

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 3, 2024

COLLEGIUM PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Virginia
(State or Other Jurisdiction
of Incorporation or Organization)

001-37372
(Commission File Number)

03-0416362
(IRS Employer Identification
No.)

100 Technology Center Drive
Suite 300
Stoughton, MA 02072
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 713-3699

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

Title of each class
Common stock, par value \$0.001 per share

Trading Symbol(s)
COLL

Name of each exchange on which registered
The NASDAQ Global Select Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.01 Completion of Acquisition or Disposition of Assets.

As previously disclosed, on July 28, 2024, Collegium Pharmaceutical, Inc. (the “Company”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Carrera Merger Sub Inc., an exempted company registered by way of continuation under the laws of the Cayman Islands and wholly owned subsidiary of the Company (“Merger Sub”), Ironshore Therapeutics Inc., an exempted company registered by way of continuation under the laws of the Cayman Islands (“Ironshore”) and Shareholder Representative Services LLC, a Colorado limited liability company, acting solely in its capacity as the representative, agent and attorney-in-fact of the securityholders of the Ironshore. Upon the closing of the acquisition (the “Closing”) on September 3, 2024 (the “Closing Date”), Merger Sub merged with and into Ironshore, with Ironshore continuing as the surviving company and a wholly-owned subsidiary of the Company (the “Merger”).

The aggregate consideration paid by the Company at the Closing pursuant to the Merger Agreement was approximately \$525 million in cash (subject to customary adjustments for net working capital, indebtedness, cash, and transaction expenses), with one potential future commercial milestone payment of \$25 million.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

As previously disclosed, on July 28, 2024, in connection with signing of the Merger Agreement, 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 “Loan Agreement”), which provided for, among other things, a \$325 million delayed draw term loan. On the Closing Date, the Company drew upon the delayed draw term loan and used the proceeds of the delayed draw term loan to fund a portion of the Merger consideration and pay fees and expenses in connection with the Merger and the Loan Agreement.

Item 7.01 Regulation FD Disclosure.

On September 4, 2024, the Company issued a press release announcing the Closing, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. In addition, on September 4, 2024, the Company posted a corporate presentation to its website that representatives of the Company may use from time to time in presentations or discussions with investors, analysts or other parties. A copy of the presentation is attached hereto as Exhibit 99.2.

The information included in this item and Exhibit 99.1 and Exhibit 99.2 are not deemed to be “filed” for purposes of Section 18 of the Exchange Act, nor shall this item or Exhibit 99.1 or Exhibit 99.2 be incorporated by reference into the Company’s filings under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such future filing.

Item 9.01 Financial Statements and Exhibits.**(a) Financial Statements of the Business Acquired.**

Financial statements, to the extent required by this Item 9.01, will be filed by amendment to this Current Report on Form 8-K within seventy-one (71) calendar days from the date that this Current Report on Form 8-K is required to be filed.

(b) Pro Forma Financial Information.

Pro forma financial information, to the extent required by this Item 9.01, will be filed by amendment to this Current Report on Form 8-K within seventy-one (71) calendar days from the date that this Current Report on Form 8-K is required to be filed.

(d) Exhibits.

[99.1](#) [Press release of the Company, dated September 4, 2024](#)

[99.2](#) [Investor Presentation of the Company, dated September 4, 2024](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

Dated: September 4, 2024

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper
Name: Colleen Tupper
Title: Executive Vice President and Chief Financial Officer



Collegium Completes Acquisition of Ironshore Therapeutics

– Adds Commercial Product Jornay PM[®], Establishing Collegium's Presence in Neurology (ADHD) –

– Collegium Updates 2024 Financial Guidance to Reflect Expected Immediate Accretion from the Ironshore Acquisition –

– 2024 Product Revenues, Net Expected in the Range of \$620.0 Million to \$635.0 Million –

STOUGHTON, Mass., September 4, 2024 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced that it has completed the acquisition of Ironshore Therapeutics Inc., a privately held company that markets and distributes Jornay PM (methylphenidate HCl), a central nervous system (CNS) stimulant for the treatment of attention deficit hyperactivity disorder (ADHD). Collegium also updated its 2024 financial guidance to include the anticipated impact of the Ironshore acquisition.

"We are pleased to have successfully closed the acquisition of Ironshore, which represents an important milestone as we build a leading, diversified specialty pharmaceutical company," said Michael Heffernan, Chairman and Interim President and Chief Executive Officer of Collegium. "With the addition of Jornay PM to our portfolio, we are establishing our presence in the large and growing ADHD market with a highly differentiated product that is poised to become our leading growth driver. By leveraging our core commercial competencies and proven track record of efficiently and successfully integrating commercial products, we are well positioned to maximize our pain portfolio, seamlessly integrate Jornay PM, and the Ironshore team, into our business and deliver on the immediate accretion to both our top- and bottom-lines."

Strategic Rationale

- Strategically aligns with Collegium's mission of building a leading, diversified specialty pharmaceutical company by broadening the commercial portfolio beyond pain management and establishing a commercial presence in neurology via the large and growing ADHD market.
- Jornay PM is poised to become Collegium's leading growth driver. Net revenue for Jornay PM is expected to be in excess of \$100 million in 2024. In the first half of 2024, Jornay PM prescriptions grew 32% year-over-year. For the full-year 2023, the product generated approximately 490,000 prescriptions, a 58% increase compared to 2022. Jornay PM is a highly differentiated treatment for ADHD due to its evening dosing, smooth therapeutic effect and dose-dependent duration.
- Jornay PM is supported by 16 Orange Book-listed patents, with expiries in 2032.
- Further strengthens Collegium's financial position through an increased revenue base, expected immediate accretion to adjusted EBITDA and accelerated cash flow generation.

For additional background on the acquisition, please read the announcement press release [here](#) and view Collegium's investor presentation.

Additional Transaction Details

Under the terms of the agreement, Collegium acquired all the outstanding shares of Ironshore for \$525 million in cash, which was funded by \$200 million of Collegium's existing cash on hand and \$325 million of Collegium's \$646 million term loan provided by investment funds managed by Pharmakon Advisors, LP. Collegium will also pay Ironshore shareholders \$25 million in additional consideration if Jornay PM net revenue exceeds a defined threshold in 2025. The balance of the \$646 million five-year term loan was used to repay Collegium's prior \$320.8 million term loan, reducing Collegium's interest rate by 300 basis points.

Financial Guidance for 2024

Collegium updates its full-year 2024 financial guidance for Product Revenues, Net, Adjusted Operating Expenses and Adjusted EBITDA, which includes four months of anticipated impact from the acquisition of Ironshore.

