Cumberland Pharmaceuticals Reports First Quarter 2011 Financial Results

- Net income doubles over prior year period
-- Company acquires Hepatoren™ (ifetroban) Injection

NASHVILLE, Tenn., May 4, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology markets, today announced first quarter 2011 financial results.

Net Revenue: For the three months ended March 31, 2011, net revenue was $10.7 million, up from $10.1 million during the corresponding period in 2010. Revenue grew year-over-year despite a brief, planned halt in shipments of Acetadote during the launch of the new product formulation.

Operating Expenses: Total operating expenses for the three months ended March 31, 2011, were comparable to the prior year period at $9.3 million. This was due to the net effect of decreases in selling and marketing expense and cost of products sold, offset by increases in research and development and general and administrative expenses.

EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) were $1.7 million for the first quarter in 2011, up from $1.0 million for the prior year period. This growth was attributable to the increase in net revenue and consistent total operating expenses.

Net Income: Net income attributable to common shareholders for the quarter ending March 31, 2011, was $0.7 million, or $0.03 per diluted share, up 122% from net income of $0.3 million, or $0.02 per diluted share, for the same period in 2010.

Balance Sheet: As of March 31, 2011, Cumberland had $66.0 million in cash and cash equivalents, compared to $65.9 million at December 31, 2010. Total assets at March 31, 2011, were $91.6 million. As of March 31, 2011, Cumberland had total debt of $6.5 million, including a current portion of $2.7 million, compared to $7.2 million in total debt at the end of 2010.

"The first quarter of 2011 was marked by several milestones for Cumberland, including the FDA approval and launch of our new Acetadote formulation and an important shift in our sales strategy to drive broad use of Caldolor," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Our financial performance was strong, with net income more than doubling over the prior year period. We believe we are on track to meet our 2011 guidance and are well on our way to accomplishing our primary objectives for the year. We are also pleased to have announced the addition of Hepatoren, a new product candidate and the fourth in our portfolio, following the end of the first quarter."

First Quarter Highlights

Caldolor

In June 2009, the U.S. Food and Drug Administration (FDA) approved Caldolor, the Company's intravenous formulation of ibuprofen, for marketing in the United States through a priority review. In September 2009, Cumberland implemented the U.S. launch of Caldolor with experienced sales professionals promoting the product across the country. Caldolor is stocked at wholesalers serving hospitals nationwide, available in both 400mg and 800mg vials.

In 2010, the Company focused its sales and marketing efforts primarily on securing formulary approval nationally for Caldolor, and the product is being stocked in a growing number of U.S. medical facilities. During the first quarter of 2011, Cumberland initiated a shift in focus to include pull-through activities necessary to build volume of use and help a larger population of patients in facilities already stocking the product.

Acetadote

FDA Approves New Formulation of Acetadote

In October 2010, the Company submitted a supplemental new drug application (sNDA) to the FDA for approval of a new formulation of Acetadote, which was the result of a phase IV commitment Cumberland made to the FDA upon receipt of initial marketing approval of the product. The new formulation addressed FDA safety concerns without compromising potency, solubility or stability. In January 2011, the FDA approved the new formulation, which does not contain Ethylene diamine

tetracetic acid or any other stabilization or chelating agents and is free of preservatives. Cumberland completed the U.S. launch of the next generation product during the first quarter of 2011, and no longer manufactures the original formulation. The Company is also prosecuting a patent application with the U.S. Patent and Trademark Office to protect the proprietary new formulation.

Supplemental New Drug Application for Acetadote

In March 2010, Cumberland submitted an application to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The 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 transplant, and that these patients can survive a significant number of days longer without transplant. In December 2010, the FDA issued a Complete Response Letter indicating that it had completed its review of the application and had identified additional items to be addressed prior to approval of the potential new indication. Cumberland has initiated discussions with FDA to gain clarity on and determine whether it can address the additional requirements for approval.

Other Highlights

In January 2011, Joey Jacobs joined Cumberland's Board of Directors. He is the former Chairman, President and Chief Executive Officer of Psychiatric Solutions, which he co-founded in 1997 and grew into a $2 billion healthcare provider. Mr. Jacobs has more than 30 years of experience in the healthcare industry, including 21 years at Hospital Corporation of America (HCA). The Company believes his hospital expertise and experience building a public healthcare company make him a valuable addition to its board. At the Company's annual shareholder meeting held on April 19, 2011, Mr. Jacobs was elected to serve as a Class I Director until 2014.

Recent Developments

Hepatoren

In April 2011, Cumberland entered into an agreement to acquire the rights to ifetroban, a Phase II product candidate. The Company has initiated clinical development under the brand name Hepatoren™ (*ifetroban*) Injection and is evaluating the candidate for the treatment of critically ill hospitalized patients suffering from Hepatorenal Syndrome (HRS). HRS is a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment. Approximately 450,000 patients in the United States suffer from medical conditions that make them susceptible to cirrhosis and a subset of these patients develop HRS every year.

Cumberland's acquisition of ifetroban includes rights to extensive clinical and non-clinical data as well as manufacturing processes, know-how and intellectual property. Ifetroban, an active thromboxane receptor antagonist, was initially developed by Bristol-Myers Squibb (BMS) for significant cardiovascular indications. BMS conducted an extensive development program, including seven Phase II trials for its own target indications, and eventually donated the program to Vanderbilt University. Researchers at Vanderbilt 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 CET, the Company's majority-owned subsidiary, assuming responsibility for development and commercialization.

