

**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): **January 8, 2025**

**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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common stock, par value \$0.001 per share	COLL	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 7.01 Regulation FD Disclosure.**

On January 8, 2025, Collegium Pharmaceutical, Inc. (the "Company") issued a press release announcing full-year revenue, adjusted operating expense and adjusted EBITDA guidance for 2025. A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished, not filed, under Item 7.01 of this Current Report on Form 8-K.

In addition, on January 8, 2025, 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 and is being furnished, not filed, under Item 7.01 of this Current Report on Form 8-K.

To the extent that the information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 furnished herewith, are not descriptions of historical facts regarding the Company, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The Company 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 Current Report on Form 8-K, including Exhibits 99.1 and 99.2 furnished herewith, include, among others, statements related to the Company's full-year 2025 financial guidance, including projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for its products and the Company's 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 the Company's current expectations. Actual results may differ materially from management's expectations and such forward-looking statements in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 furnished herewith, could be affected as a result of various important factors, including risks relating to, among others: unknown liabilities; risks related to future opportunities and plans for the Company's products, including uncertainty of the expected financial performance of such products; unknown liabilities; the Company's ability to commercialize and grow sales of its products; the Company's ability to successfully integrate the operations of Ironshore Therapeutics Inc. ("Ironshore") into its organization, and realize the anticipated benefits associated with the acquisition of Ironshore; the Company's ability to manage its relationships with licensors; the success of competing products that are or become available; the Company's ability to maintain regulatory approval of its products, and any related restrictions, limitations, and/or warnings in the label of an approved product; the size of the markets for the Company's products, and the Company's ability to service those markets; the Company's ability to obtain reimbursement and third-party payor contracts for its products; the rate and degree of market acceptance of the Company's products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for the Company's products; the outcome of any patent infringement or other litigation that may be brought by or against the Company; the outcome of any governmental investigation related to the Company's business; the Company's ability to secure adequate supplies of active pharmaceutical ingredient for each of its products and manufacture adequate supplies of commercially saleable inventory; the Company's ability to obtain funding for its operations and business development; regulatory developments in the U.S.; the Company's expectations regarding its ability to obtain and maintain sufficient intellectual property protection for its products; the Company's ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency compliance; the Company's customer concentration; and the accuracy of the Company's estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in the Company's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Committee. Any forward-looking statements that the Company makes in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 furnished herewith, speak only as of the date of this Current Report on Form 8-K. The Company assumes no obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, after the date of this Current Report on Form 8-K.

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**Item 9.01**      **Financial Statements and Exhibits.**

(d)      Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release, dated January 8, 2025.</a>
<a href="#">99.2</a>	<a href="#">Investor Presentation, dated January 8, 2025.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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: January 8, 2025

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper

Name: Colleen Tupper

Title: Executive Vice President and Chief Financial Officer

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### Collegium Provides 2025 Financial Guidance and Business Update

– Product Revenues, Net Expected in the Range of \$735 Million to \$750 Million –

– *Jornay PM*<sup>®</sup> Net Revenue Expected to be in Excess of \$135 Million –

– Adjusted EBITDA\* Expected in the Range of \$435 Million to \$450 Million –

– Adjusted Operating Expenses\* Expected in the Range of \$220 Million to \$230 Million –

**STOUGHTON, Mass., January 8, 2025** -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today announced its 2025 full-year financial guidance and provided a business update.

“In 2024, we executed on our priorities of maximizing the pain portfolio and strategically deploying capital, delivering record financial results and closing the acquisition of Ironshore,” said Vikram Karnani, President and Chief Executive Officer of Collegium. “Looking ahead to 2025 and beyond, Collegium will embark upon a new phase of growth. *Jornay PM*, as a highly differentiated product to treat ADHD, is positioned to be our lead growth driver, and our focus will be on commercial expansion. We are committed to maximizing and delivering strong performance across our entire portfolio as we build a leading, diversified biopharmaceutical company serving people living with serious medical conditions.”

“Our 2025 financial guidance reflects expected significant top- and bottom-line growth driven by the addition of *Jornay PM* and continued performance from our pain portfolio. We expect *Jornay PM* net revenue in 2025 to be in excess of \$135 million,” said Colleen Tupper, Chief Financial Officer of Collegium. “We plan to make targeted investments in *Jornay PM* throughout 2025, which we expect will accelerate growth in the near-term, while creating significant momentum in 2026 and beyond. In addition, we will continue to strategically deploy capital in a disciplined manner to create long-term value for our shareholders.”