	<u>Prior</u>	<u>Updated</u>
Product Revenues, Net	\$580.0 to \$595.0 million	\$620.0 to \$635.0 million
Adjusted Operating Expenses (Excluding Stock-Based Compensation)	\$120.0 to \$125.0 million	\$150.0 to \$155.0 million
Adjusted EBITDA (Excluding Stock-Based Compensation)	\$380.0 to \$395.0 million	\$395.0 to \$405.0 million

About JORNAY PM®

JORNAY PM (methylphenidate HCl extended-release capsules) is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

- JORNAY PM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.
- Before prescribing JORNAY PM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout JORNAY PM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse and addiction.

See additional important safety information below.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- *Risks to Patients with Serious Cardiac Disease:* Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

- *Increased Blood Pressure and Heart Rate.*
- *Psychiatric Adverse Reactions:* Including exacerbation of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder, induction of a manic episode in patients with bipolar disorder, and new psychotic or manic symptoms. Prior to initiating treatment, screen patients for risk factors for psychiatric adverse reactions. If such symptoms occur, consider discontinuing JORNAY PM.
- *Priapism:* Patients should seek immediate medical attention.
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Observe patients for digital changes during treatment.
- *Weight Loss and Long-Term Suppression of Growth in Pediatric Patients:* Monitor height and weight.
- *Increased Intraocular Pressure (IOP) and Glaucoma:* Patients at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist. Closely monitor patients with a history of abnormally increased IOP or open angle glaucoma.
- *Onset or Exacerbation of Motor and Verbal Tics, and Worsening of Tourette's Syndrome.*

ADVERSE REACTIONS

- The most common ($\geq 5\%$ and twice the rate of placebo) adverse reactions with methylphenidate are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- Additional adverse reactions ($\geq 5\%$ and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

DRUG INTERACTIONS

- Antihypertensive drugs: Monitor blood pressure data. Adjust dosage of antihypertensive drug as needed.

To report SUSPECTED ADVERSE REACTIONS, contact Ironshore Pharmaceuticals Inc. at 1-877-938-4766 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please visit <https://ironshorepharma.com/jornay-pm-label> for additional important safety information and the Full Prescribing Information, including Boxed Warning, for JORNAY PM.

About Collegium Pharmaceutical, Inc.

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit Collegium's website at www.collegiumpharma.com.

Non-GAAP Financial Measures

We have included information about certain non-GAAP financial measures in this press release. We use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe 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.

In this press release we discuss the following financial measures that are not calculated in accordance with GAAP.

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 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.

We have not provided a reconciliation of our full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(i)(B) of Regulation S-K, because we are unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation, including, but not limited to, stock-based compensation expense, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of our control or cannot be reasonably predicted. While we are unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period. A reconciliation of adjusted EBITDA or adjusted operating expenses would imply a degree of precision and certainty as to these future items that does not exist and could be confusing to investors.

Collegium Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to the anticipated benefits of the acquisition of Ironshore Therapeutics, the anticipated financial impact of the acquisition of Ironshore Therapeutics, our expectations for Jornay PM revenues, our full-year 2024 financial guidance, including projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from Collegium's current expectations, including risks relating to, among others: risks related to our ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of the consummation of the acquisition on the market price of our common stock and/or operating results; risks related to significant transaction costs or the acquisition of unknown liabilities; risks related to future opportunities and plans for Ironshore Therapeutics and Jornay PM, including uncertainty of the expected financial performance of Jornay PM; risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, and our ability to service those markets; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of our products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; the outcome of any governmental investigation related to our business; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency (DEA) compliance; our customer concentration; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Investor Presentation



September 2024 | Nasdaq: COLL

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this presentation include, among others, statements related to the anticipated benefits of the acquisition of Ironshore Therapeutics, the anticipated financial impact of the acquisition of Ironshore Therapeutics, our expectations for Jorjay PM revenues, our full-year 2024 financial guidance, including projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from Collegium's current expectations, including risks relating to, among others: risks related to our ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully, disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of the consummation of the acquisition on the market price of our common stock and/or operating results; risks related to significant transaction costs or the acquisition of unknown liabilities; risks related to future opportunities and plans for Ironshore Therapeutics and Jorjay PM, including uncertainty of the expected financial performance of Jorjay PM, risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, and our ability to service those markets; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of our products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; the outcome of any governmental investigation related to our business; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency (DEA) compliance; our customer concentration; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this presentation speak only as of the date of this presentation. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this presentation.

Non-GAAP Financial Measures

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.

In this presentation, we discuss the following financial measures that are not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income 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.

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- 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;
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- 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;
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- 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 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 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.

Reconciliations of adjusted EBITDA, adjusted operating expenses, adjusted net income, and adjusted earnings per share to the most directly comparable GAAP financial measures are included in this presentation.

The Company has not provided a reconciliation of its full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(ii)(B) of Regulation S-K, because the Company is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation, including, but not limited to, stock-based compensation expense, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of the Company's control or cannot be reasonably predicted. While the Company is unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period. A reconciliation of adjusted EBITDA or adjusted operating expenses would imply a degree of precision and certainty as to these future items that does not exist and could be confusing to investors.

Healthier people. Stronger communities.

Mission Driven

Building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions.

Doing Good As We Do Well

Partnering with organizations driving equitable access to STEM education in underserved communities to support the next generation of scientists.



Committed To Environmental, Social And Governance (ESG) Initiatives

Operating with integrity, accountability and responsibility and investing in the long-term sustainability of our business and the health of our broader communities.

Read our ESG report at collegiumpharma.com.





