
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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

(State or other jurisdiction of
incorporation or organization)

03-0416362

(I.R.S. Employer
Identification Number)

**100 Technology Center Drive
Stoughton, MA**

(Address of principal executive offices)

02072

(Zip Code)

(781) 713-3699

(Registrant's telephone number, including area code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company

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

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

As of October 31, 2024, there were 32,250,236 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 successfully integrate the operations of Ironshore Therapeutics Inc. (“Ironshore”) into our organization, and realize the anticipated benefits associated with the acquisition;
- our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts with favorable terms for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredients for each of our products, manufacture adequate quantities of commercially salable inventory and maintain our supply chain;
- our ability to effectively manage our relationships with licensors and to commercialize products that we in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our business development;
- our ability to 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 38,960	\$ 238,947
Marketable securities	80,997	71,601
Accounts receivable, net	228,456	179,525
Inventory	38,032	32,332
Prepaid expenses and other current assets	32,365	15,195
Restricted cash	25,000	—
Total current assets	443,810	537,600
Property and equipment, net	14,614	15,983
Operating lease assets	6,169	6,029
Intangible assets, net	946,875	421,708
Restricted cash	1,047	1,047
Deferred tax assets	72,509	26,259
Other noncurrent assets	4,171	825
Goodwill	145,959	133,857
Total assets	\$ 1,635,154	\$ 1,143,308
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	\$ 3,142	\$ 8,692
Accrued liabilities	47,600	37,571
Accrued rebates, returns and discounts	313,874	227,331
Current portion of term notes payable	64,583	183,333
Current portion of operating lease liabilities	1,271	988
Business combination consideration payable	28,956	—
Total current liabilities	459,426	457,915
Term notes payable, net of current portion	565,716	221,713
Convertible senior notes	236,911	262,125
Operating lease liabilities, net of current portion	5,914	6,124
Deferred royalty obligation	118,812	—
Deferred revenue	10,000	—
Contingent consideration	4,096	—
Total liabilities	1,400,875	947,877
Commitments and contingencies (refer to Note 16)		
Shareholders' equity:		
Preferred stock, \$0.001 par value; authorized shares - 5,000,000	—	—
Common stock, \$0.001 par value; authorized shares - 100,000,000; 39,616,456 issued and 32,230,016 outstanding shares as of September 30, 2024 and 38,192,441 issued and 31,868,549 outstanding shares as of December 31, 2023	40	38
Additional paid-in capital	582,762	565,949
Treasury stock, at cost; 7,386,440 shares as of September 30, 2024 and 6,323,892 shares as of December 31, 2023	(172,381)	(137,381)
Accumulated other comprehensive income	393	14
Accumulated deficit	(176,535)	(233,189)
Total shareholders' equity	234,279	195,431
Total liabilities and shareholders' equity	\$ 1,635,154	\$ 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 September 30, 2024		Nine Months Ended September 30, 2023	
	2024	2023	2024	2023
Product revenues, net	\$ 159,301	\$ 136,709	\$ 449,500	\$ 417,022
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	21,706	20,081	60,611	74,237
Intangible asset amortization	40,801	36,317	109,833	111,246
Total cost of product revenues	62,507	56,398	170,444	185,483
Gross profit	96,794	80,311	279,056	231,539
Operating expenses				
Selling, general and administrative	61,955	35,298	147,272	126,266
Total operating expenses	61,955	35,298	147,272	126,266
Income from operations	34,839	45,013	131,784	105,273
Interest expense	(18,394)	(20,768)	(51,320)	(64,058)
Interest income	3,280	4,538	12,164	11,312
Loss on extinguishment of debt	(4,145)	—	(11,329)	(23,504)
Income before income taxes	15,580	28,783	81,299	29,023
Provision for income taxes	6,245	8,149	24,645	12,808
Net income	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215
Earnings per share — basic	\$ 0.29	\$ 0.61	\$ 1.75	\$ 0.47
Weighted-average shares — basic	32,259,468	33,744,209	32,339,401	34,226,488
Earnings per share — diluted	\$ 0.27	\$ 0.53	\$ 1.51	\$ 0.46
Weighted-average shares — diluted	40,163,266	42,058,821	40,400,483	35,149,154

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	Three Months Ended September 30, 2024		Nine Months Ended September 30, 2023	
	2024	2023	2024	2023
Net income	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities, net of tax	575	(14)	379	(52)
Total other comprehensive income (loss)	575	(14)	379	(52)
Comprehensive income	<u>\$ 9,910</u>	<u>\$ 20,620</u>	<u>\$ 57,033</u>	<u>\$ 16,163</u>

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net income	\$ 56,654	\$ 16,215
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization expense	109,833	111,246
Depreciation expense	2,815	2,547
Deferred income taxes	(16,658)	(1,815)
Stock-based compensation expense	24,804	20,134
Non-cash lease benefit	(67)	(258)
Non-cash interest expense for amortization of debt discount and issuance costs	4,592	6,672
Non-cash interest expense for deferred royalty obligation	473	—
Loss on extinguishment of debt	11,329	23,504
Net amortization of premiums and discounts on investments	(1,652)	(667)
Changes in operating assets and liabilities:		
Accounts receivable	(4,520)	1,268
Inventory	11,455	12,376
Prepaid expenses and other assets	(12,122)	42
Accounts payable	(12,088)	106
Accrued liabilities	(61,952)	(4,479)
Accrued rebates, returns and discounts	7,440	14,520
Net cash provided by operating activities	<u>120,336</u>	<u>201,411</u>
Investing activities		
Acquisition of Ironshore (net of cash acquired)	(267,538)	—
Purchases of property and equipment	(1,082)	(297)
Purchases of marketable securities	(84,003)	(51,418)
Maturities of marketable securities	76,626	6,000
Net cash used in investing activities	<u>(275,997)</u>	<u>(45,715)</u>
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plan	827	460
Proceeds from the exercise of stock options	10,073	5,401
Payments made for employee stock tax withholdings	(18,891)	(8,128)
Repurchases of common stock, including the ASR agreement	(35,000)	(50,000)
Repayment of term notes	(91,667)	(116,667)
Proceeds from term note modification, net of fees paid to lender of \$11,825	313,175	—
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	(33,245)	—
Repayment of assumed debt from Ironshore acquisition	(164,598)	—
Net cash used in financing activities	<u>(19,326)</u>	<u>(72,352)</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(174,987)	83,344
Cash, cash equivalents and restricted cash at beginning of period	239,994	176,235
Cash, cash equivalents and restricted cash at end of period	<u>\$ 65,007</u>	<u>\$ 259,579</u>
Reconciliation of cash, cash equivalents and restricted cash to the Condensed Consolidated Balance Sheets:		
Cash and cash equivalents	\$ 38,960	\$ 258,532
Restricted cash	26,047	1,047
Total cash, cash equivalents and restricted cash	<u>\$ 65,007</u>	<u>\$ 259,579</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 47,210	\$ 57,679
Cash paid for income taxes	<u>\$ 51,469</u>	<u>\$ 17,293</u>
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment included in accounts payable and accrued liabilities	\$ —	\$ 53
Contingent consideration	<u>\$ 4,096</u>	<u>—</u>
Business combination consideration payable	<u>\$ 28,956</u>	<u>—</u>

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”), Symproic, and Jornay PM (“Jornay”).

