Table of Contents

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 September 30, 2022

OR

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

For the transition period from to

Commission file number: 001-37372

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 October 31, 2022, there were 33,571,923 shares of Common Stock, $0.001 par value per share, outstanding.

TABLE OF CONTENTS

Forward-Looking Statements

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

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

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

- our ability to commercialize and grow sales of our products, particularly in light of current global challenges stemming from the COVID-19 pandemic;
- our ability to realize projected cost savings associated with the acquisition of BioDelivery Sciences International, Inc. ("BDSI");
- our ability to obtain and 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 in the face of global challenges, such as the COVID-19 pandemic;
- our ability to effectively manage our relationships with licensors and to commercialize products that we in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our business development;
- 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;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Quarterly Report on Form 10-Q.

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

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

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 134,126	$ 186,426
Accounts receivable, net	195,402	105,844
Inventory	64,652	17,394
Prepaid expenses and other current assets	11,036	5,879
Total current assets	405,216	315,543
Property and equipment, net	19,744	19,491
Operating lease assets	7,061	7,644
Intangible assets, net	609,747	268,723
Restricted cash	2,547	2,547
Deferred tax assets	26,474	78,042
Other noncurrent assets	57	87
Goodwill	130,094	—
Total assets	$ 1,200,940	$ 692,077
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 7,637	$ 4,189
Accrued expenses	22,796	29,214
Accrued rebates, returns and discounts	241,218	196,996
Current portion of term notes payable	141,667	48,353
Current portion of operating lease liabilities	1,179	814
Total current liabilities	414,497	279,566
Term notes payable, net of current portion	441,258	61,666
Convertible senior notes	140,644	139,966
Operating lease liabilities, net of current portion	7,347	7,951
Total liabilities	1,003,746	489,149
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; 36,599,298 issued and 33,775,236 outstanding shares at September 30, 2022 and 35,806,119 issued and 33,655,402 outstanding shares at December 31, 2021	37	36
Additional paid-in capital	525,585	502,095
Treasury stock, at cost; 2,824,062 shares at September 30, 2022 and 2,150,717 shares at December 31, 2021	(54,283)	(42,861)
Accumulated deficit	(274,145)	(256,342)
Total shareholders’ equity	197,194	202,928
Total liabilities and shareholders’ equity	$ 1,200,940	$ 692,077

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenues, net	$ 127,013	$ 78,843	$ 334,313	$ 249,506
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	30,622	15,934	80,638	47,170
Intangible asset amortization	37,552	16,796	93,976	50,386
Total cost of products revenues	68,174	32,730	174,614	97,556
Gross profit	58,839	46,113	159,699	151,950
Operating expenses				
Research and development	—	1,450	3,983	7,842
Selling, general and administrative	38,372	30,514	134,154	92,358
Total operating expenses	38,372	31,964	138,137	100,200
Income from operations	20,467	14,149	21,562	51,750
Interest expense	(19,046)	(5,115)	(42,638)	(16,257)
Interest income	11	3	20	9
Income (loss) before income taxes	1,432	9,037	(21,056)	35,502
Provision for (benefit from) income taxes	975	991	(3,253)	(61,049)
Net income (loss)	$ 457	$ 8,046	$ (17,803)	$ 96,551
Earnings (loss) per share — basic	$ 0.01	$ 0.23	$ (0.52)	$ 2.74
Weighted-average shares — basic	34,058,802	35,373,909	33,912,832	35,210,966
Earnings (loss) per share — diluted	$ 0.01	$ 0.22	$ (0.52)	$ 2.42
Weighted-average shares — diluted	34,570,319	36,261,174	33,912,832	41,274,190

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine Months Ended September 30,	
	2022	**2021**
Operating activities		
Net (loss) income	$ (17,803)	$ 96,551
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Amortization expense	93,976	50,386
Depreciation expense	1,859	1,312
Deferred income taxes	(7,313)	(63,026)
Stock-based compensation expense	17,204	19,343
Non-cash lease expense	341	20
Non-cash interest expense for amortization of debt discount and issuance costs	5,902	2,627
Changes in operating assets and liabilities:		
Accounts receivable	(34,063)	(65,679)
Inventory	30,124	(2,260)
Prepaid expenses and other assets	998	1,230
Accounts payable	3,436	(2,286)
Accrued expenses	(24,719)	(6,028)
Accrued rebates, returns and discounts	(12,040)	35,169
Operating lease assets and liabilities	3	—
Net cash provided by operating activities	57,905	67,359
Investing activities		
Purchases of property and equipment	(682)	(1,429)
Acquisition of BDSI (net of cash acquired)	(572,069)	—
Net cash used in investing activities	(572,751)	(1,429)
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plans	337	755
Proceeds from the exercise of stock options	4,948	9,613
Payments made for employee stock tax withholdings	(3,999)	(4,149)
Repurchases of common stock	(6,422)	(15,524)
Repayment of term notes	(50,000)	(37,500)
Proceeds from term note modification	517,682	—
Net cash provided by (used in) financing activities	462,546	(46,805)
Net (decrease) increase in cash, cash equivalents and restricted cash	(52,300)	19,125
Cash, cash equivalents and restricted cash at beginning of period	188,973	176,663
Cash, cash equivalents and restricted cash at end of period	$ 136,673	$ 195,788
Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets:		
Cash and cash equivalents	$ 134,126	$ 193,241
Restricted cash	2,547	2,547
Total cash, cash equivalents and restricted cash	$ 136,673	$ 195,788
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 35,280	$ 14,573
Cash paid for income taxes	$ 10,037	$ 2,329
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment in accounts payable and accrued expenses	$ 260	$ 301
Accrued repurchases of common stock	$ —	$ 1,956
Inventory used in the construction and installation of property and equipment	$ —	$ 516

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 the following commercial products: Xtampza ER, Nucynta ER and Nucynta IR (the "Nucynta Products"), Belbuca, Symproic, and Elyxyb.

Xtampza ER

The Company's first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the United States Food and Drug Administration (the "FDA") approved the Company's new drug application ("NDA") for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza ER.

Nucynta Products

In December 2017, the Company entered into a Commercialization Agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which the Company acquired the right to commercialize the Nucynta Products in the United States. In February 2020, the Company entered into an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which the Company acquired from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition"), including the license from Gr✔nenthal GmbH ("Gr✔nenthal"). Upon closing, the Nucynta Commercialization Agreement was effectively terminated and the Company's only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Gr✔nenthal. Nucynta ER is an extended-release formulation of tapentadol that 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 an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

Belbuca, Symproic, and Elyxyb

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 (the "Merger Agreement"), dated as of February 14, 2022, by and among the Company, Bristol Acquisition Company Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Purchaser"), and BDSI, a Delaware corporation (the "BDSI Acquisition"). Upon closing, the Company acquired the Belbuca, Symproic, and Elyxyb products. The Company began shipping and recognizing product sales related to Belbuca, Symproic, and Elyxyb after the closing. Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, that 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. Elyxyb was approved by the FDA in May 2020 for the acute treatment of migraine with or without aura in adults.

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.

The Company believes that its cash and cash equivalents at September 30, 2022, 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 September 30, 2022, results of operations for the three and nine months ended September 30, 2022 and 2021, and cash flows for the nine months ended September 30, 2022 and 2021. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the full year.

The preparation of the Condensed Consolidated Financial Statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Estimates in the Company's consolidated financial statements include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of products, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, impairment of intangible assets and tax valuation allowances. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions. The consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's most recently filed Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Annual Report").

Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values, with some exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value can be determined, the asset or liability is recognized; if fair value is not determinable, then no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net assets acquired in a business combination and is not amortized, but is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment.

Research and Development Expenses

Research and development expenses have historically consisted of product development expenses incurred in identifying, developing, and testing product candidates. Product development expenses primarily consisted of labor, benefits, and related employee expenses for personnel directly involved in product development activities, fees paid to contract research organizations for managing clinical and non-clinical trials, and regulatory costs.

As of April 1, 2022, the Company focused entirely on commercial products rather than research and development and redirected resources from research and development activities. As such, there were no expenses incurred in research and development after the three months ended June 30, 2022.

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.

In May 2021, the FASB issued Accounting Standards Update ("ASU") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.* This ASU clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021 and may be applied prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company adopted this standard effective January 1, 2022 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.* This ASU amends Accounting Standards Codification, or ASC, 805 to add contract assets and contract liabilities to the list of exceptions to the recognition and measurement principles that apply to business combinations and to require that an entity (acquirer) recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606. As a result of the amendments made by the ASU, it is expected that an acquirer will generally recognize and measure acquired contract assets and contract liabilities in a manner consistent with how the acquiree recognized and measured them in its pre-acquisition financial statements. The ASU's amendments are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The amendments should be applied prospectively to business combinations occurring on or after the effective date of the amendments. Early adoption of the amendments is permitted, including adoption in an interim period. An entity that early adopts in an interim period should apply the amendments (i) retrospectively to all business combinations for which the acquisition date occurs on or after the beginning of the fiscal year that includes the interim period of early application and (ii) prospectively to all business combinations that occur on or after the date of initial application. The Company adopted this standard effective January 1, 2022 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

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

3. Revenue from Contracts with Customers

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

Revenue Recognition

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

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 are based on product-level returns rates, recent unprocessed return claims, as well as 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). 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).