2024 Focus: Operational Execution

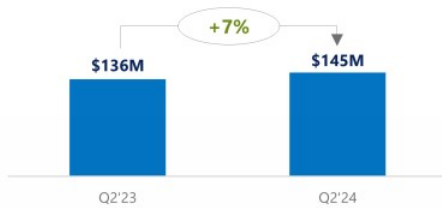
Building a Leading, Diversified Specialty Pharmaceutical Company

DELIVER ON FINANCIAL COMMITMENTS

Maximize Pain Portfolio



Strong Q2'24 Pain Portfolio Net Revenue Growth



STRATEGICALLY DEPLOY CAPITAL

Capital Deployment Priorities

- **Conduct** disciplined business development focused on commercial-stage, durable assets
- **Pay** down debt
- **Opportunistically** return capital to shareholders

Highly Accretive Commercial-Stage Acquisition With Strong Growth Potential



Executing on Our Strategy

Maximizing value of pain portfolio and delivering strong financial results¹

- **Strong pain portfolio performance** resulted in Q2'24 net product revenue growth of 7% YoY² and adjusted EBITDA growth of 12% YoY²
- **Grew** Q2'24 Belbuca[®] revenue 21% YoY and Xtampza[®] ER revenue 8% YoY
- **Bolstered** value of Nucynta Franchise in 2025 and beyond through authorized generic agreement with Hikma Pharmaceuticals and 6-month pediatric exclusivity extension

Diversifying portfolio with leading growth driver

- **Completed** acquisition of Ironshore Therapeutics establishing Collegium's presence in neurology (ADHD) and diversifying the portfolio
- **Added** Jornay PM to portfolio which is poised to become the leading growth driver
- **Establishing** a new therapeutic area of focus in neurology

Strategically deploying capital

- **Redeemed remaining \$26.4M** aggregate principal amount of convertible senior notes due 2026
- **Returned \$35.0M** to shareholders by repurchasing 1.06 million shares at an average price of \$32.94 through ASR program¹

1. This financial data was provided by Collegium in its Form 8-K and/or its Form 10-Q filed with the SEC on August 8, 2024.
2. Represents a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2.

2024 Financial Guidance¹

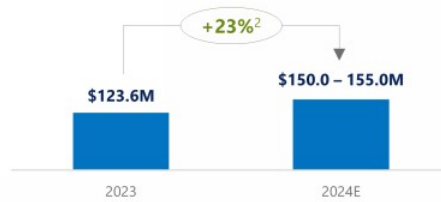
Reflects Acquisition of Ironshore as of September 2024

Product Revenues, Net



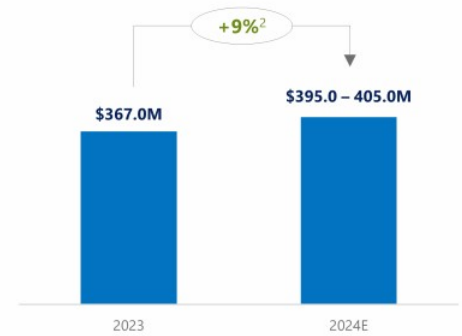
Adjusted Operating Expenses³

(Excluding Stock-Based Compensation)



Adjusted EBITDA³

(Excluding Stock-Based Compensation)



1. This financial data was provided by Collegium in its press release filed with the SEC on September 4, 2024.

2. This financial data is calculated based on data provided by Collegium in its press release filed with the SEC on September 4, 2024, and represents the percent change of the mid-point of 2024 financial guidance ranges compared to 2023 results.

3. Represents a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2.

Disciplined Capital Deployment

Execute on Business Development

- **Strong track record** of successful business development which added Nucynta Franchise and Belbuca to become leader in responsible pain management
- **Acquisition of Ironshore** establishes commercial presence in neurology (ADHD), diversifies portfolio, and adds Jornay PM which is poised to become a leading growth driver

Pay Down Debt

- New 5-year \$646M Pharmakon term loan at **reduced cost of capital**; interest rate lowered by 300 bps, longer term, lower amortization, and increased prepayment flexibility¹
- At year end, expect **net leverage to be <2.0x** based on estimated 2024 pro forma combined adjusted EBITDA²
- **Redeemed remaining \$26.4M** principal amount of 2.625% convertible senior notes due 2026; **positively impacts full-year diluted EPS**, and potentially reduces technical short positions

Leverage Share Repurchase Program

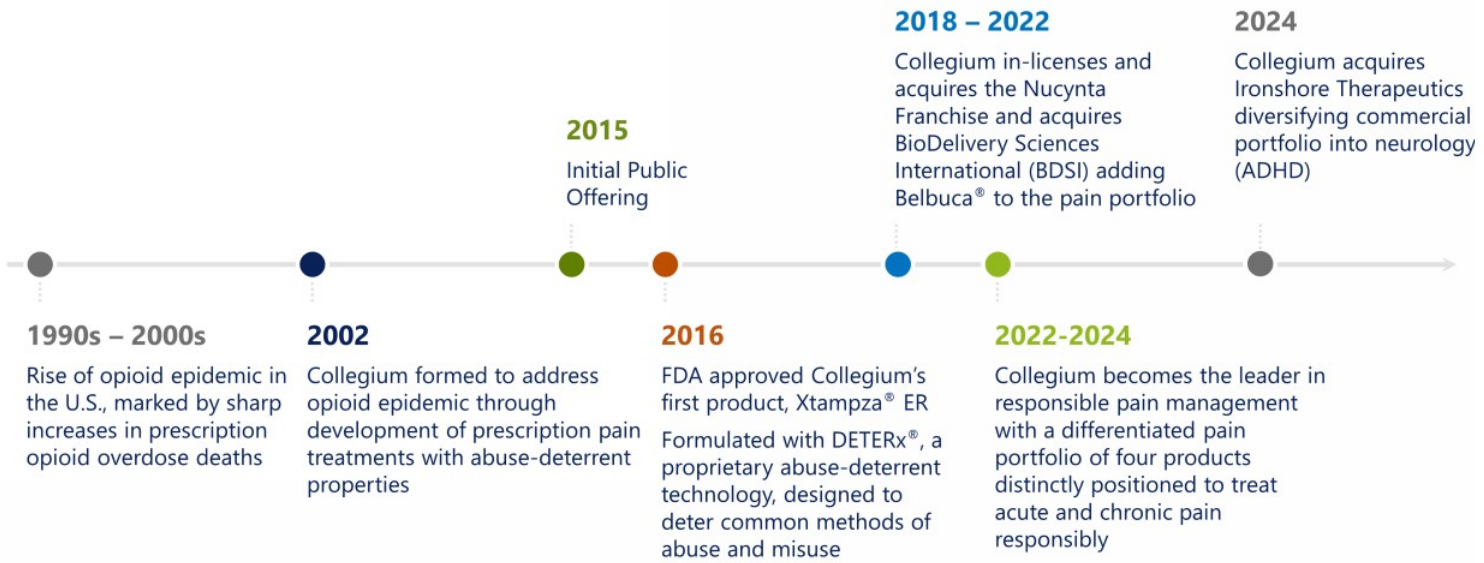
- To date, **returned \$172M** to shareholders by repurchasing 7.39 million shares at average price of \$23.28³
- **\$115M remaining** under share repurchase program authorized by Board through Q2'25


1. Details regarding the Pharmakon term-loan debt amortization schedule were provided by Collegium on Form 8-K filed with the SEC on July 29, 2024.

