



## Cumberland Pharmaceuticals Reports Second Quarter 2010 Financial Results

### - New Drug Applications for Caldolor submitted in Australia and South Korea -- Company converts Field Sales Force to Cumberland employees

NASHVILLE, Tenn., Aug 16, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX), a specialty pharmaceutical company focused on the hospital acute care and gastroenterology markets, today announces financial results for the second quarter ending June 30, 2010, and provides revenue guidance for full year 2010.

**Net Revenue:** For the three months ended June 30, 2010, net revenue was \$10.7 million, up 9% from \$9.8 million for the same period in 2009. This increase was primarily attributable to increased revenue from Acetadote. Net revenue for the six months ended June 30, 2010, was \$20.9 million, up 9% from \$19.2 million for the corresponding prior year period. This increase was also primarily due to an increase in Acetadote revenue over the prior year period.

**Operating Expenses:** Total operating expenses for the three months ended June 30, 2010, were \$9.7 million compared with \$9.2 million for the same period in 2009. This increase was due to a 33% increase in sales and marketing expense, from \$4.4 million in the second quarter 2009 to \$5.8 million in the second quarter 2010, and was primarily due to the expansion of the Company's hospital sales force for the launch of Caldolor. That increase was offset by a reduction in research and development expense, from \$2.6 million in the second quarter 2009 to \$1.0 million in the second quarter 2010 due to a milestone expense related to FDA approval of Caldolor in June 2009.

Operating expenses for the six-month period ended June 30, 2010, were \$19.1 million compared with \$16.5 million for the same period in 2009. This was due to the aforementioned increase in selling and marketing expense from expansion of the Company's hospital sales force offset by the decrease in expense related to research and development.

**Net Income:** Net income for the three months ended June 30, 2010, was \$0.3 million, or \$0.01 per diluted share, compared with \$0.3 million, or \$0.02 per diluted share, for the same period in 2009. The change in net income was due primarily to an increase in net revenue offset by increased operating expenses. While net income for the second quarter 2010 was consistent compared with the prior year period, earnings per share decreased due to an increase in shares outstanding from the Company's initial public offering in August 2009. Weighted-average diluted shares outstanding at June 30, 2009, was 16.0 million, growing to 21.2 million at June 30, 2010.

Net income for the six months ended June 30, 2010, was \$0.6 million, or \$0.03 per diluted share, compared with \$1.5 million, or \$0.09 per diluted share, for the same period in 2009. The decrease in net income was primarily a result of increased sales and marketing expense from the Company's hospital sales force expansion in the third quarter 2009. The decrease in earnings per share was affected by the decrease in net income as well as the aforementioned increase in shares outstanding.

**EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA)** for the three months ended June 30, 2010, was \$1.2 million compared with \$0.8 million for the same period in the prior year. Excluding \$0.2 million and \$1.2 million in non-cash stock compensation expense for the three months ended June 30, 2010, and 2009, respectively, adjusted EBITDA was \$1.4 million and \$2.0 million, respectively. For the six months ended June 30, 2010, EBITDA was \$2.3 million compared with \$3.1 million for the prior year period. Excluding \$0.3 million and \$1.3 million in non-cash stock compensation expense for the six months ended June 30, 2010, and 2009, respectively, adjusted EBITDA was \$2.6 million and \$4.4 million, respectively.

**Balance Sheet:** As of June 30, 2010, Cumberland had \$71.5 million in cash and cash equivalents, compared with \$73.8 million as of March 31, 2010. Total assets as of June 30, 2010, were \$96.7 million compared with \$98.7 million at March 31, 2010. The Company had \$13.8 million in outstanding debt at the end of the second quarter, compared with \$15.3 million at March 31, 2010. A large majority of proceeds from the Company's initial public offering remains available for planned portfolio expansion as well as continued development of currently marketed products.

"We are pleased to have achieved top line revenue growth in the second quarter and are committed to building our three marketed products while we pursue new portfolio additions," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Our business development and product development teams are evaluating several new product opportunities. We also remain acutely focused on expanding hospital formulary approval for Caldolor and have taken a fresh look at the market and our strategy to build that brand for long-term success."