#### Recent Business Highlights

- Completed integration of Ironshore Therapeutics Inc. (Ironshore), and accelerated growth in *Jornay PM* average weekly prescriptions during the 2024 back-to-school season.
- In November 2024, Vikram Karnani joined Collegium as President and Chief Executive Officer and was appointed to the Board of Directors.
- In 2024, repurchased \$60 million in shares under the \$150 million share repurchase program authorized by Collegium’s Board of Directors in January 2024, including \$25 million repurchased in the fourth quarter of 2024 and \$35 million repurchased through an accelerated share repurchase program in May 2024.

#### Financial Guidance for 2025

- Product revenues, net are expected in the range of \$735 million to \$750 million.
- Adjusted EBITDA (excluding stock-based compensation) is expected in the range of \$435 million to \$450 million.
- Adjusted operating expenses (excluding stock-based compensation) are expected in the range of \$220 million to \$230 million.

\* *Non-GAAP financial measure. Please refer to the “Non-GAAP Financial Measures” section for details regarding these measures.*



#### **About Collegium Pharmaceutical, Inc.**

Collegium is building a leading, diversified biopharmaceutical company committed to improving the lives of people living with serious medical conditions. The Company has a leading portfolio of responsible pain management medications and recently acquired Jornay PM, a treatment for ADHD, establishing a presence in neuropsychiatry. Collegium's strategy includes growing its commercial portfolio, with Jornay PM as the lead growth driver, and deploying capital in a disciplined manner. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company's website at [www.collegiumpharma.com](http://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 that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, where applicable, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

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

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

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
  - we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
  - adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
  - adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes;
  - adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
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- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consist of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete an 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 2025 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 the Company's 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.

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## 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 our full-year 2025 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 the Company's current expectations, including risks relating to, among others: unknown liabilities; 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 successfully integrate the operations of Ironshore into our organization, and realize the anticipated benefits associated with the acquisition; 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, or 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.

## Investor Contact:

Argot Partners  
[ir@collegiumpharma.com](mailto:ir@collegiumpharma.com)

## Media Contact:

Cheryl Wheeler  
Head of Corporate Communications  
[communications@collegiumpharma.com](mailto:communications@collegiumpharma.com)

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# Investor Presentation

January 2025 | Nasdaq: COLL

*Healthier people.  
Stronger communities.*



## 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," "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 related to our full-year 2024 and 2025 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, expects 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 expectations, including risks relating to, among others: unknown liabilities; 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 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 manage our relationships with licensors; the success or failure of our products; 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 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; 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 rights; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance; our customer concentration; and the accuracy of our estimates of 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 made 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, provides a more complete understanding of our business. These 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 expense, and other non-recurring expenses 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; 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 may vary significantly from period to period and may vary from 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 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 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.

Reconciliations of adjusted EBITDA and adjusted operating expenses 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 and 2025 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonably efforts of the Company 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 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 are not 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.



# Building a Leading, Diversified Biopharmaceutical Company

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# Successful Track Record in Building a Leading, Diversified Biopharmaceutical Company

## Strong Commercial Execution

### Product Revenues, Net



## Robust Financial Results

### Adjusted EBITDA<sup>4</sup>



## Strategic Capital

**\$1.6B**

Invested in business development to date<sup>5</sup>

**Jornay<sup>®</sup>**  
methylphenidate HCl  
extended-release capsules

**NUCYNTA<sup>®</sup>**  
gabapentin tablets

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 November 7, 2024, and represents the mid-point of 2024 financial performance. 4. Represents a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2. 5. Represents the sum of the purchase price consideration paid for the Nucynta Acquisition in 2022, and the upfront cash paid to complete the Ironshore acquisition in 2024 as disclosed on Annual Report on Form 10-K filed with the SEC on February 25, 2021, Annual Report on Form 10-K filed with the SEC on February 23, 2023, and Form 8-K filed with the SEC on September 4, 2024, respectively. 6. This financial data was provided by Collegium in its Form 10-Q filed with the SEC on November 8, 2024, and Form 8-K filed with the SEC on January 8, 2025.

