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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

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 July 31, 2024, there were 32,213,751 shares of Common Stock, $0.001 par value per share, outstanding.

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Forward-Looking Statements

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

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

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

- our ability to commercialize and grow sales of our products;
- our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts with favorable terms for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the announcement and pendency of our acquisition of Ironshore Therapeutics Inc. ("Ironshore");
- our ability to complete our announced acquisition of Ironshore, successfully integrate Ironshore's operations into our organization following closing, and realize the anticipated benefits associated with the acquisition;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredients for each of our products, manufacture adequate quantities of commercially salable inventory and maintain our supply chain;
- our ability to effectively manage our relationships with licensors and to commercialize products that we in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our business development;
- our ability to 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;
- 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 172,894	$ 238,947
Marketable securities	98,737	71,601
Accounts receivable, net	183,855	179,525
Inventory	27,862	32,332
Prepaid expenses and other current assets	26,850	15,195
Total current assets	510,198	537,600
Property and equipment, net	14,976	15,983
Operating lease assets	5,592	6,029
Intangible assets, net	352,676	421,708
Restricted cash	1,047	1,047
Deferred tax assets	34,184	26,259
Other noncurrent assets	858	825
Goodwill	133,857	133,857
Total assets	$ 1,053,388	$ 1,143,308
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 2,412	$ 8,692
Accrued liabilities	38,726	37,571
Accrued rebates, returns and discounts	236,208	227,331
Current portion of term notes payable	183,333	183,333
Current portion of operating lease liabilities	1,038	988
Total current liabilities	461,717	457,915
Term notes payable, net of current portion	132,845	221,713
Convertible senior notes	236,650	262,125
Operating lease liabilities, net of current portion	5,593	6,124
Total liabilities	836,805	947,877
Commitments and contingencies (refer to Note 14)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000; 39,532,358 issued and 32,319,577 outstanding shares as of June 30, 2024 and 38,192,441 issued and 31,868,549 outstanding shares as of December 31, 2023	40	38
Additional paid-in capital	567,976	565,949
Treasury stock, at cost; 7,212,781 shares as of June 30, 2024 and 6,323,892 shares as of December 31, 2023	(165,381)	(137,381)
Accumulated other comprehensive (loss) income	(182)	14
Accumulated deficit	(185,870)	(233,189)
Total shareholders’ equity	216,583	195,431
Total liabilities and shareholders’ equity	$ 1,053,388	$ 1,143,308

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Product revenues, net	$ 145,276	$ 135,546	$ 290,199	$ 280,313
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	19,955	24,257	38,905	54,156
Intangible asset amortization	34,515	37,463	69,032	74,929
Total cost of product revenues	54,470	61,720	107,937	129,085
Gross profit	90,806	73,826	182,262	151,228
Operating expenses				
Selling, general and administrative	43,335	38,193	85,317	90,968
Total operating expenses	43,335	38,193	85,317	90,968
Income from operations	47,471	35,633	96,945	60,260
Interest expense	(15,587)	(21,863)	(32,926)	(43,290)
Interest income	4,397	4,027	8,884	6,774
Loss on extinguishment of debt	(7,184)	—	(7,184)	(23,504)
Income before income taxes	29,097	17,797	65,719	240
Provision for income taxes	9,491	4,790	18,400	4,659
Net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)
Earnings (loss) per share — basic	$ 0.60	$ 0.38	$ 1.46	$ (0.13)
Weighted-average shares — basic	32,433,025	34,622,284	32,379,807	34,471,624
Earnings (loss) per share — diluted	$ 0.52	$ 0.34	$ 1.24	$ (0.13)
Weighted-average shares — diluted	40,383,694	42,849,952	40,510,943	34,471,624

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)
Other comprehensive loss:				
Unrealized losses on marketable securities, net of tax	(58)	(38)	(196)	(38)
Total other comprehensive loss	(58)	(38)	(196)	(38)
Comprehensive income (loss)	$ 19,548	$ 12,969	$ 47,123	$ (4,457)

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Operating activities		
Net income (loss)	$ 47,319	$ (4,419)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Amortization expense	69,032	74,929
Depreciation expense	1,869	1,712
Deferred income taxes	(7,925)	(682)
Stock-based compensation expense	17,487	13,107
Non-cash lease benefit	(44)	(213)
Non-cash interest expense for amortization of debt discount and issuance costs	3,384	4,548
Loss on extinguishment of debt	7,184	23,504
Net amortization of premiums and discounts on investments	(1,138)	(98)
Changes in operating assets and liabilities:		
Accounts receivable	(4,330)	15,640
Inventory	4,470	20,475
Prepaid expenses and other assets	(11,688)	(1,749)
Accounts payable	(6,144)	(1,075)
Accrued liabilities	982	(884)
Accrued rebates, returns and discounts	8,877	(17,402)
Net cash provided by operating activities	129,335	127,393
Investing activities		
Purchases of property and equipment	(838)	(232)
Purchases of marketable securities	(73,403)	(41,661)
Maturities of marketable securities	47,207	—
Net cash used in investing activities	(27,034)	(41,893)
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plan	356	169
Proceeds from the exercise of stock options	9,924	5,099
Payments made for employee stock tax withholdings	(18,749)	(7,956)
Repurchases of common stock, including the ASR agreement	(35,000)	—
Repayment of term notes	(91,667)	(70,833)
Proceeds from issuances of 2029 Convertible Notes, net of issuance costs of $6,280	—	235,220
Repurchase of 2026 Convertible Notes, including premium	—	(138,638)
Redemption of 2026 Convertible Notes, including premium and redemption costs	(33,218)	—
Net cash (used in) provided by financing activities	(168,354)	23,061
Net (decrease) increase in cash, cash equivalents and restricted cash	(66,053)	108,561
Cash, cash equivalents and restricted cash at beginning of period	239,994	176,235
Cash, cash equivalents and restricted cash at end of period	$ 173,941	$ 284,796
Reconciliation of cash, cash equivalents and restricted cash to the Condensed Consolidated Balance Sheets:		
Cash and cash equivalents	$ 172,894	$ 283,749
Restricted cash	1,047	1,047
Total cash, cash equivalents and restricted cash	$ 173,941	$ 284,796
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 29,542	$ 37,187
Cash paid for income taxes	$ 35,881	$ 10,011
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment in accounts payable and accrued liabilities	$ 200	$ —
Miscellaneous costs of redemption of 2026 Convertible Notes	$ 27	$ —

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 Belbuca, Xtampza ER, Nucynta IR and Nucynta ER (collectively the "Nucynta Products"), and Symproic.

The Company's operations are subject to certain risks and uncertainties. The principal risks include the Company's ability 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.

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 June 30, 2024, the results of operations for the three and six months ended June 30, 2024 and 2023, and cash flows for the six months ended June 30, 2024 and 2023. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results to be expected for the full year.

The preparation of the Condensed Consolidated Financial Statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Estimates in the Company's consolidated financial statements include revenue recognition, including the estimates of product returns, discounts and allowances related to commercial sales of products, estimates related to the fair value of assets acquired and liabilities assumed, including acquired intangible assets and the fair value of inventory acquired, estimates utilized in the ongoing valuation of inventory related to potential unsaleable product, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, impairment of intangible assets and deferred 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, 2023 (the "Annual Report").

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

Recently Adopted Accounting Pronouncements

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

The Company has not been required to adopt any accounting standards that had a significant impact on its Condensed Consolidated Financial Statements during the six months ended June 30, 2024.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07*, Segment Reporting (Topic 280).* The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023 for the Company's annual report, and interim periods within fiscal years beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740).* The amendments in this update expand income tax disclosure requirements, including additional information pertaining to the rate reconciliation, income taxes paid, and other disclosures. This update is effective for annual periods beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

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 or other outlets for the treatment of patients.

Revenue Recognition

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

The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

Performance Obligations

The Company determined that performance obligations are satisfied, and revenue is recognized, when a customer takes control of the Company's product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable. Payment is typically received 30 to 90 days after satisfaction of the Company's performance obligations.

Transaction Price and Variable Consideration

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The transaction price for product sales includes variable consideration related to sales deductions, including: (i) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (ii) product returns, including return estimates; and, (iii) trade allowances and chargebacks, including fees for distribution services, 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.

Rebates and Incentives

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.

Product Returns

Provisions for product returns, including returns for Belbuca, Xtampza, the Nucynta Products, and Symproic, are based on product-level returns rates, including processed as well as unprocessed return claims, in addition to relevant market events and other factors. Estimates of future product returns are made at the time of revenue recognition to determine the amount of consideration to which the Company expects to be entitled (that is, excluding the products expected to be returned). At the end of each reporting period, the Company analyzes trends in returns rates and updates its assessment of variable consideration. To the extent the Company receives amounts in excess of what it expects to be entitled to receive due to a product return, the Company does not recognize revenue when it transfers products to customers but instead recognizes those excess amounts received as a refund liability. The Company updates the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds with the corresponding adjustments recognized as revenue (or reductions of revenue).

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

Trade Allowances and Chargebacks

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.

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). 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.

Significant Judgments

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 occur 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.

Provision and Allowance Activity

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the six months ended June 30, 2024 and 2023:

	Rebates and Incentives [1]	Product Returns [2]	Trade Allowances and Chargebacks [3]
Balance as of December 31, 2023	$ 149,826	$ 77,505	$ 20,917
Provision related to current period sales	197,088	19,937	79,615
Changes in estimate related to prior period sales	325	2,406	(79)
Credits/payments made	(192,073)	(18,806)	(78,578)
Balance as of June 30, 2024	$ 155,166	$ 81,042	$ 21,875

	Rebates and Incentives [1]	Product Returns [2]	Trade Allowances and Chargebacks [3]
Balance as of December 31, 2022	$ 156,937	$ 73,554	$ 22,058
Provision related to current period sales	211,709	20,958	73,382
Changes in estimate related to prior period sales	(1,623)	1,230	593
Credits/payments made	(227,167)	(22,509)	(73,076)
Balance as of June 30, 2023	$ 139,856	$ 73,233	$ 22,957

(1) Provisions for rebates and incentives include 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 Condensed 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 Condensed Consolidated Balance Sheets.

(3) Provisions for trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Condensed Consolidated Balance Sheets.

As of June 30, 2024, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Belbuca	$ 52,198	$ 43,136	$ 102,861	$ 87,348
Xtampza ER	44,571	41,245	90,384	89,114
Nucynta IR	25,203	28,158	51,163	56,057
Nucynta ER	19,272	19,171	38,458	40,307
Symproic	4,032	3,836	7,333	7,487
Total product revenues, net	$ 145,276	$ 135,546	$ 290,199	$ 280,313

4. Earnings Per Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)
Adjustment for interest expense recognized on convertible senior notes	1,477	1,677	2,942	—
Net income (loss) - diluted	$ 21,083	$ 14,684	$ 50,261	$ (4,419)
Denominator:				
Weighted-average shares outstanding — basic	32,433,025	34,622,284	32,379,807	34,471,624
Effect of dilutive securities:				
Stock options	393,128	236,426	430,273	—
Restricted stock units	949,383	481,478	1,093,741	—
Performance share units	—	—	—	—
Employee stock purchase plan	1,853	660	817	—
Convertible senior notes	6,606,305	7,509,104	6,606,305	—
Weighted average shares outstanding — diluted	40,383,694	42,849,952	40,510,943	34,471,624
Earnings (loss) per share — basic	$ 0.60	$ 0.38	$ 1.46	$ (0.13)
Earnings (loss) per share — diluted	$ 0.52	$ 0.34	$ 1.24	$ (0.13)

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2029 in cash, shares or a combination of the two. On April 11, 2024, the Company provided notice of redemption for the remaining $26,350 aggregate principal amount of its 2.625% convertible senior notes due in 2026 (the "2026 Convertible Notes"). The 2026 Convertible Notes were fully redeemed on June 18, 2024. The Company settled the redemption of the 2026 Convertible Notes in cash. The 2026 Convertible Notes represented 902,799 shares which were excluded from the calculation of diluted earnings per share for the three and six months ended June 30, 2024 as their inclusion would have had an antidilutive effect. 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Stock options	—	751,930	—	1,368,968
Restricted stock units	5,150	1,073,613	6,200	2,522,025
Performance share units	223,680	503,880	223,680	503,880
Convertible senior notes	—	—	—	7,509,104

For PSUs, these securities were excluded from the calculation of diluted earnings per share as the 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.

5. Fair Value of Financial Instruments

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. An active market is defined as a market where transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
Level 2 inputs:	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
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.

The Company invests in instruments within defined credit parameters to minimize credit risk while ensuring liquidity.

There were no transfers between Levels 1, 2, and 3 during the six months ended June 30, 2024 and 2023.

The following table presents the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument as of June 30, 2024 and December 31, 2023:

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
June 30, 2024				
Cash equivalents:				
Money market funds	$ 21,208	$ 21,208	$ —	$ —
Commercial paper	997	—	997	—
Marketable securities:				
Corporate debt securities	62,428	—	62,428	—
U.S. Treasury securities	22,935	—	22,935	—
Government-sponsored securities	7,491	—	7,491	—
Commercial paper	5,883	—	5,883	—
Total assets measured at fair value	$ 120,942	$ 21,208	$ 99,734	$ —
December 31, 2023				
Cash equivalents:				
Money market funds	$ 77,299	$ 77,299	$ —	$ —
U.S. Treasury securities	4,729	—	4,729	—
Marketable securities:				
Corporate debt securities	41,612	—	41,612	—
U.S. Treasury securities	25,468	—	25,468	—
Government-sponsored securities	4,521	—	4,521	—
Total assets measured at fair value	$ 153,629	$ 77,299	$ 76,330	$ —

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

Assets and Liabilities Not Carried at Fair Value

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 June 30, 2024, the fair value of the Company's 2.875% convertible senior notes due in 2029 was $269,652 and the net carrying value was $236,650.

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 June 30, 2024, the carrying amount of the term notes reasonably approximated the estimated fair value.

As of June 30, 2024, and December 31, 2023, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, accounts payable, accrued liabilities, and accrued rebates, returns and discounts reasonably approximated their estimated fair values.

6. Marketable Securities

Available-for-sale debt securities were classified on the Condensed Consolidated Balance Sheets at fair value as follows:

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 997	$ 4,729
Marketable securities	98,737	71,601
Total	$ 99,734	$ 76,330

The following table summarizes the available-for-sale securities held as of June 30, 2024 and December 31, 2023:

June 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$ 62,603	$ 6	$ (181)	$ 62,428
U.S. Treasury securities	22,938	—	(3)	22,935
Government-sponsored securities	7,492	3	(4)	7,491
Commercial paper	6,883	—	(3)	6,880
Total	$ 99,916	$ 9	$ (191)	$ 99,734
December 31, 2023				
Corporate debt securities	$ 41,610	$ 47	$ (45)	$ 41,612
U.S. Treasury securities	30,189	8	—	30,197
Government-sponsored securities	4,517	4	—	4,521
Total	$ 76,316	$ 59	$ (45)	$ 76,330

The following table summarizes the contractual maturities of available-for-sale securities other than investments in money market funds as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Matures within one year	$ 62,076	$ 61,672
Matures after one year through five years	37,658	14,658
Total	$ 99,734	$ 76,330

The unrealized losses on the Company's available-for-sale securities were immaterial as of June 30, 2024 and December 31, 2023. In addition, there were no sales of marketable securities during the three and six months ended June 30, 2024. Net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive loss were not material to the Company's Condensed Consolidated Statements of Operations.

The Company did not record any allowances for credit losses to adjust the fair value of available-for-sale debt securities during the three and six months ended June 30, 2024. The Company reviews its investments for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and considers whether evidence indicating the cost of the investment is recoverable outweighs evidence to the contrary. The Company generally does not intend to sell any investments prior to recovery of their amortized cost basis for any investment in an unrealized loss position. As such, the Company did not hold any securities with other-than-temporary impairment as of June 30, 2024 and December 31, 2023.

7. Inventory

Inventory as of June 30, 2024 and December 31, 2023 consisted of the following:

	June 30, 2024	December 31, 2023
Raw materials	$ 7,152	$ 10,384
Work in process	5,926	6,740
Finished goods	14,784	15,208
Total inventory	$ 27,862	$ 32,332

The aggregate charges related to excess and obsolete inventory for the three and six months ended June 30, 2024 were $60 and $433, respectively. The aggregate charges related to excess and obsolete inventory for the three and six months ended June 30, 2023 were $155 and $1,061, respectively. These expenses were recorded as a component of cost of product revenues.

8. Goodwill and Intangible Assets

As of June 30, 2024 and December 31, 2023, the Company's goodwill balance was $133,857. The Company's goodwill resulted from the acquisition of BioDelivery Sciences International, Inc. ("BDSI") on March 22, 2022 (the "BDSI Acquisition").

The following table sets forth the cost, accumulated amortization, and carrying amount of intangible assets as of June 30, 2024 and December 31, 2023:

	June 30, 2024			December 31, 2023		
	Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Belbuca	$ 360,000	$ (171,517)	$ 188,483	$ 360,000	$ (133,821)	$ 226,179
Nucynta Products	521,170	(410,400)	110,770	521,170	(382,710)	138,460
Symproic	70,000	(16,577)	53,423	70,000	(12,931)	57,069
Total intangible assets	$ 951,170	$ (598,494)	$ 352,676	$ 951,170	$ (529,462)	$ 421,708

The following table presents amortization expense recognized in cost of product revenues for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Belbuca	$ 18,848	$ 18,846	$ 37,696	$ 37,695
Nucynta Products	13,845	16,795	27,690	33,591
Symproic	1,822	1,822	3,646	3,643
Total amortization expense	$ 34,515	$ 37,463	$ 69,032	$ 74,929

As of June 30, 2024, the remaining amortization expense expected to be recognized is as follows:

Years ended December 31,	Belbuca	Nucynta Products	Symproic	Total
2024	$ 37,697	$ 27,694	$ 3,639	$ 69,030
2025	75,393	55,384	7,285	138,062
2026	75,393	27,692	7,285	110,370
2027	—	—	7,285	7,285
2028	—	—	7,285	7,285
Thereafter	—	—	20,644	20,644
Remaining amortization expense	$ 188,483	$ 110,770	$ 53,423	$ 352,676

9. Accrued Liabilities

Accrued liabilities as of June 30, 2024 and December 31, 2023 consisted of the following:

	June 30, 2024	December 31, 2023
Accrued royalties	$ 13,452	$ 14,198
Accrued product taxes and fees	5,985	5,013
Accrued payroll and related benefits	4,259	1,511
Accrued interest	2,594	2,853
Accrued bonuses	2,478	4,987
Accrued sales and marketing	2,185	1,198
Accrued inventory	1,815	—
Accrued audit and legal	1,457	700
Accrued incentive compensation	1,412	1,375
Accrued income taxes	532	2,136
Accrued other operating costs	2,557	3,600
Total accrued liabilities	$ 38,726	$ 37,571

10. Term Notes Payable

2022 Term Loan

On March 22, 2022, in connection with the closing of the BDSI Acquisition, the Company entered into an Amended and Restated Loan Agreement by and among the Company, and BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"), as amended (the "2022 Loan Agreement"). The 2022 Loan Agreement provided for a $650,000 secured term loan (the "2022 Term Loan"), the proceeds of which were used to repay the Company's existing term notes and fund a portion of the consideration to be paid to complete the BDSI Acquisition. The 2022 Loan Agreement was accounted for as a debt modification and transaction fees of $173 were expensed. In connection with the 2022 Loan Agreement, the Company paid loan commitment and other fees to the lender of $19,818, which together with preexisting debt issuance costs and note discounts of $2,049 were amortized over the term of the loan using the effective interest rate. On July 28, 2024, in connection with the acquisition of Ironshore Therapeutics Inc. ("Ironshore"), the Company amended and restated the 2022 Term Loan. Refer to Note 16, *Subsequent Events*, for more information.

The 2022 Term Loan would have matured on the 48-month anniversary of the closing of the BDSI Acquisition and was guaranteed by the Company's material domestic subsidiaries. The 2022 Term Loan was also secured by substantially all of the assets of the Company and its material domestic subsidiaries. Prior to the cessation of the London Interbank Offered Rate ("LIBOR") on June 30, 2023, the 2022 Term Loan bore interest at a rate based on LIBOR (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. On June 23, 2023, the Company entered into an amendment to the 2022 Loan Agreement to adjust the interest terms of the 2022 Term Loan to transition from LIBOR to Secured Overnight Financing Rate ("SOFR") in anticipation of the cessation of LIBOR. Effective July 1, 2023, the 2022 Term Loan bore interest at a rate based on SOFR plus a spread adjustment of 0.26% (subject to a floor of 1.20%), plus a margin of 7.5% per annum. As of June 30, 2024, the contractual interest rate was 13.1%. The Company paid $100,000 in principal payments under the 2022 Term Loan during the first year and the remaining $550,000 balance was required to be paid in equal quarterly installments over the remaining three years.

The 2022 Loan Agreement permitted voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium was 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 included 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 triggered a mandatory prepayment of the 2022 Term Loan.

The 2022 Loan Agreement contained certain covenants and obligations of the parties, including, without limitation, covenants that limited 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 have constituted 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 included 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.

The following table presents the total interest expense recognized related to the 2022 Term Loan during the three and six months ended June 30, 2024 and 2023.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Contractual interest expense	$ 12,104	$ 17,688	$ 25,755	$ 35,343
Amortization of debt issuance costs	1,318	1,963	2,798	3,987
Total interest expense	$ 13,422	$ 19,651	$ 28,553	$ 39,330

As of June 30, 2024, the effective interest rate on the 2022 Term Loan was 14.6%.

As of June 30, 2024, principal repayments under the 2022 Term Loan were as follows:

Years ended December 31,	Principal Payments
2024	$ 91,666
2025	183,333
2026	45,834
Total before unamortized discount and issuance costs	$ 320,833
Less: unamortized discount and issuance costs	(4,655)
Term notes carrying value	$ 316,178

11. Convertible Senior Notes

2026 Convertible Notes

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

The 2026 Convertible Notes were senior, unsecured obligations and bore 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 had the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders had the right to convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. On or after February 15, 2023, the Company had the right to redeem the 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, upon the occurrence of certain events. The Company had the option to settle conversions by paying or delivering, as applicable, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The 2026 Convertible Notes would have matured on February 15, 2026, unless earlier repurchased, redeemed or converted. The initial conversion rate was 34.2618 shares of common stock per $1 principal amount of the 2026 Convertible Notes, which represented an initial conversion price of approximately $29.19 per share of common stock.