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 September 30, 2024, the results of operations for the three and nine months ended September 30, 2024 and 2023, and cash flows for the nine months ended September 30, 2024 and 2023. The results of operations for the three and nine months ended September 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 nine months ended September 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, however, the Company will provide enhanced disclosures as required to comply with this standard in its financial statements for the period ended December 31, 2024.

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, Symproic, and Jornay 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 nine months ended September 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	303,570	33,587	124,194
Acquired from Ironshore	42,515	36,588	5,011
Changes in estimate related to prior period sales	(1,634)	2,419	(85)
Credits/payments made	(296,433)	(34,069)	(120,611)
Balance as of September 30, 2024	<u>\$ 197,844</u>	<u>\$ 116,030</u>	<u>\$ 29,426</u>

	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	325,725	31,904	112,550
Changes in estimate related to prior period sales	2	3,722	589
Credits/payments made	(315,170)	(31,662)	(113,263)
Balance as of September 30, 2023	<u>\$ 167,494</u>	<u>\$ 77,518</u>	<u>\$ 21,934</u>

- (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 September 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Belbuca	\$ 53,197	\$ 45,447	\$ 156,058	\$ 132,795
Xtampza ER	49,492	39,800	139,876	128,914
Nucynta IR	25,361	24,906	76,524	80,963
Nucynta ER	19,773	22,634	58,231	62,941
Jornay PM	7,961	—	7,961	—
Symproic	3,517	3,922	10,850	11,409
Total product revenues, net	<u>\$ 159,301</u>	<u>\$ 136,709</u>	<u>\$ 449,500</u>	<u>\$ 417,022</u>

Contract Liabilities

The Company's contract liabilities, or deferred revenue, primarily relate to contracts where the Company has received payment, but it has not yet satisfied or fully satisfied the related performance obligations. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company satisfies its obligations under these arrangements.

The Company's only contract liability relates to a contract with Knight Therapeutics, Inc. ("Knight"), which was entered into by Ironshore and Knight in May 2024 and was assumed as part of the Ironshore Acquisition (see Note 4, *Acquisition*). The contract provides Knight the right to sell Jornay in Canada and certain countries in Latin America, subject to regulatory approval. The contract provides for a nonrefundable upfront payment of \$10,000, sales milestones, royalties on net revenue, and reimbursement for certain manufacturing expenses. The Company identified one combined performance obligation in the contract related primarily to the sale of products. The up-front payment will be recognized as revenue as product sales are made over the term of the contract. No products have been delivered to date under this contract and therefore no revenue has been recognized through September 30, 2024.

4. Acquisition

On September 3, 2024, (the “Acquisition Date”), the Company closed its acquisition of Ironshore Therapeutics Inc. (“Ironshore”) (the “Ironshore Acquisition”) pursuant to an Agreement and Plan of Merger (the “Merger Agreement”), with Ironshore surviving the Merger as a wholly owned subsidiary of the Company. Ironshore had developed and obtained commercial approval to market Jornay in the United States. The Ironshore Acquisition was completed to expand the Company’s business beyond pain management and establish a commercial presence in neurology via the attention deficit hyperactivity disorder (“ADHD”) market. The Company obtained control through the acquisition of shares in an all-cash transaction which closed on September 3, 2024 (the “Acquisition Date”).

The acquisition consideration includes payments for the Ironshore equity and assumption of certain of its debt. The Company deposited \$25,000 into escrow at closing, to be released (i) in part, after, and subject to, determination of any adjustments related to finalization of working capital and cash at closing; and (ii) in part, and subject to, the lapse of certain indemnification obligations 12 months from the Acquisition Date. As of the Acquisition Date, and September 30, 2024, approximately \$21,956 was due to the former Ironshore equity holders and \$25,000 is recorded as restricted cash. In addition, the Company will pay approximately \$7,000 to former Ironshore equity holders as the Company has the opportunity to recover certain deposits as specified in the Merger Agreement, which amount is due no later than 225 days from the Acquisition Date. The Company also agreed to pay a \$25,000 contingent payment upon the achievement of a financial milestone based on net revenues of Jornay for the year ended December 31, 2025.

The fair value of the total consideration was approximately \$309,940 consisting of the following (in thousands):

Fair Value of Purchase Price Consideration	Amount
Fair value of purchase price consideration paid at closing:	
Initial cash consideration	\$ 276,888
Deferred payments and contingent consideration:	
Cash held in escrow related to indemnification and other settlements	21,956
Other deferred consideration	7,000
Fair value of contingent consideration	4,096
Total purchase consideration	\$ 309,940

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

The preliminary purchase price allocation is based on estimates, assumptions, valuations and other studies which have not yet been finalized. The Company is finalizing its valuation of intangible assets, tangible assets, liabilities and tax analyses, and anticipates finalizing the valuation of assets acquired and liabilities assumed as the information necessary to complete the analysis is obtained, but no later than one year after the Acquisition Date.

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

	Amounts Recognized at the Acquisition Date	
Assets Acquired		
Cash and cash equivalents	\$	9,350
Accounts receivable		44,411
Inventory		17,155
Prepaid expenses and other current assets		8,394
Property, plant and equipment, net		541
Intangible assets		635,000
Right-of-use assets		800
Deferred tax assets		29,592
Total assets	\$	745,243
Liabilities Assumed		
Accounts payable	\$	6,675
Accrued liabilities		72,034
Accrued rebates, returns and discounts		79,103
Borrowings		8,954
Lease liabilities		800
Senior secured notes payable		151,500
Deferred royalty obligation		118,339
Deferred revenue		10,000
Total liabilities	\$	447,405
Total identifiable net assets acquired		297,838
Goodwill		12,102
Total consideration transferred	\$	309,940

The valuation of the acquired intangible assets and assumed deferred royalty obligations relies on significant unobservable inputs. The Company used an income approach to value the \$635,000 for the acquired intangible asset. The valuation of the intangible asset was based on estimated projections of expected cash flows to be generated by the asset, discounted to the present value at an appropriate discount rate. The Company is amortizing the identifiable intangible asset on a straight-line basis over its useful life of 7.7 years (refer to Note 9, *Goodwill and Intangible Assets*). The acquired inventory was recorded at fair value, which includes an adjustment to record inventory from its historic cost to fair value of \$10,700. The assumed senior secured notes payable and borrowings were settled immediately after the close of the acquisition, resulting in a loss in debt extinguishment of \$4,145.

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

Total revenues attributable to Ironshore from the Acquisition Date through September 30, 2024 were \$7,961. Earnings attributable to Ironshore from the Acquisition Date through September 30, 2024, however, are not distinguishable due to the rapid integration of Ironshore's core operations into the Company.

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the three and nine months ended September 30, 2024 and 2023, as if the Ironshore Acquisition had occurred on January 1, 2023. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2023, and is not indicative of what such results would be expected for any future period (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Total revenues	\$ 178,899	\$ 157,805	\$ 512,925	\$ 474,725
Net income	\$ (5,390)	\$ (11,567)	\$ (35,969)	\$ (102,849)

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

- Employee severance-related expense of \$8,443 was reflected as of January 1, 2023;
- The Company's acquisition-related transaction costs of \$8,439 were reflected as of January 1, 2023;
- Additional amortization expense from the acquired intangibles;
- Additional cost of product revenues related to the step-up basis in inventory to record inventory at fair value; and
- Adjustments to the Company's interest expense related to additional borrowings on the 2024 Term Loan as defined in Note 11, *Term Notes Payable*, and elimination of certain Ironshore debt.

