- our ability to manufacture commercial quantities of our products 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;
- with respect to Xtampza ER, 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 any of our products, including our abuse-deterrent claims with respect to Xtampza ER, and our ability to market our products 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 a supplemental New Drug Application ("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 any of our 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.

Our opioid 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 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. As opioids, Xtampza ER, the Nucynta Products and Belbuca are subject to the Opioid Analgesic REMS.

Any modification of the Opioid Analgesic REMS by the FDA to impose additional or more burdensome requirements could increase the costs associated with marketing these products and/or reduce the willingness of healthcare providers to prescribe these products, which would have a material adverse effect on our ability to continue to successfully commercialize and generate sufficient revenue from these products.

Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

In addition to scrutiny by the FDA, advertising and promotion of any pharmaceutical product marketed in the United States is heavily scrutinized by, among others, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services, 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 government agencies.

In particular, 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.

Engaging in off-label promotion of our products, including Xtampza ER, could subject us to false claims liability under federal and state statutes, and other litigation and/or investigations, and could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of our products, including Xtampza ER.

Further, 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 be costly 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, including in connection with our pending litigation against generic competitors that have filed Paragraph IV Certifications relating to certain of our products. 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 United States Patent and Trademark Office ("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, including with respect to our recent acquisition of Belbuca and Symproic, 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. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), sponsors of approved drugs must provide six months notice to the FDA of any changes in marketing status, such as the withdrawal of the drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

Additionally, our sales, marketing and distribution capabilities may continue to be hindered as a result of the COVID-19 outbreak. As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the

Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. We 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.

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 continue to accept and use our products, or accept and use any new products that we may develop or acquire. 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 of physicians and other healthcare community members of 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;
- 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, Department of Health and Human Services, U.S. Drug Enforcement Agency ("DEA"), 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, the Nucynta Products, Belbuca, and Symproic for substantially all of our revenues for the foreseeable future, the failure of these products to maintain market acceptance would harm our business prospects.

Some of 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.

Some of 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 Controlled Substances Act ("CSA") and regulations of the DEA and the active ingredient in Belbuca, buprenorphine, is classified as a Schedule III controlled substance. A number of states also independently regulate these drugs, including oxycodone, tapentadol and buprenorphine, 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.

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 (for Schedule I and II substances), 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 imposed taxes or fees on the sale of opioids. Other states, and even the federal government, 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 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.

In August 2022, the Inflation Reduction Act of 2022 was signed into law. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated “maximum fair price” for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. The Inflation Reduction Act of 2022 also caps Medicare beneficiaries’ annual out-of-pocket drug expenses. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of the Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

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 products, including 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. 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, the Nucynta Products and Belbuca; 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 opioids.

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 in our Annual Report under the caption “Business — Government Regulation — DEA and Opioid Regulation.”

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

Once a New Drug Application (“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 abbreviated New Drug Application (“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. Additionally, under FDORA, FDA will assign therapeutic equivalence ratings for certain prescription drugs approved via the Section 505(b)(2)
NDA pathway with respect to other approved drug products and it is unclear how assignment of these ratings will impact the market opportunity for our products. 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 the past, we have initiated litigation with generic competitors that have filed Paragraph IV Certifications challenging certain of our patents. While we have entered into settlement agreements with certain competitors, we are currently pursuing litigation to defend against Paragraph IV Certifications related to Belbuca. Refer to Note 15, *Commitments and Contingencies*, for more information. We believe that we will continue to be subject to ANDA-related litigation, which can be costly and distracting and has the potential to impact the long-term value of our products.

In November 2017, the 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 the FDA’s wider focus on assisting developers of generic abuse-deterrent formulations in navigating 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 our products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated manufacturing suite 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 for Xtampza ER at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This facility requires the maintenance of regulatory approvals and other costs, all of which we absorb. We cannot guarantee that we will be able to continue 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.

We have completed the activities required to transition commercial manufacturing for Nucynta ER from Janssen to Patheon. While we were successful in our regulatory approval and validation activities, we could encounter issues in obtaining commercial supply from Patheon's facility due to technical problems or challenges obtaining adequate and/or timely DEA procurement quota.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional costs, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and 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 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 we could experience technical problems in the operation of our dedicated manufacturing suite;
- 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; and
- 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 our products, which could in turn adversely affect our results of operations and financial condition. Likewise, the inability of any of our sole or limited suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our

products. In addition, DEA regulations, through the quota procurement process, limit the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to maintain an 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 our products to be manufactured according to current good manufacturing practices ("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 inspection deficiencies, a shortage of commercial product, or potential products liability exposure for any noncompliant distributed products. Such failure could also 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 or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us.

We currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredients of our products. For example, we presently depend upon a single supplier for the active pharmaceutical ingredient for the Nucynta Products (tapentadol) and Symproic, and two active pharmaceutical ingredient suppliers for Xtampza ER and Belbuca. We contract with these suppliers for commercial supply to manufacture our products. Further, our suppliers for Xtampza ER and the Nucynta Products active pharmaceutical ingredients also supply our primary competitor in the extended-release oxycodone space, Purdue. Identifying alternate sources of active pharmaceutical ingredients for our products is generally time-consuming and costly. Any changes that our suppliers make 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 suppliers were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of any disruptions in personnel or the global supply chain), 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.

Global supply chain disruptions and shortages may limit manufacturing and commercial supply of our products and have a material impact on our business.

There are currently global supply chain disruptions and shortages caused by a variety of factors, including the COVID-19 pandemic and geopolitical turmoil, such as the Ukrainian War. While we and our suppliers are still able to receive sufficient inventory of the key materials and components needed, we could experience pressure on our supply chain, including shipping delays, higher prices from suppliers, and reduced availability of materials, including excipients and packaging components. To date, supply chain pressure has not had a material impact on our results of operations. However, if these disruptions and shortages continue, we may in the future experience a material interruption to our supply chain. Such an interruption could have a material adverse impact on our business, including but not limited to, our ability to timely manufacture and distribute our products.

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 or their distribution network is disrupted, our financial condition and results of operations may be adversely affected.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented greater than 90% of our product shipments for the year ended March 31, 2023. Our loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases or a significant disruption to transportation infrastructure or other means of distribution of our products, including as a result of the COVID-19 pandemic, 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 wholesaler 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. In addition, due to unprecedented and significant disruptions in the processing of product returns by wholesale pharmaceutical distributors, as further disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations," we formally denied a significant portion of unprocessed product claims under our return policy. We subsequently received payment for only a portion of the denied claims and vigorously pursued collections of the full amount of these short-pay receivables. Although we were able to formally settle a portion of the unprocessed product claims and receive payment therefor, payment for a significant portion of the unprocessed product claims has not been and is not expected to be received. There can be no assurance that similar disruptions in the wholesaler distribution network will not occur in the future or if they do, that we will be able to successfully manage such disruptions.

Our opioid products are 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 opioid 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 the 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 opioid products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

We have historically relied on third parties to conduct our non-clinical and clinical trials, and may continue to rely upon third parties for any product candidates we develop or acquire in the future. 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 in the future, 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 good clinical practices ("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

We may not realize all the anticipated benefits from our future acquisitions, and we may be unable to successfully integrate future acquisitions.

Our growth strategy will, in part, rely on acquisitions. We must plan and manage acquisitions effectively to achieve revenue growth and maintain profitability in our evolving market. We may not realize all the anticipated benefits from our future acquisitions, such as increased earnings, cost savings and revenue enhancements, for various reasons, including difficulties integrating operations and personnel, higher than expected acquisition and operating costs or other difficulties, inexperience with operating in new geographic regions, unknown liabilities, inaccurate reserve estimates and fluctuations in market prices.

In addition, integrating acquired businesses and properties involves a number of special risks and unforeseen difficulties can arise in integrating operations and systems and in retaining and assimilating employees. These difficulties include, among other things:

- operating a larger organization;
- coordinating geographically disparate organizations, systems, and facilities;
- integrating corporate, technological, and administrative functions;
- diverting management's attention from regular business concerns;
- diverting financial resources away from existing operations;
- increasing our indebtedness; and
- incurring potential environmental or regulatory liabilities and title problems.

Any of these or other similar risks could lead to potential adverse short-term or long-term effects on our operating results. The process of integrating our operations could cause an interruption of, or loss of momentum in, the activities of our business. Members of our management may be required to devote considerable amounts of time to this integration process, which decreases the time they have to manage our business. If our management is not able to effectively manage the integration process, or if any business activities are interrupted as a result of the integration process, our business could suffer.

Our business has been, and we may in the future continue to be, adversely affected by certain events or circumstances outside our control, including the COVID-19 pandemic and geopolitical turmoil.

Our business has been, and we may in the future continue to be, adversely affected by certain events or circumstances outside our control. For example, the COVID-19 pandemic has, and may continue to have, a substantial impact on the delivery of healthcare services in the United States. As the COVID-19 pandemic unfolded, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. We believe that the disruptions caused by COVID-19 may continue and, despite the Department of Health and Human Services planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

In addition, other events or circumstances outside of our control, including macroeconomic conditions such as recession or depression, inflation, and declines in consumer-spending could result in reduced demand for our products. An economic downturn could result in business closures, higher levels of unemployment, or declines in consumer disposable income which could 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 may make efforts to avoid or postpone seeking non-

essential medical care to allocate their resources to other priorities or essential items. These circumstances, in addition to the impact of geopolitical turmoil, social unrest, political instability, terrorism, cyberwarfare or other acts of war, may result in reduced demand for our products and negatively impact our sales, results of operations, and liquidity.