2. Adjusted EBITDA is a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2. 2024 net debt/adjusted EBITDA is calculated based on Collegium's forecast of net debt at year-end 2024, compared to the mid-point of the 2024 guidance ranges provided by Collegium in its press release and/or 10-Q filed with the SEC on August 8, 2024. This financial data assumes no additional debt is incurred.

3. This financial data is calculated from data provided by Collegium in its Form 10-Q filed with the SEC on August 8, 2024 and Annual Report on Form 10-K filed with the SEC on February 22, 2024.

Path to Building a Leading, Diversified Specialty Pharmaceutical Company





**Expansion into Neurology (ADHD):
Addition of Jornay PM**

Ironshore Acquisition Aligns with All Strategic Objectives

Immediately accretive to revenue and adjusted EBITDA, highly accretive in 2025

✓ **Differentiated, commercial-stage assets** to diversify specialty pharmaceutical portfolio

Addition of Jornay PM® **establishes a commercial presence in neurology (ADHD)** with a highly differentiated product, diversifying portfolio

✓ Significant **revenue and growth potential**

Jornay PM net revenue expected to be **>\$100M** in 2024 and poised to become the **leading growth driver** for Collegium

✓ Durable with **exclusivity into 2030s**

16 Orange Book-listed patents, with **expiries in 2032**

Collegium to leverage core competencies: commercial execution and track record of efficiently and successful integrating commercial acquisitions to maximize potential of Jornay PM

Expanding Commercial Presence into Neurology

Jornay^{PM}
methylphenidate HCl $\text{\textcircled{II}}$
extended-release capsules

- **Highly differentiated** central nervous system (CNS) stimulant prescription medicine for the treatment of attention deficit hyperactivity disorder (ADHD) in people six years of age and older in the U.S.
- Only stimulant ADHD medication with **convenient evening dosing**, eliminating need to dose during the day at work or at school
- Predictable onset upon waking with **smooth symptom control throughout the day**, reducing need for short-acting stimulant add-on and eliminating need for immediate release component
- Sustained absorption in colon that allows for **flexible, dose-dependent duration** of effect

Jornay PM Poised for Rapid Growth in the ADHD Market

LARGE AND EXPANDING ADHD MARKET

+5%

CAGR in total ADHD prescriptions from 2019-2023

STRONG PRESCRIBER BASE & MARKET ACCESS

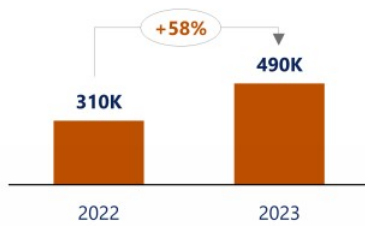
~15K

Prescribers per month

~80%

Coverage across commercial and Medicaid

SIGNIFICANT GROWTH IN JORNAY PM PRESCRIPTIONS



+32%

Year-over-year growth in H1'24

COMMERCIAL OPPORTUNITY

- **Establishes presence** in new therapeutic area with unmet need
- **Leverage proven commercial execution capabilities** to drive growth
- Jornay PM is poised to become **leading growth driver** in portfolio

Ironshore Acquisition Transaction Details

Consideration	<ul style="list-style-type: none">Collegium acquired all outstanding shares of Ironshore for \$525M in cashPotential \$25M in additional consideration if Jornay PM net revenue exceeds a defined threshold in 2025
Financing	<ul style="list-style-type: none">Funded by existing Collegium cash on hand and \$646M five-year term loan from Pharmakon with annual interest rate of SOFR+450bps after September 30, 2024 (SOFR+750bps prior to September 30, 2024) and amortized over five years; new term loan replaced the existing Collegium term loan from PharmakonFavorable terms that reduce interest rate on existing debt by 300 basis points, longer term, lower amortization and increased prepayment flexibility
Pro Forma Leverage	<ul style="list-style-type: none">Expect net leverage to be less than 2x at year-end based on estimated 2024 pro forma combined adjusted EBITDA
Expected Accretion	<ul style="list-style-type: none">Transaction immediately accretive to revenue and adjusted EBITDA at close and highly accretive to 2025 revenue and adjusted EBITDA
Timing	<ul style="list-style-type: none">Acquisition completed on September 3, 2024



Collegium: The Leader in Responsible Pain Management

Pain Portfolio Growth Drivers



	Expect prescription and revenue growth in 2024	Expect revenue growth in 2024
Strong Market Position	35.1% share of growing buprenorphine market ¹	37.8% share of OER market ¹
Large Prescriber Base	~10.5K unique prescribers in Q2'24 ²	~16.6K unique prescribers in Q2'24 ²
GtN Impacts	Expect stable GtN	Expect GtN improvement to 55-57%
Market Access	Strong commercial coverage	Strong coverage across all payor types

1. IQVIA NPA through June 2024.
 2. IQVIA Xponent through June 2024; approximate quarterly prescriber counts.



Well Positioned to Grow Belbuca Prescriptions and Revenue in 2024

Increasing momentum for Belbuca in Q2'24

GROWING BELBUCA PRESCRIPTIONS

+2.1% YoY growth in Belbuca prescriptions in Q2'24¹

+1.4% QoQ growth in Belbuca prescriptions in Q2'24¹

STRONG BRAND FUNDAMENTALS

#1 highest rated branded ER opioid in terms of product differentiation and favorability²

74% of surveyed target HCPs plan to increase prescribing²

COMMERCIAL PRIORITIES

Reinforce clinical differentiation

Pull through strong commercial access position

Expand Medicare Part D coverage

1. IQVIA NPA through June 2024.

2. ATU (Awareness, Trial, & Usage) Market Research Study, fielded Q4 2022.

Xtampza ER Poised to Grow Revenue in 2024

SUCCESSFULLY MANAGING GTN

56.2%

GtN in Q2'24

**Xtampza ER GtN expected to be
55%–57% in 2024**

STRONG BRAND FUNDAMENTALS & MARKET ACCESS POSITION

#1 highest rated ER oxycodone in terms of product differentiation and favorability¹

48% of surveyed target HCPs plan to increase prescribing, while 60% plan to decrease prescribing of OxyContin¹

Strong market access coverage across all payor types, commercial and Medicare Part D