Repurchase of a Portion of the 2026 Convertible Notes

Contemporaneously with the offering of the 2029 Convertible Notes (as defined below), the Company entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117,400 aggregate principal amount of the 2026 Convertible Notes for an aggregate of $140,100 of cash, which included accrued and unpaid interest on the 2026 Convertible Notes to be repurchased. This transaction involved a contemporaneous exchange of cash between the Company and holders of the 2026 Convertible Notes participating in the issuance of the 2029 Convertible Notes. Accordingly, the Company evaluated the transaction for modification or extinguishment accounting in accordance with Accounting Standards Codification ("ASC") Topic 470-50*, Debt – Modifications and Extinguishments* on a creditor-by-creditor basis depending on whether the exchange was determined to have substantially different terms. The repurchase of the 2026 Convertible Notes and issuance of the 2029 Convertible Notes were deemed to have substantially different terms based on the present value of the cash flows immediately prior to and after the exchange. Therefore, the repurchase of the 2026 Convertible Notes was accounted for as a debt extinguishment. The Company recorded a $23,504 loss on extinguishment of debt on the condensed consolidated statements of operations during the three months ended March 31, 2023, which includes the recognition of previously deferred financing costs of $2,264. The total remaining principal amount outstanding under the 2026 Convertible Notes following the repurchase was $26,350.

Redemption of Remaining 2026 Convertible Notes

On April 11, 2024, the Company provided notice of redemption for the remaining $26,350 aggregate principal amount of its outstanding 2026 Convertible Notes. The 2026 Convertible Notes were fully redeemed on June 18, 2024 (the "Redemption Date"). The Company settled all conversions of the 2026 Convertible Notes in cash.

In accordance with ASC 470-50, *Debt – Modifications and Extinguishments*, the Company accounted for the redemption of the 2026 Convertible Notes as a debt extinguishment. The Company paid $33,218 during the three months ended June 30, 2024 to settle the 2026 Convertible Notes, as well as accrued and unpaid interest of $229. The Company recorded a $7,184 loss on extinguishment of debt on the Condensed Consolidated Statements of Operations during the three months ended June 30, 2024, which includes recognition of previously deferred financing costs of $289 and miscellaneous costs of redemption of $27.

2029 Convertible Notes

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

The 2029 Convertible Notes are senior, unsecured obligations and bear interest at a rate of 2.875% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2023. The 2029 Convertible Notes will mature on February 15, 2029, unless earlier repurchased, redeemed or converted. Before November 15, 2028, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after November 15, 2028, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The initial conversion rate is 27.3553 shares of common stock per $1 principal amount of 2029 Convertible Notes, which represents an initial conversion price of approximately $36.56 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the 2029 Convertible Notes may convert all or any portion of their 2029 Convertible Notes, in multiples of $1 principal amount, at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2023, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
(2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the "trading price" per $1 principal amount of the 2029 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day;
(3) upon the occurrence of certain corporate events or distributions on the Company's common stock;
(4) if the Company calls any or all of the 2029 Convertible Notes for redemption, but only with respect to the 2029 Convertible Notes called for redemption; or
(5) at any time from, and including, November 15, 2028 until the close of business on the scheduled trading day immediately before the maturity date.

As of June 30, 2024, none of the above circumstances had occurred and as such, the 2029 Convertible Notes could not have been converted.

The Company may not redeem the 2029 Convertible Notes prior to February 17, 2026. On or after February 17, 2026 and on or before the 40th scheduled trading day before the maturity date, the Company may redeem the 2029 Convertible Notes, in whole or in part, at a cash redemption price equal to the principal amount of the 2029 Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on:

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

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

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

The 2029 Convertible Notes have customary default provisions, including: (i) a default in the payment when due (whether at maturity, upon redemption or repurchase upon fundamental change or otherwise) of the principal of, or the redemption price or fundamental change repurchase price for, any note; (ii) a default for 30 days in the payment when due of interest on any note; (iii) a default in the Company's obligation to convert a note in accordance with the indenture, if such default is not cured within 3 business days after its occurrence; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) a default in any of the Company's other obligations or agreements under the indenture that are not cured or waived within 60 days after notice to the Company; (vi) certain payment defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $30,000 or other defaults by the Company or certain subsidiaries with respect to such indebtedness that result in the acceleration of such indebtedness; (vii) default upon the occurrence of one or more final judgments being rendered against the Company or any of the Company's significant subsidiaries for the payment of at least $30,000; and (viii) upon the occurrence of certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

The 2029 Convertible Notes are classified on the Condensed Consolidated Balance Sheets as of June 30, 2024 as convertible senior notes.

As of June 30, 2024, the outstanding balance of the 2029 Convertible Notes consisted of the following:

	2029 Convertible Notes
Principal	$ 241,500
Less: unamortized issuance costs	(4,850)
Net carrying amount	$ 236,650

The Company determined the expected life of the 2029 Convertible Notes was equal to the six-year term. The effective interest rate on the 2029 Convertible Notes is 3.28%. As of June 30, 2024, the if-converted value of the 2029 Convertible Notes did not exceed the remaining principal amount.

As of June 30, 2024, the future minimum payments on the 2029 Convertible Notes were as follows:

Years ended December 31,	**2029 Convertible Notes**
2024	$ 3,471
2025	6,943
2026	6,943
2027	6,943
2028	6,943
Thereafter	244,972
Total minimum payments	$ 276,215
Less: interest	(34,715)
Less: unamortized issuance costs	(4,850)
Convertible Notes carrying value	$ 236,650

The following table presents the total interest expense recognized related to the 2026 Convertible Notes and 2029 Convertible Notes (together, the "Convertible Notes") during the three and six months ended June 30, 2024, and 2023:

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2024	**2023**	**2024**	**2023**
Contractual interest expense	$ 1,879	$ 1,909	$ 3,787	$ 3,388
Amortization of debt issuance costs	286	298	586	561
Total interest expense	$ 2,165	$ 2,207	$ 4,373	$ 3,949

12. Equity

The changes in shareholders' equity for the three and six months ended June 30, 2024 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock		Accumulated	Accumulated Other Comprehensive	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Income (Loss)	Equity
Balance, December 31, 2023	38,192,441	$ 38	$ 565,949	(6,323,892)	$ (137,381)	$ (233,189)	$ 14	$ 195,431
Exercise of common stock options	200,200	—	4,205	—	—	—	—	4,205
Issuance for employee stock purchase plan	18,538	—	356	—	—	—	—	356
Vesting of RSUs and PSUs	1,000,357	1	—	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(381,897)	—	(12,874)	—	—	—	—	(12,874)
Stock-based compensation	—	—	7,475	—	—	—	—	7,475
Other comprehensive loss, net of tax	—	—	—	—	—	—	(138)	(138)
Net income	—	—	—	—	—	27,713	—	27,713
Balance, March 31, 2024	39,029,639	$ 39	$ 565,111	(6,323,892)	$ (137,381)	$ (205,476)	$ (124)	$ 222,169
Exercise of common stock options	282,248	1	5,727	—	—	—	—	5,728
Vesting of RSUs and PSUs	392,140	1	—	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(171,669)	(1)	(5,874)	—	—	—	—	(5,875)
Share repurchases from ASR agreement	—	—	(7,000)	(888,889)	(28,000)	—	—	(35,000)
Stock-based compensation	—	—	10,012	—	—	—	—	10,012
Other comprehensive loss, net of tax	—	—	—	—	—	—	(58)	(58)
Net income	—	—	—	—	—	19,606	—	19,606
Balance, June 30, 2024	39,532,358	$ 40	$ 567,976	(7,212,781)	$ (165,381)	$ (185,870)	$ (182)	$ 216,583

The changes in shareholders' equity for the three and six months ended June 30, 2023 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock		Accumulated	Accumulated Other Comprehensive	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Income (Loss)	Equity
Balance, December 31, 2022	37,084,759	$ 37	$ 538,073	(3,235,823)	$ (61,924)	$ (281,344)	$ —	$ 194,842
Exercise of common stock options	234,132	—	3,848	—	—	—	—	3,848
Issuance for employee stock purchase plan	11,329	—	169	—	—	—	—	169
Vesting of RSUs and PSUs	775,904	1	—	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(289,281)	—	(7,736)	—	—	—	—	(7,736)
Stock-based compensation	—	—	6,035	—	—	—	—	6,035
Net loss	—	—	—	—	—	(17,426)	—	(17,426)
Balance, March 31, 2023	37,816,843	$ 38	$ 540,389	(3,235,823)	$ (61,924)	$ (298,770)	$ —	$ 179,733
Exercise of common stock options	72,405	—	1,251	—	—	—	—	1,251
Vesting of RSUs and PSUs	73,805	—	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(9,655)	—	(220)	—	—	—	—	(220)
Stock-based compensation	—	—	7,072	—	—	—	—	7,072
Other comprehensive loss, net of tax	—	—	—	—	—	—	(38)	(38)
Net income	—	—	—	—	—	13,007	—	13,007
Balance, June 30, 2023	37,953,398	$ 38	$ 548,492	(3,235,823)	$ (61,924)	$ (285,763)	$ (38)	$ 200,805

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 June 30, 2024, there were 2,508,506 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 and non-qualified options generally vest ratably over a four-year period of service and generally have a ten-year contractual life. Upon termination, vested stock options are generally exercisable for three months following the termination date, while unvested options are forfeited immediately upon termination. The Company's RSUs granted prior to 2024 generally vest ratably over a four-year period of service. Beginning in 2024, RSUs granted by the Company vest ratably over a three-year period of service. Upon termination, unvested RSUs are forfeited immediately. Refer to Note 13, *Stock-based Compensation*, for more information.

Share Repurchases

2023 Repurchase Program

In January 2023, the Company's Board of Directors authorized the repurchase of up to $100,000 of shares of its common stock at any time or times through December 31, 2023 (the "2023 Repurchase Program"). The 2023 Repurchase Program permitted the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act.

In July 2023, the Company's Board of Directors authorized an accelerated share repurchase ("ASR") program to repurchase $50,000 of the Company's common stock, as part of the 2023 Repurchase Program. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $50,000 on August 7, 2023, and received 1,702,852 shares, representing 80% of the upfront payment on a price per share of $23.49, the closing price on the date the agreement was executed. The remaining shares purchased by the Company were based on the volume-weighted average price of its common stock through October 31, 2023, minus an agreed upon discount between the parties. In October 2023, the ASR agreement settled and the Company received an additional 462,442 shares, bringing the total shares repurchased pursuant to the ASR agreement to 2,165,294.

In November 2023, the Company's Board of Directors authorized a second ASR program as part of the 2023 Repurchase Program to repurchase $25,000 of the Company's common stock. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $25,000 on November 9, 2023, and received 865,426 shares, representing 80% of the upfront payment on a price per share of $23.11, the closing price on the date the agreement was executed. The remaining shares purchased by the Company were based on the volume-weighted average price of its common stock through December 29, 2023, minus an agreed upon discount between the parties. In December 2023, the ASR agreement settled and the Company received an additional 57,349 shares, bringing the total shares repurchased pursuant to the ASR agreement to 922,775.

Each ASR agreement was accounted for as two distinct transactions: (1) an immediate repurchase of common stock, recorded as a treasury stock transaction; and (2) a forward contract indexed to the Company's own stock. The forward contracts, which represented the remaining shares to be delivered by the investment bank, were recorded as a reduction to stockholders' equity. Both forward contracts associated with these ASR agreements were settled and not outstanding as of December 31, 2023.

The 2023 Repurchase Program expired on December 31, 2023. Through December 31, 2023, the Company repurchased 3,088,069 shares at a weighted-average price of $24.29 per share for a total of $75,000 under the 2023 Repurchase Program. Repurchased shares were returned to the Company's pool of authorized but unissued shares. The cost of repurchased shares were recorded as treasury stock in the Consolidated Balance Sheet. Shares repurchased under the 2023 Repurchase Program resulted in an immediate reduction of shares outstanding used to calculate the weighted-average common shares outstanding for both basic and diluted earnings per share. As the Company was entitled to receive additional shares of its common stock in connection with the outstanding forward contracts, the receipt of additional shares of common stock was antidilutive. Therefore, no adjustments were made in the computation of earnings per share for the period the forwards were outstanding.

2024-2025 Repurchase Program

In January 2024, the Company's Board of Directors authorized the repurchase of up to $150,000 of the Company's common stock through June 30, 2025 (the "2024-2025 Repurchase Program"). The 2024-2025 Repurchase Program

permits the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. The timing and amount of any shares purchased on the open market will be determined based on the Company's evaluation of the market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund share repurchases.

In May 2024, the Company's Board of Directors authorized an ASR program to repurchase $35,000 of the Company's common stock, as part of the 2024-2025 Repurchase Program. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $35,000 on May 13, 2024, and received 888,889 shares, representing 80% of the upfront payment on a price per share of $31.50, the closing price on the date the agreement was executed. The remaining shares to be purchased by the Company was to be based on the volume-weighted average price of its common stock through July 31, 2024, minus an agreed upon discount between the parties. In July 2024, the ASR agreement settled and the Company received an additional 173,659 shares, bringing the total shares repurchased pursuant to the ASR agreement to 1,062,548.

The ASR agreement was accounted for as two distinct transactions: (1) an immediate repurchase of common stock, recorded as a treasury stock transaction; and (2) a forward contract indexed to the Company's own stock. The forward contract, which represented the remaining shares to be delivered by the investment bank, was recorded as a reduction to stockholders' equity as of June 30, 2024. The forward contract associated with the ASR agreement was outstanding as of June 30 2024.

As of June 30, 2024, the Company repurchased 888,889 shares at a weighted-average price of $31.50 per share for a total of $28,000 under the 2024-2025 Repurchase Program and the cost of repurchased shares was recorded as treasury stock in the Condensed Consolidated Balance Sheet. As of June 30, 2024, $115,000 remained available for share repurchases under the 2024-2025 Repurchase Program, which reflects the $7,000 forward contract that had not yet settled as of June 30, 2024.

13. Stock-based Compensation

Performance Share Units

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

A summary of the Company's PSU activity for the six months ended June 30, 2024 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2023	503,880	$ 33.13
Granted	203,000	45.06
Vested	(514,050)	32.53
Forfeited	(165,700)	43.12
Performance adjustment	196,550	32.58
Outstanding as of June 30, 2024	223,680	$ 37.45

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 six months ended June 30, 2024, and 2023 was $45.06 and $38.71, respectively.

Restricted Stock Units

The Company granted RSUs to employees during the six months ended June 30, 2024. RSUs granted prior to 2024 generally vest ratably over a four-year period of service. Beginning in 2024, RSUs granted by the Company vest ratably over a three-year period of service.

A summary of the Company's RSU activity for the six months ended June 30, 2024 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2023	2,443,907	$ 22.88
Granted	960,857	33.76
Vested	(878,447)	23.35
Forfeited	(270,847)	27.78
Outstanding as of June 30, 2024	2,255,470	$ 26.74

The weighted-average grant date fair value per share of RSUs granted for the six months ended June 30, 2024 and 2023 was $33.76 and $26.33, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the six months ended June 30, 2024, and 2023 was $29,704 and $16,480, respectively.

Stock Options

The Company's qualified incentive stock options and non-qualified options generally vest ratably over a four-year period and generally have a ten-year contractual life. Upon termination, vested stock options are generally exercisable for three months following the termination date, while unvested options are forfeited immediately upon termination.

A summary of the Company's stock option activity for the six months ended June 30, 2024 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	1,176,750	$ 19.48	4.3	$ 13,297
Exercised	(482,448)	20.57		
Cancelled	(1,000)	27.73		
Outstanding as of June 30, 2024	693,302	$ 18.71	3.9	$ 9,354
Exercisable as of June 30, 2024	692,975	$ 18.71	3.9	$ 9,350

There were no stock options granted during the six months ended June 30, 2024 and 2023.

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: (i) the first day of the purchase period; or (ii) the last day of the purchase period. During the six months ended June 30, 2024, 18,538 shares of common stock were purchased for total proceeds of $356. The expense for the three months ended June 30, 2024 and 2023 was $69 and $55, respectively. The expense for the six months ended June 30, 2024 and 2023 was $134 and $101, respectively.

Stock-based Compensation Expense

A summary of the allocation of the Company's stock-based compensation expense for the three and six months ended June 30, 2024 and 2023 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Selling, general and administrative	$ 10,012	$ 7,072	$ 17,487	$ 13,107
Total stock-based compensation expense	$ 10,012	$ 7,072	$ 17,487	$ 13,107

As of June 30, 2024, there was approximately $52,286 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.

14. Commitments and Contingencies

Legal Proceedings

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

Xtampza ER Litigation

On March 24, 2015, Purdue sued the Company in the U.S. District Court for the District of Delaware 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). The lawsuit was initiated in response to the Company filing the New Drug Application ("NDA") for Xtampza ER as a 505(b)(2) application referencing data from Purdue's OxyContin NDA, and under the Drug Price Competition and Patent Term Restoration Act of 1984, triggered a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

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 which lifted the 30-month stay of FDA approval. Following this judgment, the Company obtained final approval for Xtampza ER and launched 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 asserted infringement of Patent No. 9,073,933 in November 2015 and Patent No. 9,522,919 in April 2017. In addition, Purdue invoked two non-Orange Book-listed patents, 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 argued that the ′961 patent is invalid.

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 ruled that the Xtampza ER formulation does not infringe the ′497 and ′717 patents.

On September 15, 2019, Purdue commenced chapter 11 bankruptcy proceedings in the United States Bankruptcy Court for the Southern District of New York. Later in September 2019, Purdue gave the District Court of Massachusetts, as well as the PTAB, notice of its bankruptcy filing and sought the imposition of an automatic stay of proceedings. Both the Court and the PTAB granted Purdue's requests to stay the pending matters.

On September 1, 2020, the Bankruptcy Court entered an Order, lifting the automatic stays in both the District of Massachusetts and 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. On November 19, 2021, the PTAB: (i) denied Purdue's motion to terminate the PGR; and (ii) issued its Final Written Decision, finding that the asserted claims of the ′961 patent were invalid for lack of written description and anticipation. Purdue appealed the decision to Federal Circuit, which issued its decision on November 21, 2023, affirming the authority of the PTAB to issue its Final Written Decision and upholding the PTAB's finding of invalidity relative to the ’961 patent. Purdue has exhausted all possibility of appeal, and the judgment of invalidity of the ‘961 patent is final without further right of appeal.

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. The Company responded to Purdue's complaint with a motion to dismiss. On May 21, 2021, and in response to the Company's motion to dismiss, Purdue filed an amended complaint. 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 May 15, 2023, the Court issued an order that: (i) vacated the existing deadlines with respect to the ′933, ′919, and ′434 patents and stayed the case pending the Federal Circuit's decision in a different litigation that invalidated certain claims of the ′933 and ′919 patents; and (ii) continued the existing stay concerning the ′961 patent pending resolution of Purdue's appeal rights relating to the decision invalidating the claims of the ′961 patent. 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. 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 U.S. District Court for the District of Delaware, in which it 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. 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 Purdue's claims were barred by the doctrine of patent exhaustion. On June 19, 2019, the Court issued an order calling for discovery on a factual predicate for the patent exhaustion defense and noted that 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 notified the Court of its bankruptcy filing and sought an automatic stay of proceedings, which was granted. The Nucynta litigation currently remains subject to the bankruptcy stay.

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.

Opioid Litigation

As a result of the opioid epidemic, numerous state and local governments and other entities brought suit against manufacturers, distributors, and pharmacies alleging a variety of claims related to opioid marketing and distribution practices. In late 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered the consolidation of cases pending around the country in federal court against opioid manufacturers and distributors into a Multi-District Litigation ("MDL") in the Northern District of Ohio. The Company was initially named as a defendant in 21 of the MDL cases. By April 19, 2022, all MDL cases naming the Company were dismissed or withdrawn.

Outside of the MDL, several cases were filed against the Company in Arkansas, Pennsylvania, and Massachusetts state courts with allegations similar to those in the MDL related to opioid marketing and distribution practices, as well as allegations including violations of state consumer protections laws.

On March 21, 2019, the Arkansas state court litigation was dismissed. On December 24, 2021, the Company entered into a settlement framework with Scott+Scott Attorneys at Law, LLP, the law firm representing plaintiffs in 27 jurisdictions filed either in Pennsylvania and Massachusetts state courts, or filed in other state courts and removed to the MDL. Pursuant to the terms of the settlement, the Company paid $2,750 in exchange for dismissal, with prejudice, of each plaintiff's lawsuit and a release of claims related to such lawsuits. The Company is currently dismissed from all cases.

The Company settled to efficiently resolve these litigations and did not admit any liability or acknowledge any wrongdoing in connection with the settlement.

Opioid-Related Request and Subpoenas

The Company, like several other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing practices, from the Offices of the Attorney General of Washington, New Hampshire, Maryland, and Massachusetts.

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

Aquestive Litigation

On September 22, 2014, 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 in the District Court in the District of New Jersey alleging patent infringement against BDSI related to its Bunavail product. The RB Plaintiffs claimed that Bunavail, whose formulation and manufacturing processes have never been disclosed publicly, infringed U.S. Patent No. 8,765,167.

On January 13, 2017, Aquestive filed a complaint in the District Court for the District of New Jersey against BDSI alleging Belbuca also infringed the '167 Patent. On March 8, 2023, the parties filed a stipulation of dismissal after agreeing to settle the dispute. Under the terms of the settlement agreement, BDSI resolved both the Bunavail and Belbuca litigations in exchange for a one-time, lump-sum payment of $8,500 to Aquestive, which was recognized as an expense included in "*selling, general and administrative expenses*" in the consolidated statements of operations for the year ended December 31, 2023.

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 District Court for the Southern District of New York 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: the "*Sanford* Action" and the "*Higley* Action." In March 2022, two additional cases were filed by purported individual stockholders of BDSI in the District Court for the Eastern District of New York: the "*Justice* Action" and the *"Zomber* Action" (together with the *Stein*, *Sanford*, and *Higley* 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. 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. 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, between February and March of 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"). In March 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").

Plaintiffs in the *Higley, Zomber, and Justice* Actions each filed a notice of voluntary dismissal of their complaint in the second quarter of 2022. On July 28, 2022, plaintiff in the *Sanford* Action filed a partial voluntary dismissal of the individual named defendants, and on October 26, 2022, filed a notice of voluntary dismissal of the BDSI defendant. On February 17, 2023, the *Stein* Action was dismissed.

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.

Alvogen

On September 7, 2018, BDSI filed a complaint for patent infringement in 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 infringed BDSI's Orange Book-listed patents for Belbuca, including U.S. Patent Nos. 8,147,866, 9,655,843 and 9,901,539 (collectively, "the BEMA patents"). This complaint followed receipt by BDSI on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating it had filed an abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Belbuca Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg.

A three-day bench trial was held from March 1-3, 2021. On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's ′866 patent and certain claims in the ’539 patent. The Court entered final judgment on January 21, 2022 upholding the validity of claims of the ’866 and ’539 patents and thereby extended the effective date of any final approval by the FDA of Alvogen's ANDA until December 21, 2032, (the expiration date of the ’539 patent) and enjoining Alvogen from commercially launching its ANDA products until December 21, 2032. Alvogen filed a motion to stay certain provisions of the final judgment. BDSI filed an opposition to Alvogen's request for a stay. The Court retained jurisdiction to decide BDSI's motion for contempt, which was filed on September 21, 2021.

