Collegium Reports Third Quarter 2023 Financial Results

November 7, 2023

– Q3'23 Net Revenue of $136.7 Million, Up 8% Year-over-Year –

– Q3'23 GAAP Net Income of $20.6 Million vs. Q3'22 GAAP Net Income of $0.5 Million –

– Record Q3'23 Adjusted EBITDA of $89.4 Million, Up 19% Year-over-Year –

– Received Extension of Nucynta® Regulatory Exclusivity through July 2026 –

– Board of Directors Authorized $25.0 Million Accelerated Share Repurchase Program –

– Updated Full Year 2023 Guidance –

– Conference Call Scheduled for Today at 4:30 p.m. ET –

STOUGHTON, Mass., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today reported its financial results for the quarter ended September 30, 2023, and provided a corporate update.

"We are on track to deliver a banner year in 2023 and expect revenue for the full year to grow more than 20% year-over-year with adjusted EBITDA growing at more than one and a half times that rate. We are confident that the business is well positioned," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "Importantly, our outlook for 2025 and 2026 has been bolstered by the extension of Nucynta's regulatory exclusivity through July 2026. We are focused on creating value for our shareholders through the disciplined deployment of capital."

"We delivered a solid financial performance in the third quarter and are tightening our 2023 financial guidance ranges," said Colleen Tupper, Chief Financial Officer of Collegium. "In the third quarter, we generated record quarterly Belbuca ® revenue, paid down $45.8 million of debt and executed an Accelerated Share Repurchase program returning $50.0 million in capital to our shareholders. The financial strength of the business enables us to execute our capital deployment strategy in a disciplined manner, inclusive of our newly announced $25.0 million Accelerated Share Repurchase program."

Recent Business Highlights

- Grew portfolio net revenue to $136.7 million in the quarter ended September 30, 2023 (the "2023 Quarter"), up 8% compared to the quarter ended September 30, 2022 (the "2022 Quarter").
  - Generated record quarterly Belbuca net revenue of $45.4 million in the 2023 Quarter, up 17% year-over-year.
  - Recognized Xtampza® ER net revenue of $39.8 million in the 2023 Quarter, up 2% year-over-year. The 2022 Quarter was impacted by a favorable returns adjustment of approximately $8.1 million.
  - Increased Nucynta Franchise net revenue to $47.5 million in the 2023 Quarter, up 7% year-over-year.
- Grew Belbuca total prescriptions 1.2% year-over-year in the 2023 Quarter.
- Successfully completed contract renegotiations with payors that represent 30% of Xtampza ER total prescriptions while maintaining access in 57% of the renegotiated opportunity. As a result, Collegium expects gross-to-net improvement in 2024 to be a catalyst for revenue growth.
- 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.
- Presented 10 posters at PAINWeek Conference 2023 highlighting Collegium's diversified pain portfolio.
- Executed an Accelerated Share Repurchase program in the 2023 Quarter returning $50.0 million in capital to shareholders.
- Received U.S. Food and Drug Administration New Patient Population exclusivity for Nucynta, an immediate release formulation of tapentadol, extending the period of U.S. exclusivity from June 27, 2025, to July 3, 2026.
- Expects to submit a pediatric extension in December 2023 for the Nucynta Franchise that would potentially extend exclusivity of the Nucynta Franchise an additional six months to December 27, 2025, for Nucynta® ER and January 3, 2027, for Nucynta. The company expects a decision in the second half of 2024.
- Board of Directors authorized a $25.0 million Accelerated Share Repurchase program that will result in share repurchases in 2023 totaling $75.0 million.

Financial Guidance for 2023

- The Company updates its full-year 2023 guidance for Product Revenues, Net, Adjusted Operating Expenses and Adjusted EBITDA:

	Prior	Updated
Product Revenues, Net	$565.0 to $580.0 million	$565.0 to $570.0 million
Adjusted Operating Expenses (Excluding Stock-Based Compensation)	$135.0 to $145.0 million	$125.0 to $130.0 million

Adjusted EBITDA (Excluding Stock-Based Compensation)	$355.0 to $370.0 million	$360.0 to $365.0 million