COMMERCIAL PRIORITIES

Reinforce clinical differentiation

Pull through strong commercial and Medicare Part D access positions

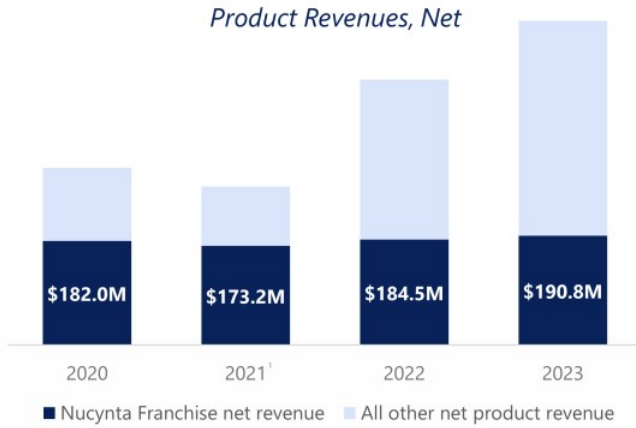
Expand coverage while managing GtN below 65%

1. ATU (Awareness, Trial, & Usage) Market Research Study, fielded Q4 2022.

Nucynta Franchise: Stable Contributor

Outlook Bolstered by Regulatory Exclusivity Extension and Authorized Generic Agreement

Stable Contributor to the Pain Portfolio



1. 2021 product revenues, net were impacted by a negative \$38.3M returns adjustment, including a negative \$24.5M returns adjustment related to Nucynta.

Improved Outlook for 2025 and Beyond

- Nucynta[®] granted New Patient Population exclusivity in pediatrics; U.S. regulatory exclusivity extended from June 27, 2025, to July 3, 2026
- 6-month pediatric exclusivity granted for Nucynta Franchise in June 2024, extending exclusivity to December 27, 2025 for Nucynta[®] ER and January 3, 2027 for Nucynta
- Authorized generic agreement with Hikma Pharmaceuticals increases value of Nucynta Franchise in 2025 and beyond through favorable economics with profit share rate beginning in mid-80% range
- Royalty declines from 14% to 7% in 2025 and will be eliminated upon Hikma's launch of the authorized generics

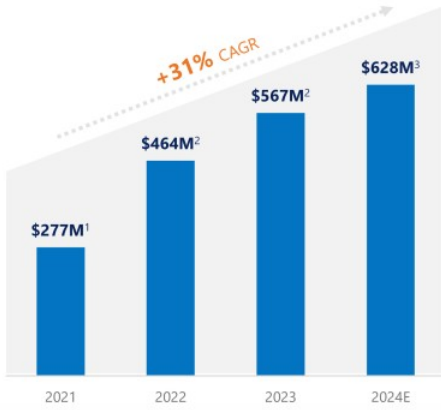


**Strong Track Record of
Execution and Achieving
Financial Commitments**

Track Record of Strong Top- and Bottom-Line Growth

GROW

Product Revenues, Net



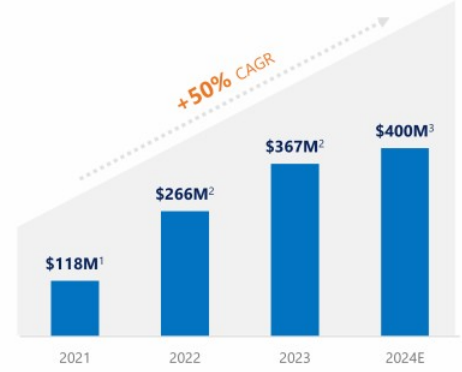
LEVERAGE

Adjusted Operating Expenses⁴



EXPAND

Adjusted EBITDA⁴



1. This financial data was provided by Collegium in its Annual Report on Form 10-K filed with the SEC on February 23, 2023.

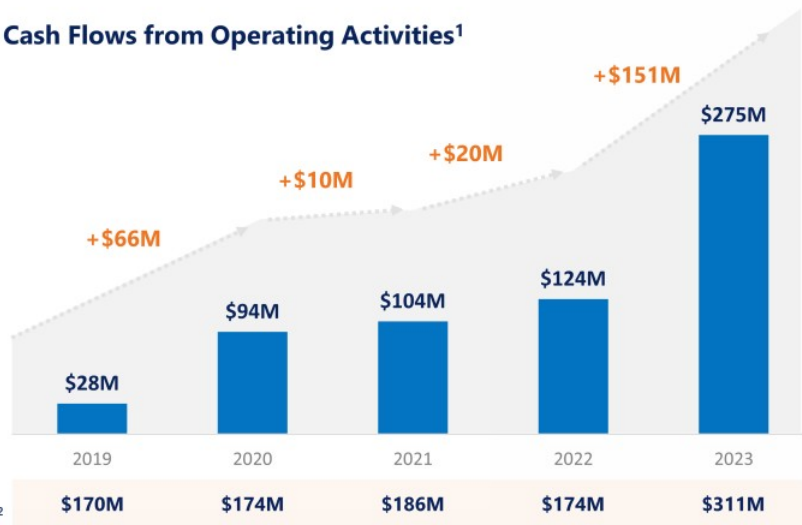
2. This financial data was provided by Collegium in its Annual Report on Form 10-K filed with the SEC on February 22, 2024.

3. This financial data was provided by Collegium in its press release filed with the SEC on September 4, 2024, and represents the mid-point of 2024 financial guidance ranges.

4. Represents a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2.

Robust Operating Cash Flow Generation from Pain Portfolio

Cash Flows from Operating Activities¹



- Strong cash generation enables disciplined capital deployment strategy
- Executed \$172M in share repurchases to date¹
- Invested ~\$1B in business development 2019–2023³

1. This financial data was provided by Collegium in its Annual Reports on Form 10-K filed with the SEC on February 25, 2021; February 24, 2022; February 23, 2023; and February 22, 2024, and in its Form 10-Q filed with the SEC on August 8, 2024.
 2. Period end cash and marketable securities excludes restricted cash.
 3. Represents the sum of the purchase price consideration paid for the Nucynta Acquisition in 2020 and the BDSI Acquisition in 2022 as disclosed on Annual Reports on Form 10-K filed with the SEC on February 25, 2021 and February 23, 2023, respectively.

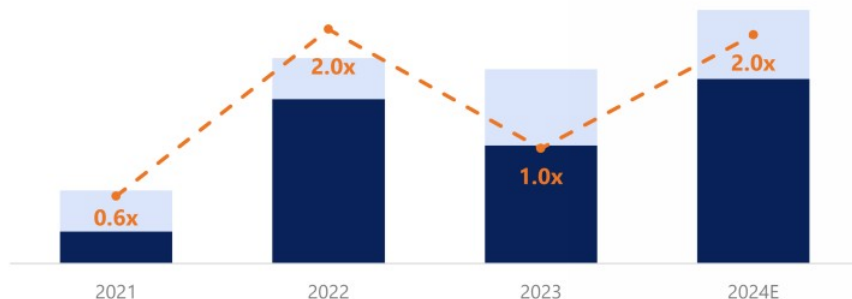




Disciplined Capital Deployment

Paydown of Debt

Principal Debt and Net Leverage¹



	2021	2022	2023	2024E
Convertible notes	\$143.8M	\$143.8M	\$267.9M	\$241.5M
Term loan	\$112.5M	\$575.0M	\$412.5M	\$645.8M

--- Net debt to adjusted EBITDA^{2,3}

1. Represents period end figures.

2. Details regarding the Pharmakon term-loan debt amortization schedule were provided by Collegium on Form 8-K filed with the SEC on July 29, 2024.