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

Acquisition Related Expenses

In the three months ended September 30, 2024, the Company incurred \$19,886 of acquisition related expenses as a result of the Ironshore Acquisition and the substantial majority were included in Selling, general, and administrative expense in the condensed consolidated statements of operations. These costs include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition; employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, Ironshore directors and officers insurance purchased at the closing of the Ironshore Acquisition, and miscellaneous other acquisition expenses incurred, including integration consulting costs and contract termination costs. The Company has accrued \$1,501 related to employee severance costs incurred as of September 30, 2024 but not yet paid. Additional charges related to severance or retention payments are not expected to be material and the remaining employee termination costs are expected to be paid by March 31, 2025. The Company expects, however, to incur additional acquisition-related expenses relating to consulting fees, contract termination costs, and other integration-related expenses during the remainder of 2024.

	Three Months Ended September 30,	
	2024	
Employee-related expenses	\$	8,443
Transaction costs		8,439
Ironshore directors and officers insurance		1,090
Other acquisition expenses		1,914
Total acquisition related expenses	\$	19,886

5. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net income	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215
Adjustment for interest expense recognized on convertible senior notes	1,416	1,645	4,358	—
Net income - diluted	<u>\$ 10,751</u>	<u>\$ 22,279</u>	<u>\$ 61,012</u>	<u>\$ 16,215</u>
Denominator:				
Weighted-average shares outstanding — basic	32,259,468	33,744,209	32,339,401	34,226,488
Effect of dilutive securities:				
Stock options	327,605	222,355	395,759	263,513
Restricted stock units	969,888	583,153	1,059,018	659,153
Performance share units	—	—	—	—
Convertible senior notes	6,606,305	7,509,104	6,606,305	—
Weighted average shares outstanding — diluted	<u>40,163,266</u>	<u>42,058,821</u>	<u>40,400,483</u>	<u>35,149,154</u>
Earnings per share — basic	\$ 0.29	\$ 0.61	\$ 1.75	\$ 0.47
Earnings per share — diluted	\$ 0.27	\$ 0.53	\$ 1.51	\$ 0.46

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options	—	749,443	—	395,405
Restricted stock units	231,644	979,200	236,794	977,250
Performance share units	223,680	503,880	223,680	503,880
Employee stock purchase plan	19,108	19,094	19,108	19,094
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.

6. 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 nine months ended September 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 September 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)
September 30, 2024				
Assets				
Cash equivalents:				
Money market funds	\$ 12,957	\$ 12,957	\$ —	\$ —
Marketable securities:				
Corporate debt securities	65,621	—	65,621	—
U.S. Treasury securities	4,586	—	4,586	—
Government-sponsored securities	6,828	—	6,828	—
Commercial paper	3,962	—	3,962	—
Total assets measured at fair value	<u>\$ 93,954</u>	<u>\$ 12,957</u>	<u>\$ 80,997</u>	<u>\$ —</u>
Liabilities				
Contingent consideration	4,096	—	—	4,096
Total liabilities measured at fair value	<u>\$ 4,096</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,096</u>
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	<u>\$ 153,629</u>	<u>\$ 77,299</u>	<u>\$ 76,330</u>	<u>\$ —</u>

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.

Contingent Consideration

The Company's contingent consideration liability is related to the Ironshore Acquisition in 2024. The Ironshore Acquisition included a contingent payment of \$25,000 related to the achievement of a financial milestone based on net revenues of Journey for the year ended December 31, 2025.

The contingent consideration liability is measured at fair value using an option pricing model. The Company classifies its contingent consideration liability as a Level 3 fair value measurement based on the significant unobservable inputs used to estimate fair value. The key assumptions considered in estimating the fair value include the estimated probability and timing of milestone achievement, such as the probability and timing of projected revenues.

Change in the Fair Value of Contingent Consideration

The following tables provide a reconciliation of the beginning and ending balances related to the contingent consideration for the Ironshore Acquisition (dollars in thousands):

	Ironshore Acquisition Contingent Consideration
Balance as of December 31, 2023	\$ —
Acquisition date fair value	4,096
Balance as of September 30, 2024	<u>\$ 4,096</u>

There were no changes in fair value of the contingent consideration liability from the Acquisition Date through the period end September 30, 2024.

Assets and Liabilities Not Carried at Fair Value

Convertible Senior Notes

The Company's convertible senior notes are considered Level 2 financial liabilities. The fair value was determined based on data points other than quoted prices that are observable, either directly or indirectly, such as broker quotes in a non-active market. As of September 30, 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 \$236,911.

Term Notes Payable

The Company's term notes are considered Level 2 financial liabilities. The fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals. As of September 30, 2024, the carrying amount of the term notes reasonably approximated the estimated fair value.

Deferred Royalty Obligation

The Company's deferred royalty obligation liability was assumed as part of the Ironshore Acquisition in 2024. Refer to Note 13, *Deferred Royalty Obligation*, for more information.

The royalty is not carried at fair value. The deferred royalty obligation is considered a level 3 fair value measurement. The fair value of the Company's deferred royalty obligation approximates the carrying value as of September 30, 2024.

Other Assets and Liabilities

As of September 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.

7. Marketable Securities

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

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ —	\$ 4,729
Marketable securities	80,997	71,601
Total	\$ 80,997	\$ 76,330

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

September 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	\$ 65,242	\$ 390	\$ (11)	\$ 65,621
U.S. Treasury securities	4,585	1	—	4,586
Government-sponsored securities	6,820	8	—	6,828
Commercial paper	3,957	5	—	3,962
Total	\$ 80,604	\$ 404	\$ (11)	\$ 80,997

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 September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Matures within one year	\$ 42,392	\$ 61,672
Matures after one year through five years	38,605	14,658
Total	\$ 80,997	\$ 76,330

The unrealized losses on the Company's available-for-sale securities were immaterial as of September 30, 2024 and December 31, 2023. In addition, there were no sales of marketable securities during the three and nine months ended September 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 nine months ended September 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 September 30, 2024 and December 31, 2023.

8. Inventory

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

	September 30, 2024	December 31, 2023
Raw materials	\$ 4,203	\$ 10,384
Work in process	17,389	6,740
Finished goods	16,440	15,208
Total inventory	\$ 38,032	\$ 32,332

The aggregate charges related to excess and obsolete inventory for the three and nine months ended September 30, 2024 were \$44 and \$477, respectively. The aggregate charges related to excess and obsolete inventory for the three and nine months ended September 30, 2023 were \$563 and \$1,624, respectively. These expenses were recorded as a component of cost of product revenues.

9. Goodwill and Intangible Assets

As of September 30, 2024 and December 31, 2023, the Company's goodwill balance was \$145,959 and \$133,857, respectively. The Company's goodwill resulted from the acquisition of BioDelivery Sciences International, Inc. ("BDSI") on March 22, 2022 (the "BDSI Acquisition") and the Ironshore Acquisition on September 3, 2024.