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

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

Chemo Research, S.L.

On March 1, 2019, BDSI filed a complaint for patent infringement in the 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 the BEMA patents. This complaint followed receipt by BDSI on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it had 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.

Chemo agreed to be bound by the decision of the Court with respect to the validity of the BEMA patents as disputed between BDSI and Alvogen. Accordingly, the December 20, 2021 ruling of the Court upholding the validity of certain claims of the BEMA patents is binding upon Chemo. In March 2022, the Court vacated the bench trial set to begin April 25, 2022 to address the remaining Chemo infringement claims. The Court has not yet set a new trial date.

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

On August 24, 2022, the Court instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. On February 8, 2023, the Court denied Chemo's request for a trial date in Spring 2023, and again instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. Chemo received a complete response letter with respect to its July 29, 2022 ANDA in April 2023. Chemo submitted a further amended ANDA to FDA in September 2023. On May 30, 2024, the parties submitted a Joint Status Report to the Court providing that Chemo received a fourth Complete Response Letter on March 27, 2024. BDSI requested that the Court stay the litigation, whereas Chemo asked the court to maintain the status quo because the Court had not yet set a trial date. The Court has taken no action in response to the parties' Joint Status Letter.

The Company plans to litigate 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.

15. 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 expense recognized for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Provision for income taxes	$ 9,491	$ 4,790	$ 18,400	$ 4,659
Effective tax rate	32.6 %	26.9 %	28.0 %	1,941.3 %

The provision for income taxes for the three and six months ended June 30, 2024 reflects the estimated annual effective tax rate as adjusted for the discrete nondeductible costs associated with the debt extinguishment that occurred during the three months ended June 30, 2024, partially offset by discrete excess tax benefits from stock-based compensation awards. The non-deductible costs from the debt extinguishment that occurred during the three and six months ended June 30, 2024 were $6,868. The provision for income taxes for the three months ended June 30, 2023 reflects the estimated annual effective tax rate. The provision for income taxes for the six months ended June 30, 2023 was impacted by discrete nondeductible costs associated with the debt extinguishment that occurred in the three months ended March 31, 2023, partially offset by discrete excess tax benefits related to stock-based compensation awards. The nondeductible costs from the debt extinguishment that occurred in the three months ended March 31, 2023 were $21,238.

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 June 30, 2024.

16. Subsequent Events

Ironshore Therapeutics, Inc. Acquisition

On July 28, 2024, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Carrera Merger Sub Inc., an exempted company with limited liability incorporated under the laws of the Cayman Islands and wholly owned subsidiary of the Company ("Merger Sub"), a Delaware corporation and wholly owned subsidiary of the Company ("Purchaser"), Ironshore and Shareholder Representative Services LLC, a Colorado limited liability company, acting solely in its capacity as the representative, agent and attorney-in-fact of the securityholders of the Ironshore. Pursuant to the Merger Agreement, Merger Sub will merge with and into Ironshore and Ironshore (i) will continue as the surviving company in the Merger (the "Surviving Company"), and (ii) become a wholly-owned subsidiary of the Company (the "Ironshore Acquisition").

Pursuant to the terms of the Merger Agreement, the aggregate initial merger consideration will be approximately $525,000 in cash, subject to customary adjustments. Following the closing of the Ironshore Acquisition, the Merger Agreement provides for one potential commercial milestone payment of $25,000 in cash to be made to Ironshore securityholders upon the achievement of such milestone. The all-cash upfront consideration will be funded by a combination of the Company's existing cash and the 2024 Term Loan (as defined below). The transaction is expected to close in the third quarter of 2024, subject to customary closing conditions.

Second Amended and Restated Loan Agreement

On July 28, 2024, the Company entered into a Second Amended and Restated Loan Agreement by and among the Company, certain of its subsidiaries party thereto as guarantors, BioPharma Credit PLC as collateral agent, and BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership (investment funds managed by Pharmakon Advisors, LP) as the lenders (the "Lenders") party thereto (the "2024 Loan Agreement"). The Loan Agreement provides for a $645,833 secured term loan (the "2024 Term Loan"), consisting of a $320,833 initial term loan and a $325,000 delayed draw term loan. On the effective date of the 2024 Loan Agreement, the Company used the proceeds of the initial term loan to refinance in full all outstanding indebtedness under the 2022 Term Loan. On the closing date of the Ironshore Acquisition, the Company will use the proceeds of the delayed draw term loan to fund a portion of the consideration to complete the Ironshore Acquisition, pay fees and expenses in connection with the Ironshore Acquisition and the 2024 Loan Agreement, and the remainder for general corporate purposes.

The 2024 Term Loan is scheduled to mature on July 28, 2029 (provided, however, that if the aggregate principal amount outstanding under the 2029 Convertibles Notes is more than $50,000 as of November 18, 2028, then the 2024 Term Loan will mature on November 18, 2028) and is guaranteed by certain of the Company's material subsidiaries. The 2024 Term Loan is secured by substantially all of the assets of the Company and its material subsidiaries. The 2024 Term Loan will bear an annual interest rate equal to: (i) until September 30, 2024, term SOFR plus a spread adjustment of 0.13% (subject to a 1.20% floor), plus a margin of 7.50% and, (ii) thereafter, term SOFR plus a spread adjustment of 0.13% (subject to a 4.00% floor), plus a margin of 4.50% per annum, and be subject to quarterly amortization payments equal to 2.50% of the original funded amount of the 2024 Term Loan. The Company paid a one-time fee of 1.25% of the initial term loan principal amount on July 29, 2024 and will pay a one-time fee of 2.25% of the delayed draw term loan principal amount due upon the borrowing of the delayed draw term loans at the closing of the acquisition of Ironshore.

The 2024 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 2024 Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The 2024 Loan Agreement also includes various customary remedies for secured lenders following an event of default, including the acceleration of the outstanding amounts under the 2024 Loan Agreement and enforcement upon the collateral securing obligations under the 2024 Loan Agreement.

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

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

Overview

We are building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. We commercialize our pain portfolio, consisting of Belbuca, Xtampza ER, Nucynta IR and Nucynta ER (collectively the "Nucynta Products"), and Symproic, in the United States.

Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative options are inadequate. We began shipping and recognizing product sales related to Belbuca in March 2022 following our acquisition of BDSI.

Xtampza ER, an abuse-deterrent, oral formulation of oxycodone, was approved by the United States Food and Drug Administration ("FDA") in April 2016 for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. We commercially launched Xtampza ER in June 2016.

The Nucynta Products are immediate-release ("IR") and extended-release ("ER") formulations of tapentadol. 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 and pediatric patients aged 6 years and older with a body weight of at least 40 kg. Nucynta ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. We began shipping and recognizing product sales on the Nucynta Products in January 2018 and began marketing the Nucynta Products in February 2018. In August 2023, the FDA granted New Patient Population exclusivity in pediatrics for Nucynta IR. This grant extended the period of U.S. exclusivity for Nucynta IR from June 27, 2025 to July 3, 2026. In June 2024, the FDA granted pediatric exclusivity to the Nucynta Products for an additional six months, to January 3, 2027 for Nucynta IR and December 27, 2025 for Nucynta ER.

Symproic was approved by the FDA in March 2017 for the treatment of opioid-induced constipation ("OIC") in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. We began shipping and recognizing product sales related to Symproic in March 2022 following our acquisition of BDSI.

Outlook

We believe that our cash and cash equivalents as of June 30, 2024, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

Results of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Product revenues, net	$ 145,276	$ 135,546	$ 290,199	$ 280,313
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	19,955	24,257	38,905	54,156
Intangible asset amortization	34,515	37,463	69,032	74,929
Total cost of product revenues	54,470	61,720	107,937	129,085
Gross profit	90,806	73,826	182,262	151,228
Operating expenses				
Selling, general and administrative	43,335	38,193	85,317	90,968
Total operating expenses	43,335	38,193	85,317	90,968
Income from operations	47,471	35,633	96,945	60,260
Interest expense	(15,587)	(21,863)	(32,926)	(43,290)
Interest income	4,397	4,027	8,884	6,774
Loss on extinguishment of debt	(7,184)	—	(7,184)	(23,504)
Income before income taxes	29,097	17,797	65,719	240
Provision for income taxes	9,491	4,790	18,400	4,659
Net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)

Comparison of the three months ended June 30, 2024 and June 30, 2023

Product revenues, net

Product revenues, net were $145.3 million for the three months ended June 30, 2024 (the "2024 Quarter"), compared to $135.5 million for the three months ended June 30, 2023 (the "2023 Quarter"). The $9.8 million increase is primarily due to increased revenue for Belbuca of $9.1 million, Xtampza of $3.3 million, and Symproic of $0.2 million, partially offset by decreased revenue for the Nucynta Products of $2.8 million.

The increase in revenue for Belbuca of $9.1 million is primarily due to higher sales volume and gross price, partially offset by higher gross-to-net adjustments related to provisions for returns and chargebacks.

The increase in revenue for Xtampza ER of $3.3 million is primarily due to lower gross-to-net adjustments related to provisions for rebates and higher gross price, partially offset by lower sales volume.

The increase in revenue for Symproic of $0.2 million is primarily due to lower gross-to-net adjustments related to provisions for rebates and higher gross price, partially offset by lower sales volume.

The decrease in revenue for the Nucynta Products of $2.8 million is primarily due to lower sales volume and higher gross-to-net adjustments related to provisions for rebates, partially offset by higher gross price.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $20.0 million for the 2024 Quarter, compared to $24.3 million for the 2023 Quarter. The $4.3 million decrease was primarily related to the 2023 Quarter including higher cost of product revenues related to the step-up basis in inventory acquired from BDSI, partially offset by higher sales volume in the 2024 Quarter for Belbuca.

Intangible asset amortization was $34.5 million for the 2024 Quarter, compared to $37.5 million for the 2023 Quarter. The $3.0 million decrease was primarily a result of the FDA granting New Patient Population exclusivity for Nucynta IR to July 3, 2026 in the third quarter of 2023, resulting in an extension of the estimated useful life of the underlying intangible asset and a reduction of amortization expense recognized during the 2024 Quarter. Intangible asset amortization expense is recognized in connection with our intangible assets. The intangible assets are amortized on a straight-line basis over the respective estimated useful lives.

Operating Expenses

Selling, general and administrative expenses were $43.3 million for the 2024 Quarter, compared to $38.2 million for the 2023 Quarter. The $5.1 million increase was primarily related to:

- an increase in salaries, wages, and benefits of $6.2 million, primarily due to expenses incurred as a result of the CEO transition announced in May 2024, including higher stock-based compensation expense of $3.7 million related to accelerated equity awards and higher severance, benefits, and related expenses incurred of $3.1 million; partially offset by
- a decrease in sales and marketing expenses of $1.4 million, primarily due to the timing of marketing related expenses.

Interest expense and Interest income

Interest expense was $15.6 million for the 2024 Quarter, compared to $21.9 million for the 2023 Quarter. The $6.3 million decrease was primarily due to lower interest expense associated with the 2022 Term Loan as a result of a lower overall principal balance, partially offset by higher interest rates impacting the variable rate on the 2022 Term Loan.

Interest income was $4.4 million for the 2024 Quarter, compared to $4.0 million for the 2023 Quarter. The $0.4 million increase was primarily due to higher interest rates earned on cash equivalents and marketable securities, partially offset by a lower overall balance invested in the 2024 Quarter compared to the 2023 Quarter.

Loss on extinguishment of debt

Loss on extinguishment of debt was $7.2 million for the 2024 Quarter, compared to none in the 2023 Quarter. The $7.2 million increase was due to the redemption of the $26.4 million convertible notes due in 2026 during the 2024 Quarter.

Taxes

The provision for income taxes was $9.5 million for the 2024 Quarter, compared to $4.8 million for the 2023 Quarter. The increase is primarily due to higher earnings in the 2024 Quarter compared to the 2023 Quarter as well as the discrete nondeductible costs associated with the debt extinguishment that occurred during the 2024 Quarter.

Comparison of the six months ended June 30, 2024 and June 30, 2023

Product revenues, net

Product revenues, net were $290.2 million for the six months ended June 30, 2024 (the "2024 Period"), compared to $280.3 million for the six months ended June 30, 2023 (the "2023 Period"). The $9.9 million increase is primarily due to increased revenue for Belbuca of $15.5 million and Xtampza of $1.3 million, partially offset by decreased revenue for the Nucynta Products of $6.7 million and Symproic of $0.2 million.

The increase in revenue for Belbuca of $15.5 million is primarily due to higher sales volume and gross price, partially offset by higher gross-to-net adjustments related to provisions for chargebacks.

The increase in revenue for Xtampza ER of $1.3 million is primarily due to lower gross-to-net adjustments related to provisions for rebates and higher gross price, partially offset by lower sales volume.

The decrease in revenue for the Nucynta Products of $6.7 million is primarily due to lower sales volume and higher gross-to-net adjustments related to provisions for rebates, partially offset by higher gross price.

The decrease in revenue for Symproic of $0.2 million is primarily due to lower sales volume and higher gross-to-net adjustments related to provisions for chargebacks, partially offset by higher gross price.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $38.9 million for the 2024 Period, compared to $54.2 million for the 2023 Period. The $15.3 million decrease was primarily related to the 2023 Period including higher cost of product revenues related to the step-up basis in inventory acquired from BDSI, partially offset by higher sales volume in the 2024 Period for Belbuca.

Intangible asset amortization was $69.0 million for the 2024 Period, compared to $74.9 million for the 2023 Period. The $5.9 million decrease was primarily a result of the FDA granting New Patient Population exclusivity for Nucynta IR to July 3, 2026 in the third quarter of 2023, resulting in an extension of the estimated useful life of the underlying intangible asset and a reduction of amortization expense recognized during the 2024 Period. Intangible asset amortization expense is recognized in connection with our intangible assets. The intangible assets are amortized on a straight-line basis over the respective estimated useful lives.

Operating Expenses

Selling, general and administrative expenses were $85.3 million for the 2024 Period, compared to $91.0 million for the 2023 Period. The $5.7 million decrease was primarily related to:

- a decrease in audit and legal expenses of $9.6 million, primarily due to an $8.5 million litigation settlement during the 2023 Period and lower litigation related expenses; and
- a decrease in sales and marketing expenses of $2.7 million, primarily due to the timing of marketing related expenses; partially offset by
- an increase in salaries, wages, and benefits of $6.9 million, primarily due to expenses incurred as a result of the CEO transition announced in May 2024, including higher stock-based compensation expense of $3.7 million related to accelerated equity awards and higher severance, benefits, and related expenses incurred of $3.1 million.

Interest expense and Interest income

Interest expense was $32.9 million for the 2024 Period, compared to $43.3 million for the 2023 Period. The $10.4 million decrease was primarily due to lower interest expense associated with the 2022 Term Loan as a result of a lower overall principal balance, partially offset by higher interest expense due to the higher convertible debt principal following the issuance of the 2029 Convertible Notes in February 2023, and higher interest rates impacting the variable rate on the 2022 Term Loan.

Interest income was $8.9 million for the 2024 Period, compared to $6.8 million for the 2023 Period. The $2.1 million increase was primarily due to higher interest rates earned on cash equivalents and marketable securities as well as a higher overall balance invested in the 2024 Period compared to the 2023 Period.

Loss on extinguishment of debt

Loss on extinguishment of debt was $7.2 million for the 2024 Period, compared to $23.5 million in the 2023 Period. The $16.3 million decrease was due to the 2023 Period including a $23.5 million loss on extinguishment resulting from the repurchase of $117.4 million of convertible notes due in 2026 in the 2023 Period. In the 2024 Period, the remaining $26.4 million of convertible notes due in 2026 were redeemed, resulting in a $7.2 million loss on extinguishment in the 2024 Period.

Taxes

The provision for income taxes was $18.4 million for the 2024 Period, compared to $4.7 million for the 2023 Period. The increase is primarily due to higher earnings in the 2024 Period compared to the 2023 Period, partially offset by higher discrete nondeductible costs associated with the debt extinguishment in the 2023 Period compared to the 2024 Period.

Liquidity and Capital Resources

Sources of Liquidity

Historically, we have funded our operations primarily through private placements and/or public offerings of our preferred stock, common stock, and convertible notes; term loan debt; and cash inflows from sales of our products. We are primarily dependent on the commercial success of Belbuca, Xtampza, and the Nucynta Products.

As of June 30, 2024, the outstanding principal balance of the 2022 Term Loan was $320.8 million, of which $183.3 million in principal payments were due within the next twelve months.

In July 2024, we amended and replaced our 2022 Term Loan with a $645.8 million secured term loan (the "2024 Term Loan"), consisting of a $320.8 million initial term loan and a $325.0 million delayed draw term loan. We used the proceeds of the initial term loan to refinance in full all outstanding indebtedness under the 2022 Term Loan. We will use the proceeds of the delayed draw term loan to fund a portion of the consideration to complete the Ironshore Acquisition, pay fees and expenses in connection with the Ironshore Acquisition and the 2024 Term Loan and the remainder for general corporate purposes.

As of June 30, 2024, the outstanding principal balance of the 2029 Convertible Notes was $241.5 million. The $241.5 million principal balance is due in 2029.

As of June 30, 2024, we had $271.6 million in cash, cash equivalents, and marketable securities. We believe that our cash, cash equivalents, and marketable securities as of June 30, 2024, together with expected cash inflows from operations, will enable us to fund our operating expenses, debt service, and capital expenditure requirements under our current business plan for the foreseeable future.

Borrowing Arrangements

The following transactions represent material changes in our borrowing arrangements from our most recently filed Annual Report.

On April 11, 2024, we provided notice of redemption for the remaining $26.4 million aggregate principal amount of our 2.625% convertible senior notes due in 2026 (the "2026 Convertible Notes"). The 2026 Convertible Notes were fully redeemed on June 18, 2024. We settled the redemption of the 2026 Convertible Notes in cash. Refer to Note 11, *Convertible Senior Notes,* for more information.

On July 28, 2024, in connection with the acquisition of Ironshore Therapeutics Inc., we amended and restated the 2022 Term Loan. Refer to Note 16, *Subsequent Events*, for more information.

Cash Flows

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash provided by operating activities	$ 129,335	$ 127,393
Net cash used in investing activities	(27,034)	(41,893)
Net cash (used in) provided by financing activities	(168,354)	23,061
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (66,053)	$ 108,561

Operating activities. Cash provided by operating activities was $129.3 million for the 2024 Period, compared to $127.4 million for the 2023 Period. The $1.9 million increase was primarily due to the increase in cash flows from operating results, which reflects operating earnings, after adjustment for non-cash items that are included in net income (loss), partially offset by the decrease in cash flows from changes in working capital.

Investing activities. Cash used in investing activities was $27.0 million for the 2024 Period, compared to $41.9 million for the 2023 Period. The $14.9 million decrease was primarily due to maturities of marketable securities, partially offset by purchases of marketable securities.

Financing activities. Cash used in financing activities was $168.4 million for the 2024 Period, compared to cash provided by financing activities of $23.1 million in the 2023 Period. The $191.5 million decrease was primarily due to:

- the repurchase of a portion of our 2026 Convertible Notes and issuance of our 2029 Convertible Notes which resulted in net proceeds of $96.6 million in the 2023 Period;
- repurchases of common stock of $35.0 million in the 2024 Period;
- the redemption and $33.2 million cash settlement of our 2026 Convertible Notes in the 2024 Period;
- an increase in repayments of term notes of $20.8 million; and
- an increase in taxes paid for employee stock withholdings of $10.8 million; partially offset by
- an increase in proceeds from stock option exercises of $4.8 million.

Funding Requirements

We believe that our cash, cash equivalents, and marketable securities as of June 30, 2024, together with expected cash inflows from operations, will enable us to fund our operating expenses, debt service, and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We have significant future capital requirements, including:

- expected operating expenses to manufacture and commercialize our products and to operate our organization;
- repayment of outstanding principal amounts and interest in connection with our 2024 Term Loan and 2029 Convertible Notes;
- royalties we pay on sales of certain products within our portfolio;
- the successful integration of Ironshore operations following the Ironshore Acquisition;
- operating lease obligations;
- minimum purchase obligations in connection with our contract manufacturer; and
- cash paid for income taxes.

In addition, we have significant potential future capital requirements, including:

- we may enter into business development transactions, including acquisitions, collaborations, licensing arrangements and equity investments, that require additional capital;
- any judgments rendered against us in connection with any of the litigation matters set forth in Note 14, *Commitments and Contingencies*, to our financial statements; and
- in January 2024, our Board of Directors authorized a new share repurchase program for the repurchase of up to $150.0 million of shares of our common stock through June 30, 2025. Future share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial conditions, the price of our common stock on the NASDAQ Global Select Market, and other factors that we may deem relevant.

Additional Information

To supplement our financial results presented on a GAAP basis, we have included information about certain non-GAAP financial measures. We believe the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting. In addition, certain non-GAAP financial measures, primarily Adjusted EBITDA, are used to measure performance when determining components of annual compensation for substantially all non-sales force employees, including senior management.

We may discuss the following financial measures that are not calculated in accordance with GAAP in our quarterly and annual reports, earnings press releases and conference calls.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. Adjusted EBITDA, as used by us, may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

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

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- 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 stock-based compensation expense from adjusted EBITDA although: (i) 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 (ii) 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;
- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset(s) being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, and miscellaneous other acquisition related expenses incurred;
- we exclude recognition of the step-up basis in inventory from acquisitions (i.e., the adjustment to record inventory from historic cost to fair value at acquisition) as the adjustment does not reflect the ongoing expense associated with sale of our products as part of our underlying business;
- we exclude losses on extinguishments of debt as these expenses are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis; and
- we exclude other expenses, from time to time, that are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis.

Adjusted EBITDA for the three and six months ended June 30, 2024 and 2023 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
GAAP net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)
Adjustments:				
Interest expense	15,587	21,863	32,926	43,290
Interest income	(4,397)	(4,027)	(8,884)	(6,774)
Loss on extinguishment of debt	7,184	—	7,184	23,504
Provision for income taxes	9,491	4,790	18,400	4,659
Depreciation	952	895	1,869	1,712
Amortization	34,515	37,463	69,032	74,929
Stock-based compensation	10,012	7,072	17,487	13,107
Litigation settlements	—	—	—	8,500
Recognition of step-up basis in inventory	—	4,748	—	14,918
CEO transition expense	3,051	—	3,051	—
Total adjustments	$ 76,395	$ 72,804	$ 141,065	$ 177,845
Adjusted EBITDA	$ 96,001	$ 85,811	$ 188,384	$ 173,426

Adjusted EBITDA was $96.0 million for the 2024 Quarter compared to $85.8 million for the 2023 Quarter. The $10.2 million increase was primarily due to higher product revenues and lower adjusted operating expenses.

