

# **Cumberland Pharmaceuticals Reports Third Quarter 2010 Financial Results**

- Second supplemental new drug application for Acetadote submitted to the FDA
- First launch of Cumberland product outside of the United States
- Company raises 2010 revenue guidance based on third quarter results

NASHVILLE, Tenn., Nov. 11, 2010 /PRNewswire-FirstCall/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX), a specialty pharmaceutical company focused on the hospital acute care and gastroenterology markets, today announced financial results for the third quarter ending September 30, 2010, increasing revenue guidance for 2010.

**Net Revenue:** For the three months ended September 30, 2010, net revenue was \$12.2 million, compared with \$13.6 million for the same period in 2009. Excluding initial wholesaler stocking of \$3.2 million for Caldolor in 2009, net product revenues were up 19% year over year. Net revenue for the nine months ended September 30, 2010, was \$33.1 million, up from \$32.8 million for the corresponding prior year period.

**Operating Expenses:** Total operating expenses for the three months ended September 30, 2010, decreased 13% to \$9.7 million, compared to \$11.2 million for the same period in 2009. This decrease was primarily due to significant initial launch costs related to Caldolor in 2009, as well as changes in the Company's product mix that reduced cost of products sold. The decrease in operating expenses coupled with strong revenue performance during the third quarter of 2010 resulted in an increase in operating income over the prior year to \$2.4 million.

Operating expenses for the nine-month period ended September 30, 2010, were \$28.8 million compared with \$27.7 million for the same period in 2009. The difference was primarily due to increased selling and marketing expense from expansion of the Company's hospital sales force in the third quarter of 2009, resulting in operating income of \$4.3 million for the nine-month period ended September 30, 2010.

**Net Income:** Net income for the three months ended September 30, 2010, was \$1.0 million, or \$0.05 per diluted share, compared with \$1.3 million, or \$0.07 per diluted share, for the prior year period. Both net income and earnings per share for the third quarter of 2009 were impacted by initial stocking of Caldolor. The decrease in earnings per share was also driven by an increase in shares outstanding related to the Company's initial public offering in August 2009.

Net income for the nine months ended September 30, 2010, was \$1.6 million, compared with \$2.8 million for the same period in 2009. The difference in net income for the nine-month periods resulted from increases in 2010 of selling and marketing expense as well as interest expense from the Company's term loan, which it entered into in the third quarter of 2009.

**EBITDA:** Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) for the three months ended September 30, 2010, was \$2.7 million compared with \$2.6 million for the same period in the prior year. Excluding \$0.2 million in non-cash stock compensation expense for the periods ended September 30, 2010 and September 30, 2009, adjusted EBITDA was \$2.9 million and \$2.8 million, respectively.

For the nine months ended September 30, 2010, EBITDA was \$5.0 million compared with \$5.7 million for the prior year period. Excluding \$0.6 million and \$1.5 million in non-cash stock compensation expense for the periods ended September 30, 2010 and September 30, 2009, respectively, adjusted EBITDA was \$5.6 million and \$7.2 million, respectively.

**Balance Sheet:** During the quarter the Company amended its senior credit facilities, reducing its term loan balance to \$6 million and expanding availability under its line of credit from \$4.0 million to \$6 million. As a result of these activities, Cumberland had \$65.5 million in cash and cash equivalents at September 30, 2010, compared with \$71.5 million at June 30, 2010. The Company's outstanding debt decreased to \$7.8 million at the end of the third quarter 2010, compared with \$13.8 million at June 30, 2010. Total assets as of September 30, 2010, were \$89.9 million compared with \$96.7 million at June 30, 2010.

"We continue to grow our established brands, Acetadote and Kristalose, and to progress our efforts to gain wide formulary acceptance for Caldolor," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "As we prepare to drive pull-through sales for Caldolor in 2011, we are assembling a growing armamentarium of training and marketing tools to shift efforts within hospitals and surgery centers to reach a much larger target audience."

Cumberland is raising its full year 2010 revenue guidance from its previous expectations of \$42 - \$43 million. The Company

now expects to see net revenue of \$43 - \$45 million for the twelve-month period ended December 31, 2010. This guidance represents the Company's best estimate of future results, which may be affected by factors described below in "Forward-Looking Statements."

# **RECENT DEVELOPMENTS**

Submission of Supplemental New Drug Application for New Formulation of Acetadote

In October 2010, Cumberland submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for approval of a new formulation of Acetadote, which is designed to replace the currently marketed product and is the result of the Company's commitment to further developing its products. Cumberland is supporting the FDA's review of the application and is preparing to make this new formulation available to patients.

The Company expects to receive a response from the FDA regarding the new formulation by early January 2011 and, if approved, would commence with the new product launch immediately. Cumberland has filed a patent application with the U.S. Patent and Trademark Office to protect this proprietary new formulation.