Cumberland is providing full year 2010 revenue guidance, which represents the Company's best estimate of likely future results and which may be affected by factors described below in "Forward-Looking Statements." The Company expects its net revenue

for the twelve-month period ended December 31, 2010, to be between \$42 and \$43 million.

## **QUARTER HIGHLIGHTS**

### **Product Development**

#### *Supplemental New Drug Application for Acetadote*

In March 2010, Cumberland submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for use of Acetadote in patients with non-acetaminophen induced acute liver failure. The sNDA included data from a clinical trial at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without transplant, and that patients requiring transplant can survive a number of days longer without transplant, providing more time for a donor organ to become available. In May 2010, the FDA accepted the sNDA and granted a priority review. In addition to expanded labeling, the Company has requested additional exclusivity for the product and, if approved, expects to begin marketing it with the new indication in 2011.

### **International Markets**

#### *Acetadote Approved for Marketing in Australia*

Cumberland has granted an exclusive license to Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, to commercialize Acetadote in Australia. In April 2010, the Therapeutics Goods Administration (TGA), which regulates drugs and medical devices in Australia, approved Acetadote for marketing. Phebra is preparing for the Australian launch of the product, which it expects to commence this year. Under the agreement, Phebra is responsible for ongoing regulatory requirements, marketing, distribution and sales of Acetadote in Australia, New Zealand and the Asia Pacific while Cumberland maintains responsibility for product formulation, development and manufacturing. Cumberland receives milestone payments and royalties on future sales in exchange for the product license.

#### *Caldolor Launched for Compassionate Use in Australia*

In 2009, Cumberland entered into an exclusive agreement with Phebra Pty Ltd. for distribution of Caldolor in Australia and New Zealand. The Therapeutics Goods Administration operates compassionate use programs allowing patients with critical clinical needs to access products not yet approved. In April 2010, Phebra made Caldolor available in Australia for compassionate use.

#### *Submission of New Drug Application for Caldolor in South Korea*

In December 2009, Cumberland entered into an exclusive agreement with DB Pharm Korea Co. Ltd., a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. Under the terms of the agreement DB Pharm Korea is responsible for seeking regulatory approval for Caldolor in South Korea, and in April 2010 submitted a New Drug Application to the Korean Food and Drug Administration. Following potential approval, DB Pharm Korea will handle ongoing regulatory reporting, product marketing, distribution and sales in the territory. Cumberland maintains responsibility for product formulation, development and manufacturing and will provide finished product for sale. In exchange for the license to the product, Cumberland will receive upfront and milestone payments as well as royalties on future sales.

#### *License Agreement for Caldolor in Canada*

In April 2010, Cumberland entered into an exclusive agreement with Alveda Pharmaceuticals Inc., a Toronto-based specialty pharmaceutical company, for commercialization of Caldolor in Canada. Under the agreement, Alveda will seek Canadian regulatory approval for Caldolor and will handle ongoing regulatory requirements, product marketing, distribution and sales upon potential approval. Cumberland will maintain responsibility for product formulation, development and manufacturing and will receive royalties on any sales in addition to upfront and milestone payments.

### **Share Repurchase Program**

In May 2010, Cumberland's Board of Directors approved a share repurchase program that authorized the Company to repurchase up to \$10 million of its outstanding common shares. During the second quarter, Cumberland repurchased approximately 200,000 shares pursuant to this program at an average price of \$6.86 per share. Purchases may continue to be made from time-to-time on the open market over a period of several months. The Company continues to believe that its shares are currently undervalued and that they represent an attractive investment.

## **RECENT DEVELOPMENTS**

## *Submission of New Drug Application for Caldolor in Australia*

In August 2010, Phebra submitted a New Drug Application to the Therapeutics Goods Administration for regulatory approval of Caldolor in Australia. If approved, Phebra will handle all ongoing regulatory requirements, product marketing, distribution and sales in the territory. Cumberland maintains responsibility for product formulation, development and manufacturing, and receives upfront and milestone payments as well as royalties on future sales in exchange for the product license.