Adjusted EBITDA was $188.4 million for the 2024 Period compared to $173.4 million for the 2023 Period. The $15.0 million increase was primarily due to higher product revenues and lower adjusted operating expenses.

Adjusted Operating Expenses

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

Adjusted operating expenses for the three and six months ended June 30, 2024 and 2023 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
GAAP operating expenses	$ 43,335	$ 38,193	$ 85,317	$ 90,968
Adjustments:				
Stock-based compensation	10,012	7,072	17,487	13,107
Litigation settlements	—	—	—	8,500
CEO transition expense	3,051	—	3,051	—
Total adjustments	$ 13,063	$ 7,072	$ 20,538	$ 21,607
Adjusted operating expenses	$ 30,272	$ 31,121	$ 64,779	$ 69,361

Adjusted operating expenses were $30.3 million in the 2024 Quarter compared to $31.1 million in the 2023 Quarter. The $0.8 million decrease was primarily driven by lower sales and marketing expenses of $1.4 million, primarily due to the timing of marketing related expenses.

Adjusted operating expenses were $64.8 million in the 2024 Period compared to $69.4 million in the 2023 Period. The $4.6 million decrease was primarily driven by:

- lower sales and marketing expenses of $2.7 million, primarily due to the timing of marketing related expenses; and
- lower audit and legal expenses (excluding litigation settlements) of $1.1 million.

Adjusted Net Income and Adjusted Earnings Per Share

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

Adjusted net income and adjusted earnings per share for the three and six months ended June 30, 2024 and 2023 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands, except share and per share data)			
GAAP net income (loss)	$ 19,606	$ 13,007	$ 47,319	$ (4,419)
Adjustments:				
Non-cash interest expense	1,604	2,261	3,384	4,548
Loss on extinguishment of debt	7,184	—	7,184	23,504
Amortization	34,515	37,463	69,032	74,929
Stock-based compensation	10,012	7,072	17,487	13,107
Litigation settlements	—	—	—	8,500
Recognition of step-up basis in inventory	—	4,748	—	14,918
CEO transition expense	3,051	—	3,051	—
Income tax effect of above adjustments (1)	(12,008)	(12,100)	(24,661)	(30,974)
Total adjustments	$ 44,358	$ 39,444	$ 75,477	$ 108,532
Non-GAAP adjusted net income	$ 63,964	$ 52,451	$ 122,796	$ 104,113
Adjusted weighted-average shares — diluted (2)	40,383,695	42,849,952	40,510,943	41,485,868
Adjusted earnings per share (2)	$ 1.62	$ 1.26	$ 3.09	$ 2.57

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate to the items that have a tax effect. The blended federal and state statutory rate for the three months ended June 30, 2024 and 2023 were 25.9% and 24%, respectively; and the blended federal and state statutory rate for the six months ended June 30, 2024 and 2023 were 26.2% and 25.6%, respectively. As such, the non-GAAP effective tax rates for the three months ended June 30, 2024 and 2023 were 21.3% and 23.5%, respectively; and the non-GAAP effective tax rates for the six months ended June 30, 2024 and 2023 were 24.6% and 22.2%, respectively.

(2) Adjusted weighted-average shares - diluted were calculated using the “if-converted” method for our convertible notes in accordance with ASC 260, *Earnings per Share*. As such, adjusted weighted-average shares – diluted includes shares related to the assumed conversion of our convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income. For the three months ended June 30, 2024 and 2023, adjusted weighted-average shares – diluted includes 6,606,305 and 7,509,104 shares, respectively, attributable to our convertible notes. For the six months ended June 30, 2024 and 2023, adjusted weighted-average shares – diluted includes 6,606,305 and 6,041,036 shares, respectively, attributable to our convertible notes. In addition, adjusted earnings per share includes other potentially dilutive securities to the extent that they are not antidilutive.

Contractual Obligations

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest rate sensitivity in connection with our investment portfolio and the 2024 Term Loan. None of these market risk sensitive instruments are held for trading purposes.

Investment Portfolio

Our investment portfolio includes financial instruments that are sensitive to interest rate risks. Our investment portfolio is used to preserve capital, maintain liquidity sufficient to meet cash flow requirements, and maximize returns commensurate with our risk appetite. We invest in instruments that meet the credit quality, diversification, liquidity, and maturity standards outlined in our investment policy.

As of June 30, 2024, our investment portfolio includes $22.2 million of cash equivalents and $98.7 million of marketable securities, which are primarily comprised of money market funds, U.S. Treasury securities, corporate debt securities, government-sponsored securities, and commercial paper. Our money market funds are short-term highly liquid investments, and our marketable securities have active secondary or resale markets to help ensure liquidity. We account for marketable securities as available-for-sale, thus, no gains or losses are realized due to changes in the fair value of our marketable securities unless we sell our investments prior to maturity or incur a credit loss. Furthermore, our investment policy includes guidelines limiting the term-to-maturity of our investments. Due to the nature of our investments, we do not believe that the fair value of our investments has a material exposure to interest rate risk.

2024 Term Loan

The 2024 Term Loan bears interest at a rate equal to: (i) until September 30, 2024, adjusted term SOFR + 7.50% and, (ii) thereafter, adjusted term SOFR + 4.50%, and is subject to quarterly amortization payments equal to 2.50% of the original funded amount of the 2024 Term Loan. Based on the outstanding principal amount of the 2024 Term Loan as of August 8, 2024 of $320.8 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately $3.2 million.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our interim Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024. 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 June 30, 2024, our interim Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth in Note 14, *Commitments and Contingencies,* to our financial statements, which is incorporated herein by reference to the extent applicable, there are no other material changes from the legal proceedings previously disclosed in our most recently filed annual report on Form 10-K for the fiscal year ended December 31, 2023 (the "Annual Report").

Item 1A. Risk Factors

Risk Factors Summary

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

- Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products we may acquire in the future;
- We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations;
- Adverse developments affecting the financial services industry could adversely affect our business, financial condition, or results of operations;
- If we cannot continue successfully commercializing our products and any products that we may acquire in the future, 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 Risk Evaluation and Mitigation Strategy ("REMS") programs, which could increase the cost, burden and liability associated with the commercialization of these products;
- Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions;
- Unfavorable outcomes in intellectual property litigation could be costly and potentially limit our ability to commercialize our products;
- If we are unable to obtain or maintain intellectual property rights for our technologies, products or any products we may acquire, 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 controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies;
- Current and future legislation may increase the difficulty and cost for us to continue to commercialize our products and may reduce the prices we are able to obtain for our products;
- Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the

rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain;

- Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory and enforcement efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business;
- If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline;
- If the third-party manufacturers of our products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated manufacturing suite at our third-party manufacturer's site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business;
- Because we currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us;
- We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors or their distribution network is disrupted, our financial condition and results of operations may be adversely affected;
- Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control;
- The announcement and pendency of our acquisition of Ironshore Therapeutics, Inc. ("Ironshore") may have an adverse effect on our business, financial condition, operating results and cash flows;
- Our ability to realize the benefits of the Ironshore acquisition is substantially dependent on the timely and effective integration of the operations of Collegium and Ironshore;
- Our business may be adversely affected by certain events or circumstances outside our control, including macroeconomic conditions and geopolitical turmoil;
- Litigation or regulatory action regarding opioid medications could negatively affect our business;
- We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do;
- Commercial sales of our products 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 that we may 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 that we may 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;
- acquire new products, or develop new indications or line extensions for existing products, in the event that revenues from our existing products are impacted by price controls, loss of intellectual property exclusivity or competition; 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, 2023, we had a U.S. federal net operating loss ("NOL") carryforward of approximately $137.5 million and state NOL carryovers of approximately $202.4 million. The U.S. federal and state NOL carryforwards expire at various dates through 2037. Federal NOLs and certain state NOLs incurred in 2018 and onward have an indefinite expiration under the Tax Cuts and Jobs Act of 2017 and applicable state statutes. We also had U.S. federal tax credits of approximately $1.0 million, and state tax credits of approximately $0.7 million. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC 382").

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

As part of the BDSI acquisition, we acquired an estimated $234.7 million of federal NOL carryovers which are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under IRC 382. We performed an IRC 382 study following the BDSI Acquisition in 2022 and concluded that there were ownership changes that occurred during the years 2006 and 2022 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses. As of December 31, 2023, remaining net operating losses of $124.3 million are subject to limitation. Refer to Note 15, *Income Taxes*, to our consolidated financial statements included in Part I of this Quarterly Report on Form 10-Q.

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

In July 2024, in connection with our entry into a definitive agreement to acquire Ironshore, we entered into a Second Amended and Restated Loan Agreement by and among us, certain of our subsidiaries party thereto as guarantors, BioPharma Credit PLC as collateral agent, and BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership (investment funds managed by Pharmakon Advisors, LP) as the lenders (the "Lenders") party thereto (the "2024 Loan Agreement"), of which $320.8 million in principal was outstanding as of August 8, 2024. In addition, we have $241.5 million in 2.875% convertible senior notes due in 2029 (the "2029 Convertible Notes").

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

- requiring the dedication of a substantial portion of our cash flows from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;
- exposing us to the risk of increased interest rates as certain of our borrowings, including the 2024 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 2029 Convertible Notes;

- placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital; and
- increasing our vulnerability to downturns in our business, our industry or the economy in general.

Holders of our 2029 Convertible Notes, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. Applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion, and any failure by us to repurchase notes or to pay the cash amounts due upon the conversion when required would constitute a default under the indenture.

Additionally, the indenture governing the 2029 Convertible Notes and our 2024 Loan Agreement contain certain covenants and obligations applicable to us, including, without limitation, covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business, which could limit our ability to capitalize on business opportunities that may arise or otherwise place us at a competitive disadvantage relative to our competitors.

Failure to comply with covenants in the indenture governing the 2029 Convertible Notes or in the 2024 Loan Agreement would constitute an event of default under those instruments, notwithstanding our ability to meet our debt service obligations. A default under the indenture or a fundamental change could also result in a default under one or more of the agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. In such event, we may not have sufficient funds to satisfy all amounts that would become due. The 2024 Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the 2024 Loan Agreement and execution upon the collateral securing obligations under the 2024 Loan Agreement. In addition, because our assets are pledged as a security under the 2024 Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets would be subject to the risk of foreclosure by our lenders.

Further, amounts outstanding under our 2024 Loan Agreement bear an annual interest rate equal to: (i) until September 30, 2024, adjusted term Secured Overnight Financing Rate (“SOFR”) + 7.50% and, (ii) thereafter, adjusted term SOFR + 4.50%, and are subject to quarterly amortization payments equal to 2.50% of the original funded amount of the 2024 Term Loan. 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 SOFR 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.

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

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in early 2023, several financial institutions closed and were taken into receivership by the Federal Deposit Insurance Corporation (“FDIC”). Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. Further, investor concerns regarding domestic or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our

ability to meet our financial obligations, which could have material adverse impacts on our liquidity and our business, financial condition, or results of operations.

Risks Related to our Products

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

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

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

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

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

Despite receiving approval by the FDA, additional data may emerge that could change the FDA’s position on the product labeling of any of our products, including our abuse-deterrent claims with respect to Xtampza ER, and our ability to market our products successfully may be adversely affected.

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

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

Our opioid products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.

The FDA has imposed a class-wide REMS on all IR, ER and long-acting opioid drug products (known as the Opioid Analgesic REMS). The FDA continually evaluates whether the REMS program is meeting its goal of ensuring that the benefit of these drugs continue to outweigh their risks, and whether the goals or elements of the program should be modified. As opioids, Xtampza ER, the Nucynta Products and Belbuca are subject to the Opioid Analgesic REMS.

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

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

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

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

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

Further, 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 realizing the full commercial potential of our products.

Risks Related to Intellectual Property

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

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

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such

proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations.

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

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

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

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

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

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

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

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

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

that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

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

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

Risks Related to the Commercialization of Our Products

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

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

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

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

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

Physicians and others in the medical community, patients, and healthcare payors may not continue to accept and use our products, or accept and use any new products that we may acquire. Acceptance and use of our products will depend on a number of factors including:

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

- actual and perceived availability and quality of coverage and reimbursement for our products from government or other third-party payors;
- negative publicity related to our products or negative or positive publicity related to our competitors' products;
- the prevalence and severity of adverse side effects;
- policy initiatives by FDA, 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, and Symproic for substantially all of our revenues for the foreseeable future, the failure of these products to maintain market acceptance would harm our business prospects.

Some of our products contain controlled substances, and 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 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 classified as Schedule II controlled substances under the Controlled Substances Act ("CSA") and regulations of the DEA and the active ingredient in Belbuca, buprenorphine, is classified as a Schedule III controlled substance. A number of states also independently regulate these drugs, including oxycodone, tapentadol and buprenorphine, as controlled substances. We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. For more information, refer to 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, or in the case of the Nucynta Products, tapentadol) 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 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 manufacturing 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 affect our ability to commercialize our products. For example, several states, including New York, have imposed taxes or fees on the sale of opioids. Other states, and even the federal government, could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing of our products may be. Moreover, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes. 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. Refer to the sections in our Annual Report entitled "Business — Government Regulation — Third-Party Payor Coverage and Reimbursement" and " — Healthcare Reform" for more information.

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

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies.

In August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would subject manufacturers of some brand-name medications without generic or biosimilar competition to a price negotiation program that results in a negotiated "maximum fair price" (or pay an excise tax for noncompliance), the establishment of rebate payment requirements on manufacturers of drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and revisions to the way manufacturers provide discounts on Part D drugs. The IRA also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000 per year, thereby eliminating the Medicare Part D coverage gap or "donut hole." Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA 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 IRA on our business and the pharmaceutical industry in general is not yet known.

Our inability to expand and maintain coverage and profitable reimbursement rates from both government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to continue to commercialize our products and our overall financial condition.

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

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

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act, and the Affordable Care Act has also been subject to challenges in the courts. Refer to 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 payors. 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 payors may not be willing to pay a premium for abuse-deterrent formulations of opioids.

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

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

Once 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. Additionally, under the Food and Drug Omnibus Reform Act of 2022, FDA will assign therapeutic equivalence ratings for certain prescription drugs approved via the Section 505(b)(2) NDA pathway with respect to other approved drug products and it is unclear how assignment of these ratings will impact the market opportunity for our products. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore, to obtain a return on the investments we have made in our products. In the past, we have initiated litigation with generic competitors that have filed Paragraph IV Certifications challenging certain of our patents. While we have entered into settlement agreements with certain competitors, we are currently pursuing litigation to defend against Paragraph IV Certifications related to Belbuca. Refer to Note 14, *Commitments and Contingencies*, to our consolidated financial statements included in Part I 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.

We may seek FDA pediatric exclusivity for some of our products. Pediatric exclusivity, if granted, adds six months of patent term and marketing exclusivity to existing exclusivity periods for all formulations, dosage forms, and indications for the active moiety, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The regulatory exclusivity period for Nucynta IR in the United States has been extended through July 3, 2026, following the grant of New Patient Population exclusivity in pediatrics by the FDA in August 2023 based on data from pediatric trials which were submitted in response to the FDA's Pediatric Written Request (the "Written Request") to evaluate the use of Nucynta as a treatment for pain in pediatric patients aged 6 years and older. In June 2024, we announced that the FDA deemed these data to be responsive to its Written Request, granting pediatric exclusivity to the entire Nucynta franchise for an additional six months, to December 27, 2025 for Nucynta ER and January 3, 2027 for Nucynta IR. Whenever we seek pediatric exclusivity, there is no guarantee that the FDA will agree that the Written Request has been satisfied and that we will receive this additional exclusivity, or that we will maintain such exclusivity, if granted.

In November 2017, the FDA issued a final guidance to assist the 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 recommended specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of the FDA's wider focus on assisting developers of generic abuse-deterrent formulations in navigating the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

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

We do not own any manufacturing facilities in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility and do not have the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our products. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as

other vendors to formulate, test, supply, store and distribute our products, and we control only certain aspects of their activities.

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

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

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

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment;
- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or we could experience technical problems in the operation of our dedicated manufacturing suite;
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products, before we may use the alternative manufacturer to produce commercial supplies;
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully; and
- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture our products could adversely affect our ability to continue to commercialize our products, which could in turn adversely affect our results of operations and financial condition. Likewise, the inability of any of our sole or limited suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our products. In addition, DEA regulations, through the quota procurement process, limit the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to maintain an appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our manufacturing and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require our products to be manufactured according to Current Good Manufacturing Practice regulations promulgated by the FDA (“cGMP”). Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to inspection deficiencies, a shortage of commercial product, or potential products liability exposure for any noncompliant distributed products. Such failure could also be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action,

including recall or seizure, total or partial suspension of production, 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. We contract with these suppliers for commercial supply to manufacture our products. Further, our suppliers of the active pharmaceutical ingredients for Xtampza ER and the Nucynta Products also supply our primary competitor in the extended-release oxycodone space, Purdue. Identifying alternate sources of active pharmaceutical ingredients for our products is generally time-consuming and costly. Any changes that our suppliers make to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our suppliers were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of any disruptions in personnel or the global supply chain), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

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

There are currently global supply chain disruptions and shortages caused by a variety of factors, including geopolitical turmoil, such as the Ukrainian War and current conflict in Israel and Gaza. 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 successfully commercialize our products. 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 three of our wholesale pharmaceutical distributors. 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, 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.

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

For certain of our products, we are subject to post-marketing requirements to conduct epidemiological studies and clinical trials, or, in some cases, to conduct post-marketing surveillance or observational studies to gather additional information about our products. For our opioid products, we generally intend to fulfill our post-marketing requirements ("PMRs") by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of the OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our opioid products. Additionally, there may be certain PMRs or post-marketing commitments that we fulfill on our own for our products, including via the conduct of post-marketing surveillance or observational studies. If such studies lead to the discovery of adverse findings regarding the safety or benefit profiles of our products, then the FDA may choose to withdraw or otherwise restrict the approval of our products or the FDA or we may determine that labeling changes are warranted based on their finding. Such withdrawal or restriction or labeling changes for our products would have an adverse impact on our business and financial condition.

Risks Related to Our Business and Strategy

The announcement and pendency of our acquisition of Ironshore may have an adverse effect on our business, financial condition, operating results and cash flows.

On July 28, 2024, we entered into a definitive agreement to acquire Ironshore. The transaction (the "Ironshore Acquisition") is expected to close in the third quarter of 2024, subject to customary closing conditions. We have devoted, and will continue to devote, significant management and other internal resources towards the completion of the Ironshore Acquisition and planning for integration. Completion of the Ironshore Acquisition is subject to conditions beyond our control that may prevent, delay or otherwise adversely affect its completion in a material way. The failure to complete the Ironshore Acquisition in a timely manner or at all could negatively impact the market price of our common stock as it currently reflects an assumption that the transaction will be completed. Furthermore, if the Ironshore Acquisition is significantly delayed or not completed, we may suffer other consequences that could adversely affect our business, results of operations and stock price, including the following:

- we would have incurred significant costs in connection with the Ironshore Acquisition that we may be unable to recover;
- we may be subject to negative publicity or be negatively perceived by the investment or business communities;
- we may be subject to legal proceedings related to the Ironshore Acquisition;
- any disruptions to our business resulting from the announcement and pendency of the Ironshore Acquisition, including any adverse changes in our relationships with our customers, suppliers, other business partners and employees, may continue or intensify in the event the Ironshore Acquisition is not consummated; and
- we may not be able to take advantage of alternative business opportunities or effectively respond to competitive pressures.

There can be no assurance that our business, financial condition, operating results and cash flows will not be adversely affected, as compared to prior to the announcement of the Ironshore Acquisition, if the Ironshore Acquisition is not consummated.

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

Our ability to realize the benefits from the acquisition of Ironshore, which is expected to close in the third quarter of 2024, is substantially dependent on the timely and effective integration of the operations of Collegium and Ironshore. The process of integrating the operations of Collegium and Ironshore 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 Ironshore'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 Ironshore's existing business relationships;
- unanticipated expenses and liabilities; and
- unanticipated issues in integrating sales, marketing and administrative functions.

If Ironshore 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 Ironshore and we had historically achieved or might achieve separately.

If we are unable to timely and effectively integrate the operations of Collegium and Ironshore, the anticipated growth opportunities and other synergies of the Ironshore 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 benefits expected from the integration of the operations of Ironshore.

Our business may be adversely affected by certain events or circumstances outside our control, including macroeconomic conditions and geopolitical turmoil.

Events or circumstances outside of our control, including macroeconomic conditions such as recession or depression, inflation, and declines in consumer-spending could result in reduced demand for our products. An economic downturn could result in business closures, higher levels of unemployment, or declines in consumer disposable income which could have an impact on the number of patients seeking and receiving treatment for conditions that might otherwise result in the prescription of our products, as patients may make efforts to avoid or postpone seeking non-essential medical care to allocate their resources to other priorities or essential items. These circumstances, in addition to the impact of geopolitical turmoil, such as the ongoing Ukrainian War and current conflict in Israel and Gaza (including any escalation or expansion), social unrest, political instability in the United States and elsewhere, terrorism, cyberwarfare or other acts of war, may result in reduced demand for our products and negatively impact our sales, results of operations, and liquidity.

Security breaches and other disruptions to our, or our vendors', information technology systems may compromise our information and expose us to liability that could adversely impact our financial condition, operations, and reputation.

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks ("Systems") to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications including, in some cases, our business proprietary information, and Electronic Data Interchange ("EDI") on purchase orders, invoices, chargebacks, among other things. Our Systems, along with those of the third parties whom we rely on to process confidential and sensitive data in a variety of contexts, are potentially vulnerable to a variety of evolving threats that may expose this data to unauthorized persons or otherwise compromise its integrity. These threats may include, but are not limited to, social-engineering attacks (including through phishing attacks), business email compromise, online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

We may expend significant resources to try to protect against these threats to our Systems. Certain data privacy and security laws, as well as industry best practice standards, may require us to implement and maintain security measures. While we have implemented security measures designed to protect our Systems and confidential and sensitive data, there can be no assurance that these measures will be effective. Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. If we, or a third party upon whom we rely, experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Further, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices.

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

Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies. These lawsuits generally allege that we had engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. In March 2022, we entered into a Master Settlement Agreement resolving 27 pending opioid-related lawsuits brought against us by cities, counties, and other subdivisions in the United States. As part of the Master Settlement Agreement, we paid $2.75 million to the plaintiffs and the cases were dismissed, with prejudice. In late

March 2023, three new cases were filed in three federal courts, naming us as one of numerous defendants, from which we have been dismissed.