Historically, estimates of the refund liability for Xtampza product returns were based on a combination of historical actual returns processed to date, taking into consideration the expiration date of product upon delivery to customers, as well as forecasted customer buying and return patterns, channel inventory levels, and other specifically known market events and trends. Sales of Xtampza increased significantly starting in 2018; as a result, the majority of Xtampza sold to customers by the Company had not been eligible for return until the year ended December 31, 2021, or beyond. For the Nucynta Products, estimates of the refund liability for product returns were based on historical returns rates as these products have been commercially sold in the U.S. since 2009 for Nucynta IR and since 2011 for Nucynta ER. Because the Company began selling the Nucynta Products in 2018, most of the Nucynta Products sold to customers by the Company were not eligible for return until the year ended December 31, 2021, or beyond.

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.

2021 Returns Adjustment

During the year ended December 31, 2021, there were unprecedented and significant disruptions in the processing of product returns. Specifically, the Company's customers, via the third-party returns processor that they and many pharmacies engage to process the majority of the Company's product returns, failed to return products to the Company in the ordinary course. The value of actual returned product during the year ended December 31, 2021 represented less than 20% of the value of the product returns claimed during that period. Due to the failure of the customers and their vendor to return product timely in the ordinary course, the Company did not physically receive returned products corresponding to the substantial majority of the returns claimed and could not validate or finalize customer return claims, nor determine if the return was or would be eligible for refund upon the physical return. The lack of timely processing of requested product returns obscures information related to the validation of product returns and increases uncertainty related to the actual volume of product that will be physically returned and credited in accordance with the Company's returns policy.

During the fourth quarter of 2021, after significant and sustained efforts with customers to resolve the unprocessed return claims, the Company formally denied a significant portion of these claims under the Company's return policy. The Company subsequently received payment for only a portion of the denied claims and vigorously pursued collections of the full amount of these short-pay receivables.

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.

During the three and nine months ended September 30, 2022, the Company revised its estimate of variable consideration associated with unprocessed returns claims due to the receipt of payment and formal settlement of certain unprocessed returns claims, which resulted in an increase to product revenues, net of $4,684.

Summary of Activity in Product Revenue Provision and Allowance Categories

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the nine months ended September 30, 2022 and 2021:

	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	38,074	18,187	7,575
Provision related to current period sales	368,880	26,508	94,859
Changes in estimate related to prior period sales	(304)	(838)	(580)
Credits/payments made	(385,298)	(20,987)	(93,946)
Balance at September 30, 2022	$ 163,731	$ 77,487	$ 21,134

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2020	$ 132,775	$ 23,779	$ 19,055
Provision related to current period sales	273,576	13,750	63,279
Changes in estimate related to prior period sales	(434)	—	6
Credits/payments made	(261,210)	(3,473)	(58,213)
Credits expired (4)	—	12,960	—
Balance at September 30, 2021	$ 144,707	$ 47,016	$ 24,127

(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.

(4) During the nine months ended September 30, 2021, $12,960 of previously credited product returns were no longer eligible for credit under the Company's returns policy as the product was not received as of the period end.

As of September 30, 2022, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Belbuca	$ 38,802	$ —	$ 84,413	$ —
Xtampza ER	38,859	30,016	103,567	98,448
Nucynta IR	27,274	29,086	83,163	88,853
Nucynta ER	17,133	19,741	53,473	62,205
Symproic	3,580	—	7,740	—
Elyxyb	218	—	352	—
Other	1,147	—	1,605	—
Total product revenues, net	$ 127,013	$ 78,843	$ 334,313	$ 249,506

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

4. Acquisitions

On March 22, 2022, the Company closed the BDSI Acquisition pursuant to the Merger Agreement, with BDSI surviving the Merger 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 preliminary purchase price allocation is based on estimates, assumptions, valuations and other studies which have not yet been finalized. Prior to the finalization of the purchase price allocation, if information becomes available that would indicate it is probable that unknown events had occurred and the amounts can be reasonably estimated, such items will be included in the final purchase price allocation and may change the carrying value of goodwill. The Company is finalizing its valuation of intangible assets, tangible assets, liabilities and tax analyses, and anticipates finalizing the purchase price allocation as the information necessary to complete the analysis is obtained, but no later than one year after the Acquisition Date.

The following tables set forth the preliminary allocation of the BDSI Acquisition purchase price to the estimated fair value of the net assets acquired at the Acquisition Date (in thousands):

	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	18,115
Accrued rebates, returns and discounts	56,261
Operating lease liabilities	481
Deferred tax liabilities	58,881
Total liabilities	$ 133,750
Total identifiable net assets acquired	539,337
Goodwill	130,094
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 is amortizing the identifiable intangible assets on a straight-line 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.

Total revenues attributable to BDSI from the Acquisition Date through September 30, 2022 were $94,110. However, earnings attributable to BDSI from the Acquisition Date through September 30, 2022 are not distinguishable due to the rapid integration of BDSI's core operations into the Company.

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the three and nine months ended September 30, 2022 and 2021, as if the BDSI Acquisition had occurred on January 1, 2021. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2021, and is not indicative of what such results would be expected for any future period (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenues	$ 127,013	$ 119,934	$ 363,664	$ 373,055
Net (loss) income	$ 12,603	$ (14,725)	$ (6,347)	$ 10,089

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and BDSI. The summary pro forma financial information primarily reflects the following pro forma adjustments:

- The Company's acquisition related transaction costs of $14,718 were reflected as of January 1, 2021
- Employee severance related expense of $8,008 was reflected as of January 1, 2021
- Additional amortization expense from the acquired intangibles
- Additional cost of product revenues related to the step-up basis in inventory to record inventory at fair value; and
- Adjustments to the Company's interest expense related to repayment of the 2020 Term Notes and entering into the 2022 Term Loan as defined in Note 11, *Term Notes Payable.*

In addition, all of the above adjustments were adjusted for the applicable tax impact.

Acquisition Related Expenses

During the three and nine months ended September 30, 2022, the Company incurred $463 and $31,209, respectively, of acquisition related expenses as a result of the BDSI Acquisition and the substantial majority were included in the *Selling, general, and administrative* expense in the condensed consolidated statements of operations. These costs 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, BDSI directors and officers insurance, and miscellaneous other acquisition expenses incurred. Additional charges related to severance or retention payments and payments of any remaining employee termination costs are not expected to be material. However, the Company expects to incur additional acquisition related expenses relating to consulting fees, contract termination costs, and other integration-related expenses during the remainder of 2022.

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Transaction costs	$ —	$ 14,718
Employee-related expenses	—	8,008
BDSI directors and officers insurance	—	4,492
Other acquisition expenses	463	3,991
Total acquisition related expenses	$ 463	$ 31,209

5. License Agreements

The Company periodically enters into license agreements to develop and commercialize its products.

Dr. Reddy's acquired product rights

Prior to the BDSI Acquisition, BDSI and Dr. Reddy's Laboratories Limited ("DRL"), entered into an asset purchase agreement (the "Elyxyb Asset Purchase Agreement") for the acquisition by BDSI from DRL of certain patents, trademarks, regulatory approvals and other rights related to Elyxyb and its commercialization in the United States and Canada (the "DRL Territory").

Pursuant to the terms of the Elyxyb Asset Purchase Agreement, a $9,000 payment was due to DRL on August 3, 2022. In addition, up to an additional $9,000 of payments are due to DRL upon achievement of certain regulatory milestones as well as for quarterly earn-out payments on potential sales of the Elyxyb Product in the DRL Territory that range from

high single digits to the low double digits (subject to reduction in certain circumstances) of net sales based on volume of sales. DRL will also be entitled to one-time payments upon the achievement of six escalating sales milestones, which range from $4,000 to be paid upon the achievement of $50,000 in net sales in a calendar year to $100,000 to be paid upon the achievement of $1,000,000 in net sales in a calendar year up to a total of $262,000.

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 our 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	$ 457	$ 8,046	$ (17,803)	$ 96,551
Adjustment for interest expense recognized on convertible senior notes:	—	—	—	3,504
Net income (loss) - diluted	$ 457	$ 8,046	$ (17,803)	$ 100,055
Denominator:				
Weighted-average shares outstanding — basic	34,058,802	35,373,909	33,912,832	35,210,966
Effect of dilutive securities:				
Stock options	191,454	435,099	—	564,171
Restricted stock units	320,063	333,572	—	405,632
Employee stock purchase plan	—	1,829	—	3,403
Warrants	—	116,765	—	164,884
Convertible senior notes	—	—	—	4,925,134
Weighted average shares outstanding — diluted	34,570,319	36,261,174	33,912,832	41,274,190
Earnings (loss) per share — basic	$ 0.01	$ 0.23	$ (0.52)	$ 2.74
Earnings (loss) per share — diluted	$ 0.01	$ 0.22	$ (0.52)	$ 2.42

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 in cash, shares or a combination of the two. 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	1,061,235	1,433,791	2,156,501	1,360,024
Restricted stock units	523,991	694,694	1,960,160	50,450
Performance share units	447,770	353,100	447,770	353,100
Employee stock purchase plan	11,553	—	—	—
Warrants	1,041,667	—	1,041,667	—
Convertible senior notes	4,925,134	4,925,134	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 nine months ended September 30, 2022 and 2021.

The following table presents the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at September 30, 2022 and December 31, 2021:

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2022				
Money market funds, included in cash equivalents	$ 2,016	$ 2,016	$ —	$ —
December 31, 2021				
Money market funds, included in cash equivalents	$ 45,078	$ 45,078	$ —	$ —

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.