Supplemental New Drug Application for Acetadote in Treating Acute Liver Failure

In March 2010, Cumberland submitted its sNDA to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA includes data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have an improved chance of survival without a transplant. The study showed that these patients can also survive a significant number of days longer without transplant, which would provide patients requiring transplant increased time for a donor organ to become available.

In May 2010, the FDA accepted the sNDA and granted a priority review with a response expected in September 2010. In August 2010, the FDA extended its review of the sNDA by three months. Cumberland now anticipates a response from the FDA regarding the sNDA in December 2010.

# Launch of Acetadote in Australia

In April 2010, the Therapeutic Goods Administration granted approval to Cumberland's partner Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, for the commercialization of Acetadote in Australia. In October 2010, Phebra commenced with the Australian launch of Acetadote and began promoting wide distribution of the product. This introduction of Acetadote in Australia marked the introduction of Cumberland's products into international markets.

In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country. Phebra is also Cumberland's marketing partner for Acetadote in certain Asia Pacific markets, and continues to work toward obtaining approval for the product in those areas as well.

#### SUPPLEMENTAL FINANCIAL INFORMATION

The following table presents a reconciliation of Cumberland's net income to EBITDA and adjusted EBITDA. The Company defines EBITDA as net income plus interest, income tax, depreciation and amortization, and presents these measures to assist investors in evaluating Cumberland's operating performance and comparing the Company's results with those of other companies. EBITDA and adjusted EBITDA should not be considered in isolation from or as a substitute for net income.

	Thre	Three Months Ended September, 30,			
	2010			2009	
Net income	\$	1,001,596	\$	1,282,412	
Income tax expense		943,141		855,660	
Depreciation & amortization		260,011		207,173	
Interest expense, net		499,120		233,987	
EBITDA	\$	2,703,868	\$	2,579,232	
Adjustments:					
Non-cash stock compensation		202,300		180,249	
Adjusted EBITDA	\$	2,906,168	\$	2,759,481	

	Nine Months Ended September 30,				
	2010			2009	
Net income	\$	1,594,871	\$	2,775,678	
Income tax expense		1,529,339		1,919,356	
Depreciation & amortization		723,687		605,514	
Interest expense, net		1,140,015		388,166	
EBITDA	\$	4,987,912	\$	5,688,714	
Adjustments:					
Non-cash stock compensation		565,993		1,501,694	
Adjusted EBITDA	\$	5,553,905	\$	7,190,408	

#### **CONFERENCE CALL AND WEBCAST**

A conference call and live Internet webcast will be held on Thursday, November 11, 2010, at 5:00 p.m. Eastern Time to discuss the Company's third quarter 2010 financial results. To participate in the call, please dial 877-303-1298 (for U.S. callers) or 253-237-1032 (for international callers). A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 800-642-1687 (for U.S. callers) or 706-645-9291 (for international callers). The Conference ID for the rebroadcast is 21780077. The live webcast and rebroadcast can be accessed via Cumberland's website at <a href="http://investor.shareholder.com/cpix/events.cfm">http://investor.shareholder.com/cpix/events.cfm</a>.

#### ABOUT CUMBERLAND PHARMACEUTICALS

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever available in the United States, and Kristalose® (lactulose) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit the Company's website at <a href="https://www.cumberlandpharma.com">www.cumberlandpharma.com</a>.

# **ABOUT CALDOLOR**

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever in adults. It is the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit <a href="https://www.caldolor.com">www.caldolor.com</a>.

#### ABOUT ACETADOTE

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is the only injectable product approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma, or where there is a history of bronchospasm. The total volume administered should be adjusted for patients weighing less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted fluid overload can occur, potentially resulting in hyponatremia, seizure, and death. For full prescribing information, visit <a href="https://www.acetadote.net">www.acetadote.net</a>.

#### ABOUT KRISTALOSE

Kristalose is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. Initial dosing may produce flatulence and intestinal cramps,

which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia and hypernatremia. Nausea and vomiting have been reported. Use with caution in diabetics. Kristalose is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. For full prescribing information, visit <a href="https://www.kristalose.com">www.kristalose.com</a>.

#### FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of Cumberland's operations are subject to factors outside its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or a failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in Cumberland's Form 10-K filed with the SEC on March 19, 2010. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets (Unaudited)

	September 30,	December 31,
	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 65,518,340	\$ 78,701,682
Accounts receivable, net of allowances	4,791,682	6,176,585
Inventories	7,646,228	4,822,873
Other current assets	1,940,778	3,472,455
Total current assets	79,897,028	93,173,595
Property and equipment, net	1,139,946	918,412
Intangible assets, net	7,580,168	7,956,009
Other assets	1,292,724	1,676,304
Total assets	\$ 89,909,866	\$ 103,724,320
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 2,666,668	\$ 9,061,973
Current portion of other long-term obligations	12,035	144,828
Accounts payable	3,416,370	5,632,796
Other accrued liabilities	3,817,822	3,784,777