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

We currently carry product liability insurance. Product liability claims may be brought against us by patients; 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. 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. Refer to the section in our Annual Report entitled "Business — Government Regulation — Healthcare Fraud and Abuse Laws and Compliance Requirements" for more information.

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 or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it might become difficult or, in certain cases, impossible for us to continue our business, and any disruption could last for a substantial period of time.

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

Risks Related to Our Common Stock

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

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these "Risk Factors," some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our business model, prospects or actual operating performance. The realization of any of these risks, or any of a broad range of other risks discussed in this report, could have a material adverse effect on the market price of our common stock.

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

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

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

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

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

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock. As of June 30, 2024, there were outstanding options to purchase an aggregate of 693,302 shares of our common stock at a weighted average exercise price of $18.71 per share, of which options to purchase 692,975 shares of our common stock were then exercisable. The exercise of options at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

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

In January 2024, our Board of Directors authorized a new share repurchase program for the repurchase of up to $150.0 million of shares of our common stock through June 30, 2025 (the "2024-2025 Repurchase Program"). The 2024-2025 Repurchase Program permits us 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. In May 2024, we entered into an accelerated share repurchase program to repurchase $35.0 million of our common stock, as part of the 2024-2025 Repurchase Program. As of June 30, 2024, we repurchased 888,889 shares at a weighted-average price of $31.50 per share for a total of $28.0 million under the 2024-2025 Repurchase Program. As of June 30, 2024, $115.0 million remained available for share repurchases under the 2024-2025 Repurchase Program. Additional share repurchases under the 2024-2025 Repurchase Program will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our common stock on the NASDAQ Global Select Market, and other factors that we may deem relevant.

We can provide no assurance that we will continue to repurchase shares of our common stock at favorable prices, if at all.

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

Recent Sales of Unregistered Securities

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

Purchases of Equity Securities

The following table sets forth shares of common stock repurchased under our 2024-2025 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 June 30, 2024:

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 (in thousands)
April 1, 2024 through April 30, 2024	3,868	$ 37.99	—	$ 150,000
May 1, 2024 through May 31, 2024	1,052,749	31.91	888,889	115,000
June 1, 2024 through June 30, 2024	3,941	33.31	—	115,000
Total	1,060,558 [2]	$ 31.94	888,889 [2]	$ 115,000

(1) The 2024-2025 Repurchase Program was announced on January 3, 2024. The 2024-2025 Repurchase Program provides for the repurchase of up to $150.0 million of outstanding shares of our common stock at any time or times through June 30, 2025. The 2024-2025 Repurchase Program did not expire during the three months ended June 30, 2024, nor do we currently plan to terminate the 2024-2025 Repurchase Program prior to expiration. However, there can be no assurance as to the timing or number of shares of any repurchases in the future.

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

The disclosure set forth in Part II – Item 2 above is incorporated herein by reference.

During the three months ended June 30, 2024, none of our directors or officers adopted, amended, or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
10.1*	Authorized Generic Agreement by and between the Company and Hikma Pharmaceuticals USA Inc., dated April 26, 2024.
10.2+	Separation Agreement, by and between the Company and Joseph Ciaffoni, dated May 24, 2024.
10.3+	Letter Agreement, by and between the Company and Michael Heffernan, dated May 24, 2024.
31.1	Certification of interim 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 interim 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)

* Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the SEC upon request.

+ Indicates management contract or compensatory plan.

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: August 8, 2024

By: /s/ MICHAEL T. HEFFERNAN
Michael T. Heffernan
Interim Chief Executive Officer
(Principal executive officer)

Date: August 8, 2024

By: /s/ COLLEEN TUPPER
Colleen Tupper
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 10.1

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AUTHORIZED GENERIC AGREEMENT

THIS AUTHORIZED GENERIC AGREEMENT (this "**Agreement**"), is made effective as of April 26, 2024 (hereinafter the "**Effective Date**"), by and between:

HIKMA PHARMACEUTICALS USA INC., a Delaware corporation, having an address at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922 (hereinafter "**Hikma**"); and

COLLEGIUM PHARMACEUTICAL, INC., a Virginia corporation, having an address at 100 Technology Center Drive, Suite 300, Stoughton, Massachusetts 02072 (hereinafter "**Collegium**").

Each of Hikma and Collegium hereinafter are referred to as a "**Party**" or collectively as the "**Parties**."

RECITALS

WHEREAS, Hikma is engaged in, among other things, the development, manufacture, distribution, and sale of pharmaceutical products;

WHEREAS, Collegium is engaged in, among other things, the development, manufacture, and supply of active pharmaceutical ingredients and finished drug pharmaceutical products;

WHEREAS, Collegium has developed NUCYNTA® ER and NUCYNTA® IR brand Tapentadol Hydrochloride tablets; and

WHEREAS, Collegium intends to supply the Nucynta ER Authorized Generic and the Nucynta IR Authorized Generic (as such terms are defined below) and Hikma intends to purchase, distribute and sell the Nucynta ER Authorized Generic and the Nucynta IR Authorized Generic in the Territory.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants and obligations set forth herein, the sufficiency of which is hereby acknowledged, Hikma and Collegium hereby agree as follows:

DEFINITIONS

In addition to terms that may be defined elsewhere in this Agreement, the following terms shall have the corresponding meanings:

"**Active Ingredient**" or "**API**" shall mean the active pharmaceutical ingredient for the Products.

"**Affiliate**" shall mean, with respect to a Party, any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such Party. "**Control**" when used with respect to a specified Person means the power to direct the management and policies of such Person directly or indirectly, whether through the ownership of voting securities, by contract or otherwise.

"**ANDA**" shall mean an abbreviated new drug application for a Product filed with the FDA, and any supplements and amendments thereto, and including all data and information comprising all modules of the ANDA and other data and information necessary for the full enjoyment and support of the ANDA.

"**Applicable Law**" shall mean, individually and collectively, any federal, state, local, national, and supra-national laws, treaties, statutes, ordinances, rules, and regulations, including any rules, regulations, or requirements having the binding effect of law, applicable national securities exchanges, automated quotation systems, or securities listing organizations, Governmental Authorities, courts, tribunals, or agencies that are in effect from time to time during the Term and applicable to a particular activity hereunder.

"**Approval(s)**" shall mean any approvals, product, and/or establishment licenses, registrations, or authorizations, including without limitation approvals under NDAs, of the applicable Regulatory Authority, which are necessary for the Manufacture, use, storage, importation, transport, promotion, pricing, or Marketing of the Products in the Territory.

"**Authorized Generic**" shall mean any generic equivalent Tapentadol Hydrochloride tablet product that: (a) contains the Compound as the sole active ingredient; (b) is Marketed in the Territory without use of the Trademark; and (c) is authorized by Collegium to be Marketed in the Territory under NDA #200533 or NDA #022304.

"**Commercially Reasonable Efforts**" shall mean, with respect to a Party, the carrying out of the Manufacturing and Marketing activities, as applicable to a Party, in a diligent and sustained manner using such efforts and resources that a company within the generic pharmaceutical industry (with respect to Hikma) or within the branded pharmaceutical industry (with respect to Collegium) would devote to authorized generic products that such Party owns (or to which it has rights) which have comparable market value, commercial potential as the Products, taking into consideration such product's stage of commercialization and life cycle, safety and efficacy, manufacturing, technical and regulatory profile, Intellectual Property protection, competitiveness in the marketplace, profitability, and other relevant factors.

"**Compound**" shall mean tapentadol hydrochloride.

"**Confidential Information**" shall mean, with respect to a Party, all information of any kind whatsoever (including without limitation, data, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies, and techniques), and all tangible and intangible embodiments thereof of any kind whatsoever (including without limitation, apparatus, compositions, documents, drawings, machinery, patent applications, records, and reports), which is disclosed by such Party to the other Party in connection with the performance of a Party's obligations hereunder. Notwithstanding the

foregoing, Confidential Information of a Party shall not include information that the other Party can establish by written documentation (a) to have been publicly known prior to disclosure of such information by the disclosing Party to the other Party, (b) to have become publicly known, without the breach of this Agreement or violation of Applicable Law on the part of the other Party, subsequent to disclosure of such information by the disclosing Party to the other Party, (c) to have been received by the other Party on a non-confidential basis at any time from a source, other than the disclosing Party, rightfully having possession of and the right to disclose such information, (d) to have been otherwise known by the other Party, free from any obligation of confidentiality, prior to disclosure of such information by the disclosing Party to the other Party, or (e) to have been independently developed by employees or agents of the other Party without the use of or reliance upon such information disclosed by the disclosing Party to the other Party.

"**Cost of Goods Sold**" or "**COGS**" shall mean [***].

"**Drug Master File**" shall mean the Drug Master File for Manufacturing the Active Ingredient that is filed with the FDA.

"**FDA**" shall mean the United States Food and Drug Administration, and any successor agency thereto.

"**First Commercial Sale**" shall mean the first arm's length commercial sale for monetary value by Hikma or any of its Affiliates of a Product to a Third Party in the Territory.

"**Generic Equivalent**" shall mean a generic Tapentadol Hydrochloride tablet product that (a) contains the Compound as its sole active ingredient, and (b) has received FDA approval for sale in the Territory pursuant to an ANDA or 505(b)(2) filing as an AB-rated equivalent (i.e., generic equivalent) to an NDA Product.

"**GMP**" shall mean current Good Manufacturing Practices promulgated by the FDA, and their equivalent promulgated by the relevant Governmental Authority of any other country in which the Products are Manufactured.

"**Governmental Authority(ies)**" shall mean any government or supranational administrative agency, commission or other governmental, or supranational authority, body or instrumentality, or any federal, state, local, domestic, or foreign governmental or supranational regulatory body.

"**Intellectual Property**" shall mean all patents, copyrights, trademarks, service marks, service names, trade names, internet domain names, applications or registration for any of the foregoing, or extensions, renewals, continuations or re-issues thereof, or amendments or modifications thereto, brand marks, brand names, trade dress, labels, logos, know-how (including, without limitation, the Know-How), technical and non-technical information, trade secrets, formulae, techniques, sketches, drawings, models, inventions, discoveries, designs, specifications, processes, apparatus, equipment, databases, research, experimental work, developments, pharmacology and clinical data, patent, clinical, regulatory and market strategies, software programs and applications, software source documents, Third Party licenses, and all intellectual and proprietary rights related to or arising out of each of the foregoing and any similar type of

titles, rights and interests and intangible assets recognized under any laws or international conventions in any country in the Territory as intellectual property to which rights of ownership accrue pursuant to such laws or conventions or under any applicable license or contract, whether now existing or hereafter created during the Term, together with all modifications, enhancements and improvements thereto.

"**Know-How**" shall mean any and all proprietary methods, devices, technology, trade secrets, inventions, compositions, designs, formulae, know-how, show-how, technical and training manuals and documentation and other information, including processes and analytical methodologies used in development, testing, analysis and manufacture, and medical and clinical testing as well as other scientific data.

"**Label**" or "**Labeling**" shall mean all labels and other written, printed, or graphic matter upon (a) the Products or any container or wrapper utilized with the Products or (b) any written material accompanying the Products, including, without limitation, package inserts.

"**Launch Date**" shall mean, as applicable, the Nucynta IR Authorized Generic Launch Date or the Nucynta ER Authorized Generic Launch Date.

"**Manufacturing**" shall mean the manufacture, testing, filling, finishing, Labeling, Packaging, storage, and quality control of the Products and the API, each in accordance with the specifications, GMP and all Applicable Law, and including the manufacturing of stability, trial and submission batches. "**Manufacture**" and "**Manufactured**" shall have correlative meanings.

"**Manufacturing Agreement**" shall mean an agreement between Collegium and Hikma pursuant to which (a) Collegium will supply Hikma its total requirements of Products for Hikma's commercialization in the Territory at Collegium's fully burdened manufacturing cost, (b) Collegium will Manufacture and supply to Hikma finished Products ready for commercial sale and (c) Collegium will be responsible for all aspects of commercial Manufacturing of the Products, including sourcing of API and managing its contract manufacturer and supply chain vendors.

"**Market**" shall mean to use, advertise, market, offer, sell, offer to sell, or to otherwise commercialize a pharmaceutical product, and "**Marketing**" and "**Marketed**" shall have a corresponding meaning. For the avoidance of doubt, Market, Marketing and Marketed shall include "commercial marketing" as defined in 21 C.F.R. §314.3(b), as that regulation exists as of the Effective Date.

"**NDA**" shall mean the new drug application for each Product approved by the FDA, and any supplements and amendments thereto, and including all data and information comprising all modules of the NDA and other data and information necessary for the full enjoyment and support of the NDA.

"**NDA Products**" shall mean, collectively, the branded Tapentadol Hydrochloride tablet products that: (a) contain the Compound as the sole active ingredient; (b) are Marketed by Collegium with use of the Trademark in the Territory; and (c) are approved for Marketing in the Territory pursuant to NDA #200533 or NDA #022304.

"**Net Profit**" shall mean [***].

"**Net Sales**" shall mean the gross revenues derived from the sale by or on behalf of Hikma or any of its Affiliates of the Products to Third Parties, in each case, after subtracting the following items, in accordance with U.S. GAAP and in accordance with Hikma's standard practices for its other pharmaceutical products, consistently applied and actually, as applicable, taken, paid, accrued, allocated or allowed with respect to each Product:

(a) [***];

(b) [***]; and

(c) [***].

For the avoidance of any doubt, sales between Hikma and any of its Affiliates do not fall within the scope of this definition of "Net Sales."

[***]

"**Nucynta ER Authorized Generic**" shall mean the Authorized Generic pharmaceutical product under NDA #200533, in 50 mg extended-release oral tablets, 100 mg extended-release oral tablets, 150 mg extended-release oral tablets, 200 mg extended-release oral tablets, and 250 mg extended-release oral tablets.

"**Nucynta IR Authorized Generic**" shall mean the Authorized Generic pharmaceutical product under NDA #022304, in 50 mg oral tablets, 75 mg oral tablets, and 100 mg oral tablets.

"**Obsolete and Slow Moving Items**" shall mean a cost associated with unsold inventory, other than inventory included in the "initial volume" of Nucynta IR Authorized Generic manufactured and labeled for Hikma pursuant to Section 1.3(d)(i), recorded in accordance with Hikma's historical accounting policies.

"**Packaging**" shall mean all primary containers, including blisters, cartons, shipping cases or any other like matter used in packaging or accompanying the Products.

"**Person**" shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

"**Products**" shall mean, collectively, the Nucynta ER Authorized Generic and the Nucynta IR Authorized Generic.

"**Regulatory Authority(ies)**" shall mean any and all Governmental Authorities whose approval is necessary to Manufacture and Market the Products in the Territory.

"**SG&A**" shall mean Hikma's sales and general administrative expenses directly related to the Products, which shall equal [***].

"**Territory**" shall mean the United States.

"**Third Party**" shall mean a party other than Hikma, Collegium, or any of their respective Affiliates.

"**Trade Dress**" shall mean the trade dress, Packaging and Labeling for the Products.

"**Trademark**" shall mean the trademark Nucynta and any other trademark, service mark, corporate name or logo owned or controlled by Collegium or any of its Affiliates and used in connection with the sale or distribution of an NDA Product in the Territory.

"**Transfer Price**" shall mean [***].

"**United States**" or "**U.S.**" shall mean the United States of America and its territories, commonwealths, and possessions, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

ARTICLE 1
DISTRIBUTION RIGHTS; LAUNCH DATE

Section 1.1 **Appointment**. Subject to the terms and conditions set forth in this Agreement, Collegium appoints Hikma as distributor of the Products in the Territory as of the applicable Launch Date for each Product and for the Term of this Agreement and, in connection with such appointment, grants to Hikma the exclusive (even as to Collegium) right to Market the Products in the Territory. Subject to the terms and conditions set forth in this Agreement, Hikma accepts the appointment to represent Collegium as its authorized distributor of the Products in the Territory as of the applicable Launch Date for each Product and for the Term of this Agreement, and will use Commercially Reasonable Efforts to maximize sales of the Products in the Territory during the Term. Hikma shall have the right to exercise its rights granted under this Section 1.1 through any of its Affiliates (for so long as it remains an Affiliate), without the consent of Collegium; provided that Hikma provides Collegium with advance notice of any such delegation and Hikma shall be responsible for the compliance of, and shall guarantee the performance of, each of its Affiliates under this Agreement. Collegium acknowledges and agrees that Hikma shall be the exclusive (even as to Collegium or its Affiliates) distributor of the Products for the Term, provided, that the foregoing shall not limit or restrict Collegium's right to Market, whether directly or indirectly, the NDA Products or any other products that contain the Compound in combination with any other API.

Section 1.2 **Pre-Launch Activities**. On a Product-by-Product basis, prior to the applicable Launch Date to the extent reasonably necessary for Hikma to be prepared to Market each Product as of the applicable Launch Date for such Product, Hikma shall have the right to engage in the following pre-launch activities set forth below:

(a) Communications, including, without limitation, the preparation of offers, with health care providers, payors and government agencies, buyers, pharmacies and wholesalers, or other buying groups, provided, that Hikma shall provide written notice to Collegium before the commencement of such communications, which notice shall also constitute notice of commencement of activities under clauses (c), (d) and (e) below, unless Hikma advises otherwise;

(b) Placing an initial order with Collegium for the Product in accordance with the Manufacturing Agreement;

(c) Including the Product at any time prior to the Launch Date in any presentation regarding its overall product pipeline to prepare for launch activities;

(d) Listing the reference price of the Product with compendia forty-eight (48) hours before anticipated launch; and

(e) Shipping Product under quarantine prior to launch, "red shroud" where appropriate.

Section 1.3 Launch Date and Launch Quantities.

(a) Subject to availability of Launch Quantities (as defined below), Hikma shall launch the Nucynta IR Authorized Generic on the earlier to occur of (such date, the "**Nucynta IR Authorized Generic Launch Date**") (i) [***] and (ii) in the event of a launch by a Third Party of a Generic Equivalent of the Nucynta IR Authorized Generic in the Territory, as soon as possible and in no event later than [***] business days after such launch actually occurs.

(b) Hikma shall launch the Nucynta ER Authorized Generic on the earlier to occur of (such date, the "**Nucynta ER Authorized Generic Launch Date**") (i) [***] and (ii) [***] days following a launch by a Third Party of a Generic Equivalent of the Nucynta ER Authorized Generic in the Territory.

(c) During the Term, each Party shall use reasonable efforts to notify the other in writing at least thirty (30) calendar days in advance of any expected occurrence of the event set forth in Section 1.3(a)(ii) and Section 1.3(b)(ii) known to such Party. Collegium shall promptly, and in any event within five (5) business days, notify Hikma in writing of the Approval or denial of pediatric exclusivity by FDA for each Product.

(d) Launch Quantities for Nucynta IR Authorized Generic.

(i) The Parties' intent is for Hikma to launch the Nucynta IR Authorized Generic in the Territory no later than the market entry of a Generic Equivalent of such Product by a Third Party in the Territory. Accordingly, and, provided that Collegium obtains DEA quota as necessary under Applicable Law to Manufacture and supply Hikma with Hikma's forecasted supply quantities of the Nucynta IR Authorized Generic in accordance with the terms of the Manufacturing Agreement, Collegium shall have a certain initial volume of the Nucynta IR Authorized Generic Manufactured and Labeled for Hikma no later than (such date, the "**Launch Delivery Date**"): [***].

(ii) Hikma may waive Collegium's obligations under clause (i) above if [***]. Notwithstanding any of the provisions in this Section 1.3(d)(ii) to the contrary, if Collegium's obligations have been timely waived, and [***], then Collegium will use Commercially Reasonable Efforts to provide Launch Quantities on, or as soon as possible after, the Launch Delivery Date.

(iii) Hikma will pay Collegium the Transfer Price for all of the "initial volume" of Nucynta IR Authorized Generic manufactured and labeled for Hikma pursuant Section 1.3(d)(i) above regardless of whether or when market entry of a Generic Equivalent by a Third Party occurs, the details of the corresponding invoicing and payment to be set forth in the Manufacturing Agreement. Any and all such "initial volume" of Nucynta IR Authorized Generic manufactured and labeled for Hikma pursuant Section 1.3(d)(i) will not be deemed Obsolete and Slow Moving Items regardless of the remaining shelf life for such inventory of Product at the time of Hikma's First Commercial Sale of such Product. [***].

ARTICLE 2
REGULATORY, MANUFACTURING, AND COMMERCIALIZATION MATTERS

Section 2.1 Regulatory Matters.

(a) DEA Quota. During the Term, Collegium shall use Commercially Reasonable Efforts to obtain DEA quota as necessary under Applicable Law to supply Hikma with Hikma's initial launch and ongoing forecasted supply quantities of the Products under the Manufacturing Agreement. [***].

(b) FDA and Other Regulatory Correspondence. Collegium shall be responsible for fulfilling all applicable notice requirements with FDA regarding the Marketing of the Products and the appointment of Hikma as distributor of the Products. Each Party shall promptly inform the other of any correspondence from the FDA or other regulatory authority, or the results of any inspections by the FDA or other regulatory authority, that would reasonably be expected to materially affect its ability to meet its obligations under this Agreement. Additionally, to the extent required by Applicable Law and requested by Hikma, Collegium agrees to file all advertising and marketing collateral and other documentation requested to be utilized by Hikma in connection with and regarding the Products, with the FDA Office of Prescription Drug Promotion within [***] business days from the date of receipt of such request from Hikma.

Section 2.2 Manufacturing and Supply.

(a) Manufacturing of the Products. Collegium shall exclusively (even as to Collegium) Manufacture and supply Hikma with, and Hikma shall exclusively purchase from Collegium, all of the quantities of the Products which Hikma requires to be sold in the Territory. As soon as reasonably practicable, and in [***], the Parties shall negotiate in good faith and enter into the Manufacturing Agreement, which will include provisions addressing remedies for failure to supply, supply deficiencies, and back-up/alternate manufacturing and other customary terms pertaining to the manufacturing and supply of the Products, and any and all agreements contemplated

thereunder providing for manufacture and supply by Collegium of the Products to Hikma in finished dosage form, packaged and labeled for commercial sale in the Territory.

(b) Quality; Nonconforming Supply. Prior to the Manufacturing of the first batch of a Product, the Parties will enter into a quality agreement (the "**Quality Agreement**"). The terms of the Quality Agreement, as amended from time to time by mutual written agreement of the Parties hereto, shall be incorporated herein by this reference. To the extent any of the terms of the Quality Agreement conflict with any of the terms of this Agreement, the applicable terms of the Quality Agreement shall control solely as to quality issues related to the Product and its Manufacture and all other terms of this Agreement shall control as to all other matters.

Section 2.3 Commercialization.