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

	September 30, 2024			December 31, 2023		
	Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Jornay	\$ 635,000	\$ (6,285)	\$ 628,715	\$ —	\$ —	\$ —
Belbuca	360,000	(190,366)	169,634	360,000	(133,821)	226,179
Nucynta Products	521,170	(424,247)	96,923	521,170	(382,710)	138,460
Symproic	70,000	(18,397)	51,603	70,000	(12,931)	57,069
Total intangible assets	<u>\$ 1,586,170</u>	<u>\$ (639,295)</u>	<u>\$ 946,875</u>	<u>\$ 951,170</u>	<u>\$ (529,462)</u>	<u>\$ 421,708</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Jornay PM	\$ 6,285	\$ —	\$ 6,285	\$ —
Belbuca	18,849	18,850	56,545	56,545
Nucynta Products	13,847	15,646	41,537	49,237
Symproic	1,820	1,821	5,466	5,464
Total amortization expense	<u>\$ 40,801</u>	<u>\$ 36,317</u>	<u>\$ 109,833</u>	<u>\$ 111,246</u>

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

Years ended December 31,	Jornay	Belbuca	Nucynta Products	Symproic	Total
2024	\$ 20,957	\$ 18,848	\$ 13,847	\$ 1,819	\$ 55,471
2025	83,829	75,393	55,384	7,285	221,891
2026	83,829	75,393	27,692	7,285	194,199
2027	83,829	—	—	7,285	91,114
2028	83,829	—	—	7,285	91,114
Thereafter	272,442	—	—	20,644	293,086
Remaining amortization expense	<u>\$ 628,715</u>	<u>\$ 169,634</u>	<u>\$ 96,923</u>	<u>\$ 51,603</u>	<u>\$ 946,875</u>

10. Accrued Liabilities

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

	September 30, 2024	December 31, 2023
Accrued bonuses	\$ 7,397	\$ 4,987
Accrued royalties	7,185	14,198
Accrued product taxes and fees	4,906	5,013
Accrued payroll and related benefits	4,332	1,511
Accrued sales and marketing	3,542	1,198
Accrued audit and legal	3,163	700
Liability for cash-settled share-based awards assumed from Ironshore Acquisition	3,044	—
Accrued inventory	2,415	—
Accrued incentive compensation	2,255	1,375
Accrued interest	1,943	2,853
Accrued severance expense related to Ironshore Acquisition	1,501	—
Accrued income taxes	1,066	2,136
Accrued other operating costs	4,851	3,600
Total accrued liabilities	<u>\$ 47,600</u>	<u>\$ 37,571</u>

11. Term Notes Payable

2024 Term Loan

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 2024 Loan Agreement provided 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 used the proceeds of the delayed draw term loan to fund a portion of the consideration to complete the Ironshore Acquisition and the 2024 Loan Agreement. The Company will use the remainder for general corporate purposes.

The 2024 Loan Agreement was accounted for as a debt modification as there was no change in the debtor or creditor and the present value of the cash flows under the terms of the new debt instrument were not at least 10% different from the present value of the remaining cash flows under the terms of the original instrument. The Company concluded that the present value of the cash flows under the terms of the new debt instrument were not at least 10% different from the present value of the remaining cash flows under the terms of the original instrument. Accordingly, the new effective interest rate was determined based on the carrying amount of the original debt instrument adjusted for the increase in debt, and transaction fees of \$126 were expensed. In connection with the 2024 Loan Agreement, the Company paid loan commitment and other fees to the lender of \$11,825, which together with preexisting debt issuance costs and note discounts of \$4,192 are amortized over the term of the loan using the effective interest rate.

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. Until September 30, 2024, the 2024 Term Loan bore an annual interest rate equal to term SOFR plus a spread adjustment of 0.13% (subject to a 1.20% floor), plus a margin of 7.50%. Following September 30, 2024, the 2024 Term Loan bears an annual interest rate equal to term SOFR plus a spread adjustment of 0.13% (subject to a 4.00% floor), plus a margin of 4.50% per annum, and is 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 paid a one-time fee of 2.25% of the delayed draw term loan principal amount on September 3, 2024. As of September 30, 2024, the contractual interest rate was 13.0%. The Company is required to pay the \$645,833 principal balance under the 2024 Term Loan in equal quarterly installments of \$16,146 over the remaining four years with a \$387,500 final payment.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Contractual interest expense	\$ 13,936	\$ 16,746	\$ 39,691	\$ 52,089
Amortization of debt discounts and debt issuance costs	947	1,821	3,745	5,808
Total interest expense	\$ 14,883	\$ 18,567	\$ 43,436	\$ 57,897

As of September 30, 2024, the effective interest rate on the 2024 Term Loan was 10.9%, which includes the impact of the reduction in the stated interest rate in the contract from 7.50% to 4.50% as part of the debt modification.

As of September 30, 2024, scheduled principal repayments under the 2024 Term Loan were as follows:

Years ended December 31,	Principal Payments
2024	\$ 16,146
2025	64,583
2026	64,583
2027	64,583
2028	435,938
Total before unamortized discount and issuance costs	\$ 645,833
Less: unamortized discount and issuance costs	(15,534)
Term notes carrying value	\$ 630,299

12. 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 September 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.

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

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

	2029 Convertible Notes	
Principal	\$	241,500
Less: unamortized issuance costs		(4,589)
Net carrying amount	\$	<u>236,911</u>

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 September 30, 2024, the if-converted value of the 2029 Convertible Notes did not exceed the remaining principal amount.

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

Years ended December 31,	2029 Convertible Notes	
2024	\$	—
2025		6,943
2026		6,943
2027		6,943
2028		6,943
Thereafter		244,972
Total minimum payments	\$	272,744
Less: interest		(31,244)
Less: unamortized issuance costs		(4,589)
Convertible Notes carrying value	\$	<u>236,911</u>

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 nine months ended September 30, 2024, and 2023:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Contractual interest expense	\$ 1,736	\$ 1,909	\$ 5,523	\$ 5,297
Amortization of debt issuance costs	261	302	847	863
Total interest expense	<u>\$ 1,997</u>	<u>\$ 2,211</u>	<u>\$ 6,370</u>	<u>\$ 6,160</u>

13. Deferred Royalty Obligation

The Company's deferred royalty obligation liability is a debt obligation of Ironshore that was assumed as part of the Ironshore Acquisition. The deferred royalty obligation relates to royalty payments on net sales of Jornay that are paid to debtholders in exchange for funding provided to Ironshore by the debtholders. The royalty rate is 7.4% for net sales prior to July 1, 2025 and 9.7% thereafter through March 2032. The royalty payments are an unsecured obligation of the Company and there are no financial covenants or other restrictive covenants. The royalty payments are to be made semi-annually in February and August of each year related to the prior six-month calendar year period.

The deferred royalty obligation will be accreted to the total estimated royalty payments over the life of the agreement, which will be recorded as interest expense using the effective interest rate. The carrying value of the obligation will decrease for royalty payments made based upon the actual Jornay sales and related royalty payments. The effective interest rate is calculated based on current estimates of future royalty payments over the life of the arrangement. To the extent estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company accounts for any such changes by adjusting the effective interest rate on a prospective basis, which will adjust future interest expense. The initial effective interest rate and the rate as of September 30, 2024 was 15.2%.

A rollforward of the deferred royalty obligation is as follows:

	Deferred Royalty Obligation	
Acquired balance as of September 3, 2024	\$	118,339
Accretion interest expense		473
Payments made		—
Net carrying amount	\$	118,812

The total interest expense recognized related to the deferred royalty obligation during the three and nine months ended September 30, 2024 was \$1,526.