The Company's convertible senior notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined based on data points other than quoted prices that are observable, either directly or indirectly, such as broker quotes in a non-active market. As of September 30, 2022, the convertible senior notes had a fair value of approximately $125,185 and a net carrying value of $140,644.

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 September 30, 2022, the outstanding principal balance of the term notes of $600,000 reasonably approximated the estimated fair value.

As of September 30, 2022, and December 31, 2021, the carrying amounts of the 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 September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Raw materials	$ 5,761	$ 3,685
Work in process	37,173	1,007
Finished goods	21,718	12,702
Total inventory	$ 64,652	$ 17,394

The aggregate charges related to excess inventory for the three and nine months ended September 30, 2022 and 2021 were immaterial. These expenses were recorded as a component of cost of product revenues.

9. Goodwill and Intangible Assets

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

	Amount
Balance at December 31, 2021	$ —
Goodwill resulting from BDSI Acquisition	130,094
Balance at September 30, 2022	$ 130,094

The Company's goodwill resulted from 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 September 30, 2022 and December 31, 2021:

	Amortization Period (Years)	As of September 30, 2022			As of December 31, 2021		
		Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Belbuca	4.8	$ 360,000	$ (39,581)	$ 320,419	$ —	$ —	$ —
Nucynta Products	8.0	521,170	(302,833)	218,337	521,170	(252,447)	268,723
Symproic	9.6	70,000	(3,824)	66,176	—	—	—
Elyxyb	14.2	5,000	(185)	4,815	—	—	—
Total intangibles		$ 956,170	$ (346,423)	$ 609,747	$ 521,170	$ (252,447)	$ 268,723

The following table presents amortization expense recognized in cost of product revenues for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Belbuca	$ 18,848	$ —	$ 39,581	$ —
Nucynta Products	16,795	16,796	50,385	50,386
Symproic	1,821	—	3,825	—
Elyxyb	88	—	185	—
Total amortization expense	$ 37,552	$ 16,796	$ 93,976	$ 50,386

As of September 30, 2022, the remaining amortization expense expected to be recognized is as follows:

Years ended December 31,	Belbuca	Nucynta Products	Symproic	Elyxyb	Total
2022	$ 18,847	$ 16,795	$ 1,822	$ 88	$ 37,552
2023	75,393	67,181	7,285	352	150,211
2024	75,393	67,181	7,285	352	150,211
2025	75,393	67,180	7,285	352	150,210
2026	75,393	—	7,285	352	83,030
Thereafter	—	—	35,214	3,319	38,533
Remaining amortization expense	$ 320,419	$ 218,337	$ 66,176	$ 4,815	$ 609,747

10. Accrued Expenses

Accrued expenses as of September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Accrued royalties	$ 6,965	$ 9,930
Accrued bonuses	3,416	2,634
Accrued product taxes and fees	3,071	2,570
Accrued audit and legal	2,775	3,623
Accrued sales and marketing	1,514	697
Accrued incentive compensation	1,341	851
Accrued payroll and related benefits	1,108	807
Accrued interest	467	1,415
Accrued restructuring expenses	—	3,222
Accrued income taxes	—	622
Accrued other operating costs	2,139	2,843
Total accrued expenses	$ 22,796	$ 29,214

11. Term Notes Payable

Prior Pharmakon Term Notes

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, the Company, together with its subsidiary, Collegium Securities Corporation, entered into a loan agreement (the "2020 Loan Agreement") with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"). The 2020 Loan Agreement provided for a $200,000 secured term loan (the "2020 Term Notes"), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement. On February 13, 2020 (the "2020 Term Loan Closing Date"), the Company received the $200,000 proceeds from the 2020 Term Notes.

On March 22, 2022 the outstanding balance under the 2020 Loan Agreement was fully paid in connection with the closing of the BDSI Acquisition and establishment of the 2022 Term Loan, as defined below (the "2022 Loan Amendment").

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, the Purchaser, and Pharmakon (the "2022 Loan Agreement"). The 2022 Loan Agreement provides 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 Amendment was accounted for as a debt modification and transaction fees of $173 were expensed. In connection with the 2022 Loan Amendment, 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 September 30, 2022, the interest rate was 9.8%. The Company is required to repay the 2022 Term Loan by paying $100,000 in principal payments during the first year and the remaining $550,000 balance will amortize 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 and nine months ended September 30, 2022 the Company recognized interest expense of $17,879 and $36,293, respectively, related to the 2022 Term Loan.

As of September 30, 2022, principal repayments under the 2022 Term Loan are as follows:

Years ended December 31,	**Principal Payments**
2022	$ 25,000
2023	162,500
2024	183,333
2025	183,333
2026	45,834
Total before unamortized discount and issuance costs	$ 600,000
Less: unamortized discount and issuance costs	(17,075)
Total term notes	$ 582,925

12. Convertible Senior Notes

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

The Company may, at its option, settle the convertible notes in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

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

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

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

As of September 30, 2022, none of the above circumstances had occurred and as such, the convertible notes could not have been converted.

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

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

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

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

As of September 30, 2022, the convertible notes outstanding consisted of the following:

Principal	$	143,750
Less: unamortized issuance costs		(3,106)
Net carrying amount	$	140,644

The Company determined the expected life of the convertible notes was equal to its six-year term. The effective interest rate on the convertible notes is 3.26%. As of September 30, 2022, 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 and nine months ended September 30, 2022, and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Contractual interest expense	$ 943	$ 943	$ 2,830	$ 2,831
Amortization of debt issuance costs	228	228	678	673
Total interest expense	$ 1,171	$ 1,171	$ 3,508	$ 3,504

As of September 30, 2022, the future minimum payments on the convertible notes were as follows:

Years ended December 31,	Future Minimum Payments
2022	$ —
2023	3,773
2024	3,773
2025	3,773
2026	145,638
Total minimum payments	$ 156,957
Less: interest	(13,207)
Less: unamortized issuance costs	(3,106)
Convertible senior notes	$ 140,644

13. Equity

The changes in shareholders' equity for the three and nine months ended September 30, 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 from Accelerated Share Repurchase ("ASR") agreement	—	—	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
Exercise of common stock options	102,283	—	1,545	—	—	—	1,545
Vesting of RSUs and PSUs	111,056	1	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(26,506)	—	(511)	—	—	—	(511)
Stock-based compensation	—	—	5,692	—	—	—	5,692
Net loss	—	—	—	—	—	(5,191)	(5,191)
Balance, June 30, 2022	36,567,830	$ 37	$ 520,038	(2,457,849)	$ (47,861)	$ (274,602)	$ 197,612
Exercise of common stock options	10,395	—	142	—	—	—	142
Issuance for employee stock purchase plan	9,206	—	134	—	—	—	134
Vesting of RSUs and PSUs	17,644	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(5,777)	—	(106)	—	—	—	(106)
Share repurchases	—	—	—	(366,213)	(6,422)	—	(6,422)
Stock-based compensation	—	—	5,377	—	—	—	5,377
Net income	—	—	—	—	—	457	457
Balance, September 30, 2022	36,599,298	$ 37	$ 525,585	(2,824,062)	$ (54,283)	$ (274,145)	$ 197,194

The changes in shareholders' equity for the three and nine months ended September 30, 2021 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance, December 31, 2020	34,612,054	$ 35	$ 519,143	—	$ —	$ (333,147)	$ 186,031
Cumulative effect adjustment for adoption of ASU 2020-06	—	—	(44,777)	—	—	5,288	(39,489)
Exercise of common stock options	289,164	—	4,102	—	—	—	4,102
Issuance for employee stock purchase plan	24,630	—	358	—	—	—	358
Vesting of RSUs and PSUs	413,538	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(135,562)	—	(3,508)	—	—	—	(3,508)
Stock-based compensation	—	—	6,879	—	—	—	6,879
Net income	—	—	—	—	—	15,662	15,662
Balance, March 31, 2021	35,203,824	$ 35	$ 482,197	—	$ —	$ (312,197)	$ 170,035
Exercise of common stock options	273,127	1	4,092	—	—	—	4,093
Vesting of RSUs and PSUs	65,107	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(18,141)	—	(421)	—	—	—	(421)
Stock-based compensation	—	—	6,516	—	—	—	6,516
Net income	—	—	—	—	—	72,843	72,843
Balance, June 30, 2021	35,523,917	$ 36	$ 492,384	—	$ —	$ (239,354)	$ 253,066
Exercise of common stock options	91,268	—	1,337	—	—	—	1,337
Issuance for employee stock purchase plan	19,089	—	397	—	—	—	397
Vesting of RSUs and PSUs	33,098	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(11,179)	—	(220)	—	—	—	(220)
Share repurchases	—	—	—	(859,040)	(17,480)	—	(17,480)
Stock-based compensation	—	—	5,948	—	—	—	5,948
Net income	—	—	—	—	—	8,046	8,046
Balance, September 30, 2021	35,656,193	$ 36	$ 499,846	(859,040)	$ (17,480)	$ (231,308)	$ 251,094

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 September 30, 2022, there were 1,982,639 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 three months following the termination date, while unvested options are forfeited immediately upon termination. Refer to Note 14, *Stock-based Compensation*, for more information.