(a) Subject to Collegium's timely performance of its obligations under this Agreement and the Manufacturing Agreement, Hikma shall use Commercially Reasonable Efforts to Market and sell the Products in the Territory under Hikma's label, including without limitation developing sales, distribution and marketing plans, and booking sales either alone or in collaboration with Third Parties in a manner to maximize sales of the Products.

(b) Notwithstanding the foregoing, Hikma in its sole discretion shall determine independently the pricing of the Products in the Territory, terms of sale, marketing, and selling decisions for the Products without any consultation with, input from, or prior notice to Collegium, and the manner and extent of the commercialization of the Products (including issues concerning labeling, launch dates, terms of sale and pricing and customer contracts).

(c) Labeling and Packaging. The Trade Dress for the Products shall be under Hikma's labeling and artwork. When requested by Collegium, but in any event reasonably in advance of when Collegium will be required to Manufacture a Product for Hikma, Hikma shall provide all artwork and supporting materials and information required to Label the Products with Hikma's trademark, logos and design. Hikma shall ensure that all Trade Dress complies with all Approvals. Hikma hereby grants to Collegium a non-exclusive license to Hikma Trade Dress, Hikma's trademarks, and trade name solely to the extent necessary for Collegium to Manufacture and supply to Hikma finished Products ready for commercial sale.

(d) Hikma's ANDA. From the Effective Date until the date Hikma provides notice under this clause (d), Hikma and its Affiliates will not, whether directly or indirectly, assist any Third Party in researching, developing, seeking or obtaining Approval for, or Marketing any Generic Equivalent of either Product, provided, that, following the one (1) year anniversary of the First Commercial Sale of each Product, Hikma will have the option to launch its own Generic Equivalent of such Product in the Territory by providing Collegium written notice of such election at least one (1) year prior to its planned launch of such Generic Equivalent. Notwithstanding the foregoing, Hikma will not have the right to Market either Product, including during the Sell-Off Period, at the same time it is selling its own Generic Equivalent of either Product.

ARTICLE 3
PAYMENT TERMS

Section 3.1 **Profit Sharing.** From and after the First Commercial Sale of a Product, during the Term, Hikma shall pay to Collegium, on a quarterly basis, the percentage of the Net Profits (the "**Collegium Profit Share Percentage**") set forth below based on the number of Third Parties selling a Generic Equivalent in the Territory at any time during the applicable quarter based on the earliest entry of the Product into First Databank or MediSpan:

Collegium Profit Share Percentage	Number of Third Parties selling a Generic Equivalent in the Territory
8[***]%	None
[***]%	[***]
[***]%	[***]
[***]%	[***]

[***].

For each calendar quarter, the Collegium Profit Share Percentage in the table above shall be applied to all Net Sales occurring on each day during such calendar quarter with the corresponding number of Third Party Generic Equivalents being sold. For example, if a single Third Party sells a Generic Equivalent for the last fifteen (15) days of a calendar quarter, then the Collegium Profit Share Percentage of eighty-[***] percent (8[**]%) shall be applied to the first forty-five (45) days of the calendar quarter and the Collegium Profit Share Percentage of [***] shall be applied to the last fifteen (15) days of the calendar quarter.

Other than amounts included in the Transfer Price, all other disbursements of monies, revenues, receipts or other consideration previously agreed to by Collegium with any Third Party with respect to the Products shall be paid by Collegium out of the Collegium Profit Share Percentage.

Section 3.2 **Mechanism of Payments.** Net Sales and Net Profit, including actual Transfer Price as calculated by Collegium and provided to Hikma, will be calculated for each calendar quarter, and the Collegium Profit Share Percentage will be paid within [***] days after the end of each calendar quarter in which the applicable Net Sales are deemed to have occurred. Hikma shall provide Collegium with monthly estimates of Net Sales and Net Profit calculations by the [***] business day after the month end so that Collegium can continue to close its books within [***] business days after the end of each month. Hikma will provide to Collegium reasonable supporting documentation as needed for the Net Sales and Net Profit calculations and will use commercially reasonable efforts to assist Collegium in responding to questions or for more information on the amounts calculated for purposes of closing its books and obtaining audit support. In addition, at least annually, Hikma will provide Collegium with a forecast of Net Sales and Net Profit so that both Collegium and Hikma can better understand expectations for Net Sales and Net Profit for the upcoming fiscal year for financial planning purposes. All payments made pursuant to this Agreement will be made in United States Dollars. All payments will be made by wire transfer of

immediately available funds, without set-off (except as permitted under Section 3.1), reduction, deduction, or withholding, including withholding for or on account of any taxes except as required by Applicable Law, to a bank account as designated in writing by Collegium.

Section 3.3 **Taxes; Withholding.** Each Party shall be responsible for and shall pay all taxes payable on any income to or derived by such Party under this Agreement. Each Party shall bear sole responsibility for payment of compensation to their respective personnel, employees and subcontractors and for all employment taxes and withholding with respect to such compensation pursuant to Applicable Law. The Parties acknowledge that no withholding is applicable to the payments from Hikma to Collegium under this Agreement. In the event, however, Applicable Law requires Hikma to withhold any tax from any payment due to Collegium under this Agreement (taking into account any legally available reduction or elimination of such tax pursuant to an applicable tax treaty), then Hikma will subtract the amount thereof from the payments to Collegium, and pay such amount to the proper taxing authority. Hikma will promptly (as available) submit to Collegium appropriate proof of payment of the withheld taxes as well as the official receipts within a reasonable period of time, provided that the amount payable by Hikma to Collegium shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this paragraph), Collegium receives an amount equal to the sum it would have received had no such deduction or withholding been made.

Section 3.4 **Audit Right.**

(a) Hikma shall have the right to have a qualified accounting firm of its own selection and at its own expense (except as provided below), examine the relevant books and records of account of Collegium for the twelve (12) months prior to such audit during reasonable business hours upon reasonable prior written notice to Collegium and not more often than once each calendar year, to determine the accuracy of Collegium's calculation of Cost of Goods Sold and the Transfer Price. If an audit finds an overpayment of any of the foregoing by Hikma, Collegium shall promptly refund the full amount of such overpayment. If an audit finds an underpayment of any of the foregoing by Hikma, Hikma shall promptly pay to Collegium the full amount of such overpayment. If an audit finds an overpayment by Hikma of greater than [***], Collegium shall promptly pay or reimburse Hikma for the cost of the audit. The accounting firm performing the audit shall treat as confidential and shall not disclose to Hikma any information other than information which could otherwise be given to Hikma pursuant to any provision of this Agreement. This right shall survive the termination of this Agreement for [***] years.

(b) Collegium shall have the right to have a qualified accounting firm of its own selection and at its own expense (except as provided below), examine the relevant books and records of account of Hikma for the twelve (12) months prior to such audit during reasonable business hours upon reasonable prior written notice to Hikma and not more often than once each calendar year, to determine the accuracy of Hikma's calculation and reporting of Net Sales and Net Profit and the components thereof. If an audit finds an overpayment of any of the foregoing by Hikma, Collegium shall promptly refund the full amount of such overpayment. If

an audit finds an underpayment of any of the foregoing by Hikma, Hikma shall promptly pay to Collegium the full amount of such underpayment. If an audit finds an underpayment by Hikma of greater than [***]%, Hikma shall promptly pay or reimburse Collegium for the cost of the audit. The accounting firm performing the audit shall treat as confidential and shall not disclose to Collegium any information other than information which could otherwise be given to Collegium pursuant to any provision of this Agreement. This right shall survive the termination of this Agreement for [***] years.

ARTICLE 4
ADDITIONAL REPRESENTATIONS AND WARRANTIES

Section 4.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) Corporate Existence. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized.

(b) Authorization and Enforcement of Obligations. Such Party:

(i) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder;

(ii) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, and enforceable against such Party in accordance with its terms; and

(iii) has sufficient legal and/or beneficial title under its Intellectual Property necessary for the purposes contemplated under this Agreement and to grant the licenses contained in this Agreement.

(c) Consents. All necessary consents, approvals and authorizations of all Governmental Authorities required to be obtained by such Party in connection with its performance of this Agreement have been obtained.

(d) No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Law and (ii) do not conflict with, or constitute a default under, any material contractual obligation of such Party.

(e) No Disbarment. Neither such Party nor its Affiliates nor any person employed or engaged by any of the foregoing in connection with the work to be performed under this Agreement has been debarred under Section 306(a) or 305(b) of The Federal Food, Drug, and Cosmetic Act and no debarred person will in the future be

employed or engaged by such Party or its Affiliates in connection with any work to be performed hereunder.

Section 4.2 **By Collegium.** In addition to any and all other representations and warranties set forth herein, Collegium hereby represents and warrants to Hikma that as of the Effective Date:

(a) it has sufficient rights to grant the rights and licenses granted herein, free and clear of any security interests, claims, encumbrances or charges of any kind that would conflict in any material respect with the rights and licenses granted under this Agreement;

(b) it has not assigned or granted to any Third Party any rights that cover the Products in the Territory; and

(c) to the knowledge of Collegium, the Manufacture of the API for use in the Products in the Territory, and the Manufacture and Marketing of the Products in the Territory shall not constitute a misappropriation, infringement or other violation of any Intellectual Property or proprietary rights of any Third Party.

ARTICLE 5
INDEMNIFICATION

Section 5.1 **Collegium's Indemnity Obligations**. Collegium shall indemnify, defend, and hold harmless Hikma, its Affiliates, and their respective successors and permitted assigns (and the respective officers, directors, stockholders, and employees of each) from and against any and all losses, liabilities, claims, actions, proceedings, damages, and expenses (including without limitation reasonable attorneys' fees and expenses) (collectively, "**Damages**") arising out of a claim, suit, action, or other proceeding brought by a Third Party (each, a "**Claim**"), to the extent related to:

(a) the Manufacturing of the Products for Hikma, including without limitation the handling, storage or use of the Products in connection therewith;

(b) any violation of Applicable Law by Collegium or its Affiliates;

(c) any breach by Collegium or its Affiliates of this Agreement, or its representations, warranties, covenants, agreements, or obligations under this Agreement;

(d) any Third Party product liability claims for the Products in the Territory; or

(e) any claims, infringement, or misappropriation relating to the Products, API or Manufacturing of the Products.

Section 5.2 **Hikma's Indemnity Obligations**. Hikma shall indemnify, defend, and hold harmless Collegium, its Affiliates and their respective successors and permitted assigns (and the respective officers, directors, stockholders, and employees of each) from and against any and all Damages arising out of a Claim, to the extent related to:

(a) the Marketing of the Products by or on behalf of Hikma or its Affiliates in the Territory;

(b) any violation of Applicable Law by Hikma or its Affiliates; or

(c) any breach by Hikma or its Affiliates of this Agreement, its representations, warranties, covenants, agreements, or obligations under this Agreement.

Section 5.3 **Indemnification Procedures**. To claim indemnification under this ARTICLE 5, a Party shall notify the other Party promptly in writing of the covered Claim in respect of which it believes it is entitled to claim indemnification, provided that the failure to give timely notice to the other Party shall not release such Party from any liability hereunder except to the extent that such Party is prejudiced thereby. The indemnifying Party shall have the right, by notice to the indemnified Party, to assume the defense of any such Claim within the [***] day period after its receipt of such notice with counsel of its choice and at its sole cost and expense. If the indemnifying Party so assumes such defense, the indemnified Party may participate therein through counsel of its choice, but at its sole cost. The indemnified Party shall render all reasonable assistance to the indemnifying Party, and all reasonable out-of-pocket costs of such assistance shall be for the account of the indemnifying Party. Neither Party may enter into any settlement, consent judgment or final disposition of any patent infringement litigation Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 5.4 **Limitation of Liability**. EXCEPT WITH RESPECT TO LIABILITY ARISING FROM A PARTY'S (A) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT IN ITS PERFORMANCE UNDER THIS AGREEMENT, (B) INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT OR (C) INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL DAMAGES, OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY, OR OTHERWISE, ARISING OUT OF THE TRANSACTIONS CONTEMPLATED HEREUNDER, INCLUDING, BUT NOT LIMITED TO, THE MARKETING, SALE, OR USE OF THE PRODUCTS.

Section 5.5 **Insurance**. Collegium and Hikma each shall maintain and keep in full force and effect during the Term and for [***] years after termination or expiration of this Agreement comprehensive general liability insurance in such amounts as it customarily maintains for similar products and activities, but in no event less than [***] per individual claim and [***] in the aggregate. Collegium shall cause Hikma to be named as an additional insured under such insurance and shall provide Hikma proof of such insurance upon request. Under no circumstances shall either Party cancel, terminate or reduce any of the foregoing insurance coverages below the minimum amounts set forth in this Section 5.5 without a minimum of [***] days' prior written notice to the other Party.

ARTICLE 6
PHARMACOVIGILANCE; RECALLS

Section 6.1 **Pharmacovigilance.** Together with the Parties entry into the Quality Agreement, the Parties shall enter into a separate pharmacovigilance agreement, or incorporate all applicable pharmacovigilance terms in the Manufacturing Agreement, setting forth each Party's responsibilities with respect to safety surveillance and monitoring for the Products in the Territory.

Section 6.2 **Product Recalls.** In the event either Party is ordered by a Regulatory Authority, Collegium believes, or the Parties mutually agree, that it is necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action (a "**Recall**") with respect to either of the Products in the Territory, the Parties will mutually agree as to how best to proceed, including the roles and responsibilities for conducting such Recall, all of which shall be set forth in and governed by the Quality Agreement. Collegium shall replace the quantities of Products returned to Hikma as a result of the Recall or destroyed as a result of the Recall in accordance with the timing set forth in this Agreement or the Quality Agreement and at no additional cost to Hikma unless such Recall is due to Hikma's negligence, gross negligence or willful act or omission or a material breach of this Agreement or violation of Applicable Law. Without limiting the foregoing, unless a Recall is due to Hikma's negligence, gross negligence or willful act or omission or a material breach of this Agreement or violation of Applicable Law, Collegium shall bear all costs and expenses resulting from the Recall, subject to its indemnification rights hereunder.

ARTICLE 7
INTELLECTUAL PROPERTY

Each Party shall retain ownership of any Intellectual Property that it owns or controls on or prior to the Effective Date (as to each Party, "**Pre-Existing IP**"). Collegium hereby grants to Hikma a royalty-free license under Collegium's Intellectual Property to Market the Products in the Territory under this Agreement. Collegium shall maintain its Pre-Existing IP that is necessary for Hikma to Market the Products in the Territory under this Agreement. Hikma and its Affiliates shall have the right to use their own Pre-Existing IP associated with Hikma's name in connection with the labeling and distribution of the Products, provided that such use is consistent with how Hikma routinely uses such Intellectual Property in connection with the labeling and distribution of its generic products. Neither Party shall use the Intellectual Property owned by the other Party in connection with any other goods or products.

ARTICLE 8
CONFIDENTIALITY AND PUBLIC DISCLOSURE

Section 8.1 **Confidentiality**. Except as expressly permitted in this Agreement, each Party shall, during the Term and for a period of five (5) years thereafter, treat as confidential and shall not publish or otherwise disclose the Confidential Information of the other Party for any purpose, and will take all necessary precautions to assure the confidentiality of such Confidential Information of the other Party. Each Party agrees to return to the other Party upon the expiration or termination of this Agreement all Confidential Information acquired from such other Party, except as to such information it may be required to retain under Applicable Law including ensuring compliance with its regulatory obligations, and in such case, the receiving Party may retain one (1) copy of such Confidential Information in its legal files for the purpose of determining its continuing obligations

under this Agreement. For the avoidance of doubt, retention of electronic copies of Confidential Information maintained pursuant to regular data archiving and record retention policies and practices shall not be deemed to be a violation of this Agreement.

Section 8.2 **Authorized Disclosure**. Except as expressly provided otherwise in this Agreement, a receiving Party shall be entitled to disclose Confidential Information of the disclosing Party as follows: (a) to the receiving Party's Affiliates, employees, officers, directors, agents, consultants, distributors, legal counsel and other Third Parties under appropriate confidentiality provisions no less stringent than those in this Agreement, in connection with the performance of its obligations or exercise of its rights under this Agreement; (b) to the extent such disclosure is reasonably necessary in defending litigation, complying with applicable governmental regulations or otherwise required by Applicable Law; provided, however, that if a receiving Party is required by Applicable Law to make any such disclosure of a disclosing Party's Confidential Information it will give reasonable advance notice, where practicably possible, to the disclosing Party of such disclosure requirement and will use its commercially reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (c) to potential or actual acquirers, merger candidates, licensees or investors or venture capital firms, investment bankers or other financial institutions, lenders or investors, and professional advisors thereof, provided, that in connection with such disclosure, such receiving Party shall inform each such disclosee of the confidential nature of such Confidential Information and cause each such disclosee to treat such Confidential Information as confidential; or (d) to the extent mutually agreed to in writing by the Parties; provided, however, that, in each case, the receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.2 to treat such Confidential Information as required under this Article 8.

Section 8.3 **Public Disclosure**. Except as set forth in this Section 8.3 or as contemplated by Section 1.2, no announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, the subject matter hereof, or either Party's performance hereunder will be made without the other Party's prior written approval, which approval shall not be unreasonably withheld. The Parties have agreed upon the form and content of their own press releases, if any, that may be issued by each of the Parties following the execution of this Agreement in the forms attached hereto as Exhibit B. Once such press release or any other written statement is approved for disclosure by the Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. Any other publicity, news release, public comment or other public announcement, whether to the press, to stockholders, or otherwise, relating to this Agreement, shall first be reviewed and approved by the Parties, except no such approval shall be required for such publicity, news release, public comment or other public announcement which, in accordance with the advice of legal counsel to the Party making such disclosure, is required by Applicable Law or for appropriate market disclosure; provided, however, that each Party shall be entitled to refer publicly to the relationship of the Parties reflected in this Agreement in a manner that is consistent with the press releases issued by the Parties. For clarity, any Party making any announcement which is required by Applicable Law will, unless prohibited by law, give the other Party an opportunity to review the form and content of such announcement and comment before it is made. The Parties shall work together to coordinate their respective filings with governmental agencies, including the United States Securities and Exchange Commission ("**SEC**"), as to the contents and existence of this Agreement as each Party shall

reasonably deem necessary or appropriate and each Party shall provide the other Party an opportunity to comment on any proposed filings to ensure consistent treatment. The Parties acknowledge that this Agreement and the Manufacturing Agreement may need to be filed by one or both Parties with the SEC. The Parties agree, prior to making any such filing with the SEC, to provide the other Party and its counsel with a proposed redacted version of this Agreement (or the Manufacturing Agreement, as applicable) which it intends to file with the SEC, and to give due consideration to any comments provided by the other Party or its counsel and use reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by such other party or its counsel.

ARTICLE 9
TERM AND TERMINATION

Section 9.1 **Term**. Unless terminated earlier pursuant to Section 9.2 below the term of this Agreement shall expire on the date that is [***] years after the First Commercial Sale of the first Product in the Territory (the "**Initial Term**"), and shall automatically renew for additional terms of [***] each (each, a "**Renewal Term**," and together with the Initial Term, the "**Term**") unless written notice is provided by a Party to the other Party no later than [***] days before the expiration of the Initial Term or the then-current Renewal Term.

Section 9.2 **Termination**.

(a) By Either Party. A Party may terminate this Agreement (i) for material breach by the other Party that is not cured within [***] days of written notice thereof; (ii) upon at least [***] calendar days prior written notice thereof if the other Party makes an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such Party, or has a receiver or trustee appointed for all or substantially all of its property, provided that in the case of an involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] calendar days after the filing thereof; and (iii) upon written notice to the other Party in the event that the Parties fail to enter into the Manufacturing Agreement prior to [***] despite the use of good faith efforts of the Parties.

(b) By Hikma. In the event that Hikma notifies Collegium that Hikma intends to launch its own Generic Equivalent of either Product pursuant to Section 2.3(d), then this Agreement shall terminate in its entirety effective upon the expiration of the Sell-Off Period for such Product.

(c) Effect of Expiration and Termination.

(i) The expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination and shall pay the respective amounts accrued prior to such termination or expiration. The provisions of Sections 3.4, 6.2 and this 9.2(c) as well as those of the Definitions, ARTICLE 5, ARTICLE 7, ARTICLE

8, and ARTICLE 11 shall survive the expiration or termination of this Agreement. Upon termination or expiration for any reason, each Party shall deliver to the other Party (and cause any of its employees, agents, or representatives to so deliver), all Confidential Information of the other Party in accordance with Section 8.1 of this Agreement.

(ii) Subject to last sentence of Section 2.3(d), Hikma shall have a right to sell off its inventory of Products supplied hereunder or under the Manufacturing Agreement during the [***] months following the earliest to occur of the effective date of (a) termination of this Agreement by Hikma pursuant to Section 9.2(a), (b) expiration of this Agreement in accordance with either Party's notice of non-renewal under Section 9.1, or (c) termination of this Agreement in accordance with Hikma's provision of notice to Collegium of Hikma's intent to launch its own Generic Equivalent under Section 2.3(d) (each, the "**Sell-Off Period**"). Hikma shall discontinue Marketing of all Products under this Agreement upon the earlier to occur of (x) Collegium's termination pursuant to Section 9.2(a) and (y) expiration of the Sell-Off Period. Without limiting the foregoing, Hikma and Collegium will work in good faith to facilitate an orderly winddown pursuant to a mutually agreed transition plan, which may include Hikma purchasing additional Product as mutually agreed by the Parties in good faith as necessary for Hikma to satisfy its then existing customer agreements during the Sell-Off Period.

(iii) Notwithstanding any of the foregoing, Hikma may inform Collegium of any tender or contractual obligation for a Product undertaken by Hikma prior to expiry or termination or which could be undertaken pursuant to a bid or offer submitted by Hikma prior to expiry or termination ("**On-going Supply Commitments**"). If there are On-going Supply Commitments for a Product of which Collegium is aware prior to expiration or termination of this Agreement, the Parties agree as follows: (a) Hikma shall be entitled to comply with its obligations under the On-going Supply Commitment after the expiry or termination until the expiry of such On-going Supply Commitment and (b) Hikma shall be entitled to purchase such Product from Collegium, who shall sell it to Hikma, and the provisions of this Agreement shall continue to be effective to the extent necessary for Hikma to comply with its On-going Supply Commitments.

