



Cumberland Pharmaceuticals Reports Third Quarter 2011 Financial Results

- Net Income Increases 83% over prior year period
- Acquiring full rights to the Kristalose trademark and the FDA registration
- Rick S. Greene named Chief Financial Officer

NASHVILLE, Tenn., Nov. 3, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology markets, today announced third quarter 2011 financial results.

Net Revenue: For the three months ended September 30, 2011, net revenue was \$13.1 million, up from \$12.2 million in the prior year period. The growth in net revenue was driven by an increase in sales of Acetadote.

For the nine months ended September 30, 2011, net revenue was \$38.1 million, up 15.3% compared with \$33.1 million for the nine months ended September 30, 2010.

Operating Expenses: Total operating expenses for the three months ended September 30, 2011, were \$10.0 million compared with \$9.7 million for the prior year period. Increases in cost of products sold, research and development expenses and general and administrative expenses were partially offset by a decrease in selling and marketing expenses compared to the prior year. For the nine months ended September 30, 2011, total operating expenses were \$30.0 million compared with \$28.8 million for the nine months ended September 30, 2010.

EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) for the three months ended September 30, 2011, were \$3.4 million, up 25% from \$2.7 million for the prior year period. EBITDA for the nine months ended September 30, 2011, grew to \$8.9 million, up 79.8% from \$5.0 million for the prior year period.

Net Income: Net income attributable to common shareholders for the three months ended September 30, 2011, was \$1.8 million, or \$0.09 per diluted share, up 83% from \$1.0 million, or \$0.05 per diluted share, for the prior year period.

For the nine months ended September 30, 2011, net income attributable to common shareholders was \$4.7 million, or \$0.23 per diluted share, up 193.1% from \$1.6 million, or \$0.08 per diluted share, for the same period in 2010.

Balance Sheet: As of September 30, 2011, cash and cash equivalents grew to \$71.1 million, compared to \$69.8 million at June 30, 2011. Total assets grew from \$94.6 million on June 30, 2011 to \$96.1 million as of September 30, 2011. Cumberland's total debt as of September 30, 2011, declined to \$4.6 million from \$5.8 million at June 30, 2011.

"Our financial performance in the third quarter of 2011 was strong, with our net income increasing 83% over the prior year period," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We achieved many milestones this quarter — including reaching an agreement to acquire the trademark and approved FDA registration for Kristalose, the appointment of Rick S. Greene as Chief Financial Officer, and the signing of new international product agreements — while maintaining strong sales of Acetadote and progressing our clinical trial programs. Our goal at Cumberland continues to be maintaining a financial discipline while delivering solid financial results and laying the ground work for future growth opportunities."

Based on its third quarter performance, Cumberland is reaffirming its full year 2011 revenue guidance of \$51 - \$55 million. This guidance represents the Company's best estimate of future results, which may be affected by factors described below in "Forward-Looking Statements."

Company Highlights

Acetadote®

New Formulation

In January 2011, the U.S. Food and Drug Administration (FDA) approved Cumberland's supplemental new drug application (sNDA) for a new formulation of Acetadote, which was the result of a phase IV commitment the Company made to the FDA upon receipt of initial marketing approval of the product. The new formulation does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. Cumberland launched the next generation product,

which replaced the previously marketed formulation, in the first quarter of 2011 and has worked to ensure widespread distribution and transition to the next generation product.

In July 2011, Cumberland filed a response with the U.S. Patent and Trademark Office for its patent application to protect proprietary discoveries related to the new Acetadote formulation. This formulation patent was allowed and issued in China in April 2011 and was recently granted in Australia in October of 2011. The Company has also filed a second U.S. patent application related to the safety profile of the new formulation.

sNDA for Non-Acetaminophen Induced Acute Liver Failure

In the first quarter of 2010, Cumberland submitted an application to the FDA for use of Acetadote in patients with non-acetaminophen acute liver failure. This sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that early-stage acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant and that these patients can also survive a significant number of days longer without transplant. In December 2010, the FDA issued a Complete Response Letter indicating that it had identified additional items that must be addressed prior to any approval.

Cumberland has been in discussions with the FDA to determine a pathway forward for this potential new indication. The Company has identified and is currently analyzing additional patient data to support the application.

Caldolor®

In June 2009, the FDA approved Caldolor, the Company's intravenous formulation of ibuprofen, for marketing in the United States. In late 2009, Cumberland launched the product in the U.S. and Caldolor is stocked at wholesalers serving hospitals nationwide.

In 2010, the Company focused its sales and marketing efforts primarily on securing formulary approval nationally for Caldolor. Early in the second quarter of 2011, Cumberland implemented a strategic shift to begin focusing on pull-through activities necessary to build volume of use and bring Caldolor to a larger population of patients in facilities stocking the product.