In the first quarter of 2011, Cumberland received clearance from the FDA for its investigational new drug (IND) submission and plans to develop ifetroban for a series of indications, initially focusing on the treatment of HRS for the hospital acute care market. In addition to commencing manufacturing, the Company is implementing a Phase II clinical study for Hepatoren and intends to develop the product as an Orphan Drug for which it will pursue seven years of marketing exclusivity. Patent applications have been filed to protect intellectual property related to the product. Cumberland believes the new product candidate is an excellent strategic fit given the Company's established presence in the hospital acute care market.

Supplemental Financial Information

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

	Three Months Ended March 31,	
	2011	**2010**
Net income	$ 721,160	$ 313,498

Income tax expense	523,584	211,737
Depreciation & amortization	262,306	231,332
Interest (income) expense, net	173,134	285,273
EBITDA	**$ 1,680,184**	**$ 1,041,840**

Conference Call and Webcast

A conference call and live Internet webcast will be held on Wednesday, May 4, 2011 at 5:00 p.m. Eastern Time to discuss the Company's first 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 800-642-1687 (for U.S. callers) or 706-645-9291 (for international callers). The Conference ID for the rebroadcast is 62581136. 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 includes 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, 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.

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 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 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 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)

	March 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,958,844	$ 65,893,970
Accounts receivable, net of allowances	5,145,590	5,145,494
Inventories	7,822,872	7,683,842
Other current assets	2,174,638	2,315,536
Total current assets	81,101,944	81,038,842
Property and equipment, net	1,196,516	1,220,010
Intangible assets, net	7,269,649	7,427,223
Other assets	2,006,940	2,367,979
Total assets	$ 91,575,049	$ 92,054,054
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 2,666,668	$ 2,666,668
Accounts payable	2,170,929	2,124,654
Other current liabilities	3,915,542	4,436,298
Total current liabilities	8,753,139	9,227,620
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	1,999,998	2,666,665
Other long-term obligations, excluding current portion	610,221	618,343
Total liabilities	13,189,309	14,338,579
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock - no par value; 100,000,000 shares authorized; 20,468,779 and 20,338,461 shares issued and outstanding as of March 31, 2011 and December 31, 2010, respectively	70,737,856	70,778,874
Retained earnings	7,719,966	6,998,806
Total shareholders' equity	78,457,822	77,777,680

Noncontrolling interests	(72,082)	(62,205)
Total equity	78,385,740	77,715,475
Total liabilities and equity	$ 91,575,049	$ 92,054,054

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

	Three Months Ended March 31,	
	2011	**2010**
Net revenues	$ 10,666,927	$ 10,130,652
Costs and expenses:		
Cost of products sold	786,938	859,288
Selling and marketing	5,288,584	5,607,512
Research and development	1,009,673	773,868
General and administrative	1,980,391	1,881,203
Amortization of product license right	171,727	171,726
Other	21,613	26,547
Total costs and expenses	9,258,926	9,320,144
Operating income	1,408,001	810,508
Interest income	42,909	60,679
Interest expense	(216,043)	(345,952)
Income before income tax expense	1,234,867	525,235
Income tax expense	(523,584)	(211,737)
Net income	711,283	313,498
Net loss attributable to noncontrolling interests	9,877	10,080
Net income attributable to common shareholders	$ 721,160	$ 323,578
Earnings per share attributable to common shareholders		
- Basic	$ 0.04	$ 0.02
- Diluted	$ 0.03	$ 0.02
Weighted-average shares outstanding		
- Basic	20,445,921	20,233,267
- Diluted	20,777,666	21,395,419

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

	Three Months Ended March 31,	
	2011	**2010**

Cash flows from operating activities:		
Net income	$ 711,283	$ 313,498
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	262,306	231,332
Nonemployee equity compensation	19,856	3,972
Stock-based compensation - employee stock options	147,207	130,915
Excess tax benefit derived from exercise of stock options	(141,080)	(206,418)
Noncash interest expense	24,010	67,380
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	(96)	2,361,638
Inventory	(139,030)	(2,583,529)
Other current assets and other assets	126,084	132,847
Accounts payable and other accrued liabilities	(23,990)	127,104
Other long-term obligations	(2,570)	(59,266)
Net cash provided by operating activities	983,980	519,473
Cash flows from investing activities:		
Additions to property and equipment	(34,260)	(64,085)
Additions to patents	(20,289)	-
Net cash used in investment activities	(54,549)	(64,085)
Cash flows from financing activities:		
Principal payments on note payable	(666,667)	(4,561,973)
Costs of financing for long-term debt and credit facility	-	(27,500)
Proceeds from exercise of stock options	433,055	807,496
Excess tax benefit derived from exercise of stock options	141,080	206,418
Payments made in connection with repurchase of common shares	(772,025)	(1,828,697)
Net cash used in financing activities	(864,557)	(5,404,256)
Net increase (decrease) in cash and cash equivalents	64,874	(4,948,868)
Cash and cash equivalents at beginning of period	65,893,970	78,701,682
Cash and cash equivalents at end of period	$ 65,958,844	$ 73,752,814
Non-cash investing and financing activities:		
Fixed asset additions not yet paid	26,689	-

SOURCE Cumberland Pharmaceuticals Inc.

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