14. Equity

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

	Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
	Shares	Amount		Shares	Amount			
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	<u>39,029,639</u>	<u>\$ 39</u>	<u>\$ 565,111</u>	<u>(6,323,892)</u>	<u>\$ (137,381)</u>	<u>\$ (205,476)</u>	<u>\$ (124)</u>	<u>\$ 222,169</u>
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	<u>39,532,358</u>	<u>\$ 40</u>	<u>\$ 567,976</u>	<u>(7,212,781)</u>	<u>\$ (165,381)</u>	<u>\$ (185,870)</u>	<u>\$ (182)</u>	<u>\$ 216,583</u>
Exercise of common stock options	9,079	—	140	—	—	—	—	140
Issuance for employee stock purchase plan	17,126	—	471	—	—	—	—	471
Vesting of RSUs and PSUs	61,930	—	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(4,037)	—	(142)	—	—	—	—	(142)
Share repurchases from Accelerated Share Repurchase ("ASR") agreement	—	—	7,000	(173,659)	(7,000)	—	—	—
Stock-based compensation	—	—	7,317	—	—	—	—	7,317
Other comprehensive income, net of tax	—	—	—	—	—	—	575	575
Net income	—	—	—	—	—	9,335	—	9,335
Balance, September 30, 2024	<u>39,616,456</u>	<u>\$ 40</u>	<u>\$ 582,762</u>	<u>(7,386,440)</u>	<u>\$ (172,381)</u>	<u>\$ (176,535)</u>	<u>\$ 393</u>	<u>\$ 234,279</u>

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

	Common Stock		Additional Paid- In Capital	Treasury Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
	Shares	Amount		Shares	Amount			
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
Exercise of common stock options	21,185	—	302	—	—	—	—	302
Issuance for employee stock purchase plan	15,176	—	291	—	—	—	—	291
Vesting of RSUs and PSUs	18,207	—	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(7,359)	—	(172)	—	—	—	—	(172)
Share repurchases from Accelerated Share Repurchase ("ASR") agreement	—	—	—	(1,702,852)	(40,000)	—	—	(40,000)
Forward contract on ASR agreement	—	—	(10,000)	—	—	—	—	(10,000)
Stock-based compensation	—	—	7,027	—	—	—	—	7,027
Other comprehensive loss, net of tax	—	—	—	—	—	—	(14)	(14)
Net income	—	—	—	—	—	20,634	—	20,634
Balance, September 30, 2023	38,000,607	\$ 38	\$ 545,940	(4,938,675)	\$ (101,924)	\$ (265,129)	\$ (52)	\$ 178,873

Common Stock

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the Company's board of directors ("Board of Directors") prior to January 1st). As of September 30, 2024, there were 2,269,568 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 15, *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 (which may be made 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 was 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 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 this ASR agreement were settled and not outstanding as of September 30, 2024.

As of September 30, 2024, the Company repurchased 1,062,548 shares at a weighted-average price of \$32.94 per share for a total of \$35,000 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 September 30, 2024, \$115,000 remained available for share repurchases under the 2024-2025 Repurchase Program.

15. 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 nine months ended September 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 September 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 nine months ended September 30, 2024, and 2023 was \$45.06 and \$38.71, respectively.

Restricted Stock Units

The Company granted RSUs to employees during the nine months ended September 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 nine months ended September 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	1,205,775	34.63
Vested	(940,377)	23.22
Forfeited	(276,827)	27.94
Outstanding as of September 30, 2024	2,432,478	\$ 27.99

The weighted-average grant date fair value per share of RSUs granted for the nine months ended September 30, 2024 and 2023 was \$34.63 and \$26.27, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the nine months ended September 30, 2024, and 2023 was \$31,868 and \$16,906, 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 nine months ended September 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	(491,527)	20.49		
Cancelled	(1,000)	27.73		
Outstanding as of September 30, 2024	684,223	\$ 18.74	3.6	\$ 13,616
Exercisable as of September 30, 2024	684,083	\$ 18.74	3.6	\$ 13,613

There were no stock options granted during the nine months ended September 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 nine months ended September 30, 2024, 35,664 shares of common stock were purchased for total proceeds of \$827. The expense for the three months ended September 30, 2024 and 2023 was \$91 and \$55, respectively. The expense for the nine months ended September 30, 2024 and 2023 was \$224 and \$155, respectively.

Stock-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general and administrative	\$ 7,317	\$ 7,027	\$ 24,804	\$ 20,134
Total stock-based compensation expense	\$ 7,317	\$ 7,027	\$ 24,804	\$ 20,134

As of September 30, 2024, there was approximately \$54,165 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 2.3 years.

16. 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 the 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.

17. 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 nine months ended September 30, 2024 and 2023:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Provision for income taxes	\$ 6,245	\$ 8,149	\$ 24,645	\$ 12,808
Effective tax rate	40.1 %	28.3 %	30.3 %	44.1 %

The provision for income taxes for the three months ended September 30, 2024 reflects the estimated annual effective tax rate as adjusted for the discrete nondeductible costs. The provision for income taxes for the nine months ended September 30, 2024, reflect the estimated annual effective tax rate was additionally impacted by non-deductible costs from the debt extinguishment that occurred during the three months ended June 30, 2024, partially offset by discrete excess tax benefits related to stock-based compensation.

The provision for income taxes for the three months ended September 30, 2023 reflects the estimated annual effective tax rate. The provision for income taxes for the nine months ended September 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 Company provides a valuation allowance when it is more likely than not that deferred tax assets will not be realized. In determining the extent to which a valuation allowance for deferred tax assets is required, the Company evaluates all available evidence including projections of future taxable income, carry back opportunities, reversal of certain deferred tax liabilities, and other tax planning strategies. The Company has maintained a valuation allowance on the portion of its deferred tax assets that are not more likely than not to be realized due to tax limitation or other conditions as of September 30, 2024.

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 product portfolio, consisting of Belbuca, Xtampza ER, Nucynta IR and Nucynta ER (collectively the “Nucynta Products”), Symproic, and Jornay PM (“Jornay”) 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 BioDelivery Sciences International, Inc. (“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.

Jornay is a central nervous system (“CNS”) stimulant prescription medicine that contains methylphenidate HCl, which was approved by the FDA in August 2018 for the treatment of attention deficit hyperactivity disorder (“ADHD”) in people six years of age and older and currently the only FDA-approved stimulant medication that is dosed in the evening. We began recognizing product sales related to Jornay in September 2024 following our acquisition of Ironshore Therapeutics Inc. (“Ironshore”) (the “Ironshore Acquisition”).

Outlook

We believe that our cash and cash equivalents as of September 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.

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

Business Combination Accounting and Valuation of Acquired Net Assets

We completed the Ironshore Acquisition on September 3, 2024, which was accounted for as a business combination. To determine whether the acquisition should be accounted for as a business combination or as an asset acquisition, we made certain judgments regarding whether the acquired set of activities and assets met the definition of a business. Judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

The acquisition method of accounting requires that we recognize the assets acquired and liabilities assumed at their acquisition date fair values. Goodwill is measured as the excess of consideration transferred over the acquisition date net fair values of the assets acquired and the liabilities assumed. The purchase price allocation is a critical accounting estimate because the estimation of fair values of acquired assets and assumed liabilities is judgmental and requires various assumptions based on non-observable inputs. An income approach, which generally relies upon projected cash flow models, is used in estimating the fair value of the acquired intangible assets, the fair value of acquired inventory and the fair value of the assumed deferred royalty obligation. These cash flow projections are based on management's estimates of economic and market conditions including the estimated future cash flows from revenues of acquired assets; the timing and projection of costs and expenses, discount rates; and tax rates.