# Next Phase of Growth – Building on a Successful Strategy



## DRIVE SIGNIFICANT Jornay PM® Growth

- **Invest in Jornay PM** to support near-term growth and create significant momentum in 2026 and beyond
- **Raise awareness** in patients and caregivers to drive prescription growth
- **Expand** commercial presence in neuropsychiatry



## MAXIMIZE Pain Portfolio

- **Maximize and enhance** durability of pain portfolio
- **Generate durable operating cash flow** from pain portfolio



## STRATEGIC Deploy Ca

- **Expand commercial** through discipline development
- **Rapidly** pay down **opportunistically** repurchase shares

# 2025 Financial Guidance Reflects Strong Top- and Bottom-Line Growth

	Guidance Range <sup>2</sup>	YoY Change <sup>3</sup>	
<b>Product Revenues, Net</b>	<b>\$735 – 750M</b>	<b>+18%</b>	<ul style="list-style-type: none"> <li>Revenue growth e by <b>&gt;\$135M in Jo revenue</b> in 2025 a portfolio perform.</li> <li><b>Continued adjust</b> to generate opera</li> </ul>
<b>Adjusted EBITDA<sup>1</sup></b>	<b>\$435 – 450M</b>	<b>+11%</b>	<ul style="list-style-type: none"> <li>Increase in adjust expenses reflects   <b>Jornay PM</b> salesf to <b>support near-t create significant 2026 and beyond</b></li> </ul>
<b>Adjusted Operating Expenses<sup>1</sup></b>	<b>\$220 – 230M</b>	<b>+48%</b>	<ul style="list-style-type: none"> <li>Jornay PM investr adjusted EBITDA r to <b>improve begin</b></li> </ul>

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

2. This financial data was provided by Collegium in its press release filed with the SEC on January 8, 2025.

3. This financial data is calculated based on data provided by Collegium in its press release filed with the SEC on November 7, 2024, and January 8, 2025, and represents the percent change of the mid-point of 2025 financial guidance ranges compared to the midpoint of 2024 financial guidance ranges.



# Expanding into Neuropsychiatry with Jornay PM

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# Expansion into Neuropsychiatry Offers Compelling Opportunity in Growing Attention Deficit Hyperactivity Disorder (ADHD) Market

## ADHD Prevalence<sup>1</sup>

**~6.5M** Pediatric and Adolescents

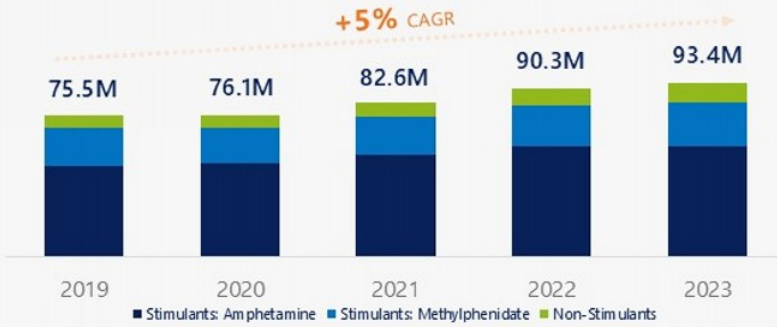
**~15.5M** Adults

## Methylphenidate Patient Mix Skews Toward Pediatric & Adolescent

**~70%** Pediatric and Adolescents

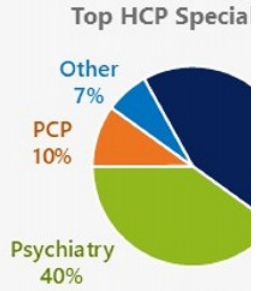
**~30%** Adults

## Growing Total ADHD Prescriptions<sup>3</sup>



## Concentrated Prescriber Base

**~20K** HCPs writing 1/3 of long-acting stimulant prescriptions<sup>4</sup>



1. Danielson et al. 2024; Staley et al. 2024. 2. IQVIA NPA Extended Insights, MAT Nov 2024. 3. IQVIA NPA. 4. ZS Associates, Journey PM GTM Strategy Project, 2024. 5. Represents LA Stimulant Prescriber Count by Specialty; IQVIA Xponent 2024.