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. These lawsuits generally allege that we had engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. In March 2022, we entered into a Master Settlement Agreement resolving 27 pending opioid-related lawsuits brought against us by cities, counties, and other subdivisions in the United States. As part of the Master Settlement Agreement, we paid $2.75 million to the plaintiffs and the cases were dismissed, with prejudice. In late March 2023, three new cases were filed in three federal courts, naming us as one of numerous defendants. The plaintiffs are a variety of municipalities in Florida, Georgia, and Ohio. These new complaints echo the allegations in the prior complaints that were dismissed or settled, as explained above. We have not yet been served with these complaints, and no schedule has been set.

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. In December 2021, we entered into an Assurance of Discontinuance with the Massachusetts Attorney General pursuant to which we provided certain assurances and agreed to pay certain of the Massachusetts Attorney General's costs of investigation, in exchange for closure of the investigation and a release of claims pertaining to the subject matter of the investigation. We are cooperating fully in the open 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.

Competition in the pain and opioid market is intense. Our competitors include 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, 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 develop technologies that are, or may be, the basis for competitive products that are safer, more effective or less costly than our products. Moreover, 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 any future product candidates we develop or acquire, 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 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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our business model, prospects or 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 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, 2023, there were outstanding options to purchase an aggregate of 1,443,996 shares of our common stock at a weighted average exercise price of $19.24 per share, of which options to purchase 1,358,588 shares of our common stock were then exercisable. The exercise of options 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.

There can be no assurance that we will repurchase additional shares of our common stock at all or at favorable prices.

In August 2021, our Board of Directors authorized a repurchase program for the repurchase of up to $100 million of shares of our common stock at any time or times through December 31, 2022 (the “Prior Repurchase Program”). We repurchased $61.9 million of shares pursuant to the Prior Repurchase Program prior to its expiration on December 31, 2022. On January 1, 2023, our Board of Directors authorized a new share repurchase program for the repurchase of up to $100 million of shares of our common stock at any time or times through December 31, 2023 (the “2023 Repurchase Program”). Under the 2023 Repurchase Program, we will be permitted to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. Although a substantial number of shares were repurchased pursuant to the Prior Repurchase Program, any future share repurchases under the 2023 Repurchase Program will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our common stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will continue to repurchase shares of our common stock at favorable prices, if at all.

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 shares of Common Stock repurchased under our Repurchase Program, as well as shares transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of performance share units and restricted stock units during the three months ended March 31, 2023:

Period	Total number of shares purchased	Average Price Paid per Share	Total number of shares purchased as part of publicly announced plans or programs (1)	Maximum approximate dollar value of shares that may yet be purchased under the plans or programs
January 1, 2023 through January 31, 2023	953	$ 26.08	—	$ 100,000
February 1, 2023 through February 28, 2023	287,640	26.75	—	100,000
March 1, 2023 through March 31, 2023	688	24.27	—	100,000
Total	289,281 (2)	$ 26.74	— (2)	$ 100,000

(1) The 2023 Repurchase Program was announced on January 4, 2023. The 2023 Repurchase Program provides for the repurchase of up to $100.0 million of outstanding shares of our common stock at any time or times through December 31, 2023. The 2023 Repurchase Program did not expire during the three months ended March 31, 2023, nor do we currently plan to terminate the 2023 Repurchase Program prior to expiration. However, there can be no assurance as to the timing or number of shares of any repurchases in the future.

(2) The difference, if any, between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program relates to common stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of performance share units and restricted stock units granted under our Amended and Restated 2014 Stock Incentive Plan.

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
4.1	Indenture, dated as of February 10, 2023, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee. (1)
10.1	Second Amendment to Loan Agreement, dated as of February 6, 2023, Amended and Restated Loan Agreement, dated as of March 22, 2022, by and among Collegium Pharmaceutical, Inc., the guarantors party thereto, BioPharma Credit PLC, and Bio Pharma Credit Investments V (Master) LP, as lenders. (2)
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)

(1) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on February 13, 2023.

(2) Previously filed as an exhibit to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 23, 2023.

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 4, 2023

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

Date: May 4, 2023

By: /s/ COLLEEN TUPPER
Colleen Tupper
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 4, 2023

Exhibit 31.2

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

I, Colleen Tupper, 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/ COLLEEN TUPPER

Colleen Tupper
Executive Vice President and Chief Financial Officer

Date: May 4, 2023

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, 2023 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 their 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 4, 2023

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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Colleen Tupper, 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 their 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/ COLLEEN TUPPER

Colleen Tupper
Executive Vice President and Chief Financial Officer

Date: May 4, 2023