Warrants

As of September 30, 2022, the warrant issued to Assertio in November 2018 was the Company's only outstanding warrant. In connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The terms of the warrant are fixed, with the exception of customary adjustments for changes in the Company's capitalization. The warrant may only be settled with the issuance of shares of common stock upon exercise and will expire in November 2022.

Share Repurchases

In August 2021, the Company's 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 "Repurchase Program"). The 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. Shares repurchased under the Repurchase Program will return to the Company's pool of authorized but unissued shares available for reissuance. The timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The Repurchase Program can be discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future.

In October 2021, the Company's board of directors authorized an accelerated share repurchase program (the "ASR Program") to repurchase $25,000 of the Company's common stock, as part of the Company's existing $100,000 Repurchase Program. Under the terms of the Company's ASR agreement with an investment bank (the "ASR Agreement"), the Company paid $25,000 on November 15, 2021, and received 1,026,694 shares, representing 80% of the upfront payment on a price per share of $19.48, the closing price on the date the ASR Agreement was executed. The remaining shares purchased by the Company was based on the volume-weighted average price of its common stock through January 7, 2022, minus an agreed upon discount between the parties. On January 7, 2022, the ASR Agreement settled, and the Company received an additional 307,132 shares, bringing the total shares repurchased pursuant to the ASR Agreement to 1,333,826.

As of September 30, 2022, the Company repurchased 2,824,062 shares at a weighted-average price of $19.22 per share for a total of $54,283 under the Repurchase Program and the cost of repurchased shares were recorded as treasury stock in the condensed consolidated Balance Sheet. As of September 30, 2022, $45,717 remained available for share repurchases under the Repurchase Program.

14. Stock-based Compensation

Performance Share Units, Restricted Stock Units and Stock Options

Performance Share Units

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

A summary of the Company's PSU activity for the nine months ended September 30, 2022 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2021	353,100	$ 31.77
Granted	241,550	24.12
Vested	(126,081)	29.12
Forfeited	(22,104)	29.60
Performance adjustment	1,305	28.96
Outstanding at September 30, 2022	447,770	$ 28.71

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 nine months ended September 30, 2022, and 2021 was $24.12 and $35.15, respectively.

Restricted Stock Units

The Company granted RSUs to employees during the nine months ended September 30, 2022. The Company's RSUs generally vest ratably over a four-year period of service. A summary of the Company's RSU activity for the nine months ended September 30, 2022 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2021	1,620,023	$ 22.48
Granted	1,272,497	17.48
Vested	(565,669)	21.93
Forfeited	(366,691)	20.58
Outstanding at September 30, 2022	1,960,160	$ 19.75

The weighted-average grant date fair value per share of RSUs granted for the nine months ended September 30, 2022 and 2021 was $17.48 and $24.35, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the nine months ended September 30, 2022, and 2021 was $10,020 and $11,165, respectively.

Stock Options

A summary of the Company's stock option activity for the nine months ended September 30, 2022 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, 2021	2,728,169	$ 18.33	5.8	$ 6,070
Granted	—	—		
Exercised	(302,752)	16.34		
Cancelled	(268,916)	21.38		
Outstanding at September 30, 2022	2,156,501	$ 18.23	5.4	$ 2,142
Exercisable at September 30, 2022	1,969,414	$ 18.18	5.2	$ 2,023

The weighted-average grant date fair value per share of stock options granted for the nine months ended September 30, 2021 was $12.60.

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 nine months ended September 30, 2022, 22,627 shares of common stock were purchased for total proceeds of $337. The expense for the three months ended September 30, 2022 and 2021 was $28 and $58, respectively. The expense for the nine months ended September 30, 2022 and 2021 was $88 and $195, respectively.

Stock-based Compensation Expense

A summary of the allocation of the Company's stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ —	$ 233	$ 1,591	$ 2,697
Selling, general and administrative	5,377	5,715	15,613	16,646
Total stock-based compensation expense	$ 5,377	$ 5,948	$ 17,204	$ 19,343

At September 30, 2022, there was approximately $36,243 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 2.4 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 NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Orange Book, in this case OxyContin. The 505(b)(2) process requires that the Company certify to the FDA that the Company does not infringe any of the patents listed for OxyContin in the Orange Book, or that the patents are invalid. The process also requires that the Company notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA, and any other Orange Book-listed patent owners that it has made such a certification. On February 11, 2015, the Company made the required certification documenting why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin, five of which have been invalidated in court proceedings, and provided the required notice to Purdue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

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

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

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

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

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

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 August 17, 2022, the Court set (i) the fact discovery deadline for February 3, 2023; and (ii) expert witness depositions to conclude by May 26, 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 both of the remaining Stein and Sanford cases, 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. Defendant BDSI's response to the complaint in the *Sanford* Action is due on November 21, 2022. 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 what were then a few hundred cases pending around the country in federal court against opioid manufacturers and distributors into a Multi-District Litigation ("MDL") in the Northern District of Ohio. Generally, these suits do not seek damages for injuries to individuals but rather compensation for the cost of public services needed to address the consequences of addicted communities, ranging from emergency response capabilities to rehabilitation services. The Company was named as a defendant in a small subset of the MDL cases. Of the 21 MDL cases that have named the Company as a defendant, the allegations against it were previously dismissed or withdrawn in 13 cases. As explained below, 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 are several cases pending against the Company in state courts in Pennsylvania and Massachusetts:

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

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

On December 24, 2021, the Company entered into a settlement framework with Scott+Scott Attorneys at Law, LLP (the "Scott Firm"), 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 an aggregate amount not to exceed $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 has been executed by the Company and all 27 plaintiffs, and the amounts subject to the settlement agreement have been paid.

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.

The parties have submitted appropriate motions to dismiss the Company with prejudice for each of the 27 cases. A notice of voluntary dismissal as to Collegium was filed in the MDL on April 19, 2022, which dismissed the Company from the eight remaining MDL cases that named it. In the consolidated Pennsylvania state court cases, a motion for leave to discontinue as to the Company was filed on April 11, 2022 for the six cases naming the Company, which has been granted. In Massachusetts state court, motions to dismiss the Company from the thirteen cases naming it were filed May

11, 2022. The Court endorsed all thirteen of these motions to dismiss on July 22, 2022, thereby dismissing the Company from those cases.

Ongoing BDSI Litigation Matters

BDSI's ongoing litigations with Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") and Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior") are provided below.

Litigation related to BUNAVAIL

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. The RB Plaintiffs claim that the formulation for BUNAVAIL, which has never been disclosed publicly, infringes its U.S. Patent No. 8,475,832 (the "'832 Patent"). On May 21, 2014, the Court granted BDSI's motion to dismiss.

On January 22, 2014, Aquestive initiated an inter partes review ("IPR") on U.S. Patent No. 7,579,019, (the "'019 Patent"). The PTAB upheld all claims of BDSI's '019 Patent in 2015 and this decision was not appealed by Aquestive.

On September 20, 2014, BDSI filed a declaratory judgment action in the United States District Court for the EDNC requesting the Court to make a determination that BDSI's BUNAVAIL product does not infringe the '832 Patent, U.S. Patent No. 7,897,080 (the "'080 Patent") and U.S. Patent No. 8,652,378 (the "'378 Patent"). BDSI obtained a final written decision of invalidity of the '080 Patent in its entirety in an inter partes reexamination proceeding. BDSI obtained a final written decision of invalidity of all relevant claims of the '832 Patent in an IPR proceeding. In an IPR proceeding for the '378 Patent, in its decision not to institute the IPR proceeding, the PTAB construed the claims of the '378 Patent. Shortly thereafter, by joint motion of the parties, the '378 Patent was removed from the District Court action.

On June 6, 2016, in an unrelated case in which Indivior and Aquestive asserted the '832 Patent against other parties, the Delaware District Court entered an order invalidating other claims in the '832 Patent. Indivior and Aquestive did not appeal the Delaware Court's holding that other claims of the '832 Patent are invalid. On February 10, 2021, the parties in BDSI's EDNC declaratory judgment action filed a covenant by Indivior and Aquestive not to sue BDSI for infringement of the '832 Patent. In view of that covenant and the prior invalidation of the '080 patent, BDSI filed a notice of voluntary dismissal of its EDNC declaratory judgement action.

On September 22, 2014, the RB Plaintiffs filed an action against BDSI (and BDSI's commercial partner) relating to BDSI's BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim 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 December 12, 2014, BDSI filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against its commercial partner. On October 28, 2014, BDSI filed multiple IPR petitions on certain claims of the '167 Patent. The USPTO instituted three of the four IPR petitions. The PTAB upheld the claims and denied collateral estoppel applied to the PTAB decisions in March 2016. BDSI appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB.

On June 19, 2018, BDSI filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the '167 Patent IPRs for further consideration on the merits.

On February 7, 2019, the PTAB issued three decisions on remand vacating institution of the three previously instituted IPRs of the '167 patent. On March 11, 2019, BDSI timely appealed the PTAB decisions on remand to U.S. Court of Appeal for the Federal Circuit. On March 20, 2019, Aquestive and Indivior moved to dismiss the appeal, and BDSI opposed that motion.

On August 29, 2019, a three-judge panel of the Court of Appeals for the Federal Circuit granted the motion and dismissed BDSI's appeal. On September 30, 2019, BDSI filed a petition for an en banc rehearing of the order dismissing BDSI's appeal by the full Federal Circuit Court of Appeals.