# Highly Differentiated Product in the ADHD Market

## HCPs' Perspective<sup>1</sup>

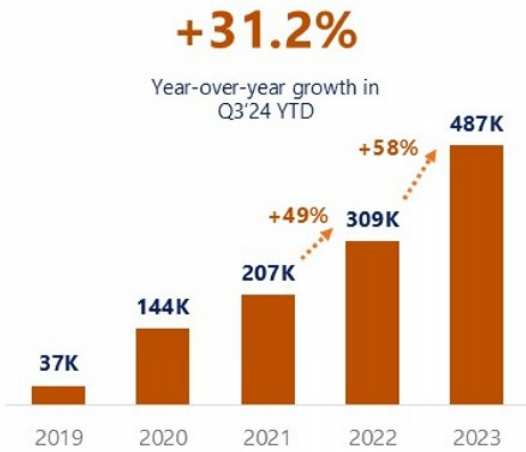
**MOST SIGNIFICANT ADHD CHALLENGE** is all-day symptom control *without* the need for a short-acting stimulant add-on

**MORNING SYMPTOM CONTROL** cited as a *top product benefit*

- 
- **Highly differentiated** central nervous system (CNS) stimulant medicine for the treatment of ADHD in people six years of age and older in the U.S.
  - Only stimulant ADHD medication with **convenient evening dosing** and **predictable onset upon awakening**, eliminating need to take medication in the morning and wait for onset of action
  - **Smooth symptom control throughout the day**, eliminating need for an immediate release component and reducing need for short-acting stimulant add-on
  - Sustained absorption in colon that allows for **flexible, dose-dependent duration** of effect

# Jornay PM Generated Significant Growth in 2024 Marked by a Acceleration Under Collegium's Ownership

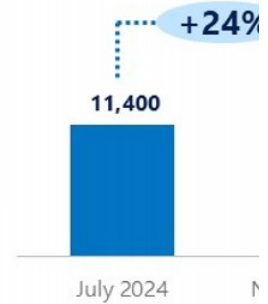
## SIGNIFICANT GROWTH IN JORNAY PM PRESCRIPTIONS<sup>1</sup>



## STRONG AND GROWING PRESCRIBER BASE<sup>2</sup>



## ACCELERATION WEEKLY PRESCRIPTIONS<sup>3</sup> "BACK-TO-SCHOOL"



With Collegium resources and investment, Jornay PM is poised for significant growth in the ADHD market.



1. IQVIA NPA through September 2024.  
 2. IQVIA Xponent through September 2024; approximate quarterly prescriber counts.  
 3. IQVIA RAPID through November 22, 2024.

# Jornay PM: Strong Brand Fundamentals from HCP's Perspective

## Jornay PM Recognized for Symptom Control by HCPs:

### #1 recognized

branded ADHD medication for achieving all-day symptom control with one dose

### #1 recognized

branded ADHD medication for controlling after school/work and evening symptoms

## Jornay PM Considered Highly Favorable and Patient/Caregiver Requests Influence Prescribing

### #1 highest rated

branded ADHD medication in terms of product favorability

### Patient/Caregiver requests

is a top influencer of trial by HCP

# Investing in Jornay PM to Drive Revenue Growth

## COMMERCIAL PRIORITIES FOCUSED ON GROWTH

### Increase Awareness and Adoption with Expanded Set of Prescribers

- Expand and optimize salesforce to cover full market opportunity
- Leverage non-personal promotion to increase awareness and use of Jornay PM

### Raise Caregiver and Patient Awareness to Drive HCP Request

- Initiate digital marketing and social media strategies to target caregivers and patients
- Develop and launch new patient support resources

## JORNAY PM NEAR-TERM REVENUE EXPECTATIONS



**2025 investments into Jornay PM expected to support near-term growth and create significant momentum in 2026 and beyond**

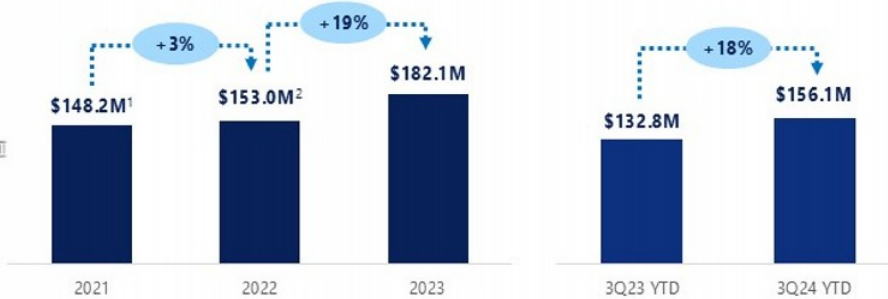
# The Leader in Responsible Pain Management