## *Field Sales Force Conversion*

In July 2010, Cumberland began the process of converting its field sales force, which promotes Kristalose and Caldolor, from contract representatives with Ventiv Health to Cumberland employees. The contractual relationship with Ventiv provided Cumberland with a right to convert the sales force to Cumberland employees at its discretion. In 2007, Cumberland converted its hospital sales force from its contractual status in the same manner. The Company expects to complete the field sales force conversion in September 2010 and is pleased to welcome these individuals as Cumberland employees.

## **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.

	Three Months Ended June 30,	
	2010	2009
	----	----
Net income	\$279,777	\$287,415
Income tax expense	374,461	232,637
Depreciation & amortization	232,344	202,282
Interest (income) expense, net	355,622	74,064
EBITDA	1,242,204	796,398
Adjustments:		
Non-cash stock compensation	204,343	1,164,383
Adjusted EBITDA	\$1,446,547	\$1,960,781
	=====	=====
	Six Months Ended June 30,	
	2010	2009
	----	----
Net income	\$593,275	\$1,493,266
Income tax expense	586,198	1,063,696
Depreciation & amortization	463,676	398,341
Interest (income) expense, net	640,895	154,179
EBITDA	2,284,044	3,109,482
Adjustments:		
Non-cash stock compensation	340,242	1,321,445
Adjusted EBITDA	\$2,624,286	\$4,430,927
	=====	=====

## **CONFERENCE CALL AND WEBCAST**

A conference call and live Internet webcast will be held on Monday, August 16, 2010, at 5:00 p.m. Eastern Time to discuss the

Company's second 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 90510603. The live webcast and rebroadcast can be accessed via Cumberland's website at <http://investor.shareholder.com/cpix/events.cfm>.

## **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(R) (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor(R) (*ibuprofen*) Injection, the first injectable treatment for pain and fever available in the United States, and Kristalose(R) (*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 [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

## **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 [www.caldolor.com](http://www.caldolor.com).

## **ABOUT ACETADOTE**

Acetadote is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose, the leading cause of poisonings presenting in emergency departments in the country(1).

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 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 [www.acetadote.net](http://www.acetadote.net).

(1) National Poison Data System, American Association of Poison Control Centers

## **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 [www.kristalose.com](http://www.kristalose.com).

## **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)

	June 30, 2010 ----	December 31, 2009 ----
ASSETS		
Current assets:		
Cash and cash equivalents	\$71,495,305	\$78,701,682
Accounts receivable, net of allowances	3,960,129	6,176,585
Inventories	7,967,089	4,822,873
Other current assets	3,238,151	3,472,455
	-----	-----
Total current assets	86,660,674	93,173,595
Property and equipment, net	958,766	918,412
Intangible assets, net	7,705,084	7,956,009
Other assets	1,377,506	1,676,304
	-----	-----
Total assets	\$96,702,030	\$103,724,320
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$6,000,000	\$9,061,973
Current portion of other long-term obligations	24,592	144,828
Accounts payable	5,993,006	5,632,796
Other accrued liabilities	3,409,097	3,784,777
	-----	-----
Total current liabilities	15,426,695	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	5,938,027	8,938,027
Other long-term obligations, excluding current portion	209,327	184,632
	-----	-----

Total liabilities	23,400,000	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;		
20,358,586 and 20,180,486(1) shares		
issued and outstanding		
as of June 30, 2010 and December 31,		
2009, respectively	68,199,165	67,711,746
Retained earnings	5,153,008	4,542,126
	-----	-----
Total shareholders' equity	73,352,173	72,253,872
	-----	-----
Noncontrolling interests	(50,143)	(32,536)
Total equity	73,302,030	72,221,336
	-----	-----
Total liabilities and equity	\$96,702,030	\$103,724,320

