

**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 1, 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:

<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 3, 2024, Collegium Pharmaceutical, Inc. (the "Company") issued a press release announcing full-year revenue, adjusted operating expense and adjusted EBITDA guidance for 2024. The Company also announced that the Board of Directors of the Company authorized a new share repurchase program from January 2024 through June 2025 to repurchase up to \$150 million of the Company's shares of common stock, which program is described in more detail under Item 8.01 of this Current Report on Form 8-K. 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 3, 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 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 2024 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: risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; unknown liabilities; 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 obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; the size of the markets for our products and product candidates, 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 and product candidates; 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 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 8.01 Other Information.**

On January 1, 2024, the Board of Directors of the Company authorized a new share repurchase program to repurchase up to \$150 million of the Company's shares of common stock through June 30, 2025. The timing and amount of any shares purchased on the open market will be determined based on the Company's evaluation of the market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund the share repurchase program.

**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 3, 2024.</a>
<a href="#">99.2</a>	<a href="#">Investor Presentation, dated January 3, 2024.</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 3, 2024

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper

Name: Colleen Tupper

Title: Executive Vice President and Chief Financial Officer

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### Collegium Provides 2024 Financial Guidance

- Product Revenues, Net Expected in the Range of \$580.0 Million to \$595.0 Million –
- Adjusted Operating Expenses\* Expected in the Range of \$120.0 Million to \$125.0 Million –
- Adjusted EBITDA\* Expected in the Range of \$380.0 Million to \$395.0 Million –
- \$150.0 Million Share Repurchase Program Authorized by the Board of Directors –

**STOUGHTON, Mass., January 3, 2024** -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company, today announced its 2024 full-year financial guidance and provided a business update.

“2023 was a banner year for Collegium. We are on track to grow revenue over 20% and adjusted EBITDA over 35% in 2023 compared to 2022, leading to strong cash flow generation that enabled us to rapidly pay down debt and opportunistically repurchase shares. Our operational accomplishments position the Company to deliver top- and bottom-line growth in 2024 and strengthen our outlook for 2025 and 2026,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “In 2024, we are focused on operational execution, which includes achieving our financial commitments and deploying capital to create value for shareholders.”

“We expect record revenue, driven by Belbuca<sup>®</sup> and Xtampza<sup>®</sup> ER growth, and disciplined operating spend, to result in record adjusted EBITDA in 2024,” said Colleen Tupper, Chief Financial Officer of Collegium. “We plan to deploy capital to rapidly pay down debt and opportunistically utilize our new \$150 million share repurchase program to return value to our shareholders.”

#### Recent Business Highlights

- Collegium’s board of directors authorized a new share repurchase program to repurchase up to \$150.0 million in common stock over 18 months.
- Returned \$75.0 million in capital to shareholders in 2023 under the share repurchase program authorized by Collegium’s board of directors in January 2023, including \$25.0 million repurchased through an accelerated share repurchase program since November 9, 2023.
- Successfully completed Xtampza ER contract renegotiations with payors that represent 30% of Xtampza ER total prescriptions in 2023. As a result, Xtampza ER gross-to-net is expected to be in the range of 56% to 58% in 2024.
- Renegotiated a major Medicare Part D contract for Belbuca, maintaining its access position and materially reducing the rebate, and won a new Medicare Part D plan for Belbuca representing approximately one million covered lives.

#### Financial Guidance for 2024

- Product revenues, net are expected in the range of \$580.0 million to \$595.0 million.
- Adjusted operating expenses (excluding stock-based compensation) are expected in the range of \$120.0 million to \$125.0 million.
- Adjusted EBITDA (excluding stock-based compensation) is expected in the range of \$380.0 million to \$395.0 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 a 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 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; and
- 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.

#### *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 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 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 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 manage our relationships with licensors; the success of competing products that are or become available; our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; the size of the markets for our products and product candidates, 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 and product candidates; 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:

Christopher James, M.D.  
Vice President, Investor Relations  
[ir@collegiumpharma.com](mailto:ir@collegiumpharma.com)

### Media Contact:

Marissa Samuels  
Vice President, Corporate Communications  
[communications@collegiumpharma.com](mailto:communications@collegiumpharma.com)

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# Investor Presentation



January 2024 | Nasdaq: COLL

#### Forward-Looking Statements

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#### 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 use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

In 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 (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;
- 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 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; and
- 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.

