

Collegium Reports Third Quarter 2022 Financial Results

November 3, 2022

- Generated Record Net Revenue of \$127.0 Million -
- Completed Xtampza® ER Contract Renegotiations, Confirmed Xtampza ER Gross-To-Net Will be Less Than 65% Beginning January 2023 -
 - Returned \$10M in Capital to Shareholders Through Share Repurchases -
 - Updated Full Year 2022 Guidance -
 - Conference Call Scheduled for Today at 4:30 p.m. ET -

STOUGHTON, Mass., Nov. 03, 2022 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical. Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company, today reported its financial results for the quarter ended September 30, 2022 and provided a corporate update.

"We made significant progress in the third quarter as we continued to successfully execute on Phase 2, Generate Momentum, of our three-phase action agenda, positioning Collegium for a strong finish to 2022 and a banner year in 2023," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "Our seamless integration of BDSI has enabled us to increase our targeted run rate synergies related to the acquisition. Building on that momentum, we are pleased to report that we successfully completed our contract renegotiations for Xtampza[®] ER, delivering on our commitment to achieve gross-to-net of less than 65% beginning in January 2023 while maintaining broad access. The Company is well positioned for Phase 3, Accelerate, at the start of 2023, where we expect to generate strong top- and bottom-line growth."

"Our third quarter results reflect our operational momentum, as we delivered record revenue and adjusted EBITDA, durable operating leverage, and positive operating cash flows, while continuing to rapidly pay down debt," said Colleen Tupper, Chief Financial Officer of Collegium. "We are updating our 2022 financial guidance and remain committed to our disciplined evaluation of opportunities to strategically deploy our capital, including our top priority of business development and opportunistic share repurchases like those we completed in the second half of this year, to create value for our shareholders."

Nine Months Ended September 30, 2022 Business Highlights

- Completed Xtampza ER contract renegotiations, maintaining broad access while significantly decreasing rebates to ensure an Xtampza ER gross-to-net of less than 65% effective January 1, 2023
- Increased Collegium's market share of the Branded ER market to 49.7% in September 2022
- Increased BDSI run rate synergy target to approximately \$85 million
- Returned \$10.0 million in capital to shareholders, including \$6.4 million in the quarter ended September 30, 2022, and an additional \$3.6 million in October 2022. As of November 3, 2022, \$42.1 million remains under the \$100.0 million share repurchase program authorized by Collegium's board of directors in August 2021
- Achieved dismissal, pursuant to a master settlement agreement, of all 27-pending opioid industry-related lawsuits brought against the Company by cities, counties, and other subdivisions in the United States
- Presented 11 poster presentations at the PAINWeek 2022 National Conference highlighting our diversified pain portfolio

Financial Guidance for 2022

 The Company updates its full-year 2022 guidance for Total Product Revenues, Total Adjusted Operating Expenses, and Total Adjusted EBITDA:

	Prior	Updated
Total Product Revenues	\$450.0 to \$465.0 million	\$455.0 to \$465.0 million
Total Adjusted Operating Expenses (Excluding Stock-Based Compensation and Acquisition Related Expenses)	\$125.0 to \$135.0 million	\$125.0 to \$130.0 million
Total Adjusted EBITDA (Excluding Stock-Based Compensation and Acquisition Related Expenses)	\$245.0 to \$255.0 million	\$250.0 to \$255.0 million