ARTICLE 10
COMPLIANCE, ANTI-BRIBERY, AND ANTI-CORRUPTION

Section 10.1 **Compliance**. In performing their obligations under this Agreement, the Parties agree to abide by Applicable Law, including without limitations, the FDA's "*Guidance for Industry-Supported Scientific and Educational Activities*"; "*Guidelines for Gifts to Physicians*", issued by the American Medical Association; PhRMA Code on Interaction with Healthcare Professionals; and any other governing accrediting body standards applicable to the performance of this Agreement as described herein. In addition to the foregoing, each Party warrants, represents, and undertakes to the other Party that it:

(a) shall comply with all Applicable Laws relating to anti-bribery and anti-corruption (including the UK Bribery Act 2010, should it apply, and the United States Foreign Corrupt Practices Act 1977) (the "**Anti-Bribery Laws**");

(b) shall not engage in any activity, practice or conduct which would constitute an offence under the UK's Bribery Act 2010 if such activity, practice, or conduct had been carried out in the United Kingdom;

(c) shall not do, or omit to do, any act that will cause or lead the other Party (or any of its Affiliates, directors, officers or employees) to be in breach of the Anti-Bribery Laws;

(d) shall promptly report to the other Party any request or demand for any undue financial, pecuniary, or other advantage of any kind received by it (or any of its Affiliates, directors, officers or employees) in connection with the performance of this Agreement;

(e) has and shall maintain in place during this Agreement's Term its own policies and procedures, including procedures to mitigate the risks of non-compliance with the Anti-Bribery Laws and this Section 10.1, and will comply, monitor, and enforce them as appropriate;

(f) has not and will not, and will procure that its directors, officers, employees, and Affiliates have not and will not, make, promise, or offer (or accept, request, demand, receive, or agree to receive) any gift, payment, reward, rebate, contribution, commission, or any improper influence, incentive, inducement, or advantage of any kind (financial or otherwise and including any '*facilitation*' or '*grease*' payment to facilitate or expedite particular functions in relation to this Agreement and the obligations under it), directly or indirectly, to or from any foreign public official, government, or administrative officer, political party, political, or charitable organization or other party or person (or imply or infer that such party will or might do any such thing at any time in the future), which would contravene any industry best practice, Anti-Bribery Laws applicable to the Parties and their respective Affiliates;

(g) is not and has not been, and none of its directors, officers, employees, or Affiliates is or has been, the subject of any investigation, inquiry, or enforcement proceedings by any Governmental Body or any other person regarding any offence or alleged offence under any Anti-Bribery Laws in any jurisdiction, and no such investigation, inquiry, or proceedings have been threatened or are pending and there are no circumstances likely to give rise to any such investigation, inquiry or proceedings. For the purposes of this ARTICLE 10 only, "**Governmental Body**" shall mean any (a) federal, state, local, municipal, foreign, or other government or (b) governmental or quasi-governmental body of any nature (including any regulatory authority, whereby a regulatory authority shall mean any competent regulatory authority, agency, or other governmental authority that has jurisdiction over the transactions contemplated hereunder), governmental division, governmental or political subdivision, department, agency or instrumentality, bureau, branch, office, commission, council, tribunal (including a judicial tribunal), or board of any governmental body, or any federal, state, local, or foreign court or arbitrator; and

(h) is not a foreign public official nor is it associated with a foreign public official.

Section 10.2 Prevention of the Facilitation of Tax Evasion. To the extent applicable, each Party shall, and shall procure that all persons who are "associated" with such Party for the purposes of section 44 of the United Kingdom Criminal Finances Act 2017 (the "CFA 2017") and who are engaged to perform this Agreement ("**Associates**") shall at all times comply with, in the absence of its own policies in this regard, the other Party's policy in respect of the prevention of the criminal facilitation of tax evasion (the "**Prevention of Tax Evasion Policy**") details of which have been disclosed by each Party to the other Party. Accordingly, each Party hereby warrants, represents, and/or undertakes that:

(a) it and all its Associates have acted and will act in compliance with all Applicable Law relating to the criminal facilitation of tax evasion (including the CFA 2017) in the performance of this Agreement;

(b) it shall provide the other Party with all reasonable assistance to enable the other Party to comply with the CFA 2017 including, without limitation, monitoring compliance by its Associates with the Prevention of Tax Evasion Policy and informing the other Party of any request by a Third Party to criminally facilitate tax evasion in connection with its performance of its obligations under this Agreement;

(c) it shall, use commercially reasonable efforts to, so far as reasonably possible, impose a contractual obligation not to criminally facilitate tax evasion on each of its Third Party Associates engaged in connection with its performance of its obligations under this Agreement;

(d) it shall promptly inform the other Party upon becoming aware of any facts or circumstances which would or may constitute a breach or potential breach, in connection with the performance of this Agreement with respect to the Prevention of Tax Evasion Policy or any Applicable Law relating to the criminal facilitation of tax evasion in any jurisdiction in which such Party or any of its Associates perform its or their obligations under this Agreement.

Section 10.3 Anti-Slavery.

(a) Each Party shall:

(i) comply with all Applicable Law related to Modern Slavery from time to time in force, including but not limited to the United Kingdom Modern Slavery Act 2015 (Modern Slavery Act) and the California Transparency in Supply Chains Act 2010 (TISCA);

(ii) not engage in any activity, practice or conduct that would constitute Modern Slavery. For the purposes of this Section 10.3, "**Modern Slavery**" shall mean "*forced or compulsory labor*" as defined in Article 2 of the International Labor Organization Forced Labor Convention 1930 and/or "*trafficking in persons*" as defined Article 3 of the Protocol to Prevent,

Suppress and Punish Trafficking in Persons, Supplementing the United Nations Convention Against Transnational Organized Crime (Palermo, 2000);

(iii) comply with, in the absence of its own policies in this regard, the Code of Conduct devised and applied by Hikma's ultimate parent, Hikma Pharmaceuticals PLC, and its subsidiaries, including Hikma, as amended from time to time, to the extent provided in writing to Collegium; and

(iv) participate in such training in connection with any Modern Slavery issues as Hikma or its ultimate parent, Hikma Pharmaceuticals PLC, may reasonably request.

(b) Each Party shall be responsible for any failure by any of its subcontractors or suppliers and their respective subcontractors and suppliers to:

(i) comply with, in the absence of its own policies in this regard, the Code of Conduct devised and applied by Hikma's ultimate parent Hikma Pharmaceuticals PLC and its subsidiaries, including Hikma, as amended from time to time;

(ii) comply with all applicable laws, statutes, and regulations related to Modern Slavery from time to time in force, including but not limited to the Modern Slavery Act and TISCA; and

(iii) not engage in any activity, practice, or conduct that would constitute Modern Slavery.

(c) Each Party shall promptly inform the other Party of the instigation of any formal action related to Modern Slavery, including (but not limited to):

(i) a formal cause of action;

(ii) a regulatory complaint; and

(iii) a non-judicial complaint, including but not limited to, those filed with international relief agencies, international governmental, and non-governmental associations.

(d) Each Party warrants and represents that neither such Party nor, to the best of its knowledge and belief, any of its board members, executive officers, owners, or employees has ever been convicted of any offence involving Modern Slavery.

(e) Each Party further warrants and represents that it is not aware, to the best of its knowledge and belief, of any instances of Modern Slavery directly or indirectly linked to its business operations, products, services, or supply chains.

ARTICLE 11
MISCELLANEOUS

Section 11.1 **Notices**. All notices or other communications given pursuant hereto by one Party hereto to the other Party shall be in writing and shall be by email with PDF attachment, courier service or personal delivery, in each case to the appropriate addresses set forth below (or to such other addresses as a Party may designate as to itself by notice to the other Party):

If to Hikma, to it at:

Hikma Pharmaceuticals USA Inc.
200 Connell Drive
Berkeley Heights, New Jersey 07922
Attention: Legal Department
Telephone: (908) 673-1486
Email: [***]

With a copy to (which shall not constitute notice):

Hikma Pharmaceuticals USA Inc.
200 Connell Drive
Berkeley Heights, New Jersey 07922
Attention: Hafrun Fridriksdottir, President
Email: [***]

If to Collegium, to it at:

Collegium Pharmaceutical, Inc.
100 Technology Center Drive | Suite 300
Stoughton, MA 02072
Attention: Shirley Kuhlmann,
EVP, Chief Administrative Officer & GC
Email: [***]

With a copy to (which shall not constitute notice):

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02110
Attention: Robert M. Crawford
Email: [***]

Section 11.2 **Assignment**. Neither Party shall, without first obtaining the other Party's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed, assign or transfer this Agreement to any Person, in whole or in part; provided, however, that each Party may assign or transfer this Agreement to any of its Affiliates without such consent, and the assigning Party shall remain liable for its obligations hereunder. Any purported assignment in violation of this provision shall be void and without effect. All of the terms and provisions of this Agreement

shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and permitted assigns.

Section 11.3 **Equitable Relief**. In the event of the actual or threatened breach by Collegium of any of the terms of ARTICLE 7 or ARTICLE 8 hereof, Hikma shall have the right to seek specific performance and injunctive relief. The rights granted by this Section 11.3 are in addition to all other remedies and rights available at law or in equity.

Section 11.4 **Severability**. If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and the Agreement shall be construed as if such portion had not been included herein, provided however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith.

Section 11.5 **Entire Agreement**. This Agreement, the Manufacturing Agreement and all Exhibits attached hereto and thereto contain the sole and entire agreement and understanding of the Parties hereto and their respective Affiliates and representatives related to the subject matter hereof and supersede all oral or written agreements (including without limitation term sheets) concerning the subject matter made prior to the Effective Date.

Section 11.6 **Amendment; Waiver**. This Agreement cannot be amended, changed, modified, or supplemented orally, and no amendment, change, modification, or supplement of this Agreement shall be recognized nor have any effect, unless the writing in which it is set forth is signed by Collegium and Hikma, nor shall any waiver of any of the provisions of this Agreement be effective unless in writing and signed by the Party to be charged therewith. The failure of either Party to enforce, at any time, or for any period of time, any provision hereof or the failure of either Party to exercise any option herein shall not be construed as a waiver of such provision or option and shall in no way affect that Party's right to enforce such provision or exercise such option. No waiver of any provision hereof shall be deemed to be, or shall constitute, a waiver of any other provision, or with respect to any succeeding breach of the same provision.

Section 11.7 **Governing Law; Jurisdiction**. This Agreement, the interpretation and enforcement of its terms and all claims or causes of action (whether in contract, tort, or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of New York, United States of America, without giving effect to the choice of law principles of any jurisdiction. The Parties agree to bring any actions or proceedings arising out of this Agreement in the federal and state courts located in the State of New York and to be bound by the decision of a court of competent jurisdiction.

Section 11.8 **Force Majeure**.

(a) Excuse of Performance. The obligations of the each Party hereunder shall be suspended during the time and to the extent that such Party is prevented from

complying therewith due to any event or circumstances beyond the control and without the fault or negligence of that Party so affected (which circumstance is hereinafter referred to as "**Force Majeure Event**"), including but not limited to inevitable accidents, perils of navigation, floods, fire, storms, earthquakes, lockouts, explosion, hostilities, war (whether declared or undeclared), civil disturbances, order or acts of any government, whether de jure or de facto or any official purporting to act under authority of any such government, illegality arising from domestic or foreign laws or regulations, insurrections, quarantine or custom restrictions, strikes, lockouts, or other labor difficulty at a Party's (or a Party's Affiliates or Third Party manufacturers') facilities, or acts of God or other similar events beyond the reasonable control of such Party resulting in hindrance of the performance by either Party of its respective obligations hereunder.

(b) Notice of Force Majeure Event. As soon as reasonably practicable after being affected by a Force Majeure Event, the Party so affected shall furnish to the other Party all particulars of the Force Majeure Event and the manner in which its performance is thereby prevented or delayed. The Party whose obligations hereunder have been suspended shall promptly and diligently pursue appropriate action to enable it to lift the Force Majeure Event, except that such Party shall not be obligated to settle any strike, lockout or other labor difficulty on terms contrary to its wishes.

(c) Removal of Condition. In the event that any Force Majeure Event cannot be removed or overcome within six (6) months (or such other period as the Parties jointly shall determine) from the date the Party affected first became affected, then either Party may, as the expiration of such period by notice to the other Party terminate this Agreement and neither Party be liable to the other Party for damages with respect to such Force Majeure Event.

Section 11.9 Bankruptcy. The Parties agree that all rights and licenses granted to Hikma under this Agreement are rights and licenses in "intellectual property" within the scope of Section 101(35A) (or its successors) of the United States Bankruptcy Code ("**Code**") or any other similar U.S. federal, state or foreign law ("**Debtor Relief Law**"). In addition to and without limitation of the foregoing, and subject to Hikma continuing to comply with the terms of this Agreement, including its obligation to continue to pay the Collegium Profit Share Percentage, Hikma will have and may fully all rights available to it under the Code or any other Debtor Relief Law, including under Section 365(n) of the Code or its successors solely to the extent necessary to permit Hikma to continue to market the Products in the Territory during the then-remaining Term.

Section 11.10 Singular and Plural Forms. The use herein of the singular form shall also denote the plural form, and the use herein of the plural form shall denote the singular form, as in each case the context may require.

Section 11.11 Headings. The headings contained in this Agreement are for convenience of reference only and shall not constitute a part hereof or define, limit, or otherwise affect the meaning of any of the terms or provisions hereof.

Section 11.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which, taken together, shall constitute one and the same instrument. Original signatures transmitted and received by means of facsimile or other electronic transmission of a scanned document, (e.g., pdf or similar format) will constitute true and valid signatures for all purposes hereunder and will have the same force and effect as the delivery of an original.

Section 11.13 Independent Contractor. The relationship between Collegium and Hikma is solely that of independent contractors, it being understood that this Agreement does not establish a joint venture, agency, partnership or employer/employee relationship between the Parties. Neither Party shall have authority to act for or bind the other Party in any manner, whatsoever, as agent or otherwise. Any and all contracts and agreements entered into by either Party shall be for that Party's sole account and risk and shall not bind the other Party in any respect.

Section 11.14 Third Party Beneficiaries. No Section of this Agreement is intended to confer upon any Person other than the Parties any rights or remedies hereunder.

Section 11.15 Further Assurances. Subject to the terms and conditions of this Agreement, each of the Parties hereto agrees to use commercially reasonable efforts to do all things reasonably necessary under this Agreement, subject to Applicable Laws, to consummate and make effective the transactions contemplated hereby. If, at any time after the date hereof, any further action is reasonably necessary to carry out the purposes of this Agreement, then, as soon as is reasonably practicable, each Party to this Agreement will take, or cause its proper officers to take, such action.

[Signature Page Follows]

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers effective as of the Effective Date.

HIKMA PHARMACEUTICALS USA INC.

By: /s/ Hafrun Fridriksdottir
Name: Hafrun Fridriksdottir
Title: President, Generics

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Shirley Kuhlmann
Name: Shirley Kuhlmann
Title: EVP, Chief Administrative Officer & GC

[Signature Page to Authorized Generic Agreement]

SEPARATION AND RELEASE AGREEMENT

This Separation and Release Agreement (the "Agreement") is made by and between Joseph Ciaffoni (the "Executive") and Collegium Pharmaceutical, Inc. (the "Company"). The Executive together with the Company shall be referred to as the "Parties."

WHEREAS, the Parties entered into an Amended & Restated Employment Agreement dated as of December 27, 2020, as amended by the Amendment to Employment Agreement dated January 20, 2022, (the "Employment Agreement");

WHEREAS, capitalized terms used but not defined in this Agreement have the meanings given to them in the Employment Agreement;

WHEREAS, the Executive's employment with the Company will be ending as set forth in the Agreement as a termination by the Company without Cause (the "Separation");

WHEREAS, in connection with the Separation, the Company shall pay the Executive (i) accrued but unpaid Base Salary through the Separation Date (as defined below), (ii) any expense reimbursements to be paid in accordance with Company policy, and (iii) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law (collectively, the "Accrued Benefits");

WHEREAS, in connection with the Separation, the Executive is eligible to receive the severance pay and benefits as set forth in, and subject to the terms and conditions of, Section 5.1 of the Employment Agreement (the "Severance Benefits");

WHEREAS, Section 5.1 of the Employment Agreement provides that the Severance Benefits are conditioned on: (a) the Executive's execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the 45th day following the effective date of his cessation of employment, of a general release of claims against the Company and its affiliates in a form reasonably prescribed by the Company (the "Release"); and (b) the Executive's continued compliance with the Restrictive Covenants; and

WHEREAS, this Agreement is the Release referenced in Section 5.1 of the Employment Agreement.

NOW, THEREFORE, the Executive and the Company agree to the terms and conditions of this Agreement as set forth below:

1. Separation from Employment.

   (a) The Executive's last day of employment with the Company shall be May 24, 2024 (the "Separation Date"). As of the Separation Date, the Executive shall not be eligible to participate in, or be covered by, any employee benefit plan or program offered by or through the Company, and the Executive shall not receive any benefits or payments from the Company, except the Accrued Benefits, as otherwise provided in this Agreement, or under the terms of applicable benefits plans. Additionally, as of the Separation Date, the Executive will no longer have authorization to incur any expenses on behalf of the Company.

   (b) In accordance with Section 5 of the Employment Agreement, upon the Separation Date, unless otherwise requested by the Company, the Executive shall resign immediately from all officer and

director positions he then holds with the Company and its affiliates. The Executive shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

(c) Regardless if this Agreement becomes effective and irrevocable, information about the Executive's benefits and rights to continue insurance coverage, including eligibility to extend health benefits at Executive's own cost under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), will be provided separately to the Executive.

2. Severance Benefits. Subject to the requirements set forth in this Agreement and Section 5.1 of the Employment Agreement, the Company will provide the following Severance Benefits; provided however, notwithstanding the foregoing, the vesting contemplated by Sections 2(c) and 2(d) below are subject to the requirements set forth in this Agreement and Section 5.1 of the Employment Agreement except for the requirement of the expiration of the revocation period set forth in Section 17 of this Agreement:

(a) continuation of Executive's Base Salary for a period equal to eighteen (18) months, payable in accordance with the Company's standard payroll practices;

(b) payment equal to (i) Executive's target annual bonus described in Section 4.2.1 of the Employment Agreement multiplied by (ii) 1.5, paid in eighteen (18) substantially equal installments over an eighteen-month period and in accordance with the Company's standard payroll practices;

(c) accelerated vesting of any unvested restricted stock, stock options and other equity incentives awarded to Executive by the Company that are solely subject to time-based vesting criteria equal to what would have vested had Executive remained employed for eighteen (18) additional months (the "Time-Based Equity Awards"); *provided* that the accelerated vesting contemplated by this subsection shall occur as of the later of (i) the Separation Date or (ii) the date the Executive signs this Agreement before the expiration of the Consideration Period (such later date, the "Time-Based Equity Awards Accelerated Vesting Date"); *provided*, *further*, that in order to effectuate the accelerated vesting contemplated by this subsection, the unvested portion of the Executive's Time-Based Equity Awards that would otherwise be forfeited on the Separation Date will be delayed until the earlier of (A) the date the Executive signs this Agreement before the expiration of the Consideration Period (at which time acceleration will occur), or (B) the expiration of the Consideration Period without Executive having signed this Agreement (at which time the unvested portion of the Executive's Time-Based Equity Awards will be forfeited). Notwithstanding the foregoing, no additional vesting of any unvested restricted stock, stock options and other equity incentives shall occur during the period between the Separation Date and the Time-Based Equity Awards Accelerated Vesting Date. All other unvested restricted stock, stock options and other equity incentives awarded to Executive that are solely subject to time-based vesting criteria shall terminate and be forfeited on the Separation Date;

(d) vesting and settlement of any unvested restricted stock unit, restricted stock, stock options and other equity incentives awarded to Executive by the Company that are subject to performance-based vesting equal to what would have vested in connection with any annual or cumulative performance vesting period that ends during the eighteen (18) month period immediately following the Separation Date, such determination to be made by the Committee in its reasonable discretion (the "Performance-Based Equity Awards"); *provided*, however, that with respect to Performance-Based Equity Awards that are based on total shareholder return ("TSR"), the determination of vesting shall be based on TSR for the applicable performance period through the

Separation Date; *provided* that, subject to the determination being made by the Committee, the vesting and settlement contemplated by this subsection shall occur (if at all) on the first practicable business day following the Committee's determination that the Performance-Based Equity Awards have vested (the "Performance-Based Equity Awards Vesting Date"); *provided*, *further*, that in order to effectuate the vesting and settlement contemplated by this subsection, the unvested portion of the restricted stock unit, restricted stock, stock options and other equity incentives awarded to Executive by the Company that are subject to performance-based vesting that would otherwise be forfeited on the Separation Date will be delayed until the earlier of (A) the expiration of the Consideration Period without Executive having signed this Agreement (at which time the unvested portion will be forfeited), or (B) Performance-Based Equity Awards Vesting Date. Notwithstanding the foregoing, no additional vesting of any unvested restricted stock unit, restricted stock, stock options and other equity incentives awarded to Executive by the Company that are subject to performance-based vesting shall occur during the period between the Separation Date and the Performance-Based Equity Awards Accelerated Vesting Date. All other unvested restricted stock unit, restricted stock, stock options and other equity incentives awarded to Executive by the Company that are subject to performance-based vesting shall terminate and be forfeited on the earlier of (A) the expiration of the Consideration Period without Executive having signed this Agreement, or (B) Performance-Based Equity Awards Vesting Date; and

(e) waiver of the applicable premium otherwise payable for COBRA continuation coverage for the Executive (and, to the extent covered immediately prior to the Separation Date, his eligible dependents) until the earlier of (i) the end of a period equal to eighteen (18) months; or (ii) the cessation of the Executive's health continuation rights under COBRA.

The Severance Benefits in Sections 2(a), 2(b), and 2(e) will be paid or provided (or begin to be paid or provided) as soon as administratively practicable after the Effective Date. The Severance Benefits remain subject to, as applicable, Section 5.5 (Compliance with Section 409A), Section 5.6 (PPACA), Section 5.7 (Section 280G), and Section 7.10 (Withholding) of the Employment Agreement.

For the avoidance of doubt, the chart below summarizes the Executive's equity incentives:

		On the Separation Date if this Agreement does not become effective	**On the Separation Date if this Agreement becomes effective**
Equity Incentives Solely Subject to Time-Based Vesting	**Vested**	Restricted Stock Units: -	Restricted Stock Units: 126,541
		Stock Options: 108,293	Stock Options: 108,293
	Unvested	Restricted Stock Units: 295,875	Restricted Stock Units : 169,334
		Stock Options: 0	Stock Options: 0
Equity Incentives Subject to Performance-Based Vesting	**Vested**	Restricted Stock Units: -	Restricted Stock Units: 199,129 (from PSU vesting)

	Unvested	Restricted Stock Units: 288,000	Restricted Stock Units: 165,700

Schedule 1 hereto reflects a schedule of the payments anticipated to be made pursuant to Section 2(a) and 2(b) above and the anticipated payment dates.