#### 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 (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 2023 or 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(a)(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)

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





# 2024 Focus: Operational Execution

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# 2024 Priorities: Operational Execution

DELIVER ON

## Financial Commitments

- **ACHIEVE** record revenue, adjusted EBITDA and net income
- **GENERATE** record free cash flow

STRATEGICALLY

## Deploy Capital

- **RAPIDLY** pay down debt, de-levering on a quarterly basis
- **OPPORTUNISTICALLY** leverage \$150M share repurchase program

# 2024 Financial Guidance<sup>1</sup>

## Product Revenues, Net

**\$580–595M**

Up **3.5%** YoY<sup>2</sup>

## Adjusted Operating Expenses<sup>3</sup>

(Excluding Stock-Based Compensation)

**\$120–125M**

Down **(3.9)%** YoY<sup>2</sup>

## Adjusted EBITDA<sup>3</sup>

(Excluding Stock-Based Compensation)

**\$380–395M**

Up **6.9%** YoY<sup>2</sup>

1. This financial data was provided by Collegium in its press release filed with the SEC on January 3, 2024.

2. This financial data is calculated based on data provided by Collegium in its press release filed with the SEC on January 3, 2024, and in its press release filed with the SEC on November 7, 2023, and represents the percent change of the mid-point of 2024 financial guidance ranges compared to the mid-point of 2023 financial guidance ranges.

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

# Disciplined Capital Deployment

## Rapidly Pay Down Debt

- Expect net debt/adjusted EBITDA of **~1.0x by year-end 2023; de minimis by year-end 2024**<sup>1,2</sup>
- **Repaid \$162.5M** of Pharmakon loan in 2023 (\$650M issued 3/22/2022) and will repay \$183.3M in 2024<sup>2</sup>
- Pharmakon loan expected to be **paid in full in Q1'26**<sup>2</sup>

## Leverage Share Repurchase Program

- From 2021 to 2023, **returned \$137M** to shareholders; repurchased 6.3M shares at average price of \$21.65<sup>3</sup>
- Board authorized **new \$150M share repurchase program**

1. Adjusted EBITDA is a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2. 2023 net debt/adjusted EBITDA is calculated based on Collegium's forecast of net debt at year-end 2023, compared to the mid-point of the 2023 guidance ranges provided by Collegium in its press release filed with the SEC on November 7, 2023. 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 January 3, 2024. This financial data assumes no additional debt is incurred.

2. Details regarding the Pharmakon term-loan debt amortization schedule were provided by Collegium on form SC TO-C filed with the SEC on February 14, 2022.

3. This financial data is calculated from data provided by Collegium in its Annual Report on Form 10-K filed with the SEC on February 23, 2023, in its Quarterly Report on Form 10-Q filed with the SEC on November 7, 2023, and in its press release filed with the SEC on January 3, 2024.



# Collegium: The Leader in Responsible Pain Management

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# Path to Building a Leading Pain Portfolio

Rated #1 in responsible pain management by HCPs<sup>1</sup>; portfolio holds over 50% market share of branded ER market<sup>2</sup>



1. ATU (Awareness, Trial, & Usage) Market Research Study, fielded Q4 2022.  
2. IQVIA NPA through November 2023 (Belbuca, Xtampza ER, and Nucynta<sup>®</sup> ER).

# Pain Portfolio Growth Drivers



	Expect prescription and revenue growth in 2024	Expect revenue growth in 2024
<b>Strong Market Position</b>	<b>36.6% share</b> of growing buprenorphine market <sup>1</sup>	<b>37.1% share</b> of OER market <sup>1</sup>
<b>Large Prescriber Base</b>	<b>~9.8K unique prescribers</b> in Q3'23 <sup>2</sup>	<b>~17.7K unique prescribers</b> in Q3'23 <sup>2</sup>
<b>GtN Impacts</b>	Expect <b>stable GtN</b>	Expect <b>GtN improvement to 56-58%</b>
<b>Market Access</b>	Strong <b>commercial</b> coverage	Strong coverage across <b>all payor types</b>