- Total net product revenues were \$127.0 million for the quarter ended September 30, 2022 (the "2022 Quarter"), compared to \$78.8 million for the quarter ended September 30, 2021 (the "2021 Quarter").
- GAAP operating expenses were \$38.4 million for the 2022 Quarter, compared to \$32.0 million for the 2021 Quarter. Adjusted operating expenses, which exclude stock-based compensation expense of \$5.4 million and acquisition related expenses of \$0.5 million, were \$32.5 million for the 2022 Quarter, compared to \$26.0 million for the 2021 Quarter, which excluded stock-based compensation expense of \$5.9 million.
- GAAP net income for the 2022 Quarter was \$0.5 million, with \$0.01 GAAP earnings per share (basic and diluted), compared to GAAP net income for the 2021 Quarter of \$8.0 million, with \$0.23 GAAP earnings per share (basic) and \$0.22 GAAP earnings per share (diluted). Non-GAAP adjusted net income for the 2022 Quarter was \$42.5 million, with \$1.10 adjusted earnings per share, compared to non-GAAP adjusted net income for the 2021 Quarter of \$25.7 million, with \$0.65 adjusted earnings per share.
- Adjusted EBITDA for the 2022 Quarter was \$74.9 million, compared to \$37.3 million for the 2021 Quarter.
- The Company exited the 2022 Quarter with a cash balance of \$134.1 million, up from \$122.7 million as of June 30, 2022, after taking into account \$25 million in debt repayments completed in the 2022 Quarter.

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, November 3, 2022, 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 2022 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 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 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, 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 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 expenses incurred; and
- 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.

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.

The Company has not provided a reconciliation of its full-year 2022 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures because it 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. These items are uncertain and depend on various factors that could have a material impact on GAAP net income and operating expenses for the guidance period.

Adjusted Net Income and Adjusted Earnings Per Share

Adjusted net income is a non-GAAP financial measure that represents GAAP net income 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 2022 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures because it 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. These items are uncertain and depend on various factors that could have a material impact on GAAP net income and operating expenses for the guidance period.

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," "anticipates," "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 2022 financial guidance, including total 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. Actual results may differ materially from management's expectations and such forward-looking statements in this press release could be affected as a result of various important factors, including risks relating to, among others: risks related to the ability to realize the anticipated benefits of our acquisition of BDSI, including the possibility that the expected benefits from the BDSI acquisition will not be realized or will not be realized within the expected time period; unknown liabilities; risks related to future opportunities and plans for the products acquired with BDSI, 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, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P.; 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)

		December 31, 2021		
Cash and cash equivalents	\$	134,126	\$	186,426
Accounts receivable, net		195,402		105,844
Inventory		64,652		17,394
Prepaid expenses and other current assets		11,036		5,879
Property and equipment, net		19,744		19,491
Operating lease assets		7,061		7,644
Intangible assets, net		609,747		268,723
Restricted cash		2,547		2,547
Deferred tax assets		26,474		78,042
Other noncurrent assets		57		87
Goodwill		130,094		_
Total assets	\$	1,200,940	\$	692,077

Accrued rebates, returns and discounts	241,218	196,996
Term notes payable	582,925	110,019
Convertible senior notes	140,644	139,966
Operating lease liabilities	8,526	8,765
Shareholders' equity	 197,194	202,928
Total liabilities and stockholders' equity	\$ 1,200,940	\$ 692,077

Collegium Pharmaceutical, Inc.

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

	Three Months Ended September 30,				Nir	ne Months End	ded September 30,	
	2022 2021				2022	2021		
Product revenues, net	\$	127,013	\$	78,843	\$	334,313	\$	249,506
Cost of product revenues								
Cost of product revenues (excluding intangible asset amortization)		30,622		15,934		80,638		47,170
Intangible asset amortization		37,552		16,796		93,976		50,386
Total cost of products revenues		68,174		32,730		174,614		97,556
Gross profit		58,839		46,113		159,699		151,950
Operating expenses								
Research and development		_		1,450		3,983		7,842
Selling, general and administrative		38,372		30,514		134,154		92,358
Total operating expenses		38,372		31,964		138,137		100,200
Income from operations		20,467		14,149		21,562		51,750
Interest expense		(19,046)		(5,115)		(42,638)		(16,257)
Interest income		11		3		20		9
Income (loss) before income taxes		1,432		9,037		(21,056)		35,502
Provision for (benefit from) income taxes		975		991		(3,253)		(61,049)
Net income (loss)	\$	457	\$	8,046	\$	(17,803)	\$	96,551
Earnings (loss) per share — basic	\$	0.01	\$	0.23	\$	(0.52)	\$	2.74
Weighted-average shares — basic		34,058,802		35,373,909		33,912,832		35,210,966
Earnings (loss) per share — diluted	\$	0.01	\$	0.22	\$	(0.52)	\$	2.42
Weighted-average shares — diluted		34,570,319		36,261,174		33,912,832		41,274,190