During the third quarter of 2011, Cumberland also continued to progress four clinical studies to further evaluate Caldolor in patients. Two of these trials are designed to support pediatric use, including a pediatric fever study to evaluate safety, efficacy and pharmacokinetics of Caldolor in hospitalized children as well as a pediatric pain study. Two new registry studies will gather additional data in adults, including a study evaluating Caldolor in treating pain and fever in a wide range of hospitalized patients and another evaluating the product for management of pain in surgical patients.

Hepatoren™

In early 2011, Cumberland entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. The Company has initiated clinical development under the brand name Hepatoren™ (ifetroban) Injection and is evaluating the product for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome, or HRS, a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment.

Ifetroban was initially developed extensively by a large pharmaceutical company for certain cardiovascular indications. The development program was eventually donated to Vanderbilt University, where researchers identified ifetroban as a potentially valuable compound in treating patients for several other niche indications. Cumberland acquired the rights to the ifetroban program from Vanderbilt through Cumberland Emerging Technologies and intends to develop it for several potential indications, including as an Orphan Drug for HRS for which it will pursue seven years of marketing exclusivity.

The FDA has cleared the Company's Investigational New Drug Application, or IND, for this product candidate and Cumberland has initiated a Phase II dose escalation study to evaluate Hepatoren for the treatment of HRS. The Company has manufactured clinical supplies and filed patent applications to protect intellectual property related to the new indication. The Company has established study sites at institutions around the country and patient screening is now underway. Cumberland believes Hepatoren is an excellent strategic fit given the Company's established presence in the hospital acute care market.

International Markets

The application for regulatory approval of Caldolor in Canada has been submitted by Cumberland's partner Alveda Pharma. Review of the application for approval of Caldolor in Australia submitted by our partner Phebra Pty Ltd is under review by the Australian regulatory authorities. We are also currently working to identify appropriate arrangements for the registration and commercialization of our products in other markets.

Kristalose®

Cumberland has reached an agreement to acquire the remaining rights associated with the Kristalose brand, including the trademark and the approved FDA registration for the product. Cumberland will provide a royalty on product sales in exchange for these assets.

Development Programs

Cumberland Emerging Technologies, or CET, entered into a new collaboration agreement with Washington University in St. Louis to co-develop promising biopharmaceutical technologies. Washington University is a national leader in medical research and ranks among the top U.S. institutions in funding by the National Institutes of Health. This collaboration represents the fourth major university partnership for CET, which has similar arrangements with Vanderbilt University, the University of Tennessee and the University of Mississippi.

Company Update

Effective October 2011, Cumberland named Rick S. Greene as Chief Financial Officer. He had previously been serving as the interim Vice President of Finance and Accounting since April 2011. Mr. Greene has over 20 years of experience in financial management and reporting. Prior to joining Cumberland, Mr. Greene supported the accounting activities associated with the Company's Initial Public Offering and the ongoing preparation of quarterly financial information following Cumberland's stock exchange listing.

Supplemental Financial Information

The following table presents a reconciliation of Cumberland's net income to EBITDA. The Company defines EBITDA as net income attributable to common shareholders 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 should not be considered in isolation from or as a substitute for net income.

	Three Months Ended September 30,	
	2011	2010
Net income attributable to common shareholders	\$ 1,847,412	\$ 1,001,596
Income tax expense	1,278,472	943,141
Depreciation & amortization	274,182	260,011
Interest (income) expense, net	(19,069)	499,120
EBITDA	\$ 3,380,997	\$ 2,703,868

	Nine Months Ended September 30,	
	2011	2010
Net income attributable to common shareholders	\$ 4,746,191	\$ 1,594,871
Income tax expense	3,238,421	1,529,339
Depreciation & amortization	801,483	723,687
Interest (income) expense, net	181,409	1,140,015
EBITDA	\$ 8,967,504	\$ 4,987,912

Conference Call and Webcast

A conference call and live Internet webcast will be held on Thursday, November 3, 2011 at 5:00 p.m. Eastern Time to discuss the Company's third quarter 2011 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 855-859-2056 (for U.S. callers) or 404-537-3406 (for international callers). The Conference ID for the rebroadcast is 18137911. 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 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 marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information, please visit the Company's website at 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 was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticarial, 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.

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 medications. 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 www.acetadote.net.

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.

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 of 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 failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's Form 10-K filed with the SEC on March 11, 2011. 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.