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# Well Positioned to Maximize and Enhance Durability of Pain I

## SUCCESSFUL COMMERCIAL EXECUTION RESULTING IN SIGNIFICANT NET REVENUE GROWTH

**BELBUCA**<sup>®</sup>  
(buprenorphine) Buccal Film



**Xtampza**<sup>®</sup> ER  
(oxycodone) EXTENDED-RELEASE CAPSULES II



**Collegium**  
PHARMACEUTICAL

1. This financial data was provided by BioDelivery Sciences International, Inc. in its Annual Report on Form 10-K filed with the SEC on March 9, 2022.  
2. Collegium acquired Belbuca<sup>®</sup> as part of the BDSI acquisition on March 22, 2022. Represents proforma Belbuca net revenue.  
3. ATU (Awareness, Trial, & Usage) Market Research Study, fielded Q4 2022.

## STRONG BRAND FU

**#1** highest rated brand in terms of product differentiation favorability

**74%** of surveyed target audience increase prescribing

**#1** highest rated ER of product differentiation

**48%** of surveyed target audience increase prescribing, while decrease prescribing of

# Nucynta Franchise: Robust Revenue Contributor in 2025 and

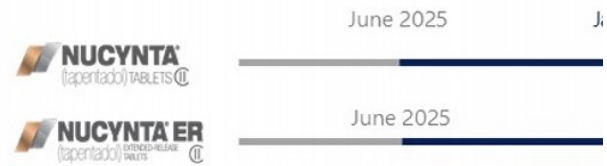
## Durable Revenue Contributor

Product Revenues, Net



## Improved Outlook for 2025 and 2027

Recent Grünenthal Settlement with Teva re-opens market to anticipated generic entry for Nucynta® ER in 2027



Authorized Generic agreement with H. Lundbeck Pharmaceuticals positions Collegium to compete in the event of generic entrants in 2027 and 2027 providing >80% royalties when there are generic entrants

**Strong Track Record of  
Execution and Delivering on  
Financial Commitments**

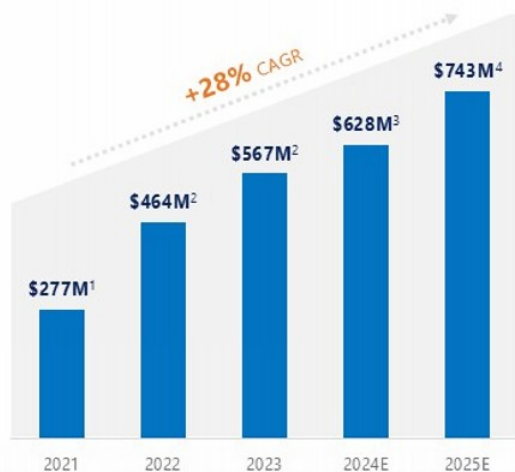
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# Track Record of Strong Top- and Bottom-Line Growth

## GROW

### Product Revenues, Net



## LEVERAGE

### Adjusted Operating Expenses<sup>5</sup>



## EXPAN

### Adjusted EB



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 November 7, 2024, and represents the mid-point of 2024 financial guidance ranges.