3. General Release. In consideration for, among other terms, the Severance Benefits, to which the Executive acknowledges he would not otherwise be entitled, the Executive irrevocably and unconditionally releases and forever discharges the Company, all of its affiliated and related entities, its and their respective predecessors, successors and assigns, employee benefit plans and the fiduciaries of such plans, and the current and former officers, directors, shareholders, employees, consultants, attorneys, accountants, fiduciaries and agents of each of the foregoing in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown, that, as of the date when the Executive signs this Agreement, he has, ever had, now claims to have or ever claimed to have had against any or all of the Releasees ("Claims"). This release includes, without limitation, the complete waiver and release of all Claims: relating to the Executive's employment by and termination of employment with the Company; arising in connection with or under the Employment Agreement or any other agreement between the Executive and any of the Releasees; of breach of express or implied contract; of wrongful termination of employment, whether in contract or tort; of intentional, reckless or negligent infliction of emotional distress; of breach of any express or implied covenant of employment, including the covenant of good faith and fair dealing; of interference with contractual or advantageous relations, whether prospective or existing; of deceit or misrepresentation; of discrimination or retaliation under federal, state or local law, including, without limitation, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Age Discrimination in Employment Act (ADEA), and Massachusetts General Laws Chapter 151B; under any other federal, state, local or foreign statute, rule, ordinance or regulation, including, without limitation, the Worker Adjustment and Retraining Notification Act, the Fair Labor Standards Act, the Family and Medical Leave Act and the Massachusetts Family and Medical Leave Law; of promissory estoppel or detrimental reliance; of violation of public policy; for wages, bonuses, commissions, incentive compensation, stock, stock options, vacation pay or any other compensation or benefits, regardless of whether based on the Massachusetts Wage Act, M.G.L. c. 149, §§148-150C, or any other law or agreement; for fraud, slander, libel, defamation, disparagement, personal injury, negligence, or other torts; and for injury or damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief, and attorneys' fees. The Executive understands that this general release of Claims includes, without limitation, any and all Claims against the Company in respect of any stock-based awards of any kind and as a Company stockholder or option holder arising up to and through the date that the Executive signs this Agreement. The Executive agrees not to accept damages of any nature, other equitable or legal remedies for Executive's own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Agreement. The Executive understands that this general release does not extend to any rights or claims that may arise out of acts or events that occur after the date on which the Executive signs this Agreement, or to Claims that cannot be released as a matter of law. As a material inducement to the Company to enter into this Agreement, the Executive represents that he has not assigned to any third party and has not filed with any agency or court any Claim released by this Agreement. This release does not affect the Executive's rights or obligations under this Agreement, nor shall it affect the Executive's rights, if any, under any "employee benefit plan," as that term is defined in Section 3(3) of the Employee Retirement Income Security Act, 29 U.S.C. §1002(3).

4. Acknowledgements. Executive acknowledges, represents and warrants each of the following:

(a) With respect to the payment of an annual bonus as set forth in Section 5.1.1 of the Employment Agreement, the Executive acknowledges and agrees that the Company paid him any and all annual bonuses with respect to the years that ended prior to the Separation Date and that, therefore, the Executive is not entitled to payment pursuant to Section 5.1.1 of the Employment Agreement.

(b) Other than the Severance Benefits offered as consideration for this Agreement (which the Executive is not entitled to unless and until the Executive executes, does not revoke, and complies with this Agreement and complies with the Restrictive Covenants), the Company has paid or provided all compensation, salary, wages, bonuses, and any and all other benefits and compensation due to the Executive.

(c) Executive acknowledges and agrees that effective as of the Separation Date (or such later date designated in the applicable plan documents), except for rights under COBRA and/or as otherwise provided by applicable law, the Executive ceased to be eligible to participate in or receive benefits under any benefit plans or programs, including, without limitation, medical, dental and vision insurance plans, life insurance plans, short and long-term disability plans, 401(k) plans and any other benefit plans, sponsored or maintained by the Company or any of the other Releasees; and

(d) Executive acknowledges and agrees that the preceding information is factually accurate as to the Executive and may be used as a sworn statement of fact in any proceeding between the Executive and the Company.

5. Restrictive Covenants. Subject to the protected disclosures in Section 6 of this Agreement, the Executive acknowledges his obligations under the Restrictive Covenants (as defined in the Employment Agreement) including, without limitation, to maintain the confidentiality of the Company's confidential information and to refrain from certain solicitation activities; provided, however, that the post-employment restrictions in Sections 6.1.1 and 6.1.2 in the Employment Agreement are hereby waived, terminated, and superseded by the post-employment restrictions stated in Exhibit A to this Agreement, to which the Executive hereby agrees to in connection with the separation of the Executive's employment with the Company; provided, for the avoidance of doubt, that the Executive's Restrictive Covenants otherwise remain in effect. The Executive's post-employment obligations including, without limitation, the restriction to refrain from the competitive activities stated in Exhibit A to this Agreement, shall be subject to Section 6 of this Agreement and Section 6.5 (Acknowledgements), Section 6.6.1 (Specific Enforcement), Section 6.6.2 (Judicial Modification), Section 6.6.3 (Enforceability), Section 6.6.4 (Disclosure of Restrictive Covenants), and Section 6.6.5 (Extension of Restricted Period) of the Employment Agreement.

6. Protected Disclosures. Nothing contained in this Agreement, any other agreement with the Company, or any Company policy or code limits the Executive's ability, with or without notice to the Company, to: (i) file a charge or complaint with any federal, state or local governmental agency or commission (a "Government Agency"), including without limitation, the Equal Employment Opportunity Commission, the National Labor Relations Board or the Securities and Exchange Commission (the "SEC"); (ii) communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including by providing non-privileged documents or information; (iii) exercise any rights under Section 7 of the National Labor Relations Act, which are available to non-supervisory employees, including assisting co-workers with or discussing any employment issue as part of engaging in concerted activities for the purpose of mutual aid or protection;

(iv) discuss or disclose information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that the Executive has reason to believe is unlawful; or (v) testify truthfully in a legal proceeding. Any such communications and disclosures must be consistent with applicable law and the information disclosed must not have been obtained through a communication that was subject to the attorney-client privilege (unless disclosure of that information would otherwise be permitted consistent with such privilege or applicable law). If a Government Agency or any other third party pursues any claim on the Executive's behalf, the Executive waives any right to monetary or other individualized relief (either individually or as part of any collective or class action), but this does not apply to (and the Company shall not attempt in any way to limit) any right the Executive may have to receive an award pursuant to the whistleblower provisions of any applicable law or regulation for providing information to the SEC or any other Government Agency.

7. Future Cooperation. The Executive agrees to cooperate reasonably with the Company and all of its affiliates (including its and their outside counsel) in connection with (i) the contemplation, prosecution and defense of all phases of existing, past and future litigation about which the Company believes the Executive may have knowledge or information; and (ii) responding to requests for information from regulatory agencies or other governmental authorities (together "Cooperation Services"). The Executive further agrees to make himself available to provide Cooperation Services at mutually convenient times during and outside of regular business hours as reasonably deemed necessary by the Company's counsel. The Company shall not utilize this section to require the Executive to make himself available to an extent that would unreasonably interfere with full-time employment responsibilities that the Executive may have. Cooperation Services include, without limitation, appearing without the necessity of a subpoena to testify truthfully in any legal proceedings in which the Company or an affiliate calls the Executive as a witness. The Company shall reimburse the Executive for any reasonable travel expenses that the Executive incurs due to the Executive's performance of Cooperation Services, after receipt of appropriate documentation consistent with the Company's business expense reimbursement policy.

8. Non-Disparagement. Subject to the protected disclosures in Section 6 of this Agreement, the Executive agrees not to make any disparaging statements concerning the Company or any of its affiliates or concerning the products, services or current or former officers, directors, shareholders, employees or agents of the Company or any of its affiliates.

9. Return of Company Property. By executing this Agreement, Executive confirms that he has returned to the Company all Company property, including, without limitation, computer equipment, cellphones, software, keys and access cards, credit cards, files and any documents (including computerized data and any copies made of any computerized data or software) containing information concerning the Company or its affiliates, its or their business, or its or their business relationships (in the latter two cases, actual or prospective) ("Company Property"). Executive certifies that he has not transferred, downloaded, deleted or otherwise altered files or information on any Company laptop or any other Company devices prior to returning them to the Company. Executive agrees to commit to deleting and finally purging any duplicates of files or documents that may contain Company or its affiliates information from any non-Company computer or other device that remains in the Executive's possession. In the event that the Executive discovers that he continues to retain any Company Property, the Executive shall return it to the Company immediately. For the avoidance of doubt, the obligations in this Section 9 are supplemental to, and not in lieu of, the return of property obligations under the Employment Agreement.

10. Breach. If the Executive breaches any of the Executive's obligations under this Agreement or the Restrictive Covenants, in addition to any other legal or equitable remedies it may have for such breach, the Company shall have the right to terminate its payments to the Executive or for the Executive's benefit under this Agreement. The termination of such payments in the event of the Executive's breach will not

affect the Executive's continuing obligations under this Agreement or the Restrictive Covenants.

11. No Admission of Wrongdoing. The making of this Agreement is not intended, and shall not be construed, as an admission that the Company or any of the Releasees to have violated any federal, state or local law (statutory or decisional), ordinance or regulation, breached any contract or committed any wrongdoing whatsoever against the Executive or otherwise.

12. Clawback Policy; Entire Agreement. The Executive acknowledges and agrees that payments the Executive may have previously received from the Company and/or may be entitled to receive under this Agreement are or may be subject to clawback or forfeiture pursuant to (i) the Company's Clawback Policy, as may be amended and/or restated from time to time (the "Clawback Policy"); and (ii) applicable law. The Executive has received and had an opportunity to review the Clawback Policy and agrees to take all required action to enable the enforcement of the Clawback Policy. This Agreement, together with Exhibit A, constitutes the entire agreement between the Executive and the Company, and this Agreement supersedes any previous agreements or understandings between the Executive and the Company, *provided* that the following remain in effect: (a) the Clawback Policy; (b) the Restrictive Covenants (subject to the modifications in this Agreement); (c) plans and agreements for restricted stock unit, restricted stock, stock options and other equity incentives granted to the Executive, subject to Sections 2(c) and 2(d) of this Agreement; and (d) any other obligations specifically preserved in this Agreement.

13. Waiver. No waiver of any provision of this Agreement shall be effective unless made in writing and signed by the waiving party. The failure of a party to require the performance of any term or obligation of this Agreement, or the waiver by a party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

14. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

15. Governing Law; Interpretation. This Agreement shall be interpreted and enforced under the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles. In the event of any dispute, this Agreement is intended by the parties to be construed as a whole, to be interpreted in accordance with its fair meaning, and not to be construed strictly for or against either the Executive or the Company or the "drafter" of all or any portion of this Agreement.

16. Absence of Reliance. In signing this Agreement, the Executive is not relying upon any promises or representations made by anyone at or on behalf of the Company.

17. Time for Consideration; Effective Date. The Executive acknowledges that he has knowingly and voluntarily entered into this Agreement and that the Company advises the Executive to consult with an attorney before signing this Agreement. By entering into this Agreement, the Executive acknowledges that the Executive has been given the opportunity to consider this Agreement for twenty-one (21) days from the Executive's receipt of this Agreement before signing it (the "Consideration Period"). The Parties agree that any changes to this Agreement do not restart the Consideration Period and that, to accept this Agreement, the Executive must (a) sign the original or a PDF copy of this Agreement on or after the Separation Date and before the expiration of the Consideration Period, and (b) return the signed original or a signed PDF copy of this Agreement so that it is received by Jennifer Porter (***) at or before the expiration of the Consideration Period. If the Executive signs this Agreement before the end of the

Consideration Period, the Executive acknowledges that such decision was entirely voluntary and that he had the opportunity to consider this Agreement for the entire Consideration Period. Except for certain Claims in Section 3 that require a statutory revocation period to be released, the release of Claims in Section 3 is enforceable as of the date that the Executive signs this Agreement. For the period of seven (7) business days from the date when the Executive signs this Agreement, the Executive has the right to revoke this Agreement by written notice to Ms. Porter, provided that such notice is delivered so that it is received at or before the expiration of the seven (7) business day revocation period. This Agreement shall not become fully effective or fully enforceable during the revocation period. This Agreement shall become fully effective and fully enforceable on the first business day following the expiration of the revocation period, provided that the Executive does not revoke during the revocation period (the "Effective Date").

18. Counterparts. This Agreement may be executed by means of electronic signature or in any number of counterparts, where all such counterparts taken together will be deemed to constitute one and the same instrument. A signed or e-signed copy of this Agreement delivered by facsimile, e-mail, or other means of electronic transmission is deemed to have the same legal effect as delivery of an original signed Agreement.

19. Legal Fees. The Company will reimburse the Executive up to $7,500, inclusive of applicable taxes, in respect of legal fees incurred by the Executive in connection with the review and execution of this Agreement. The payment will be made directly to the law firm retained by the Executive upon submission to the Company of any invoice reflecting the total amount due.

<remainder of page intentionally left blank; signature page follows>

IN WITNESS WHEREOF, the Company has caused this Separation and Release Agreement, together with Exhibit A, to be executed by its duly authorized officer, and Executive has executed this Separation and Release Agreement, together with Exhibit A, on the date(s) indicated below.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Michael Heffernan
Name: Michael Heffernan
Title: Director, Interim President and Chief Executive Officer
Date: May 24, 2024

JOSEPH CIAFFONI

/s/ Joseph Ciaffoni

Date: May 24, 2024

Exhibit 10.3

LETTER AGREEMENT

This Letter Agreement (this "**Letter Agreement**") is entered into as of May 24, 2024, by and between Collegium Pharmaceutical, Inc. (the "**Company**") and Michael Heffernan ("**Chairman**," and together with the Company, the "**Parties**").

RECITALS

WHEREAS, Chairman is currently Chairman of the Board of Directors (the "**Board**") of the Company;

WHEREAS, the Company desires to obtain from Chairman, and Chairman desires to provide to the Company, services as Interim President and Chief Executive Officer of the Company (the "**Interim CEO Services**") commencing as of May 24, 2024, (the "**Effective Date**") and ending as of the date Chairman's Interim CEO Services terminate in accordance with the terms of this Letter Agreement (such period, the "**Term**"); and

WHEREAS, the Parties desire to address other matters related to Chairman's provision of the Interim CEO Services.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Provisions Related to Interim CEO Services**.

(a) During the Term, Chairman's base salary shall be payable at an annual rate of $291,666, paid in accordance with the Company's payroll practices. During the Term, Chairman may participate in any Company employee benefit plans for which Chairman qualifies, subject to the terms and conditions of such plans (including any applicable minimum service requirements or waiting periods).

(b) During the Term, Chairman will be employed by the Company, will serve as the Interim Chief Executive Officer of the Company and will report directly to the Board. In addition to performing the duties and responsibilities associated with that position, from time to time the Company may assign to Chairman other duties and responsibilities reasonable and consistent with such position. Chairman shall continue to serve as Chairman of the Board during the Term.

2. **Duration of Interim CEO Services**. The Parties anticipate that the Term will continue until the Company hires a new Chief Executive Officer (the "**New CEO**"). Nevertheless, for the avoidance of doubt, Chairman's employment with the Company is "at will," meaning either Chairman or the Company may terminate the employment relationship (and the Term) at any time and for any reason, with or without cause, and with or without notice. For the avoidance of doubt, termination of the Interim CEO Services and the Term shall not affect Chairman's continued role as Chairman of the Board.

3. **Choice of Law; Exclusive Venue**. THIS LETTER AGREEMENT, AND ALL ISSUES AND QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS LETTER AGREEMENT, WILL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE COMMONWEALTH OF MASSACHUSETTS, WITHOUT GIVING EFFECT TO ANY CHOICE OF LAW OR CONFLICT OF LAW RULES OR PROVISIONS (WHETHER OF THE COMMONWEALTH OF MASSACHUSETTS OR ANY OTHER JURISDICTION) THAT WOULD CAUSE THE APPLICATION OF THE LAWS OF ANY JURISDICTION OTHER THAN THE COMMONWEALTH OF MASSACHUSETTS. ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS LETTER AGREEMENT WILL BE INSTITUTED IN A STATE OR FEDERAL COURT IN THE COMMONWEALTH OF MASSACHUSETTS, AND CHAIRMAN AND THE COMPANY HEREBY CONSENT TO THE PERSONAL AND EXCLUSIVE JURISDICTION OF SUCH COURT(S) AND HEREBY WAIVE ANY OBJECTION(S) THAT THEY MAY HAVE TO PERSONAL JURISDICTION, THE LAYING OF VENUE OR ANY SUCH PROCEEDING AND ANY CLAIM OR DEFENSE OF INCONVENIENT FORUM.

4. **Other Company Policies**. During the Term, Chairman will be subject to all policies of the Company in effect from time to time with respect to employees or officers of the Company, including (without limitation) policies regarding ethics, personal conduct, securities trading, clawback and hedging and pledging of securities.

5. **Other Compensation; Effect on Director Compensation**. Notwithstanding anything to the contrary in this Letter Agreement, unless otherwise determined by the Board, Chairman will not participate in the Company's annual equity incentive plan or long-term incentive policy. During the Term, Chairman's non-employee director cash fees will cease and new equity awards will not be issued to Chairman in Chairman's capacity as a member of the Board. However, Chairman's employment as Interim CEO will count for purposes of the service-based vesting conditions of equity awards previously granted to Chairman by the Company in Chairman's capacity as a non-employee director.

6. **Confidentiality**. In connection with Chairman's employment by the Company, Chairman will have access to confidential and proprietary information of the Company and of third parties that have provided information to the Company in confidence ("**Confidential Information**"). Both during and after Chairman's service to the Company, Chairman will not disclose Confidential Information to any third party, permit any third party to have access to the Confidential Information, or use the Confidential Information for any purpose other than in connection with Chairman's performance of services for the Company. Notwithstanding the foregoing, nothing in this Letter Agreement, any other agreement with the Company, or any Company policy or practice shall limit Chairman's ability, with or without notice to the Company, to: (i) communicate with any federal, state or local governmental agency or commission (a "**Government Agency**"), including without limitation the Equal Employment Opportunity Commission, the National Labor Relations Board or the Securities and Exchange Commission (the "**SEC**"), or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including by providing non-privileged documents or information; (ii) file a charge or complaint with any Government Agency; (iii) refuse to engage in unlawful activity without being subjected to retaliation; (iv) share compensation information concerning the Chairman or others (provided that this does not permit Chairman to disclose compensation information concerning others that Chairman obtains because his job responsibilities require or allow access to such information); or (v) testify truthfully in a legal proceeding. Any such communications and disclosures must be consistent with applicable law and the information disclosed must not have been obtained through a communication that was subject to the attorney-client privilege (unless disclosure of that information would otherwise be permitted consistent with such privilege or applicable law). The Company will not limit any right Chairman may have to receive an award by an order of a Government Agency pursuant to the whistleblower provisions of any applicable law or regulation for providing information to the SEC or any other Government Agency. Chairman understands that, pursuant to the federal Defend Trade Secrets Act of 2016, Chairman will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

7. **Assignment of Inventions**. Chairman agrees that all Confidential Information, and all deliverables, discoveries, inventions, ideas, concepts, trademarks, service marks, logos, processes, products, formulas, computer programs or software, source codes, object codes, algorithms, machines, apparatuses, items of manufacture or composition of matter, or any new uses therefore or improvements thereon, or any new designs or modifications or configurations of any kind, or works of authorship of any kind, including, without limitation, compilations and derivative works, whether or not patentable or copyrightable, conceived, developed, reduced to practice or otherwise made by Chairman, either alone or with others, in the course of Chairman's Interim CEO Services , whether or not conceived, developed, reduced to practice or made on the Company's premises (collectively, "**Company Inventions**"), and any and all services and products which embody, emulate or employ any such Company Invention or Confidential Information shall be the sole property of the Company, as applicable, and all copyrights, patents, patent rights, trademarks and reproduction rights to, and other proprietary rights in, each such Company Invention or Confidential Information, whether or not patentable or copyrightable, shall belong exclusively to the Company. Chairman agrees that all such Company Inventions shall constitute works made for hire under the copyright laws of the United States. Chairman hereby assigns and, to the extent any such assignment cannot be made at the present time, agrees to assign, to the Company (or one its designees) any and all Company Inventions, and all copyrights, patents and other proprietary rights that Chairman may have in any such Company Invention. The preceding sentence specifically includes without limitation the right to file and/or own wholly (without restrictions) applications for United States and foreign patents, trademark registration and copyright registration, and any patent, or trademark or copyright registration issuing thereon.

8. **Withholding**. Chairman's compensation during the Term will be subject to tax withholding to the extent required by applicable law.

9. **Assignment by Company**. The Company may assign its rights under this letter to any successor to all or substantially all the business or assets of the Company by means of liquidation, dissolution, merger, consolidation, transfer of assets or otherwise.

10. **Cooperation**. Chairman agrees that during and after Chairman's employment with the Company, and subject to reimbursement of reasonable expenses, Chairman will cooperate reasonably with the Company and its counsel with respect to any matter (including, without limitation, litigation, investigations or government proceedings) in which Chairman was in any way involved during Chairman's service to the Company. Chairman agrees to render such cooperation in a timely manner on reasonable notice from the Company, as long as the Company, following the cessation of Chairman's employment, exercises commercially reasonable efforts to schedule and limit its need for Chairman's cooperation under this paragraph so as not to interfere with Chairman's personal and other professional commitments.

11. **Representations; Work Authorization; Entire Agreement**. Chairman represents that Chairman is not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) Chairman from entering into employment with or carrying out Chairman's responsibilities for the Company, or which is in any way inconsistent with the terms of this Letter Agreement. Chairman also represents that he will not use or disclose any trade secret or other proprietary or confidential information of any previous employer or any other party. Chairman agrees to provide to the Company, within three days of Chairman's hire date, documentation of Chairman's eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. This Letter Agreement sets forth the complete agreement between Chairman and the Company with regard to Chairman's employment with the Company, and supersedes any prior representations or agreements about this matter, whether written or verbal. In signing this Letter Agreement, Chairman is not relying on any representations made by anyone at or on behalf of the Company other than as expressly set forth in this Letter Agreement.

12. **Counterparts.** This Letter Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Letter Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Letter Agreement.

IN WITNESS WHEREOF, the Parties have executed this Letter Agreement effective on the date and year indicated below.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Shirley Kuhlmann
Name: Shirley Kuhlmann
Title: Executive Vice President, Chief Administrative Officer and General Counsel
Date: May 24, 2024

MICHAEL HEFFERNAN

By: /s/ Michael Heffernan
Name: Michael Heffernan
Date: May 24, 2024

Exhibit 31.1

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

I, Michael T. Heffernan, 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/ MICHAEL T. HEFFERNAN

Michael T. Heffernan
Interim President and Chief Executive Officer

Date: August 8, 2024

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: August 8, 2024

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 June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael T. Heffernan, Interim 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/ MICHAEL T. HEFFERNAN

Michael T. Heffernan
Interim President and Chief Executive Officer

Date: August 8, 2024

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 June 30, 2024 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: August 8, 2024