(1) 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	
	June 30,	
	-----	-----
	2010	2009
	----	----
Net revenues	\$10,739,935	\$9,820,613
Costs and expenses:		
Cost of products sold	863,725	777,076
Selling and marketing	5,848,123	4,383,802
Research and development	1,034,800	2,630,725
General and administrative	1,782,834	1,236,435
Amortization of product license		

right	171,726	171,726
Other	28,867	26,733
	-----	-----
Total costs and expenses	9,730,075	9,226,497
	-----	-----
Operating income	1,009,860	594,116
Interest income	50,334	10,160
Interest expense	(405,956)	(84,224)
	-----	-----
Net income before income taxes	654,238	520,052
Income tax expense	(374,461)	(232,637)
	-----	-----
Net income	279,777	287,415
Net loss at subsidiary attributable to noncontrolling interests	7,527	8,456
	-----	-----
Net income attributable to common shareholders	\$287,304	\$295,871
	=====	=====
Earnings per share attributable to common shareholders		
- basic	\$0.01	\$0.03
- diluted	\$0.01	\$0.02
Weighted-average shares outstanding		
- basic	20,445,560	10,467,781
- diluted	21,207,645	16,046,844

Six months ended June  
30,

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2010	2009
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Net revenues	\$20,870,587	\$19,225,212
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Costs and

expenses:		
Cost of products sold	1,723,013	1,510,294
Selling and marketing	11,455,635	8,523,989
Research and development	1,808,668	3,400,842
General and administrative	3,664,037	2,681,298
Amortization of product license right	343,452	343,452
Other	55,414	54,196
	-----	-----
Total costs and expenses	19,050,219	16,514,071
	-----	-----
Operating income	1,820,368	2,711,141
Interest income	111,013	27,756
Interest expense	(751,908)	(181,935)
	-----	-----
Net income before income taxes	1,179,473	2,556,962
Income tax expense	(586,198)	(1,063,696)
	-----	-----
Net income	593,275	1,493,266
Net loss at subsidiary attributable to noncontrolling interests	17,607	20,695
	-----	-----
Net income attributable to common shareholders	\$610,882	\$1,513,961
	=====	=====
Earnings per share attributable to common shareholders		
- basic	\$0.03	\$0.15
- diluted	\$0.03	\$0.09
Weighted-average shares outstanding		
- basic	20,340,000	10,394,883
- diluted	21,302,119	16,087,448



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

	Six Months Ended June 30,	
	2010	2009
	----	----
Cash flows from operating activities:		
Net income	\$593,275	\$1,493,266
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	463,676	398,341
Non-employee equity compensation	45,554	1,008,381
Stock-based compensation - employee stock options	318,139	313,064
Excess tax benefit derived from exercise of stock options	(462,814)	(2,842,825)
Non-cash interest expense	132,866	29,376
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,216,456	(125,024)
Inventory	(3,144,216)	654,400
Other current assets and other assets	349,777	743,951
Accounts payable and other accrued liabilities	337,995	(986,592)
Other long-term obligations	(95,541)	582,254
	-----	-----
Net cash provided by operating activities	755,167	1,268,592
	-----	-----
Cash flows from investing activities:		
Additions to property and equipment	(126,315)	(85,863)
Additions to patents	(80,734)	(34,551)
	-----	-----
Net cash used in investment activities	(207,049)	(120,414)
	-----	-----
Cash flows from financing activities:		
Costs of initial public offering	-	(154,179)
Principal payments on note payable	(6,061,973)	(416,667)
Costs of financing for long-term debt and credit facility	(55,000)	(15,475)
Proceeds from exercise of stock options	979,292	4,296
Excess tax benefit derived from exercise of stock options	462,814	2,842,825
Payments made in connection with repurchase of common shares	(3,079,628)	(2,707,419)
	-----	-----
Net cash used in financing activities	(7,754,495)	(446,619)
	-----	-----
Net (decrease) increase in cash and cash equivalents	(7,206,377)	701,559
Cash and cash equivalents at beginning		

of period	78,701,682	11,829,551
	-----	-----
Cash and cash equivalents at end of period	\$71,495,305	\$12,531,110
	=====	=====
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$503,250	\$116,848
Income taxes	50,650	93,969
Non-cash investing and financing activities:		
Increase in accounts payable and accrued expenses		
of initial public offering	-	119,646
Common shares repurchased during period but not paid		
as of the end of the period	203,802	-

SOURCE Cumberland Pharmaceuticals Inc.

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