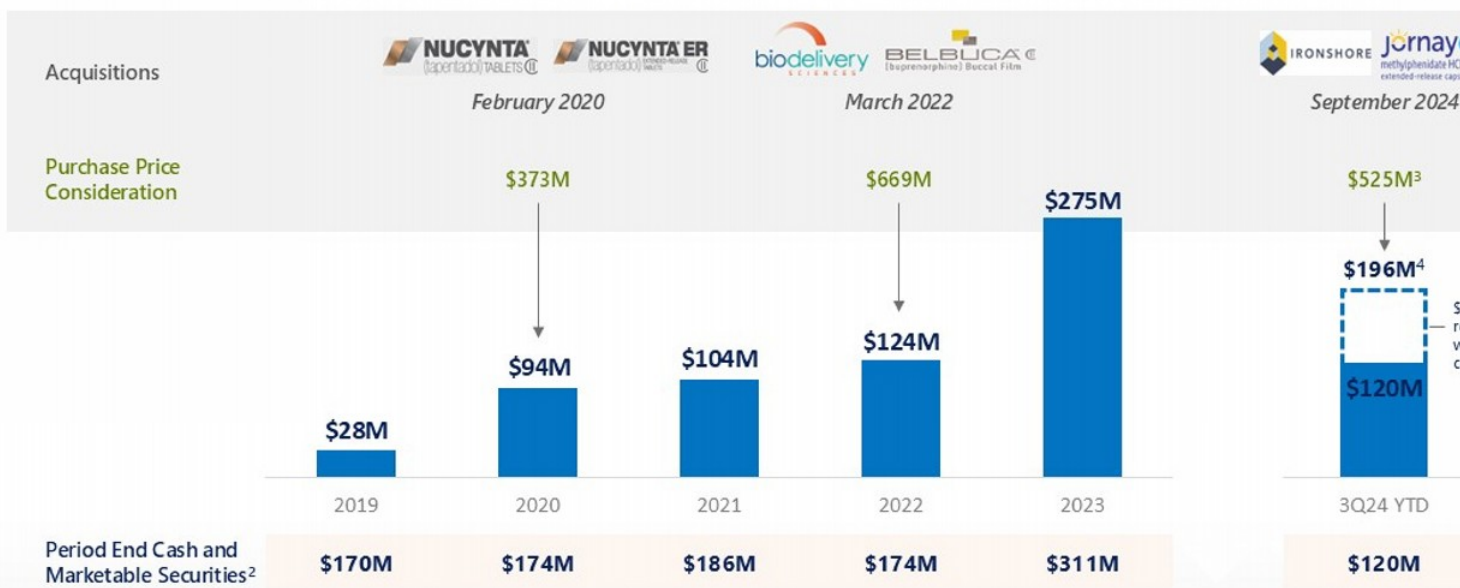
4. This financial data was provided by Collegium in its press release filed with the SEC on January 8, 2025, and represents the mid-point of 2025 financial guidance ranges.

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



# Robust Operating Cash Flow Generation from Pain Portfolio 2019 Through Third Quarter 2024

## Cash Flows from Operating Activities<sup>1</sup>



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 November 7, 2024. 2. Period end cash and marketable securities excludes restricted cash. 3. Represents the upfront cash paid to complete the acquisition of Ironshore as disclosed on filed with the SEC on September 4, 2024. 4. Represents operating cash with \$60.9M of Ironshore liabilities that were paid off at close but are not included in the accounting "Purchase Price" of Ironshore and \$15.4M of acquisition expenses added back.



# Disciplined Capital Deployment

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# Track Record of Successful Business Development Drives Top-Bottom-Line Growth

## \$1.6B Invested in Acquisitions<sup>1</sup>



Nucynta Franchise (February 2020)



BDSI (March 2022)

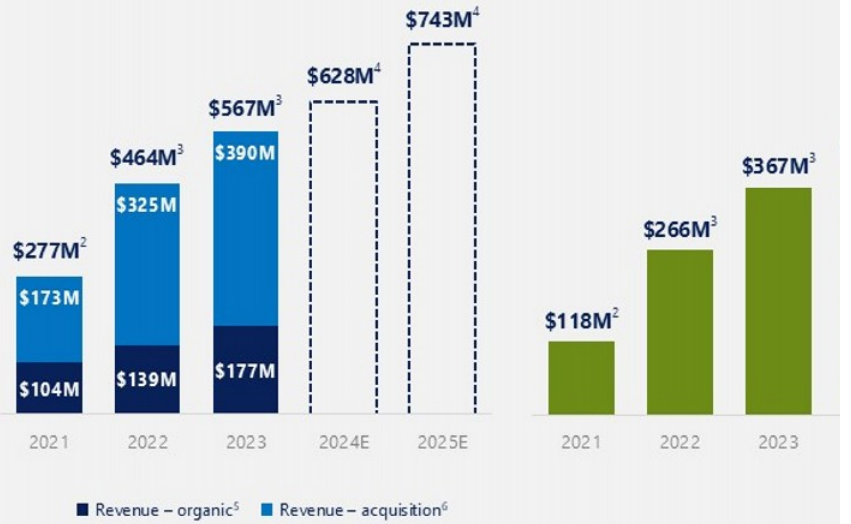


Ironshore Therapeutics (September 2024)