On January 13, 2020, by the Court of Appeals for the Federal Circuit denied BDSI's petition for en banc rehearing of the dismissal of BDSI's appeal relating to inter partes review proceedings on the '167 patent. On June 11, 2020, BDSI filed a petition for certiorari seeking U.S. Supreme Court review of the Federal Circuit's decision. On October 5, 2020, the U.S. Supreme Court denied BDSI's petition for certiorari.

On May 18, 2021, the RB Plaintiffs filed an amended complaint dropping BDSI's commercial partner from the action it began on September 22, 2014. On June 1, 2021, BDSI answered the amended complaint asserting counterclaims of non-infringement, invalidity, and unenforceability. On December 16, 2021, the parties completed claim construction briefing on the disputed claim terms of the '167 patent. The Court has not set a date for the claim construction hearing. Fact discovery is set to close ninety days after the court issues its order on claim construction. Expert discovery is set to close 141 days after the close of fact discovery. The Court has not set a trial date. 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 BELBUCA

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. In lieu of answering the complaint, BDSI filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. On July 25, 2017, the New Jersey Court administratively terminated the case pending the parties' submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case was later transferred to the Delaware District Court. On October 31, 2017, BDSI filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC.

On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted BDSI's motion to transfer the case to the EDNC. On November 20, 2018, BDSI moved the EDNC to dismiss the complaint for patent infringement for failure to state a claim for relief.

On August 6, 2019, the EDNC granted BDSI's motion to dismiss, and dismissed the complaint without prejudice. On or about November 11, 2019, Aquestive refiled a complaint in the EDNC against BDSI alleging that BELBUCA infringes the '167 Patent. On January 13, 2020, in lieu of answering the complaint, BDSI filed a motion to dismiss the complaint. After that motion was denied, BDSI answered the complaint on April 16, 2020. Aquestive moved to dismiss BDSI's counterclaim of unenforceability, but the court denied that motion.

On December 16, 2021, the parties completed claim construction briefing on the disputed claim terms of the '167 patent. The Court has not set a date for the claim construction hearing. Fact discovery is set to close ninety days after the court issues its order on claim construction. Expert discovery is set to close 141 days after the close of fact discovery. The Court has not set a trial date. 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.

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 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539 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 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 on March 1, 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, 2021 trial with Alvogen. On December 20, 2021, the Court issued an opinion upholding the validity of claims in BDSI’s ‘866 patent, which expires in 2027, and claims in the ’539 patent, which expires in 2032, to which Chemo is bound. 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. The Court instructed the parties to file a joint status report on February 1, 2023.

On August 1, 2022, BDSI received a second Paragraph IV certification notice letter from Chemo indicating that Chemo has amended its ANDA to 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, on September 12, 2022, BDSI filed a complaint for patent infringement in Federal District Court for the District of Delaware.

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 follows 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 commence on November 9, 2020 to adjudicate issues concerning the validity of the BEMA patents. On October 6, 2020, the Court rescheduled the bench trial with Alvogen to commence on March 1, 2021. A three-day bench trial against Alvogen was conducted commencing on March 1, 2021. At the conclusion of trial, the Court ordered the parties to submit post-trial briefs. Post-trial briefing was completed on May 26, 2021. BDSI subsequently moved the Court to strike (i.e., remove from the Court’s consideration) three patent invalidity defenses raised for the first time in Alvogen’s post-trial briefs and two documents improperly cited in Alvogen’s post-trial briefs. On June 28, 2021, the Court granted BDSI’s motion to strike in its entirety. In addition, on June 28, 2021, the Court enjoined Alvogen from launching its generic product until the Court issued its final decision on the merits.

On September 21, 2021, BDSI filed under seal a Motion for Order to Show Cause why Defendants Should not be Held in Contempt for Violating the Court Order of June 28, 2021 (the “Motion”). On June 28, 2021, citing the statute authorizing the Court to extend the 30-month stay under the Hatch-Waxman Act, the Court ordered Alvogen not to “launch” its generic product until it could reach a final decision on the merits in the case. In the Motion, BDSI contends that Alvogen violated the order of the United States District Court for the District of Delaware commencing in or about August 2021 by, among other things, offering the generic product for sale through five compendia / price reporting services, including First Databank, Medi-Span (Wolters Kluwer), Red Book, Gold Standard and ScriptPro. As alleged in the Motion, after Alvogen’s product launch, certain payers began declining insurance coverage for BDSI’s brand BELBUCA and directing use of Alvogen’s generic substitute and/or made it more difficult for patients to obtain

insurance coverage for BELBUCA. In addition to filing the Motion, BDSI demanded that Alvogen withdraw its compendia listings. Alvogen claims to have withdrawn its compendia product listings on or about September 9, 2021.

On December 20, 2021, the Court issued an opinion upholding the validity of claims in BDSI's '866 patent, which expires in 2027, and claims in the '539 patent, which expires in 2032. Alvogen conceded infringement of those claims prior to the trial. The Court entered final judgment of infringement and of failure to prove invalidity 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 (i) Alvogen's motion to stay the final judgment and (ii) BDSI's motion for contempt.

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 has 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. The Federal Circuit scheduled oral argument on the parties' appeal for November 1, 2022.

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"). Pursuant to the AoD, the Company provided certain assurances and agreed to pay the Massachusetts Attorney General $185, including $65 relating to that office's costs of investigation, in exchange for closure of the investigation and a release of claims pertaining to the subject matter of the investigation. The Company is currently cooperating with each of the foregoing 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 provision (benefit) recognized for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Provision for (benefit from) income taxes	$ 975	$ 991	$ (3,253)	$ (61,049)
Effective tax rate	68.1%	11.0%	15.4%	(172.0%)

The benefit from income taxes in the nine months ended September 30, 2022 reflects the tax benefit of the current year loss, which includes the impact of discrete nondeductible transaction costs and excess tax benefits, compared to the benefit in the nine months ended September 30, 2021, which reflected the impact of releasing a majority of the Company's valuation allowance.

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 September 30, 2022.

In connection with the BDSI Acquisition, the Company acquired net operating losses and is completing a study to determine the amount of net operating losses that are available and the limitations on use of these acquired operating losses as well as any valuation allowance required on these or other deferred tax assets.

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 on Form 10-Q, 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 on Form 10-Q, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

OVERVIEW

We are building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Our portfolio includes Xtampza ER, the Nucynta Products, Belbuca, Symproic, and Elyxyb.

Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone that 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 ("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. 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, pursuant to the Merger Agreement. Upon closing, we acquired the Belbuca, Symproic, and Elyxyb products. We began shipping and recognizing product sales related to Belbuca, Symproic, and Elyxyb in March 2022.

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 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. Elyxyb was approved by the FDA in May 2020 for the acute treatment of migraine with or without aura in adults.

We believe the acquisition of Belbuca, Symproic, and Elyxyb 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.

We are promoting our pain portfolio (Xtampza ER, the Nucynta Products, Belbuca, and Symproic) to approximately 8,600 health care professionals who write approximately 62% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 100 sales representatives and managers. Additionally, we are currently launching Elyxyb with a sales team of 29 sales representatives and managers promoting to approximately 3,000 headache specialists and thought leaders within key markets.

Outlook

We were historically not profitable and incurred net losses in each year since inception until 2020. Substantially all our net losses resulted from costs incurred in connection with selling, general and administrative costs associated with our operations and research and development programs, and we expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities.

The BDSI Acquisition diversifies and expands our business by adding Belbuca and Symproic to our highly differentiated pain portfolio, and Elyxyb, as a new product launch opportunity that provides entry into neurology. We expect the addition of these products to further strengthen our financial position through increased revenue scale, immediate and significant earnings accretion, and accelerated cash flow generation, driven by synergies of merging operations. While we incurred significant transaction costs and other acquisition related expenses during the period ended September 30, 2022 to complete the BDSI Acquisition and to integrate BDSI's operations, we expect acquisition related expenses to decrease significantly throughout the remainder of 2022 and expect significant synergies to be reflected in the results of our operations for the remainder of 2022. 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 Acquisition Date.

As of the date of the filing of this Quarterly Report on Form 10-Q, we expect the COVID-19 pandemic will continue to impact our revenue. Notwithstanding the lifting of COVID-19 restrictions in many jurisdictions, and amidst continuing public health concerns relating to the spread of COVID-19, pain patient office visits continue to be depressed compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products. We believe that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease.

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.

Changes in our critical accounting policies with respect to our Annual Report include business combination accounting and valuation of acquired assets, including goodwill and intangible assets, as described below.

Business Combination Accounting and Valuation of Acquired Assets

We completed the BDSI Acquisition on March 22, 2022, which was accounted for as a business combination. To determine whether the acquisition should be accounted for as a business combination or as an asset acquisition, we made certain judgments regarding whether the acquired set of activities and assets met the definition of a business. Judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

The acquisition method of accounting requires that we recognize the assets acquired and liabilities assumed at their acquisition date fair values. Goodwill is measured as the excess of consideration transferred over the acquisition date net fair values of the assets acquired and the liabilities assumed. The purchase price allocation is a critical accounting estimate because the estimation of fair values of acquired assets and assumed liabilities is judgmental and requires various assumptions based on non-observable inputs. An income approach, which generally relies upon projected cash

flow models, is used in estimating the fair value of the acquired intangible assets. These cash flow projections are based on management's estimates of economic and market conditions including the estimated future cash flows from revenues of acquired assets; the timing and projection of costs and expenses, discount rates; and tax rates.