Financial Results for Quarter Ended September 30, 2023

- Product revenues, net were $136.7 million for the 2023 Quarter, compared to $127.0 million for the 2022 Quarter, representing an 8% increase year-over-year.
- GAAP operating expenses were $35.3 million for the 2023 Quarter, compared to $38.4 million for the 2022 Quarter, representing an 8% decrease year-over-year. Adjusted operating expenses, which exclude stock-based compensation expense and other adjustments to reflect changes that occur in our business but do not represent ongoing operations, were $28.3 million for the 2023 Quarter, compared to $32.5 million for the 2022 Quarter, representing a 13% decrease year-over-year.
- GAAP net income for the 2023 Quarter was $20.6 million, with $0.61 GAAP earnings per share (basic) and $0.53 GAAP earnings per share (diluted), compared to GAAP net income for the 2022 Quarter of $0.5 million, with $0.01 GAAP earnings per share (basic and diluted). Non-GAAP adjusted net income for the 2023 Quarter was $55.0 million, with $1.34 adjusted earnings per share, compared to non-GAAP adjusted net income for the 2022 Quarter of $42.5 million, with $1.10 adjusted earnings per share.
- Adjusted EBITDA for the 2023 Quarter was $89.4 million, compared to $74.9 million for the 2022 Quarter, representing a 19% increase year-over-year.
- The Company exited the 2023 Quarter with cash, cash equivalents and marketable securities of $304.6 million, up from $173.7 million as of December 31, 2022.

Conference Call Information

The Company will host a conference call and live audio webcast on Tuesday, November 7, 2023, at 4:30 p.m. Eastern Time. To access the conference call, please dial (877) 407-8037 (U.S.) or (201) 689-8037 (International) and reference the “Collegium Q3 2023 Earnings Call.” An audio webcast will be accessible from the Investors section of the Company’s website: www.collegiumpharma.com. The webcast will be available for replay on the Company’s website approximately two hours after the event.

About Collegium Pharmaceutical, Inc.

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

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 our quarterly and annual reports, earnings press releases and conference calls, we may 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 press release.

The Company has not provided a reconciliation of its full-year 2023 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 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.

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 2023 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: risks related to the ability to realize the anticipated benefits of our acquisitions at all or within the expected time period; unknown liabilities; risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; the impact of the COVID-19 pandemic on our ability to conduct our business, reach our customers, and supply the market with our 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.

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Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 258,532	$ 173,688

Marketable securities	46,033	—
Accounts receivable, net	181,851	183,119
Inventory	34,125	46,501
Prepaid expenses and other current assets	16,545	16,681
Property and equipment, net	16,645	19,521
Operating lease assets	6,243	6,861
Intangible assets, net	456,222	567,468
Restricted cash	1,047	2,547
Deferred tax assets	25,738	23,950
Other noncurrent assets	740	100
Goodwill	133,857	133,695
Total assets	$ 1,177,578	$ 1,174,131
Accounts payable and accrued liabilities	35,304	39,623
Accrued rebates, returns and discounts	245,012	230,491
Term notes payable	449,219	560,078
Convertible senior notes	261,823	140,873
Operating lease liabilities	7,347	8,224
Shareholders' equity	178,873	194,842
Total liabilities and stockholders' equity	$ 1,177,578	$ 1,174,131

Collegium Pharmaceutical, Inc.

Unaudited Condensed Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenues, net	$ 136,709	$ 127,013	$ 417,022	$ 334,313
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	20,081	30,622	74,237	80,638
Intangible asset amortization	36,317	37,552	111,246	93,976
Total cost of products revenues	56,398	68,174	185,483	174,614
Gross profit	80,311	58,839	231,539	159,699
Operating expenses				
Research and development	—	—	—	3,983
Selling, general and administrative	35,298	38,372	126,266	134,154
Total operating expenses	35,298	38,372	126,266	138,137
Income from operations	45,013	20,467	105,273	21,562
Interest expense	(20,768)	(19,046)	(64,058)	(42,638)
Interest income	4,538	11	11,312	20
Loss on extinguishment of debt	—	—	(23,504)	—
Income (loss) before income taxes	28,783	1,432	29,023	(21,056)
Provision for (benefit from) income taxes	8,149	975	12,808	(3,253)
Net income (loss)	$ 20,634	$ 457	$ 16,215	$ (17,803)
Earnings (loss) per share — basic	$ 0.61	$ 0.01	$ 0.47	$ (0.52)
Weighted-average shares — basic	33,744,209	34,058,802	34,226,488	33,912,832
Earnings (loss) per share — diluted	$ 0.53	$ 0.01	$ 0.46	$ (0.52)
Weighted-average shares — diluted	42,058,821	34,570,319	35,149,154	33,912,832