## Impact of Accretive Acquisitions

### Product Revenues, Net

### Adjusted EBIT



1. Represents the sum of the purchase price consideration paid for the Nucynta Acquisition in 2020, the BDSI Acquisition in 2022, and the upfront cash paid to complete the Ironshore acquisition in 2024 as disclosed on an Annual Report on Form 10-K filed with the SEC on February 25, 2021, Annual Report on Form 10-K filed with the SEC on February 23, 2023, and Form 8-K filed with the SEC on September 4, 2024, respectively. 2. This financial data was provided by Collegium on February 23, 2023. 3. This financial data was provided by Collegium on Form 10-K filed with the SEC on February 22, 2024. 4. Represents the midpoint of 2024 and 2025 guidance ranges provided by Collegium on February 22, 2024, and January 8, 2025, respectively. 5. Represents Xtampza<sup>®</sup> ER product revenues. 6. Represents Nucynta<sup>®</sup>, Nucynta ER, Belbuca, Symproic<sup>®</sup>, and Other product revenues. 7. Represents a non-GAAP financial measure on slide 2.

# Opportunistic Share Repurchases Deliver Value to Shareholders

## Returned \$197M to Shareholders from 2021 to 2024 YTD

**Repurchased 8.2M shares at average price of \$24.00**

Average Repurchase Price

2021 - **\$19.93**

2022 - **\$17.57**

2023 - **\$24.29**

2024 - **\$31.88**



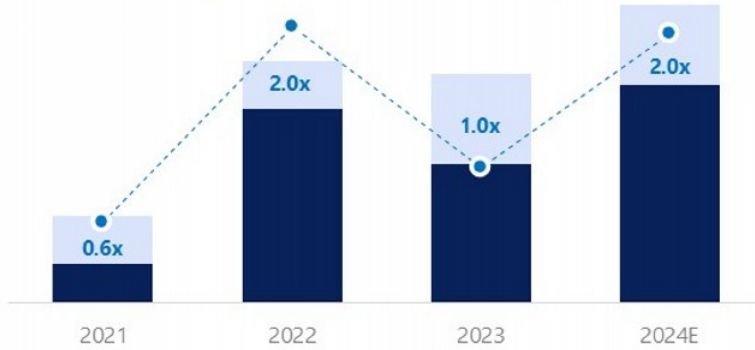
**Board Authorized \$150M Share Repurchase Program Through Q2'25**



1. This financial data is calculated from data provided by Collegium in its Form 8-K filed with the SEC on January 8, 2025, Form 10-Q filed with the SEC on November 7, 2024 and Annual Report on Form 10-K filed with the SEC on February 22, 2024.

# Balance Sheet Strength and Flexibility Driven by Disciplined Debt Management

Principal Debt and Net Leverage<sup>1</sup>



	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<sup>2,3</sup>

## 2024 Pharmakon Term

- \$645.8M five-year term loan with Ph to fund \$325.0M of Ironshore acquis \$320.8M used to replace prior Pharr
- Favorable terms that **reduce interest existing debt by 300 basis points**, lower amortization and increased pr flexibility
- Reduced interest rate on new loan e interest expense stable for the next
- **Expect net leverage to be less than end** based on estimated 2024 pro f adjusted EBITDA<sup>2,3</sup>

1. Represents period end figures. This financial data was provided by Collegium on Form 10-K filed with the SEC on February 24, 2022, February 23, 2023, and February 22, 2024. 2024 estimates are based on scheduled debt calculated from data provided the SEC on November 7, 2024.

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 November 7, 2024. This financial data assumes no additional debt is incurred.



# Strong IP Management

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# Patent Protected Commercial Portfolio



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



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 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 Franch settlement between Grunenthal and Teva for an entry date in July 2027, the regulatory status of other filers, the Authorized Generic agreement with Hikma and the judgment upholding its Orange-Book listed patents exclusivity termination and 2028 expiries of the last Orange Book-listed patents for Nucynta ER; and (v) for Symproic, which does not have any ANDA filers yet, the November 2031 expiry of its Orange Book



# Summary

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# 2025 and Beyond: Jornay PM Leading Collegium's Next Phase Growth

## Creating value for shareholders by:

**Growing** revenue

**Increasing** profitability

**Generating**  
strong cash flows

**Strategically deploying**  
capital



## EXECUTE ON

### Commercial portfolio growth:

- Drive significant Jornay PM growth
- Maximize the pain portfolio

## STRATEGICALLY

### Deploy capital in a disciplined manner:

- Expand commercial portfolio through disciplined business
- Rapidly pay down debt and opportunistically repurchase

# Important Safety Information

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# Important Safety Information about 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. Abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved 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 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 anaphylaxis 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 hypertension.