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

Results of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Product revenues, net	\$ 159,301	\$ 136,709	\$ 449,500	\$ 417,022
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	21,706	20,081	60,611	74,237
Intangible asset amortization	40,801	36,317	109,833	111,246
Total cost of product revenues	62,507	56,398	170,444	185,483
Gross profit	96,794	80,311	279,056	231,539
Operating expenses				
Selling, general and administrative	61,955	35,298	147,272	126,266
Total operating expenses	61,955	35,298	147,272	126,266
Income from operations	34,839	45,013	131,784	105,273
Interest expense	(18,394)	(20,768)	(51,320)	(64,058)
Interest income	3,280	4,538	12,164	11,312
Loss on extinguishment of debt	(4,145)	—	(11,329)	(23,504)
Income before income taxes	15,580	28,783	81,299	29,023
Provision for income taxes	6,245	8,149	24,645	12,808
Net income (loss)	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215

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

Product revenues, net

Product revenues, net were \$159.3 million for the three months ended September 30, 2024 (the “2024 Quarter”), compared to \$136.7 million for the three months ended September 30, 2023 (the “2023 Quarter”). The \$22.6 million increase is primarily due to increased revenue for Xtampza of \$9.7 million, Belbuca of \$7.7 million, and Jornay of \$8.0 million, partially offset by decreased revenue for the Nucynta Products of \$2.4 million.

The increase in revenue for Xtampza ER of \$9.7 million is primarily due to lower gross-to-net adjustments related to provisions for rebates and returns as well as higher gross price, partially offset by lower sales volume.

The increase in revenue for Jornay of \$8.0 million is due to the acquisition of the product from Ironshore in the 2024 Quarter.

The increase in revenue for Belbuca of \$7.7 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 decrease in revenue for the Nucynta Products of \$2.4 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 \$21.7 million for the 2024 Quarter, compared to \$20.1 million for the 2023 Quarter. The \$1.6 million increase was due to the addition of Jornay as a result of the Ironshore Acquisition in 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. Intangible asset amortization was \$40.8 million for the 2024 Quarter, compared to \$36.3 million for the 2023 Quarter. The \$4.5 million increase was primarily due to the addition of the Jornay intangible asset during the 2024 Quarter, partially offset by a decrease as a result of the FDA granting New Patient Population exclusivity for Nucynta IR through 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.

Operating Expenses

Selling, general and administrative expenses were \$62.0 million for the 2024 Quarter, compared to \$35.3 million for the 2023 Quarter. The \$26.7 million increase was primarily related to:

- an increase in acquisition-related expense of \$19.9 million due to the Ironshore Acquisition;
- an increase in salaries, wages and benefits of \$4.0 million primarily due to additional headcount added in the 2024 Quarter as a result of the Ironshore Acquisition, including the sales force that promotes Jornay; and
- an increase in sales and marketing expenses of \$3.0 million, primarily due to the timing of marketing related expenses as well as additional sales and marketing expenses to support Jornay.

Interest expense and Interest income

Interest expense was \$18.4 million for the 2024 Quarter, compared to \$20.8 million for the 2023 Quarter. The \$2.4 million decrease was primarily due to lower interest expense associated with the 2022 Term Loan and 2024 Term Loan as a result of lower interest rates, partially offset by additional interest costs from borrowings to partially finance the acquisition of Ironshore.

Interest income was \$3.3 million for the 2024 Quarter, compared to \$4.5 million for the 2023 Quarter. The \$1.2 million decrease was primarily due to a lower overall balance invested in the 2024 Quarter compared to the 2023 Quarter as a result of cash being used to fund the Ironshore Acquisition in the 2024 Quarter.

Loss on extinguishment of debt

Loss on extinguishment of debt was \$4.1 million for the 2024 Quarter, compared to none in the 2023 Quarter. The \$4.1 million increase was due to the redemption and extinguishment of assumed debt from the Ironshore Acquisition during the 2024 Quarter.

Taxes

The provision for income taxes was \$6.2 million for the 2024 Quarter, compared to \$8.1 million for the 2023 Quarter. The \$1.9 million decrease is primarily due to lower earnings in the 2024 Quarter compared to the 2023 Quarter primarily due to acquisition related-expense incurred during the 2024 Quarter due to the Ironshore Acquisition.

Comparison of the nine months ended September 30, 2024 and September 30, 2023

Product revenues, net

Product revenues, net were \$449.5 million for the nine months ended September 30, 2024 (the “2024 Period”), compared to \$417.0 million for the nine months ended September 30, 2023 (the “2023 Period”). The \$32.5 million increase is primarily due to increased revenue for Belbuca of \$23.3 million, Xtampza of \$11.0 million and Jornay of \$8.0 million, partially offset by decreased revenue for the Nucynta Products of \$9.1 million.

The increase in revenue for Belbuca of \$23.3 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 \$11.0 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 Jornay of \$8.0 million is due to the acquisition of the product from Ironshore in the 2024 Quarter.

The decrease in revenue for the Nucynta Products of \$9.1 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 \$60.6 million for the 2024 Period, compared to \$74.2 million for the 2023 Period. The \$13.6 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 cost of product revenues for Jornay as well as higher sales volume in the 2024 Period for Belbuca.

Intangible asset amortization was \$109.8 million for the 2024 Period, compared to \$111.2 million for the 2023 Period. The \$1.4 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. This decrease was partially offset by an increase in intangible asset amortization following the Ironshore Acquisition in the 2024 Period.

Operating Expenses

Selling, general and administrative expenses were \$147.3 million for the 2024 Period, compared to \$126.3 million for the 2023 Period. The \$21.0 million increase was primarily related to:

- an increase in acquisition related expense of \$19.9 million due to the Ironshore Acquisition; and
- an increase in salaries, wages and benefits of \$10.9 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, as well as an increase of \$4.1 million in other salaries, wages and benefits expense, including the

impact of the additional headcount added in the 2024 Quarter as a result of the Ironshore Acquisition, including the sales force for Jornay; partially offset by

- a decrease in audit and legal expenses of \$9.9 million, primarily due to an \$8.5 million litigation settlement during the 2023 Period and lower litigation related expenses.

Interest expense and Interest income

Interest expense was \$51.3 million for the 2024 Period, compared to \$64.1 million for the 2023 Period. The \$12.8 million decrease was primarily due to lower interest expense associated with the 2022 Term Loan and 2024 Term Loan as a result of a lower average overall principal balance during the 2024 Period, partially offset by additional interest costs from borrowings on September 3, 2024 to partially finance the acquisition of Ironshore.

Interest income was \$12.2 million for the 2024 Period, compared to \$11.3 million for the 2023 Period. The \$0.9 million increase was primarily due to higher interest rates earned on cash equivalents and marketable securities as well as a higher overall average balance invested in the 2024 Period compared to the 2023 Period.

Loss on extinguishment of debt

Loss on extinguishment of debt was \$11.3 million for the 2024 Period, compared to \$23.5 million in the 2023 Period. The \$12.2 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. In addition, in the 2024 Period, assumed debt from the Ironshore Acquisition was redeemed, resulting in a loss on extinguishment of \$4.1 million in the 2024 Period.

Taxes

The provision for income taxes was \$24.6 million for the 2024 Period, compared to \$12.8 million for the 2023 Period. The \$11.8 million increase is primarily due to higher earnings in the 2024 Period compared to the 2023 Period. These increases were partially offset by the 2023 Period including higher non-deductible costs associated with debt extinguishments.

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, the Nucynta Products, and Jornay.