While we use our best estimates and assumptions as part of the process to value assets acquired and liabilities assumed at the acquisition date, our estimates are inherently uncertain and subject to refinement. During the measurement period, which occurs before finalization of the purchase price allocation, changes in assumptions and estimates that result in adjustments to the fair values of assets acquired and liabilities assumed, if based on facts and circumstances existing at the acquisition date, are recorded on a retroactive basis as of the acquisition date, with the corresponding offset to goodwill. Any adjustments not based on facts and circumstances existing at the acquisition date, or if subsequent to the conclusion of the measurement period, will be recorded to our consolidated statements of operations.

RESULTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Product revenues, net	$ 127,013	$ 78,843	$ 334,313	$ 249,506
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	30,622	15,934	80,638	47,170
Intangible asset amortization	37,552	16,796	93,976	50,386
Total cost of products revenues	68,174	32,730	174,614	97,556
Gross profit	58,839	46,113	159,699	151,950
Operating expenses				
Research and development	—	1,450	3,983	7,842
Selling, general and administrative	38,372	30,514	134,154	92,358
Total operating expenses	38,372	31,964	138,137	100,200
Income from operations	20,467	14,149	21,562	51,750
Interest expense	(19,046)	(5,115)	(42,638)	(16,257)
Interest income	11	3	20	9
Income (loss) before income taxes	1,432	9,037	(21,056)	35,502
Provision for (benefit from) income taxes	975	991	(3,253)	(61,049)
Net income (loss)	$ 457	$ 8,046	$ (17,803)	$ 96,551

Comparison of the three months ended September 30, 2022 and September 30, 2021

Product revenues, net

Product revenues, net were $127.0 million for the three months ended September 30, 2022 (the “2022 Quarter”), compared to $78.8 million for the three months ended September 30, 2021 (the “2021 Quarter”). The $48.2 million increase is primarily due to increases in revenue for products acquired from BDSI of $43.7 million, including $38.8 million for Belbuca, as well as an increase in revenue for Xtampza ER of $8.9 million, partially offset by a decrease in revenue for the Nucynta Products of $4.4 million.

The increase in revenue for products acquired from BDSI was due to the acquisition of these products in March 2022.

The increase in revenue for Xtampza ER of $8.9 million is primarily due to an increase in gross price and lower gross-to-net adjustments primarily related to provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in a $8.1 million increase in revenue, partially offset by decreased sales volume.

The decrease in revenue for the Nucynta Products of $4.4 million is primarily due to provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in a $3.4 million decrease in revenue, as well as decreased sales volume and higher gross-to-net adjustments related to rebates, partially offset by an increase in gross price.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $30.6 million for the 2022 Quarter, compared to $15.9 million for the 2021 Quarter. The $14.7 million increase was primarily related to an increase in cost of product revenues for products acquired from BDSI, including $10.5 million related to the recognition of the step-up basis in inventory for product sold during the 2022 Quarter. This increase was partially offset by lower cost of product revenues associated with our other products, which was primarily related to a decrease in sales volume for the Nucynta Products and Xtampza ER.

Intangible asset amortization was $37.6 million for the 2022 Quarter, compared to $16.8 million for the 2021 Quarter. The $20.8 million increase in intangible asset amortization was due to the BDSI Acquisition, in which $435.0 million of consideration was allocated to our acquired intangible assets, Belbuca, Symproic, and Elyxyb. These intangible assets are being amortized on a straight-line basis over the respective estimated useful lives.

Operating Expenses

Research and development expenses were zero for the 2022 Quarter, compared to $1.5 million for the 2021 Quarter. The $1.5 million decrease was due to the discontinuation of research and development activities as we focus on supporting our commercial products rather than research and development.

Selling, general and administrative expenses were $38.4 million for the 2022 Quarter, compared to $30.5 million for the 2021 Quarter. The $7.9 million increase was primarily related to:

- an increase in sales, marketing, and consulting expenses of $4.6 million, primarily due to expenses incurred to support the ongoing commercialization of Belbuca and Symproic, as well as the recent commercial launch of Elyxyb;
- an increase in salaries, wages, and benefits of $694,000 due to our continued focus on commercial products which resulted in redirection of personnel from research and development activities to commercial activities;
- an increase in legal expenses of $598,000 due to litigation related to Belbuca;
- an increase in regulatory fees of $491,000 primarily due to the acquisition of Belbuca, Symproic, and Elyxyb following the BDSI Acquisition; and
- an increase in acquisition related expenses classified as selling, general and administrative of $463,000 which primarily consisted of employee-related severance expenses and other miscellaneous acquisition expenses incurred, including expenses associated with terminating contracts and services acquired from BDSI.

As a result of the BDSI Acquisition, we expect to incur additional acquisition related expenses relating to consulting fees, contract termination costs, and other integration related expenses during the remainder of 2022.

Interest expense and Interest income

Interest expense was $19.0 million for the 2022 Quarter, compared to $5.1 million in the 2021 Quarter. The $13.9 million increase was primarily due to the 2022 Loan Agreement that we entered into in connection with the BDSI Acquisition.

Interest income was $11,000 for the 2022 Quarter, compared to $3,000 in the 2021 Quarter, which increased primarily due to higher interest rates on money market funds.

Taxes

Provision for income taxes was $975,000 for the 2022 Quarter, compared to $991,000 in the 2021 Quarter. The $16,000 decrease was primarily due to disallowed stock-based compensation expense in the 2021 Quarter. The provision for income taxes in the 2022 Quarter reflects the impact of nondeductible expenses. For the 2021 Quarter, the provision for income taxes reflects the impact of disallowed stock-based compensation expense. The effective tax rate was 68.1% and 11.0% for the 2022 Quarter and 2021 Quarter, respectively.

Comparison of the nine months ended September 30, 2022 and September 30, 2021

Product revenues, net

Product revenues, net were $334.3 million for the nine months ended September 30, 2022 (the "2022 Period"), compared to $249.5 million for the nine months ended September 30, 2021 (the "2021 Period"). The $84.8 million increase is due to increases in revenue for products acquired from BDSI of $94.1 million, including $84.4 million for Belbuca, as well as an increase in revenue for Xtampza ER of $5.1 million, partially offset by a decrease in revenue for the Nucynta Products of $14.4 million.

The increase in revenue for products acquired from BDSI was due to the acquisition of these products in March 2022.

The increase in revenue for Xtampza ER of $5.1 million is primarily due to an increase in gross price and lower gross-to-net adjustments primarily related to provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in an $8.1 million increase in revenue, partially offset by decreased sales volume.

The decrease in revenue for the Nucynta Products of $14.4 million is primarily due to higher gross-to-net adjustments related to rebates and provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in a $3.4 million decrease in revenue as well as decreased sales volume, partially offset by an increase in gross price.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $80.6 million for the 2022 Period, compared to $47.2 million for the 2021 Period. The $33.4 million increase was primarily related to an increase in cost of product revenues for products acquired from BDSI, including $23.8 million related to the recognition of the step-up basis in inventory for product sold during the 2022 Period, partially offset by lower cost of product revenues associated with our other products, which was primarily related to a decrease in sales volume for the Nucynta Products and Xtampza ER.

Intangible asset amortization was $94.0 million for the 2022 Period, compared to $50.4 million for the 2021 Period. The $43.6 million increase in intangible asset amortization was due to the BDSI Acquisition, in which $435.0 million of consideration was allocated to our acquired intangible assets, Belbuca, Symproic, and Elyxyb. These intangible assets are being amortized on a straight-line basis over the respective estimated useful lives.

Operating Expenses

Research and development expenses were $4.0 million for the 2022 Period, compared to $7.8 million for the 2021 Period. The $3.8 million decrease was primarily due to the discontinuation of research and development activities as we focus on supporting our commercial products rather than research and development.

Selling, general and administrative expenses were $134.2 million for the 2022 Period, compared to $92.4 million for the 2021 Period. The $41.8 million increase was primarily related to:

- an increase in acquisition related expenses classified as selling, general and administrative of $30.5 million which primarily consisted of financial advisory, banking, legal, and regulatory fees, other consulting fees, employee-related severance expenses, BDSI directors and officers insurance, and miscellaneous other acquisition expenses incurred;
- an increase in sales, marketing, and consulting expenses of $7.1 million, primarily due to expenses incurred to support the ongoing commercialization of Belbuca and Symproic, as well as the recent commercial launch of Elyxyb;
- an increase in regulatory fees of $2.0 million primarily due to fees incurred for Belbuca, Symproic, and Elyxyb following the BDSI Acquisition;
- 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 since the onset of the COVID-19 pandemic; and
- an increase in legal expenses of $1.3 million due to litigation related to Belbuca; partially offset by

- a decrease in salaries, wages, and benefits of $2.6 million, due to us entering into a plan to reduce our workforce, primarily our salesforce, in the fourth quarter of 2021, partially offset by increases in personnel costs for employees retained following the BDSI Acquisition.

As a result of the BDSI Acquisition, we expect to incur additional acquisition related expenses relating to consulting fees, contract termination costs, and other integration related expenses during the remainder of 2022.

Interest expense and Interest income

Interest expense was $42.6 million for the 2022 Period, compared to $16.3 million in the 2021 Period. The $26.3 million increase was primarily due to the 2022 Loan Agreement that we entered into in connection with the BDSI Acquisition.