Collegium Pharmaceutical, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net income (loss)	$ 20,634	$ 457	$ 16,215	$ (17,803)
Adjustments:				
Interest expense	20,768	19,046	64,058	42,638

Interest income	(4,538)	(11)	(11,312)	(20)
Loss on extinguishment of debt	—	—	23,504	—
Provision for (benefit from) income taxes	8,149	975	12,808	(3,253)
Depreciation	835	488	2,547	1,859
Amortization	36,317	37,552	111,246	93,976
Stock-based compensation expense	7,027	5,377	20,134	17,204
Litigation settlements	—	—	8,500	—
Acquisition related expenses	—	463	—	31,209
Recognition of step-up basis in inventory	198	10,519	15,116	23,760
Total adjustments	$ 68,756	$ 74,409	$ 246,601	$ 207,373
Adjusted EBITDA	$ 89,390	$ 74,866	$ 262,816	$ 189,570

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Operating Expenses to Adjusted Operating Expenses
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP operating expenses	$ 35,298	$ 38,372	$ 126,266	$ 138,137
Adjustments:				
Stock-based compensation	7,027	5,377	20,134	17,204
Litigation settlements	—	—	8,500	—
Acquisition related expenses	—	463	—	31,209
Total adjustments	$ 7,027	$ 5,840	$ 28,634	$ 48,413
Adjusted operating expenses	$ 28,271	$ 32,532	$ 97,632	$ 89,724

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income (Loss) to Adjusted Net Income and Adjusted Earnings Per Share
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net income (loss)	$ 20,634	$ 457	$ 16,215	$ (17,803)
Adjustments:				
Non-cash interest expense	2,124	2,467	6,672	5,902
Loss on extinguishment of debt	—	—	23,504	—
Amortization	36,317	37,552	111,246	93,976
Impairment expense	—	—	—	—
Stock-based compensation expense	7,027	5,377	20,134	17,204
Restructuring	—	—	—	—
Litigation settlements	—	—	8,500	—
Acquisition related expenses	—	463	—	31,209
Recognition of step-up basis in inventory	198	10,519	15,116	23,760
Discrete deferred tax benefit from valuation allowance release	—	—	—	—
Income tax effect of above adjustments [1]	(11,300)	(14,290)	(42,274)	(43,698)
Total adjustments	$ 34,366	$ 42,088	$ 142,898	$ 128,353
Non-GAAP adjusted net income	$ 55,000	$ 42,545	$ 159,113	$ 110,550
Adjusted weighted-average shares — diluted [2]	42,058,820	39,495,453	41,679,546	39,368,629
Adjusted earnings per share [2]	$ 1.34	$ 1.10	$ 3.91	$ 2.88

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate to the items that have a tax effect. The blended federal and state statutory rate for the three months ended September 30, 2023 and 2022 were 25.6% and 26.0%, respectively; and the blended federal and state statutory rate for the nine months ended September 30, 2023 and 2022 were 25.6% and 26.0%, respectively. As such, the non-GAAP effective tax rates for the three months ended September 30, 2023 and 2022 were 24.7% and 25.3%, respectively; and the non-GAAP effective tax rates for the nine months ended September 30, 2023 and 2022 were 22.8% and 25.4%, respectively.
(2) Adjusted weighted-average shares - diluted were calculated using the “if-converted” method for our convertible notes in accordance with ASC 260, *Earnings per Share*. As such, adjusted weighted-average shares – diluted includes shares related to the assumed conversion of our convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income. For the three months ended September 30, 2023 and 2022, adjusted weighted-average shares – diluted includes 7,509,104 and 4,925,134, respectively, attributable to our convertible notes. For the nine

months ended September 30, 2023 and 2022, adjusted weighted-average shares – diluted includes 6,530,392 and 4,925,134, respectively, attributable to our convertible notes. In addition, for the three and nine months ended September 30, 2023 and 2022, adjusted earnings per share also includes other potentially dilutive securities to the extent that they are not antidilutive given that non-GAAP adjusted net income was in an income position.

Source: Collegium Pharmaceutical, Inc.