Total current liabilities	9,912,895	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	3,333,332	8,938,027
Other long-term obligations, excluding current portion	211,757	184,632
Total liabilities	15,283,935	29,572,984
Commitments and contingencies		
Redeemable common stock	-	1,930,000
Equity:		
Shareholders' equity:		
Common stock - no par value; 100,000,000 shares authorized;		
20,353,849 and 20,180,486(1) shares issued and outstanding		
as of September 30, 2010 and December 31, 2009, respectively	68,521,470	67,711,746
Retained earnings	6,161,252	4,542,126
Total shareholders' equity	74,682,722	72,253,872
Noncontrolling interests	(56,791)	(32,536)
Total equity	74,625,931	72,221,336
Total liabilities and equity	\$ 89,909,866	\$ 103,724,320

<sup>(1)</sup> Number of shares issued and outstanding represent total shares of common stock regardless of classification on the consolidated balance sheet. The number of shares of redeemable common stock at December 31, 2009 was 142,016.

# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Statements of Income (Unaudited)

	Three months ended September 30,			Nine months ended September 30,				
		2010		2009		2010		2009
Net revenues	\$	12,190,870	\$	13,597,760	\$	33,061,457	\$	32,822,972
Costs and expenses:								
Cost of products sold		909,434		1,761,069		2,632,447		3,271,363
Selling and marketing		5,692,048		6,087,807		17,147,683		14,611,796
Research and development		1,138,955		640,877		2,947,623		4,041,719
General and administrative		1,806,975		2,537,627		5,471,012		5,218,925
Amortization of product								
license right		171,732		171,726		515,184		515,178
Other		27,869		26,595		83,283		80,791
Total costs and expenses		9,747,013		11,225,701		28,797,232		27,739,772
Operating income		2,443,857		2,372,059		4,264,225		5,083,200
Interest income		48,675		14,285		159,688		42,041
Interest expense		(547,795)		(248,272)		(1,299,703)		(430,207)
Income before income taxes		1,944,737		2,138,072		3,124,210		4,695,034
Income tax expense		(943,141)		(855,660)		(1,529,339)		(1,919,356)

Net income		1,001,596	1,282,412	1,594,871		2,775,678
Net loss at subsidiary attributable	to					
noncontrolling interests		6,648	 5,725	 24,255		26,420
Net income attributable to common shareholders	<u>\$</u>	1,008,244	\$ 1,288,137	\$ 1,619,126	\$_	2,802,098
Earnings per share attributable to	common	shareholders				
- basic	\$	0.05	\$ 0.08	\$ 0.08	\$	0.23
- diluted	\$	0.05	\$ 0.07	\$ 0.08	\$	0.16
Weighted-average shares outstar	nding					
- basic		20,327,867	15,745,069	20,335,911		12,197,876
- diluted		20,803,182	19,183,606	21,135,762		17,143,348

# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended September 3		
	2010	2009	
Cash flows from operating activities:			
Net income	\$ 1,594,871	\$ 2,775,678	
Adjustments to reconcile net income to net cash flows from			
operating activities:			
Depreciation and amortization expense	723,687	605,514	
Non-employee equity compensation	62,547	1,046,192	
Stock-based compensation - employee stock options	503,446	455,502	
Excess tax benefit derived from exercise of stock options	(1,256,913)	(2,842,825)	
Non-cash interest expense	328,475	83,420	
Net changes in assets and liabilities affecting			
operating activities:			
Accounts receivable	1,384,903	(4,054,710)	
Inventory	(2,823,355)	75,185	
Other current assets and other assets	1,461,538	936,286	
Accounts payable and other accrued liabilities	(840,429)	3,299,235	
Other long-term obligations	(105,668)	(455,723)	
Net cash provided by operating activities	1,033,102	1,923,754	
Cash flows from investing activities:			
Additions to property and equipment	(311,301)	(199,312)	
Additions to patents	(132,047)	(71,358)	
Net cash used in investment activities	(443,348)	(270,670)	
Cash flows from financing activities:			
Proceeds from initial public offering	_	85,000,000	
Costs of initial public offering	_	(7,385,124)	
Proceeds from borrowings on long-term debt	-	18,000,000	
Principal payments on note payable	(12,000,000)	(5,000,000)	
Costs of financing for long-term debt and credit facility	(82,500)	(189,660)	
Proceeds from exercise of stock options	1,182,139	64,275	
Excess tax benefit derived from exercise of stock options	1,256,913	2,842,825	
Repurchase of common shares	(4,129,648)	(27,273,677)	

Net cash (used in) provided by financing activities	(13,773,096)	66,058,639		
Net (decrease) increase in cash and cash equivalents	(13,183,342)	67,711,723		
Cash and cash equivalents at beginning of period	78,701,682	11,829,551		
Cash and cash equivalents at end of period	\$ 65,518,340	\$ 79,541,274		
Supplemental disclosure of cash flow information:				
Non-cash investing and financing activities:				
Deferred financing costs	-	335,075		
Common shares repurchased during period but not paid				
as of the end of the period	22,207	-		

SOURCE Cumberland Pharmaceuticals Inc.

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