Interest income was $20,000 for the 2022 Period, compared to $9,000 in the 2021 Period, which increased primarily due to higher interest rates on money market funds.

Taxes

Benefit from income taxes was $3.3 million for the 2022 Period, compared to $61.0 million in the 2021 Period. The $57.7 million decrease was primarily due to the 2021 Period including a discrete tax benefit related to the Company's valuation allowance release in the 2021 Period. The benefit from income taxes in the 2022 Period reflects the tax benefit from the net loss, which includes the impact of discrete nondeductible transaction costs and excess tax benefits. For the 2021 Period, the benefit from income taxes reflects the discrete tax benefit associated with the release of the Company's tax valuation allowance on the majority of its net operating losses and other deferred tax assets. The effective tax rate was 15.4% and (172.0)% for the 2022 Period and 2021 Period, respectively.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have incurred cumulative net losses and negative cash flows from operations since inception until 2020. Historically, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public offerings of common stock and convertible notes, and commercial bank debt. 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 the 2020 Term Notes 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 are required to pay $100.0 million in principal payments during the first year of the 2022 Term Loan and 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 September 30, 2022, the outstanding principal balance of the 2022 Term Loan and the convertibles notes was $600.0 million and $143.8 million, respectively. As of September 30, 2022, and December 31, 2021, we had $134.1 million and $186.4 million in cash and cash equivalents, respectively.

We believe that our cash and cash equivalents at September 30, 2022, 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 at least one year from the date the consolidated financial statements were issued.

2022 Modified Borrowing Arrangements

On March 22, 2022, in connection with the BDSI Acquisition closing, we entered into the 2022 Loan Agreement for the 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 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 our material domestic subsidiaries. The 2022 Term Loan will bear interest at a rate based upon LIBOR (subject to a LIBOR

floor of 1.20%), plus a margin of 7.5% per annum. As of September 30, 2022, the interest rate was 9.8%. We are required to repay the 2022 Term Loan by paying $100.0 million in principal payments during the first year and the remaining $550.0 million principal balance will amortize 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 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.

Cash Flows

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash provided by operating activities	$ 57,905	$ 67,359
Net cash used in investing activities	(572,751)	(1,429)
Net cash provided by (used in) financing activities	462,546	(46,805)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (52,300)	$ 19,125

Operating activities. Cash provided by operating activities was $57.9 million in the 2022 Period, compared to $67.4 million in 2021 Period. The $9.5 million decrease was primarily due to lower net income exclusive of non-cash items as a result of higher operating expenses, mainly acquisition related expenses in connection with the BDSI Acquisition, combined with changes in working capital. The changes in working capital were primarily driven by the change in accounts receivable, inventory, accrued expenses, and accrued rebates, returns, and discounts due to the timing of collections, shipments, and payments.

Investing activities. Cash used in investing activities was $572.8 million in the 2022 Period, compared to $1.4 million in the 2021 Period. The $571.4 million increase was primarily related to the BDSI Acquisition, net of cash acquired, which closed in the 2022 Period.

Financing activities. Cash provided by financing activities was $462.5 million for the 2022 Period, compared to cash used in financing activities of $46.8 million in the 2021 Period. The $509.3 million increase was primarily related to the repayment of the 2020 Term Notes and subsequent execution of the 2022 Term Loan as described in Note 11, *Term Notes Payable.*

Funding Requirements

We believe that our cash and cash equivalents as of September 30, 2022, 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 at least one year from the date the consolidated financial statements were issued. 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. 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 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, 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 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 expenses incurred; and
- 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.

Adjusted EBITDA for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP Net income (loss)	$ 457	$ 8,046	$ (17,803)	$ 96,551
Adjustments:				
Interest expense	19,046	5,115	42,638	16,257
Interest income	(11)	(3)	(20)	(9)
Provision for (benefit from) income taxes	975	991	(3,253)	(61,049)
Depreciation	488	448	1,859	1,312
Amortization	37,552	16,796	93,976	50,386
Stock-based compensation expense	5,377	5,948	17,204	19,343
Acquisition related expenses	463	—	31,209	—
Recognition of step-up basis in inventory	10,519	—	23,760	—
Total adjustments	$ 74,409	$ 29,295	$ 207,373	$ 26,240
Adjusted EBITDA	$ 74,866	$ 37,341	$ 189,570	$ 122,791

Adjusted EBITDA was $74.9 million for the 2022 Quarter compared to $37.3 million for the 2021 Quarter. The $37.6 million increase was primarily due to higher revenue and gross profit, partially offset by higher adjusted operating expenses, as discussed below.

Adjusted EBITDA was $189.6 million for the 2022 Period compared to $122.8 million for the 2021 Period. The $66.8 million increase was primarily due to higher revenue and gross profit, partially offset by higher adjusted operating expenses, as discussed below.

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 and nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP Operating expenses	$ 38,372	$ 31,964	$ 138,137	$ 100,200
Adjustments:				
Stock-based compensation	5,377	5,948	17,204	19,343
Acquisition related expenses	463	—	31,209	—
Total adjustments	$ 5,840	$ 5,948	$ 48,413	$ 19,343
Adjusted operating expenses	$ 32,532	$ 26,016	$ 89,724	$ 80,857

Adjusted operating expenses were $32.5 million in the 2022 Quarter compared to $26.0 million in the 2021 Quarter. The $6.5 million increase was primarily driven by higher selling, general and administrative expenses, excluding acquisition related expenses, as discussed in *Results of Operations*.

Adjusted operating expenses were $89.7 million in the 2022 Period compared to $80.9 million in the 2021 Period. The $8.8 million increase was primarily driven by higher selling, general and administrative expenses, excluding acquisition related expenses, as discussed in *Results of Operations*.

Adjusted Net Income and Adjusted Earnings Per Share

Adjusted net income is a non-GAAP financial measure that represents GAAP net income 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 and nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP Net income (loss)	$ 457	$ 8,046	$ (17,803)	$ 96,551
Adjustments:				
Non-cash interest expense	2,467	833	5,902	2,627
Amortization	37,552	16,796	93,976	50,386
Stock-based compensation expense	5,377	5,948	17,204	19,343
Acquisition related expenses	463	—	31,209	—
Recognition of step-up basis in inventory	10,519	—	23,760	—
Discrete deferred tax benefit from valuation allowance release	—	—	—	(62,649)
Income tax effect of above adjustments (1)	(14,290)	(5,899)	(43,698)	(1,627)
Total adjustments	$ 42,088	$ 17,678	$ 128,353	$ 8,080
Non-GAAP adjusted net income	$ 42,545	$ 25,724	$ 110,550	$ 104,631
Adjusted weighted-average shares — diluted (2)	39,495,453	41,186,308	39,368,629	41,274,190
Adjusted earnings per share	$ 1.10	$ 0.65	$ 2.88	$ 2.60

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate of 26% to the items that have a tax effect. As such, the non-GAAP effective tax rates for the three months ended September 30, 2022 and 2021 were 25.3% and 25.0%, respectively, and the non-GAAP effective tax rates for the nine months ended September 30, 2022 and 2021 were 25.4% and 16.8%, respectively.

(2) Adjusted weighted-average shares - diluted were calculated using the “if-converted” method for the Convertible Senior Notes in accordance with ASC 260, *Earnings per Share*. As such, for the three and nine months ended September 30, 2022 and 2021 adjusted earnings per share includes 4,925,134 shares related to the assumed conversion of the Convertible Senior Notes and the associated cash interest expense added-back to non-GAAP adjusted net income. In addition, for the nine months ended September 30, 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

With the exception of the 2022 Term Loan as discussed in Note 11, *Term Notes Payable*, there have been no material changes to the contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in our 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 fiscal year ended December 31, 2021, other than from the increased borrowings under our 2022 Term Loan.

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

As of September 30, 2022, our cash and cash equivalents included money market funds of $2.0 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 September 30, 2022 of $600.0 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately $6.0 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 September 30, 2022. 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 September 30, 2022, 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. As permitted by SEC guidance, which provides that a newly acquired company may be excluded from management’s evaluation of disclosure controls and procedures for up to a year from the date of acquisition, BDSI was excluded from the evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2022. BDSI, which we acquired in March 2022, represented approximately 7% of the Company’s total consolidated assets (excluding goodwill, intangibles, and the recognition of step-up basis in inventory) as of September 30, 2022, and 28% of our consolidated total revenue for the nine months ended September 30, 2022.