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income to Adjusted EBITDA

(in thousands) (unaudited)

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2022		2021		2022		2021
GAAP Net income (loss)	\$	457	\$	8,046	\$	(17,803)	\$	96,551
Adjustments:								
Interest expense		19,046		5,115		42,638		16,257
Interest income		(11)		(3)		(20)		(9)
Provision for (benefit from) income taxes		975		991		(3,253)		(61,049)
Depreciation		488		448		1,859		1,312
Amortization		37,552		16,796		93,976		50,386
Stock-based compensation expense		5,377		5,948		17,204		19,343
Acquisition related expenses		463		_		31,209		_
Recognition of step-up basis in inventory		10,519				23,760		<u> </u>
Total adjustments	\$	74,409	\$	29,295	\$	207,373	\$	26,240
Adjusted EBITDA	\$	74,866	\$	37,341	\$	189,570	\$	122,791

Collegium Pharmaceutical, Inc.

(unaudited)

	Three Month	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022		2021		2022		2021		
GAAP Operating expenses	\$ 38,	372 \$	31,964	\$	138,137	\$	100,200		
Adjustments:									
Stock-based compensation	5,	377	5,948		17,204		19,343		
Acquisition related expenses		163			31,209		_		
Total adjustments	\$ 5,	340 \$	5,948	\$	48,413	\$	19,343		
Adjusted operating expenses	\$ 32,	32 \$	26,016	\$	89,724	\$	80,857		

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income 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,			
	2022 2021			2022			2021	
GAAP Net income (loss)	\$	457	\$	8,046	\$	(17,803)	\$	96,551
Adjustments:								
Non-cash interest expense		2,467		833		5,902		2,627
Amortization		37,552		16,796		93,976		50,386
Stock-based compensation expense		5,377		5,948		17,204		19,343
Acquisition related expenses		463		_		31,209		_
Recognition of step-up basis in inventory		10,519		_		23,760		_
Discrete deferred tax benefit from valuation allowance release		_		_		_		(62,649)
Income tax effect of above adjustments (1)		(14,290)		(5,899)		(43,698)		(1,627)
Total adjustments	\$	42,088	\$	17,678	\$	128,353	\$	8,080
Non-GAAP adjusted net income	\$	42,545	\$	25,724	\$	110,550	\$	104,631
A.F		20 405 452		44 406 200		20 260 620		41 274 100
Adjusted weighted-average shares — diluted (2)	_	39,495,453	_	41,186,308	_	39,368,629	_	41,274,190
Adjusted earnings per share	\$	1.10	\$	0.65	\$	2.88	\$	2.60

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate of 26% to the items that have a tax effect. As such, the non-GAAP effective tax rates for the three months ended September 30, 2022 and 2021 were 25.3% and 25.0%, respectively, and the non-GAAP effective tax rates for the nine months ended September 30, 2022 and 2021 were 25.4% and 16.8%, respectively. (2) Adjusted weighted-average shares - diluted were calculated using the "if-converted" method for the Convertible Senior Notes in accordance with ASC 260, Earnings per Share. As such, for the three and nine months ended September 30, 2022 and 2021 adjusted earnings per share includes 4,925,134 shares related to the assumed conversion of the Convertible Senior Notes and the associated cash interest expense added-back to non-GAAP adjusted net income. In addition, for the nine months ended September 30, 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.