3. Adjusted EBITDA is a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2. 2024 net debt/adjusted EBITDA is calculated based on Collegium's forecast of net debt at year-end 2024, compared to the mid-point of the 2024 guidance ranges provided by Collegium in its press release filed with the SEC on September 4, 2024. This financial data assumes no additional debt is incurred.

2024 Pharmakon Term Loan¹

- \$645.8M five-year term loan with Pharmakon used to fund \$325.0M of Ironshore acquisition and \$320.8M used to replace prior Pharmakon term loan
- Favorable terms that reduce interest rate on existing debt by 300 basis points, longer term, lower amortization and increased prepayment flexibility
- Reduced interest rate on new loan expected to keep interest expense stable for the next 12 months
- Expect net leverage to be less than 2x at year-end based on estimated 2024 pro forma combined adjusted EBITDA^{2,3}



Opportunistic Share Repurchases¹

Returned \$172M of Capital to Shareholders from 2021 to 2024 YTD

**Repurchased 7.39M shares
at average price of \$23.28**

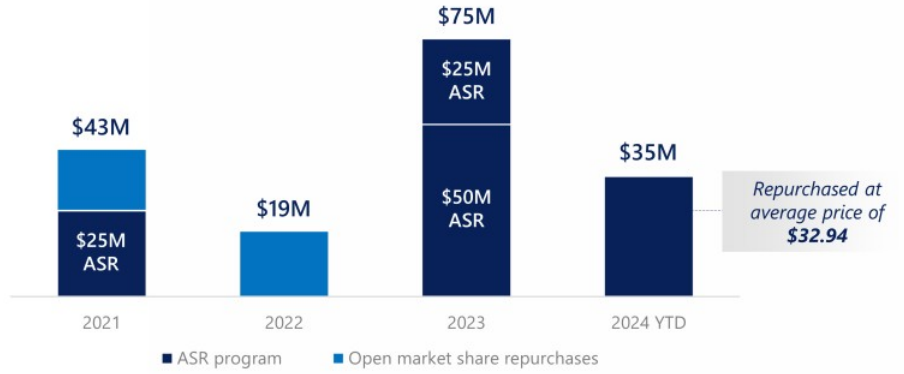
Average Repurchase Price

2021 - **\$19.93**

2022 - **\$17.57**

2023 - **\$24.29**

2024 - **\$32.94**



Board Authorized \$150M Share Repurchase Program Through Q2'25

1. This financial data is calculated from data provided by Collegium in its Form 10-Q filed with the SEC on August 8, 2024 and Annual Report on Form 10-K filed with the SEC on February 22, 2024.

Track Record of Successful Business Development

Strategically Compelling Pain Management Acquisitions



Nucynta Franchise (February 2020)



BDSI (March 2022)

Successful business development established Collegium as the leader in responsible pain management and added diversified revenue streams and growth opportunities to the business

Impact of Accretive Acquisitions

Product Revenues, Net



Adjusted EBITDA⁵



Acquisition in Neurology (ADHD)



Ironshore Therapeutics (September 2024)

Highly accretive acquisition that establishes new presence in neurology (ADHD), diversifies revenue and adds Jornay PM which is poised to become a leading growth driver

1. This financial data was provided by Collegium on Form 10-K filed with the SEC on February 23, 2023.
 2. This financial data was provided by Collegium on Form 10-K filed with the SEC on February 22, 2024.
 3. Represents Xtampza ER product revenues.
 4. Represents Nucynta IR, Nucynta ER, Belbuca, Symproic, and Other product revenues.
 5. Represents a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2.



Strong IP Management

Patent Protected Commercial Portfolio



Teva currently is the **only** generic manufacturer that has resolved legal challenges to its Xtampza ER and Belbuca ANDAs. Teva does not have tentative or final approval for **either** ANDA and has **waived** its first filer exclusivity with respect to Belbuca.

Reflects (i) for Xtampza ER, the September 2033 entry date set forth in Collegium's settlement agreement with Teva; (ii) for Belbuca, the January 2027 entry date set forth in BDSI's settlement agreement with Teva; (iii) for Jornay PM, which does not have any ANDA filers yet, the March 2032 expiry of its Orange Book-listed patents; (iv) for the Nucynta Franchise, the New Patient Population exclusivity granted to Nucynta, the pediatric exclusivity granted to the Franchise, and based on the judgment upholding its Orange-Book listed patents, the July 2025 and 2028 expiries of such patents for Nucynta ER; and (v) for Symproic, which does not have any ANDA filers yet, the November 2031 expiry of its Orange Book-listed patents.





Summary

Creating Long-Term Value Through Operational Execution

DELIVER ON

Financial commitments of top- and bottom-line growth:

- Achieve record revenue, adjusted EBITDA and net income
- Generate record free cash flow

EXECUTE ON

Integration of Ironshore:

- Integrate and maximize the full potential of Jornay PM
- Establish a new therapeutic area of focus in neurology (ADHD)

STRATEGICALLY

Deploy capital in a disciplined manner:

- Expand neurology portfolio
- Pay down debt
- Opportunistically return capital to shareholders through share repurchases

Creating value for shareholders by:

- ✓ **Growing** revenue
- ✓ **Increasing** profitability
- ✓ **Generating** strong cash flows
- ✓ **Strategically deploying** capital



Important Safety Information

Important Safety Information about Jornay PM (methylphenidate HCl extended-release capsules)

JORNAY PM
(methylphenidate HCl
extended-release
capsules)

WARNING: ABUSE, MISUSE, AND ADDICTION

JORNAY PM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing JORNAY PM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout JORNAY PM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse and addiction.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at <https://ironshorepharma.com/jornay-pm-label>.