1. IQVIA NPA through November 2023.  
 2. IQVIA Xponent through September 2023; approximate quarterly prescriber counts.



# Well Positioned to Grow Belbuca Prescriptions and Revenue in 2024

## Positive Momentum for Belbuca Coming Out of 2023

### GROWING BELBUCA PRESCRIPTIONS<sup>1</sup>

YoY growth in Belbuca prescriptions



### EXPANDING BUPRENORPHINE MARKET

**+6.5%**

YoY growth in total buprenorphine prescriptions  
November 2023 YTD<sup>2</sup>

### STRONG BRAND FUNDAMENTALS & PAYOR PROGRESS

**#1** highest rated branded ER opioid in terms of product differentiation and favorability<sup>3</sup>

**74%** of surveyed target HCPs plan to increase prescribing<sup>3</sup>

In 2023, successfully renegotiated major Medicare Part D plan representing **12%** of Belbuca prescriptions; maintained formulary position at significantly lower rebate

Achieved new payor win for Belbuca in Medicare Part D plan representing **~1M** covered lives

1. IQVIA NPA. Q4'23 QTD YoY growth represents October and November 2023 compared to the same period in 2022.

2. IQVIA NPA for 2023 YTD through November compared to the same period in 2022.

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

# Xtampza ER Poised to Grow Revenue in 2024

Improved GtN Expected to Drive Revenue Growth in 2024

Plans representing **84%** of Xtampza ER prescriptions renegotiated in 2022 and 2023



**77%** of renegotiation opportunity maintained position at equal or better rebate



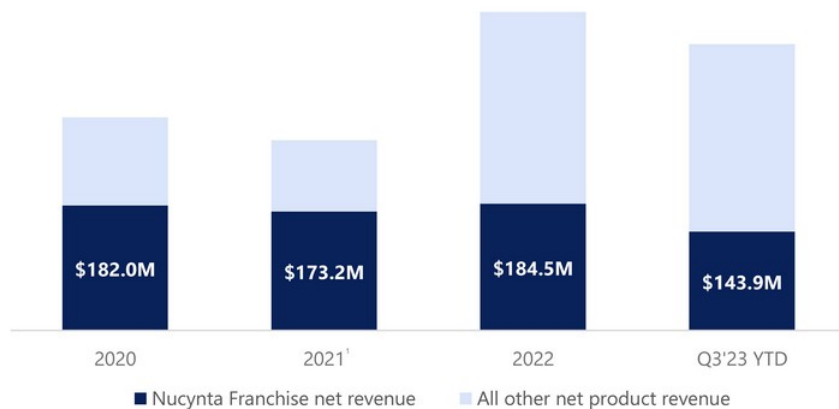
**23%** of renegotiation opportunity removed from formulary to parity position with Oxycontin® with no rebate

**Xtampza ER GtN expected to improve to 56%–58% in 2024**

# Nucynta Franchise: Stable Contributor with Mid-Term Outlook Bolstered by Regulatory Exclusivity Extension

## Stable Contributor to the Pain Portfolio

Product Revenues, Net



## Improved Outlook for 2025 and 2026

- Nucynta<sup>®</sup> granted New Patient Population exclusivity; U.S. regulatory exclusivity extended from June 27, 2025, to July 3, 2026
- Potential for 6-month pediatric exclusivity (Dec. 2025 for Nucynta<sup>®</sup> ER, Jan. 2027 for Nucynta)
- Royalty declines from 14% to 7% in 2025

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



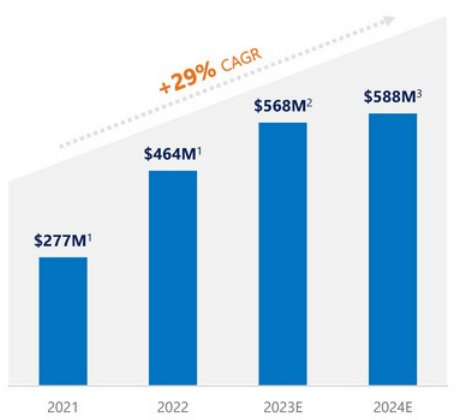
**Strong Track Record of  
Execution and Achieving  
Financial Commitments**