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 used the proceeds of the delayed draw term loan to fund a portion of the consideration to complete the Ironshore Acquisition and, pay fees and expenses in connection with the Ironshore Acquisition and the 2024 Term Loan. We will use the remainder for general corporate purposes.

As of September 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 September 30, 2024, we had \$120.0 million in cash, cash equivalents, and marketable securities. We believe that our cash, cash equivalents, and marketable securities as of September 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 12, *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 11, *Term Note Payable*, for more information.

Cash Flows

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash provided by operating activities	\$ 120,336	\$ 201,411
Net cash used in investing activities	(275,997)	(45,715)
Net cash (used in) provided by financing activities	(19,326)	(72,352)
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (174,987)</u>	<u>\$ 83,344</u>

Operating activities. Cash provided by operating activities was \$120.3 million for the 2024 Period, compared to \$201.4 million for the 2023 Period. The \$81.1 million decrease was primarily due to cash used to settle certain liabilities assumed from Ironshore, including \$28.4 million of Ironshore’s cash-settled share-based awards liabilities, \$23.5 million of accrued operating liabilities, and \$9.0 million of Ironshore cash-settled warrant liabilities. In addition, various acquisition-related expenses were incurred and paid in the 2024 Period, including \$7.6 million in transaction costs, \$6.7 million in employee-related expenses, and \$1.1 million in Ironshore directors and officers insurance expense in the 2024 Period related to the Ironshore Acquisition.

Investing activities. Cash used in investing activities was \$276.0 million for the 2024 Period, compared to \$45.7 million for the 2023 Period. The \$230.3 million increase was primarily due to \$267.5 million cash paid to acquire Ironshore (net of cash acquired) and \$32.6 million increase in purchases of marketable securities, partially offset by \$70.6 million increase in maturities of marketable securities.

Financing activities. Cash used in financing activities was \$19.3 million for the 2024 Period, compared to \$72.4 million in the 2023 Period. The \$53.1 million decrease was primarily due to:

- an increase in proceeds received from the modification of term loans of \$313.2 million;
- a decrease in repayments of term notes of \$25.0 million;
- a decrease in cash used to repurchase common stock of \$15.0 million;
- an increase in cash provided from stock option exercises of \$4.7 million; partially offset by
- the payoff of assumed debt from Ironshore of \$164.6 million in the 2024 Period;
- 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;
- the \$33.2 million cash settlement of our 2026 Convertible Notes in the 2024 Period; and
- an increase in payments for employee stock tax withholdings of \$10.8 million.

Funding Requirements

We believe that our cash, cash equivalents, and marketable securities as of September 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;
- cash paid for income taxes;
- deferred royalty obligation in connection with Jornay, and
- contingent payment upon the achievement of a financial milestone based on net revenues of Jornay.

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 16, *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 nine months ended September 30, 2024 and 2023 was as follows:

	Three Months Ended September 30, 2024		Nine Months Ended September 30, 2023	
	2024	2023	2024	2023
	(in thousands)			
GAAP net income	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215
Adjustments:				
Interest expense	18,394	20,768	51,320	64,058
Interest income	(3,280)	(4,538)	(12,164)	(11,312)
Loss on extinguishment of debt	4,145	—	11,329	23,504
Provision for income taxes	6,245	8,149	24,645	12,808
Depreciation	946	835	2,815	2,547
Amortization	40,801	36,317	109,833	111,246
Stock-based compensation	7,317	7,027	24,804	20,134
Litigation settlements	—	—	—	8,500
Recognition of step-up basis in inventory	1,301	198	1,301	15,116
CEO transition expense	—	—	3,051	—
Acquisition related expenses	19,886	—	19,886	—
Total adjustments	\$ 95,755	\$ 68,756	\$ 236,820	\$ 246,601
Adjusted EBITDA	\$ 105,090	\$ 89,390	\$ 293,474	\$ 262,816

Adjusted EBITDA was \$105.1 million for the 2024 Quarter compared to \$89.4 million for the 2023 Quarter. The \$15.7 million increase was primarily due to higher product revenues.

Adjusted EBITDA was \$293.5 million for the 2024 Period compared to \$262.8 million for the 2023 Period. The \$30.7 million increase was primarily due to higher product revenues.

Adjusted Operating Expenses

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)			
GAAP operating expenses	\$ 61,955	\$ 35,298	\$ 147,272	\$ 126,266
Adjustments:				
Stock-based compensation	7,317	7,027	24,804	20,134
Litigation settlements	—	—	—	8,500
CEO transition expense	—	—	3,051	—
Acquisition related expenses	19,886	—	19,886	—
Total adjustments	\$ 27,203	\$ 7,027	\$ 47,741	\$ 28,634
Adjusted operating expenses	<u>\$ 34,752</u>	<u>\$ 28,271</u>	<u>\$ 99,531</u>	<u>\$ 97,632</u>

Adjusted operating expenses were \$34.8 million in the 2024 Quarter compared to \$28.3 million in the 2023 Quarter. The \$6.5 million was primarily driven by:

- higher salaries, wages and benefits (excluding stock-based compensation expense) of \$3.8 million due to additional headcount added in the 2024 Quarter as a result of the Ironshore Acquisition, including the sales force for Jornay; and
- higher sales and marketing expenses of \$3.0 million, primarily due to the timing of marketing related expenses as well as additional sales and marketing expenses to support Jornay following in the Ironshore Acquisition.

Adjusted operating expenses were \$99.5 million in the 2024 Period compared to \$97.6 million in the 2023 Period. The \$1.9 million increase was primarily driven by:

- higher salaries, wages and benefits (excluding stock-based compensation expense) of \$3.8 million due to additional headcount added in the 2024 Quarter as a result of the Ironshore Acquisition, including the sales force for Jornay; partially offset by
- lower audit and legal expenses (excluding litigation settlements) of \$1.4 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 nine months ended September 30, 2024 and 2023 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands, except share and per share data)			
GAAP net income	\$ 9,335	\$ 20,634	\$ 56,654	\$ 16,215
Adjustments:				
Non-cash interest expense	1,681	2,124	5,065	6,672
Loss on extinguishment of debt	4,145	—	11,329	23,504
Amortization	40,801	36,317	109,833	111,246
Stock-based compensation	7,317	7,027	24,804	20,134
Litigation settlements	—	—	—	8,500
Recognition of step-up basis in inventory	1,301	198	1,301	15,116
CEO transition expense	—	—	3,051	—
Acquisition related expenses	19,886	—	19,886	—
Income tax effect of above adjustments ⁽¹⁾	(20,974)	(11,300)	(45,635)	(42,274)
Total adjustments	\$ 54,157	\$ 34,366	\$ 129,634	\$ 142,898
Non-GAAP adjusted net income	\$ 63,492	\$ 55,000	\$ 186,288	\$ 159,113
Adjusted weighted-average shares — diluted ⁽²⁾	40,163,266	42,058,820	40,400,483	41,679,546
Adjusted earnings per share ⁽²⁾	\$ 1.61	\$ 1.34	\$ 4.71	\$ 3.91

(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 September 30, 2024 and 2023 were 28.1% and 25.6%, respectively; and the blended federal and state statutory rate for the nine months ended September 30, 2024 and 2023 were 27.1% and 25.6%, respectively. As such, the non-GAAP effective tax rates for the three months ended September 30, 2024 and 2023 were 27.9% and 24.7%, respectively; and the non-GAAP effective tax rates for the nine months ended September 30, 2024 and 2023 were 26.0% and 22.8%, 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 September 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 nine months ended September 30, 2024 and 2023, adjusted weighted-average shares – diluted includes 6,606,305 and 6,530,392 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

With the exception of the 2024 Term Loan as discussed in Note 11, *Term Notes Payable*, and deferred royalty obligation as discussed in Note 13, *Deferred Royalty Obligation*, 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 September 30, 2024, our investment portfolio includes \$13.0 million of cash equivalents and \$81.0 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 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 November 7, 2024 of \$645.8 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately \$6.5 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 September 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 September 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. As permitted by SEC guidance, which provides that a newly acquired company may be excluded from management’s evaluation of disclosure controls and procedures for up to a year from the date of acquisition, Ironshore was excluded from the evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2024. Ironshore, which we acquired in September 2024, represented approximately 8% of the Company’s total consolidated assets (excluding goodwill, intangibles, and the recognition of step-up basis in inventory) and 2% of our consolidated total revenue for the nine months ended September 30, 2024.