Important Safety Information about Jornay PM (methylphenidate HCl extended-release capsules)

JORNAY PM
(methylphenidate HCl
extended-release
capsules)

WARNINGS AND PRECAUTIONS

JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- **Risks to Patients with Serious Cardiac Disease:** Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.
- **Increased Blood Pressure and Heart Rate.**
- **Psychiatric Adverse Reactions:** Including exacerbation of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder, induction of a manic episode in patients with bipolar disorder, and new psychotic or manic symptoms. Prior to initiating treatment, screen patients for risk factors for psychiatric adverse reactions. If such symptoms occur, consider discontinuing JORNAY PM.
- **Priapism:** Patients should seek immediate medical attention.
- **Peripheral Vasculopathy, including Raynaud's Phenomenon:** Observe patients for digital changes during treatment.
- **Weight Loss and Long-Term Suppression of Growth in Pediatric Patients:** Monitor height and weight.
- **Increased Intraocular Pressure (IOP) and Glaucoma:** Patients at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist. Closely monitor patients with a history of abnormally increased IOP or open angle glaucoma.
- **Onset or Exacerbation of Motor and Verbal Tics, and Worsening of Tourette's Syndrome.**

ADVERSE REACTIONS

- The most common ($\geq 5\%$ and twice the rate of placebo) adverse reactions with methylphenidate are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- Additional adverse reactions ($\geq 5\%$ and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

DRUG INTERACTIONS

- **Antihypertensive drugs:** Monitor blood pressure data. Adjust dosage of antihypertensive drug as needed.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at <https://ironshorepharma.com/jornay-pm-label>.



Important Safety Information about XTAMPZA ER (oxycodone) extended-release capsules

XTAMPZA ER
(Oxycodone) extended-release capsules

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF XTAMPZA ER

Addiction, Abuse, and Misuse

Because the use of XTAMPZA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of XTAMPZA ER, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of XTAMPZA ER are essential.

Accidental Ingestion

Accidental ingestion of even one dose of XTAMPZA ER, especially by children, can result in a fatal overdose of oxycodone.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of XTAMPZA ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at XtampzaER.com/PI.



Important Safety Information about XTAMPZA ER (oxycodone) extended-release capsules

XTAMPZA ER
(Oxycodone) extended-release capsules

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

Cytochrome P450 3A4 Interaction

The concomitant use of XTAMPZA ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Regularly evaluate patients receiving XTAMPZA ER and any CYP3A4 inhibitor or inducer.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at XtampzaER.com/PI.



Important Safety Information about BELBUCA (buprenorphine buccal film)

BELBUCA
(buprenorphine buccal
film)

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF BELBUCA

Addiction, Abuse, and Misuse

BELBUCA exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of BELBUCA, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of BELBUCA are essential. Misuse or abuse of BELBUCA by chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in the uncontrolled delivery of buprenorphine and poses a significant risk of overdose and death.

Accidental Exposure

Accidental exposure of even one dose of BELBUCA, especially in children, can result in a fatal overdose of buprenorphine.

Risks from Concomitant Use with Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of BELBUCA and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and Other Serious Risks at [Belbuca.com/#isi-block](https://belbuca.com/#isi-block)

 Collegium.
PHARMACEUTICAL

Important Safety Information about NUCYNTA ER (tapentadol) extended-release tablets

NUCYNTA ER
(tapentadol) extended-release tablets

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA ER

Addiction, Abuse, and Misuse

Because the use of NUCYNTA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA ER, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA ER are essential. Instruct patients to swallow NUCYNTA ER tablets whole; crushing, chewing, or dissolving NUCYNTA ER tablets can cause rapid release and absorption of a potentially fatal dose of tapentadol.

Accidental Ingestion

Accidental ingestion of even one dose of NUCYNTA ER, especially by children, can result in a fatal overdose of tapentadol.

Interaction with Alcohol

Instruct patients not to consume alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking NUCYNTA ER. The co-ingestion of alcohol with NUCYNTA ER may result in increased plasma tapentadol levels and a potentially fatal overdose of tapentadol.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of NUCYNTA ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at Nucynta.com/erPI.

 Collegium.
PHARMACEUTICAL

Important Safety Information about NUCYNTA ER (tapentadol) extended-release tablets

NUCYNTA ER
(tapentadol) extended-release tablets

Neonatal Opioid Withdrawal Syndrome

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at Nucynta.com/erPI.



Important Safety Information about NUCYNTA (Tapentadol) tablets

NUCYNTA
(tapentadol) tablets

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA TABLETS

Addiction, Abuse, and Misuse

Because the use of NUCYNTA tablets exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA tablets, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA tablets are essential.

Accidental Ingestion

Accidental ingestion of even one dose of NUCYNTA tablets, especially by children, can result in a fatal overdose of tapentadol.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of NUCYNTA tablets and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks at Nucynta.com/irPI.

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Important Safety Information about SYMPROIC (naldemedine) tablets

SYMPROIC
(naldemedine) tablets

SYMPROIC may cause serious side effects, including:

- Tear in your stomach or intestinal wall (perforation). Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that does not go away, stop taking SYMPROIC and get emergency medical help right away
- Opioid withdrawal. You may have symptoms of opioid withdrawal during treatment with SYMPROIC including sweating, chills, tearing, warm or hot feeling to your face (flush), sneezing, fever, feeling cold, abdominal pain, diarrhea, nausea, and vomiting. Tell your healthcare provider if you have any of these symptoms

Do not take SYMPROIC if you:

- Have a bowel blockage (intestinal obstruction) or have a history of bowel blockage
- Are allergic to SYMPROIC or any of the ingredients in SYMPROIC. See the Medication Guide for a complete list of ingredients in SYMPROIC. Tell your healthcare provider or pharmacist before you start or stop any medicines during treatment with SYMPROIC

Before you take SYMPROIC, tell your healthcare provider about all of your medical conditions, including if you:

- Have any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome
- Have liver problems
- Are pregnant or plan to become pregnant. Taking SYMPROIC during pregnancy may cause opioid withdrawal symptoms in your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with SYMPROIC
- Are breastfeeding or plan to breastfeed. It is not known if SYMPROIC passes into your breast milk. You should not breastfeed during treatment with SYMPROIC and for 3 days after your last dose. Taking SYMPROIC while you are breastfeeding may cause opioid withdrawal symptoms in your baby. You and your healthcare provider should decide if you will take SYMPROIC or breastfeed. You should not do both
- The most common side effects of SYMPROIC include stomach (abdomen) pain, diarrhea, nausea and vomiting (gastroenteritis)
- Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of SYMPROIC. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

See full prescribing Information and other serious risks at [Symproic.com/#isi](https://www.symproic.com/#isi).

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Important Safety Information about SYMPROIC (naldemedine) tablets

SYMPROIC
(naldemedine) tablets

INDICATIONS AND USAGE

SYMPROIC is indicated 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.