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)

## 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 stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery 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 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, discontinue 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 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 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 changes.

## 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

## **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 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, careful 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. 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](http://xtampzaER.com/PI).



# Important Safety Information about 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 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 prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrom may result in an increase in oxycodone plasma concentration. Regularly evaluate patients receiving XTAMPZA ER and any CYP3A4 inhibitor or induc

See full prescribing information, including Boxed Warning on Addiction, Abuse and Misuse, and other serious risks at [xtampzaER.com/PI](http://xtampzaER.com/PI).

# Important Safety Information about 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 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, careful 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 overdose 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. Avoid concomitant use 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. 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 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://www.belbuca.com/#isi-block).



# Important Safety Information about 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 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, careful 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 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 can 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](http://Nucynta.com/erPI).



# Important Safety Information about 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. 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 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](http://Nucynta.com/erPI).

# Important Safety Information about 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 and prescribe and dispense the lowest effective dosage for the shortest duration of treatment. Because the risks of addiction, abuse, and misuse can develop even after a short period of use, assess each patient 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. Avoid concomitant use 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. 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](http://Nucynta.com/irPI).



# Important Safety Information about 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 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 (flu: 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 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 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 d. 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. 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 more information 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).

# Important Safety Information about 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 who require frequent (e.g., weekly) opioid dosage escalation.



## CONTRAINDICATIONS

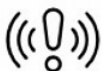
SYMPROIC is contraindicated in:

- 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 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, Crohn's disease). 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 (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, 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 response to SYMPROIC. 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, 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 of adverse reactions of opioid withdrawal was 1% (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 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 100 mg (500 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 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 than 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).

# Important Safety Information about 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 harm to the 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 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 and the infant. If breastfeeding 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 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 differences 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. 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).

# Non-GAAP Reconciliations

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# Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA (in thousands, unaudited)

	Three Months Ended September 30,		Years Ended December 31,		
	2024	2023	2023	2022	2021
GAAP net income (loss)	\$ 9,335	\$ 20,634	\$ 48,155	\$ (25,002)	\$ 71,517
Adjustments:					
Interest expense	18,394	20,768	83,339	63,213	21,014
Interest income	(3,280)	(4,538)	(15,615)	(1,047)	(12)
Loss on extinguishment of debt	4,145	—	23,504	—	—
Provision for (benefit from) income taxes	6,245	8,149	27,578	(3,845)	(74,891)
Depreciation	946	835	3,496	2,684	1,736
Amortization	40,801	36,317	145,760	131,469	67,181
Impairment expense	—	—	—	4,786	—
Stock-based compensation	7,317	7,027	27,136	22,874	24,255
Restructuring	—	—	—	—	4,578
Litigation settlements	—	—	8,500	—	2,935
Recognition of step-up basis in inventory	1,301	198	15,116	39,584	—
Acquisition related expenses	19,886	—	—	31,297	—
Total adjustments	\$ 95,755	\$ 68,756	\$ 318,814	\$ 291,015	\$ 46,796
Adjusted EBITDA	\$ 105,090	\$ 89,390	\$ 366,969	\$ 266,013	\$ 118,313



# Reconciliation of GAAP Operating Expenses to Adjusted Operating Expenses

(in thousands, unaudited)

	Three Months Ended September 30,		Years Ended December 31,		
	2024	2023	2023	2022	2021
GAAP operating expenses	\$ 61,955	\$ 35,298	\$ 159,208	\$ 176,169	\$ 132,989
Adjustments:					
Stock-based compensation	7,317	7,027	27,136	22,874	24,255
Restructuring	—	—	—	—	4,578
Litigation settlements	—	—	8,500	—	2,935
Acquisition related expenses	19,886	—	—	31,297	—
Total adjustments	\$ 27,203	\$ 7,027	\$ 35,636	\$ 54,171	\$ 31,768
Adjusted operating expenses	\$ 34,752	\$ 28,271	\$ 123,572	\$ 121,998	\$ 101,221