Changes in Internal Control Over Financial Reporting

We are currently in the process of evaluating and integrating the acquired operations, processes, and internal controls of BDSI and have begun incorporating those processes and procedures into our existing internal control environment. There have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that 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 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.
- 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 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, the Nucynta Products, and Belbuca are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products;
- We could fail to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations;
- Failure to comply with ongoing governmental regulations for marketing any product, 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 numbers 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;
- Our ability to realize the benefits of the acquisition of BDSI is substantially dependent on the timely and effective integration of the operations of Collegium and BDSI;
- Our business may continue to be adversely affected by the COVID-19 pandemic;
- 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 our products and any future product candidates, may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.
- 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, 2021, we had a federal net operating loss ("NOL") carryforward of approximately $119.3 million and state NOL carryovers of approximately $103.0 million, which are available to offset future taxable income. The U.S. federal and state NOL carryforwards expire at various dates through 2036. We also had U.S. federal tax credits of approximately $4.5 million, and state tax credits of approximately $1.0 million. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended. As part of the BDSI acquisition, we acquired an estimated $237 million of federal NOL carryovers, an estimated $164 million of state NOL carryovers, and U.S. federal tax credits of an estimated $10 million, all of which 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. The Company is still finalizing the tax analyses related to the BDSI Acquisition and anticipates finalizing the purchase price allocation and related tax analyses as the information necessary to complete the analysis is obtained. The finalization of these analyses will be complete no later than one year after the Acquisition Date. 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 February 2020, in connection with the Nucynta Acquisition, we incurred $143.8 million in principal amount of indebtedness in the form of 2.625% Convertible Senior Notes due in 2026 (the "Convertible Notes"). In addition, we have $650.0 million in secured indebtedness 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"). We may also incur additional indebtedness to meet future financing needs. Our existing and future levels of indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;
- exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under 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;
- increasing our vulnerability to downturns in our business, our industry or the economy in general, including any such downturn related to the impact of the COVID-19 pandemic.

Holders of our Convertible Notes will have the right to require us to repurchase our Convertible Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion of our Convertible Notes. Further, our noteholders, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. Applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion. Additionally, our 2022 Loan Agreement contains 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 indenture governing the Convertible Notes or in the 2022 Loan Agreement would constitute an event of default under these instruments, notwithstanding our ability to meet our debt service

obligations. Our failure to repurchase notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. In such event, we may not have sufficient funds to satisfy all amounts due under our other indebtedness (including the 2022 Loan Agreement) and the notes. 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. If we fail to comply with such covenants and terms, we may be in default and the maturity of the related debt could be accelerated and become immediately due and payable. In addition, because our assets are pledged as a security under the 2022 Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets are subject to the risk of foreclosure by our lenders. Moreover, a default on indebtedness under the 2022 Loan Agreement could result in a default under the terms of the indenture governing our Convertible Notes. There is no guarantee that we would be able to satisfy our obligations if any of our indebtedness is accelerated.

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.

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.

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products and in March 2022 we acquired and began marketing Belbuca, Symproic and Elyxyb. Our business and future success are substantially dependent on our ability to continue successfully commercializing these products.

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;
- 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 an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

The FDA can require changes to the product labeling for 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.

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

Xtampza ER has FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of Xtampza ER.

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

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

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

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

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could 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 and Aquestive Therapeutics, Inc., could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

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

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which

offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Our Products

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

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

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

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

Additionally, our sales, marketing and distribution capabilities may be hindered as a result of the COVID-19 outbreak. The safety and well-being of our employees is our highest priority and we expect to maintain mitigating measures until such time as mandated closures or other restrictions are lifted and public health officials change their recommendations, and we have, and will continue to, equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations, whether in person or from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to continue successfully commercializing our products. Notwithstanding the lifting of some COVID-19 restrictions in many jurisdictions, and amidst continuing public health concerns relating to the spread of COVID-19, particularly variants thereof, weekly pain patient office visits continue to be depressed compared to pre-COVID periods, which we believe in turn may account for fewer patients beginning therapy with our products. We believe that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease. If we are unable to successfully commercialize our products during the COVID-19 outbreak, our ability to generate sufficient product revenue may be adversely affected.

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

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

- approved indications, warnings and precautions language that may be less desirable than competitive products;
- perceptions 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, HHS, 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, Symproic and Elyxyb 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 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 recently imposed taxes or fees on the sale of opioids. Other states, and even the federal government, as proposed in the LifeBOAT Act introduced by a bipartisan group of Senators in May 2021, 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.

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 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 product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

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

Further changes to and under the Affordable Care Act remain possible. 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 opioid.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use, including the Comprehensive Addiction and Recovery Act and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. These laws are described in more detail in our Annual Report under the caption “Business- Governmental 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 an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In 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. For more information, refer to Note 15, *Commitments and Contingencies*, to our consolidated financial statements included in Part IV of this Quarterly Report on Form 10-Q. 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, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In the second half of 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

If the third-party manufacturers of 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 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 will need to absorb. We cannot guarantee that we will be able to leverage the dedicated manufacturing suite in a profitable manner. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.

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 cost, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and Nucynta ER, exposes us to the following risks, any of which could impact commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products including the ongoing COVID-19 pandemic, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.
- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or 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.
- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

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

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require our products to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. 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 disruptions in personnel or the global supply chain resulting from the COVID-19 outbreak), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

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. 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 period ended September 30, 2022. 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 ongoing COVID-19 outbreak, could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these 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, the Company formally denied a significant portion of unprocessed product claims under the Company's return policy. The Company subsequently received payment for only a portion of the denied claims and intends to vigorously pursue collections of the full amount of these short-pay receivables. Additional unprocessed return claims have and are expected to continue to expire prior to their physical return. Although the Company has and expects to continue to deny credit for product returns that are not in accordance with its return policy, uncertainty exists related to the ultimate resolution of these claims. We intend to pursue vigorously collections of the full amount of the receivable, but there can be no assurance that we will be able to do so or that similar disruptions in the wholesaler distribution network will not occur in the future.

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

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

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

Risks Related to Our Business and Strategy

Our ability to realize the benefits from the acquisition of BDSI is substantially dependent on the timely and effective integration of the operations of Collegium and BDSI.

Our ability to realize the benefits from the acquisition of BDSI, which closed on March 22, 2022, is substantially dependent on the cost savings resulting from the timely and effective integration of the operations Collegium and BDSI. The process of integrating the operations of Collegium and BDSI could encounter unexpected costs and delays, which include:

- failure to implement our business plans for the combined businesses and consolidation or expansion of production capacity as planned and where applicable;

- unexpected losses of key employees, customers or suppliers;
- unanticipated issues in conforming BDSI's standards, processes, procedures and internal controls with our operations;
- increasing the scope, geographic diversity and complexity of our operations;
- diversion of management's attention from other business concerns;
- adverse effects on our or BDSI's existing business relationships;
- unanticipated expenses and liabilities; and
- unanticipated issues in integrating sales, marketing and administrative functions.

If BDSI has unanticipated or larger than anticipated liabilities for patent and trademark infringement claims, violations of laws, commercial disputes, taxes and other known and unknown types of liabilities, there may be liabilities that we underestimated or did not discover in the course of performing our due diligence investigation of our acquired companies and businesses. In addition, we may not be able to maintain or increase the levels of revenue, earnings or operating efficiency that BDSI and we had historically achieved or might achieve separately.

If we are unable to timely and effectively integrate the operations of Collegium and BDSI, the anticipated cost savings, growth opportunities and other synergies of the BDSI Acquisition may not be realized fully or at all, or may take longer to realize than expected, which would adversely affect our costs. Further, even if the integration is timely and effective, we may never realize the cost savings expected from the integration of the operations of our two companies.

Our business may continue to be adversely affected by the COVID-19 pandemic. In addition, our business and liquidity may in the future be adversely affected by other economic circumstances outside of our control.
The COVID-19 pandemic has, and will likely continue to have, a substantial impact on the delivery of healthcare services in the United States. Healthcare providers have reduced staffing and limited access for non-patients, including our sales professionals. Notwithstanding the lifting of COVID-19 restrictions in many jurisdictions, and amidst continuing public health concerns relating to the spread of COVID-19, weekly pain patient office visits continue to be depressed compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products. We believe that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

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

In addition, other economic circumstances outside of our control 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 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 alleged 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 all 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 will be dismissed, with prejudice.

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

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

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

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill Medicare, Medicaid or other third-party

payors directly, we may provide reimbursement guidance and support regarding our products to our customers and patients. Federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

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

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

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

Risks Related to Our Common Stock

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

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these Risk Factors, some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations. 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 warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock. As of September 30, 2022, there were outstanding options to purchase an aggregate of 2,156,501 shares of our common stock at a weighted average exercise price of $18.23 per share, of which options to purchase 1,969,414 shares of our common stock were then exercisable. In addition, as of September 30, 2022, we had an outstanding warrant to purchase 1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

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 the Repurchase Program, and as of September 30, 2022, the remaining value of shares that may be repurchased pursuant to the Repurchase Program was $45.7 million. Any additional share repurchases 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 September 30, 2022:

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
July 1, 2022 through July 31, 2022	2,392		$ 17.88	—		$ 52,139
August 1, 2022 through August 31, 2022	2,830		18.88	—		52,139
September 1, 2022 through September 30, 2022	366,768		17.54	366,213		45,717
Total	371,990	[2]	$ 17.55	366,213	[2]	$ 45,717

(1) The Repurchase Program was announced on August 16, 2021. The 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, 2022. The Repurchase Program did not expire during the three months ended September 30, 2022, nor does the Company currently plan to terminate the 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.

In October 2022, the Company repurchased an additional $3.6 million or 205,600 shares at a weighted-average price of $17.48 per share for a cumulative total of $57.9 million under the Repurchase Program. As of October 31, 2022, the $42.1 million remained available for share repurchases under the Repurchase Program.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
31.1	Certification of Chief Executive Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

COLLEGIUM PHARMACEUTICAL, INC.

Date: November 3, 2022

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

Date: November 3, 2022

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: November 3, 2022

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: November 3, 2022

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 September 30, 2022 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: November 3, 2022

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 September 30, 2022 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: November 3, 2022