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

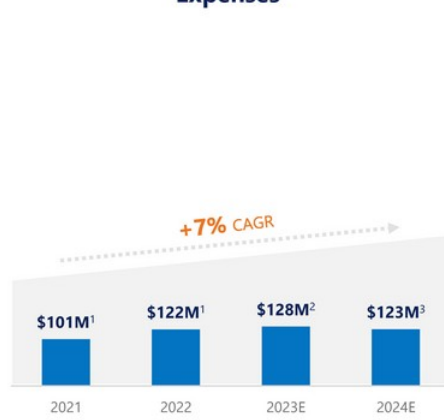
## GROW

### Product Revenues, Net



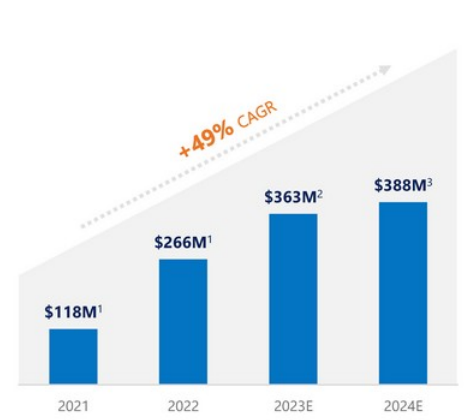
## LEVERAGE

### Adjusted Operating Expenses<sup>4</sup>



## EXPAND

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



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

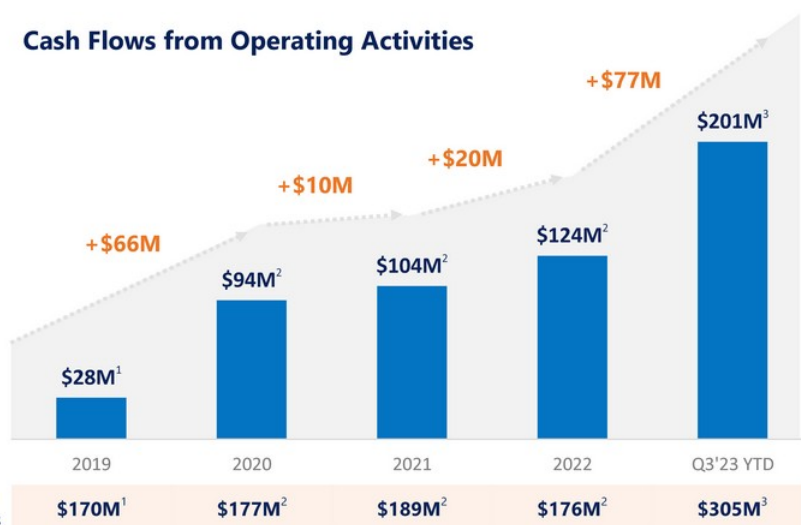
2. This financial data was provided by Collegium in its press release filed with the SEC on November 7, 2023, and represents the mid-point of 2023 financial guidance ranges.

3. This financial data was provided by Collegium in its press release filed with the SEC on January 3, 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 Activities



- Maximizing differentiated pain portfolio to generate robust operating cashflows
- Strong cash generation enables disciplined capital deployment strategy
- Executed \$137M in share repurchases 2019–2023<sup>4</sup>
- Invested ~\$1B in business development 2019–2023<sup>5</sup>

1. This financial data was provided by Collegium in its Annual Report on Form 10-K filed with the SEC on February 24, 2022.

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

3. This financial data was provided by Collegium in its Quarterly Report on Form 10-Q filed with the SEC on November 7, 2023.

4. This financial data is calculated from data provided by Collegium in its Annual Reports on Form 10-K filed with the SEC on February 23, 2023, in its Quarterly Report on Form 10-Q filed with the SEC on November 7, 2023, and in its press release filed with the SEC on January 3, 2024.

5. 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

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# Rapid Paydown of Debt

## Pharmakon Loan Principal Balance



- Expect net debt/adjusted EBITDA of ~1.0x by year-end 2023; de minimis by year-end 2024<sup>1,2</sup>
- Repaid \$162.5M of Pharmakon loan in 2023 (\$650M issued 3/22/2022) and will repay \$183.3M in 2024<sup>2</sup>
- Pharmakon loan expected to be paid in full in Q1'26<sup>2</sup>

## Convertible Debt

- \$267.9M in convertible debt principal as of 9/30/2023
- In February 2023, completed a \$241.5M convertible note financing:
  - Due in February 2029
  - Interest rate of 2.875%
  - Conversion premium: ~30% (conversion price of \$36.56 per share)
- Used portion of proceeds to repurchase \$117.4M of principal related to previously issued convertible notes due 2026
- Later maturity provides more financial flexibility in the management of debt
- Net increase in principal balance of convertible debt was \$124.1M from 12/31/2022