CONTRAINDICATIONS

SYMPROIC is contraindicated in:

- Patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation
- Patients with a history of a hypersensitivity reaction to Naldemedine. Reactions have included bronchospasm and rash

WARNINGS AND PRECAUTIONS

Gastrointestinal Perforation: Cases of gastrointestinal perforation have been reported with use of another peripherally acting opioid antagonist in patients with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies, or peritoneal metastases). Take into account the overall risk-benefit profile when using SYMPROIC in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue SYMPROIC in patients who develop this symptom.

Opioid Withdrawal: Clusters of symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, increased lacrimation, hot flush/flushing, pyrexia, sneezing, feeling cold, abdominal pain, diarrhea, nausea, and vomiting have occurred in patients treated with SYMPROIC. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. Take into account the overall risk-benefit profile and monitor for symptoms of opioid withdrawal when using SYMPROIC in such patients.

ADVERSE REACTIONS



- The most common adverse reactions with SYMPROIC compared to placebo in two pooled 12-week studies were: abdominal pain (8% vs 2%), diarrhea (7% vs 2%), nausea (4% vs 2%), and gastroenteritis (2% vs 1%).
- The incidence of adverse reactions of opioid withdrawal in two pooled 12-week studies was 1% (8/542) for SYMPROIC and 1% (3/546) for placebo. In a 52-week study, the incidence was 3% (20/621) for SYMPROIC and 1% (9/619) for placebo.

OVERDOSAGE

Single doses of Naldemedine up to 100 mg (500 times the recommended dose) and multiple doses of up to 30 mg (150 times the recommended dose) for 10 days have been administered to healthy subjects in clinical studies. Dose-dependent increases in gastrointestinal-related adverse reactions, including abdominal pain, diarrhea, and nausea, were observed. Single doses of Naldemedine up to 3 mg (15 times the recommended dose) and multiple doses of 0.4 mg (twice the recommended dose) for 28 days have been administered to patients with OIC in clinical studies. Dose dependent increases in gastrointestinal-related adverse reactions, including abdominal pain, diarrhea, nausea, and vomiting, were observed. Also, chills, hyperhidrosis, and dizziness were reported more frequently at 1 and 3 mg doses and hyperhidrosis at the 0.4 mg dose. No antidote for Naldemedine is known. Hemodialysis is not an effective means to remove Naldemedine from the blood.

See full prescribing Information and other serious risks at [Symproic.com/#isi](https://www.symproic.com/#isi).

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Important Safety Information about SYMPROIC (naldemedine) tablets

SYMPROIC
(naldemedine) tablets

USE IN SPECIFIC POPULATIONS



Pregnancy:

There are no available data with Naldemedine in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. There is a potential for opioid withdrawal in a fetus when SYMPROIC is used in pregnant women. SYMPROIC should be used during pregnancy only if the potential benefit justifies the potential risk.

Fetal/Neonatal Adverse Reactions

Naldemedine crosses the placenta and may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier.

Lactation

There is no information regarding the presence of Naldemedine in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions, including opioid withdrawal in breastfed infants, a decision should be made to discontinue breastfeeding or discontinue the drug, taking into account the importance of the drug to the mother. If drug is discontinued in order to minimize drug exposure to a breastfed infant, advise women that breastfeeding may be resumed 3 days after the final dose of SYMPROIC.

Pediatric Use

The safety and effectiveness of SYMPROIC have not been established in pediatric patients.

Geriatric Use

Of the 1163 patients exposed to SYMPROIC in clinical studies, 183 (16%) were 65 years of age and over, while 37 (3%) were 75 years and over. No overall differences in safety or effectiveness between these and younger patients were observed, but greater sensitivity of some older individuals cannot be ruled out. In a population pharmacokinetic analysis, no age-related alterations in the pharmacokinetics of Naldemedine were observed.

Hepatic Impairment

The effect of severe hepatic impairment (Child-Pugh Class C) on the pharmacokinetics of Naldemedine has not been evaluated. Avoid use of SYMPROIC in patients with severe hepatic impairment. No dose adjustment of SYMPROIC is required in patients with mild or moderate hepatic impairment.

See full prescribing Information and other serious risks at [Symproic.com/#isi](https://www.symproic.com/#isi).

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Non-GAAP Reconciliations

Collegium Pharmaceutical, Inc.
Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA
(in thousands)
(unaudited)

	Three Months Ended June 30,		Years Ended December 31,		
	2024	2023	2023	2022	2021
GAAP net income (loss)	\$ 19,606	\$ 13,007	\$ 48,155	\$ (25,002)	\$ 71,517
Adjustments:					
Interest expense	15,587	21,863	83,339	63,213	21,014
Interest income	(4,397)	(4,027)	(15,615)	(1,047)	(12)
Loss on extinguishment of debt	7,184	—	23,504	—	—
Provision for (benefit from) income taxes	9,491	4,790	27,578	(3,845)	(74,891)
Depreciation	952	895	3,496	2,684	1,736
Amortization	34,515	37,463	145,760	131,469	67,181
Impairment expense	—	—	—	4,786	—
Stock-based compensation	10,012	7,072	27,136	22,874	24,255
Restructuring	—	—	—	—	4,578
Litigation settlements	—	—	8,500	—	2,935
Acquisition related expenses	—	—	—	31,297	—
Recognition of step-up basis in inventory	—	4,748	15,116	39,584	—
CEO transition expense	3,051	—	—	—	—
Total adjustments	\$ 76,395	\$ 72,804	\$ 318,814	\$ 291,015	\$ 46,796
Adjusted EBITDA	\$ 96,001	\$ 85,811	\$ 366,969	\$ 266,013	\$ 118,313

Collegium Pharmaceutical, Inc.
Reconciliation of GAAP Operating Expenses to Adjusted Operating Expenses
(in thousands)
(unaudited)

	Three Months Ended June 30,		Years Ended December 31,		
	2024	2023	2023	2022	2021
GAAP operating expenses	\$ 43,335	\$ 38,193	\$ 159,208	\$ 176,169	\$ 132,989
Adjustments:					
Stock-based compensation	10,012	7,072	27,136	22,874	24,255
Restructuring	—	—	—	—	4,578
Litigation settlements	—	—	8,500	—	2,935
Acquisition related expenses	—	—	—	31,297	—
CEO transition expense	3,051	—	—	—	—
Total adjustments	\$ 13,063	\$ 7,072	\$ 35,636	\$ 54,171	\$ 31,768
Adjusted operating expenses	\$ 30,272	\$ 31,121	\$ 123,572	\$ 121,998	\$ 101,221