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

September 30, December 31,

	<u>2011</u>	<u>2010</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 71,074,807	\$ 65,893,970
Accounts receivable, net of allowances	4,505,411	5,145,494
Inventories	6,874,599	7,683,842
Other current assets	<u>3,423,574</u>	<u>2,315,536</u>
Total current assets	85,878,391	81,038,842
Property and equipment, net	1,198,805	1,220,010
Intangible assets, net	7,029,186	7,427,223
Other assets	<u>1,972,284</u>	<u>2,367,979</u>
Total assets	<u>\$ 96,078,666</u>	<u>\$ 92,054,054</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ -	\$ 2,666,668
Accounts payable	3,280,289	2,124,654
Other current liabilities	<u>4,172,942</u>	<u>4,436,298</u>
Total current liabilities	7,453,231	9,227,620
Revolving line of credit	4,575,951	1,825,951
Long-term debt, excluding current portion	-	2,666,665
Other long-term obligations, excluding current portion	<u>592,427</u>	<u>618,343</u>
Total liabilities	<u>12,621,609</u>	<u>14,338,579</u>
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock - no par value; 100,000,000 shares authorized; 20,215,910 and 20,338,461 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	71,802,068	70,778,874
Retained earnings	<u>11,744,997</u>	<u>6,998,806</u>
Total shareholders' equity	<u>83,547,065</u>	<u>77,777,680</u>
Noncontrolling interests	<u>(90,008)</u>	<u>(62,205)</u>
Total equity	<u>83,457,057</u>	<u>77,715,475</u>
Total liabilities and equity	<u>\$ 96,078,666</u>	<u>\$ 92,054,054</u>

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Net revenues	\$ 13,054,278	\$ 12,190,870	\$ 38,110,946	\$ 33,061,457

Costs and expenses:				
Cost of products sold	1,341,256	909,434	3,411,354	2,632,447
Selling and marketing	5,060,546	5,692,048	16,253,574	17,147,683
Research and development	1,233,025	1,138,955	3,269,746	2,947,623
General and administrative	2,117,684	1,806,975	6,442,139	5,471,012
Amortization of product license right	171,727	171,732	515,180	515,184
Other	31,680	27,869	80,735	83,283
Total costs and expenses	<u>9,955,918</u>	<u>9,747,013</u>	<u>29,972,728</u>	<u>28,797,232</u>
Operating income	3,098,360	2,443,857	8,138,218	4,264,225
Interest income	52,459	48,675	147,628	159,688
Interest expense	<u>(33,390)</u>	<u>(547,795)</u>	<u>(329,037)</u>	<u>(1,299,703)</u>
Income before income taxes	3,117,429	1,944,737	7,956,809	3,124,210
Income tax expense	<u>(1,278,472)</u>	<u>(943,141)</u>	<u>(3,238,421)</u>	<u>(1,529,339)</u>
Net income	1,838,957	1,001,596	4,718,388	1,594,871
Net loss at subsidiary attributable to noncontrolling interests	<u>8,455</u>	<u>6,648</u>	<u>27,803</u>	<u>24,255</u>
Net income attributable to common shareholders	<u>\$ 1,847,412</u>	<u>\$ 1,008,244</u>	<u>\$ 4,746,191</u>	<u>\$ 1,619,126</u>
Earnings per share attributable to common shareholders				
- basic	\$ 0.09	\$ 0.05	\$ 0.23	\$ 0.08
- diluted	\$ 0.09	\$ 0.05	\$ 0.23	\$ 0.08
Weighted-average shares outstanding				
- basic	20,327,537	20,327,867	20,414,593	20,335,911
- diluted	20,534,647	20,803,182	20,657,567	21,135,762

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

	<u>Nine Months Ended September 30,</u>	
	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:		
Net income	\$ 4,718,388	\$ 1,594,871
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	801,483	723,687
Non-employee equity compensation	119,313	62,547
Stock-based compensation - employee stock options	467,850	503,446
Excess tax benefit derived from exercise of stock options	(2,657,259)	(1,256,913)
Non-cash interest expense	131,469	328,475
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	640,083	1,384,903
Inventory	809,243	(2,823,355)
Other current assets and other assets	(1,240,700)	1,461,538
Accounts payable and other accrued liabilities	3,911,450	(840,429)
Other long-term obligations	(9,262)	(105,668)
Net cash provided by operating activities	<u>7,692,058</u>	<u>1,033,102</u>

Cash flows from investing activities:		
Additions to property and equipment	(241,885)	(311,301)
Additions to patents	<u>(140,356)</u>	<u>(132,047)</u>
Net cash used in investment activities	<u>(382,241)</u>	<u>(443,348)</u>
Cash flows from financing activities:		
Principal payments on note payable	(5,333,333)	(12,000,000)
Net borrowings on line of credit	2,750,000	-
Costs of financing for long-term debt and credit facility	-	(82,500)
Proceeds from exercise of stock options	681,634	1,182,139
Excess tax benefit derived from exercise of stock options	2,657,259	1,256,913
Repurchase of common shares	<u>(2,884,540)</u>	<u>(4,129,648)</u>
Net cash used in financing activities	<u>(2,128,980)</u>	<u>(13,773,096)</u>
Net increase (decrease) in cash and cash equivalents	5,180,837	(13,183,342)
Cash and cash equivalents at beginning of period	<u>65,893,970</u>	<u>78,701,682</u>
Cash and cash equivalents at end of period	<u>\$ 71,074,807</u>	<u>\$ 65,518,340</u>
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Common shares repurchased during period but not paid as of the end of the period	-	22,207

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media