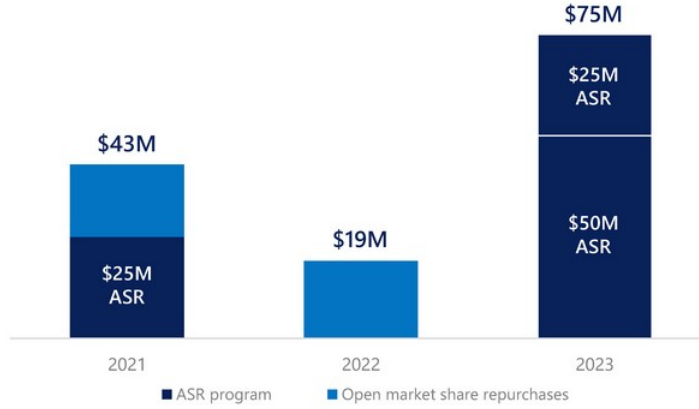
1. Adjusted EBITDA is a non-GAAP financial measure. Refer to "Non-GAAP Financial Measures" on slide 2. 2023 net debt/adjusted EBITDA is calculated based on Collegium's forecast of net debt at year-end 2023, compared to the mid-point of the 2023 guidance ranges provided by Collegium in its press release filed with the SEC on November 7, 2023. 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 January 3, 2024. This financial data assumes no additional debt is incurred.

2. Details regarding the Pharmakon term-loan debt amortization schedule were provided by Collegium on form SC TO-C filed with the SEC on February 14, 2022.

# Opportunistic Share Repurchases<sup>1</sup>

## Returned \$137M of Capital to Shareholders from 2021 to 2023

Repurchased 6.3M shares at average price of \$21.65



## Board Authorized New \$150M Share Repurchase Program

1. This financial data is calculated from data provided by Collegium in its Annual Report on Form 10-K filed with the SEC on February 23, 2023, in its Quarterly Report on Form 10-Q filed with the SEC on November 7, 2023, and in its press release filed with the SEC on January 3, 2024.

# Track Record of Successful Business Development

## Strategically Compelling Acquisitions



Nucynta Franchise (February 2020)



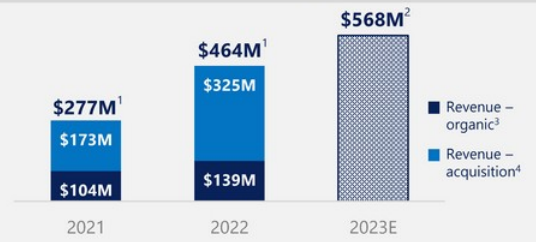
BDSI (March 2022)

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 EBITDA<sup>5</sup>



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 in its press release filed with the SEC on November 7, 2023 and represents the mid-point of 2023 financial guidance ranges.

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

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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 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 the Nucynta Franchise, the New Patient Population exclusivity granted to Nucynta, and based on the judgment upholding its Orange-Book listed patents, the July 2025 and 2028 expiries of such patents for Nucynta ER; and (iv) for Symproic, which does not have any ANDA filers yet, the November 2031 expiry of its Orange Book-listed patents.





# Summary

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# 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

## STRATEGICALLY

### Deploy capital in a disciplined manner:

- Rapidly pay down \$183.3M in debt in 2024
- Return capital to shareholders by leveraging \$150M share repurchase program

### Creating value for shareholders by:

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





# Important Safety Information

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# 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](http://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](http://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)

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# 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](http://Nucynta.com/erPI).



# 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](http://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](http://Nucynta.com/irPI).



# 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

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

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
GAAP net (loss) income	\$ (25,002)	\$ 71,517
Adjustments:		
Interest expense	63,213	21,014
Interest income	(1,047)	(12)
Benefit from income taxes	(3,845)	(74,891)
Depreciation	2,684	1,736
Amortization	131,469	67,181
Impairment expense	4,786	—
Stock-based compensation expense	22,874	24,255
Restructuring	—	4,578
Litigation settlements	—	2,935
Acquisition related expenses	31,297	—
Recognition of step-up basis in inventory	39,584	—
Total adjustments	\$ 291,015	\$ 46,796
Adjusted EBITDA	<u>\$ 266,013</u>	<u>\$ 118,313</u>

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

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
GAAP operating expenses	\$ 176,169	\$ 132,989
Adjustments:		
Stock-based compensation	22,874	24,255
Restructuring	—	4,578
Litigation settlements	—	2,935
Acquisition related expenses	31,297	—
Total adjustments	\$ 54,171	\$ 31,768
Adjusted operating expenses	<u>\$ 121,998</u>	<u>\$ 101,221</u>