Changes in Internal Control Over Financial Reporting

We are currently in the process of evaluating and integrating the acquired operations, processes, and internal controls of Ironshore. Except for the acquisition of Ironshore, which we expect to integrate into our existing internal control environment, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth in Note 16, *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;
- Our ability to realize the benefits of the Ironshore Therapeutics, Inc. ("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 17, *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 the Ironshore acquisition, 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 \$645.8 million in principal was outstanding as of November 7, 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 adjusted term Secured Overnight Financing Rate (“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, Jornay 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 supplemental NDA 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. We recently acquired the sales force supporting Jornay in connection with the Ironshore acquisition and we cannot guarantee that we will be able to build and manage the Jornay sales infrastructure, while continuing to support and maintain our existing sales organization. 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 Jornay, 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, Symproic, and Jornay 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 hydrochloride and Jornay's active ingredient, methylphenidate hydrochloride, are each classified as Schedule II controlled substances under the Controlled Substances Act ("CSA") and regulations of the DEA and the active ingredient in Belbuca, buprenorphine hydrochloride, is classified as a Schedule III controlled substance. A number of states also independently regulate these drugs, including oxycodone, tapentadol, methylphenidate 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, the Nucynta Products or Jornay increases and we cannot meet such demand in a timely fashion because of our limited supply of their active pharmaceutical ingredients, 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 drug products can vary widely. Current and future legislation may significantly change these 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 market and sell any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments are 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.

The Inflation Reduction Act of 2022 (the "IRA"), for example, contains substantial drug pricing reforms, including the establishment of a drug price negotiation program under the Medicare program that would subject manufacturers of some brand-name medications without generic or biosimilar competition to a price negotiation process that results in a negotiated "maximum fair price" (or alternatively requires manufacturer who do not participate in the negotiation process to 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 and stimulants, 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 and stimulants. 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 and stimulants, including Xtampza ER, the Nucynta Products, Belbuca and Jornay; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid and stimulant 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 and stimulant 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 16, *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 have sought in the past, and may seek in the future, 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.

Additionally, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), was enacted in 2019 requiring sponsors of approved drugs to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to respond to such requests or any legal challenges under this law, our business could be adversely impacted.

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 manufacturers, 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 manufacturers could default on their agreements 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 manufacturers 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 manufacturers were to terminate our arrangements 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. Recently, the ADHD market has encountered several supply chain interruptions, due to, among other items, limited DEA quota of methylphenidate hydrochloride, creating a shortage in supply of ADHD medication. In July 2024, the U.S. Centers for Disease Control and Prevention issued an official health advisory warning, noting that patients who rely on prescription stimulant medications to treat ADHD could experience a disruption to their treatment and disrupted access to care while the shortage persists. While Jornay has not experienced these issues to date, there is no assurance that we will not experience these issues related to Jornay in the future.

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.

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 interruptions have 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

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 closed on September 3, 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;
- unanticipated issues associated with our entrance into the ADHD market, which we have no direct prior experience in;
- unexpected losses of key employees, customers or suppliers;
- inability to successfully manage the newly acquire Jornay sales force, while continuing to build and maintain our existing sales organization;
- 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. Belbuca, Xtampza ER, and the Nucynta 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. Jornay competes with currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Products of these types are marketed by J&J Innovative Medicines, Supernus Pharmaceuticals, Inc., Tris Pharma, Novartis AG, Noven Therapeutics, LLC, UCB SA, Aytu BioScience, Inc. Adlon Therapeutics, Inc. 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 September 30, 2024, there were outstanding options to purchase an aggregate of 684,223 shares of our common stock at a weighted average exercise price of \$18.74 per share, of which options to purchase 684,083 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 September 30, 2024, we repurchased 1,062,548 shares at a weighted-average price of \$32.94 per share for a total of \$35.0 million under the 2024-2025 Repurchase Program. As of September 30, 2024, \$115 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 September 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)
July 1, 2024 through July 31, 2024	174,285	\$ 32.93	173,659	\$ 115,000
August 1, 2024 through August 31, 2024	2,352	35.62	—	115,000
September 1, 2024 through September 30, 2024	1,059	36.07	—	115,000
Total	177,696 ⁽²⁾	\$ 32.98	173,659 ⁽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 September 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.

The following table shows the “Rule 10b5-1 trading arrangements” or “non-Rule 10b5-1 trading arrangements” (as each term is defined in Item 408(a) of Regulation S-K) adopted, amended, or terminated by our directors and officers during the three months ended September 30, 2024:

Name	Title	Action	Effective Date	Trading Arrangement		Scheduled Expiration Date of Trading Plan (1)	Maximum Shares Subject to Trading Plan
				Rule 10b5-1	Non-Rule 10b5-1		
Colleen Tupper	Executive Vice President and Chief Finance Officer	Adoption	August 14, 2024	X		April 30, 2025	69,260
Scott Dreyer	Executive Vice President and Chief Commercial Officer	Adoption	August 28, 2024	X		August 22, 2025	106,450
Shirley Kuhlmann	Executive Vice President, Chief Administrative Officer, General Counsel & Secretary	Adoption	September 13, 2024	X		March 31, 2025	107,500

- (1) A trading arrangement may expire on an earlier date if all contemplated transactions are completed before such trading arrangement’s expiration date, upon termination by broker or the holder of the trading arrangement, or as otherwise provided in the trading arrangement.

Item 6. Exhibits.

Exhibit

<u>Number</u>	<u>Exhibit Description</u>
2.1* [^]	Agreement and Plan of Merger, dated as of July 28, 2024, by and among the Company, Ironshore Therapeutics Inc. and Shareholder Representative Services LLC.
10.1	Second Amended and Restated Loan Agreement by and among the Company, its subsidiaries party thereto; BioPharma Credit PLC, as collateral agent and lender; BPCR Limited Partnership, and BioPharma Credit Investments V (Master) LP, as lender, dated as of July 28, 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.

[^] Schedules omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

SIGNATURES

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

**COLLEGIUM
PHARMACEUTICAL, INC.**

Date: November 7, 2024

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

Date: November 7, 2024

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

**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: November 7, 2024

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

I, Colleen Tupper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ COLLEEN TUPPER

Colleen Tupper
Executive Vice President and Chief Financial Officer

Date: November 7, 2024

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the “Company”) for the period ended September 30, 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: November 7, 2024

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended September 30, 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: November 7, 2024
