Cumberland Pharmaceuticals Reports Fourth Quarter and Full Year 2010 Financial Results

- Fourth quarter net revenue up 20% over prior year period
-- Caldolor® approved for marketing in South Korea

NASHVILLE, Tenn., March 8, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology markets, today announced fourth quarter and full year 2010 financial results.

Net Revenue: For the three months ended December 31, 2010, net revenue was $12.8 million, up 20% from $10.7 million during the corresponding period in 2009. This quarterly revenue growth was largely driven by 16% year-over-year growth in Acetadote net revenue.

For the year ended December 31, 2010, total net revenue increased by $2.3 million to $45.9 million from $43.5 million for 2009.

Operating Expenses: Total operating expenses for the three months ended December 31, 2010, were $10.6 million, compared with $10.0 million for the same period in 2009. This increase was driven primarily by increased research and development expenses, including FDA fees.

For the year ended December 31, 2010, total operating expenses were approximately $39.4 million, compared with $37.8 million for 2009. The difference was primarily a result of increased selling and marketing as well as general and administrative expenses, partially offset by lower cost of products sold and lower research and development expenses.

EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization **(**EBITDA) was $2.5 million for the fourth quarter, up 176% from $0.9 million for the prior year period.

EBITDA was $7.5 million for the year ended December 31, 2010, compared to $6.6 million for the 2009 fiscal year.

Net Income: Net income attributable to common shareholders for the fourth quarter was $0.8 million, or $0.04 per diluted share, compared to net income of $0.3 million, or $0.01 per diluted share, for the same period in 2009. This increase in net income resulted primarily from a 223% increase in operating income and a 64% decrease in interest expense, partially offset by an increase in the Company's effective tax rate, compared to the fourth quarter of 2009.

Net income attributable to common shareholders for the year ended December 31, 2010, was $2.5 million, or $0.12 per diluted share, compared to $3.1 million, or $0.17 per diluted share, for 2009. This decrease was primarily the result of higher interest expense associated with the expansion of the Company's credit facility in the third quarter of 2009 as well as an increase in the Company's effective tax rate.

Balance Sheet: As of December 31, 2010, Cumberland had $65.9 million in cash and cash equivalents, compared to $65.5 million at the end of the third quarter. Total assets at December 31, 2010, were $92.1 million. Since the Company's initial public offering (IPO) in the third quarter of 2009, it has used offering proceeds to continue to support the Caldolor launch, to significantly expand its sales organization and to repay debt. At December 31, 2010, Cumberland had total debt of $7.2 million, including a current portion of $2.7 million, compared to $19.8 million in total debt at the end of 2009. The remaining proceeds from the Company's IPO are available for continued support of the Company's current products as well as product development and acquisitions.

"We are pleased to have delivered a strong fourth quarter and to have exceeded our 2010 revenue guidance," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "2010 milestones for Cumberland included the application submission leading to FDA approval of our new Acetadote formulation as well as our entry into international markets. Amidst challenges facing the healthcare industry, we have remained flexible in strategy to navigate ongoing changes affecting us and the customers we serve," said Kazimi. "What has not changed is our commitment to our over-arching mission of bringing new and differentiated treatments to patients while concurrently delivering favorable returns to shareholders."

Cumberland is introducing full year revenue guidance for 2011. The Company expects to see net revenue of $50 - $54 million for the twelve-month period ended December 31, 2011. This guidance represents the Company's best estimate of future results, which may be affected by factors described below in "Forward-Looking Statements."

2010 Highlights and Recent Developments

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 the 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. As of December 31, 2010, the product was stocked in 375 U.S. medical facilities. During the first quarter of 2011, Cumberland initiated a shift in focus and began transitioning part of its sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product.The Company monitors the number of institutions stocking Caldolor based on an assessment of data provided by a variety of sources.

Caldolor Approved for Marketing in South Korea

In December 2009, Cumberland entered into an exclusive partnership with DB Pharm Korea Co. Ltd., a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. In 2010, DB Pharm Korea submitted its application for regulatory approval and Cumberland today announced that the product has been approved for marketing. This approval marks the first regulatory approval for Caldolor outside of the United States. DB Pharm Korea is now preparing to launch Caldolor in South Korea. Pursuant to their agreement, DB Pharm Korea is responsible for handling ongoing regulatory requirements, product marketing, distribution and sales in South Korea, while Cumberland maintains responsibility for product formulation, development and manufacturing.

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 the commercialization of Caldolor in Canada. Under the agreement, Alveda will seek Canadian regulatory approval for Caldolor and, upon approval, will handle ongoing regulatory requirements as well as product marketing, distribution and sales throughout Canada. Cumberland will maintain responsibility for product formulation, development and manufacturing.

Caldolor Approved for Compassionate Use in Australia

In December 2009, Cumberland entered into an exclusive agreement with Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, for distribution of Caldolor in Australia and New Zealand. In April 2010, Phebra made the product available in Australia on a limited, compassionate use basis, which allows patients with critical clinical needs to access products not yet approved through their medical practitioner. Phebra is currently pursuing full regulatory approval for Caldolor in Australia and New Zealand.

Acetadote®

Launch of Acetadote in Australia

In April 2010, the Therapeutic Goods Administration granted approval to Cumberland's partner Phebra Pty Ltd. for the commercialization of Acetadote in Australia. In October 2010, Phebra commenced the Australian launch of Acetadote and began promoting wide distribution of the product. The introduction of Acetadote in Australia marked Cumberland's commercial entry into international markets. Phebra also has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country as well.

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's 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 has commenced the U.S. launch of this next generation product, which is replacing 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. 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. 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 officially accepted the sNDA and granted a priority review with a response expected in September 2010. In August 2010, the Company announced that the FDA extended its review of the sNDA by three months, resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010. In December, the FDA issued a Complete Response Letter indicating that it had completed its review of the application and had identified additional items that must be addressed prior to approval of the potential new indication. Cumberland is currently in discussions with the FDA to gain clarity on the pathway to approval for this indication.

Other Developments

Amendment of Senior Credit Facility

In September 2010, Cumberland amended its senior credit facility with Bank of America, reducing the outstanding balance on the Company's term loan from $12 million to $6 million. The amendment also expanded Cumberland's line of credit to $6 million, increasing the Company's access to funding for future growth. The debt repayment is consistent with the Company's efforts to efficiently manage capital resources.

Share Repurchase Program

In May 2010, the Company's Board of Directors authorized the repurchase of up to $10 million of Cumberland's outstanding common stock. Pursuant to the share repurchase program, Cumberland is purchasing shares of its common stock on the open market. As of December 31, 2010, Cumberland had repurchased 452,433 shares of its common stock under this program at an average purchase price of $6.54 per share.

Federal Grant Funding

As part of the Company's ongoing initiative to pursue grant funding to support research and development activities, Cumberland applied for and received funding for several of its development programs in 2010. In November, Cumberland was awarded a total of $860,000 in federal grant funding under the Qualifying Therapeutic Discovery Project, a U.S. healthcare reform initiative designed to support promising research and development programs at small life sciences firms.

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 December 31,	
	2010	**2009**
Net income	$ 832,140	$ 283,201
Income tax expense	1,322,081	104,836
Depreciation & amortization	254,711	210,985
Interest expense, net	83,301	305,398
EBITDA	**$ 2,492,233**	**$ 904,420**

	Year ended December 31,	
	2010	**2009**
Net income	$ 2,427,011	$ 3,058,879
Income tax expense	2,851,420	2,024,192

Depreciation & amortization	978,398	816,499
Interest expense, net	1,223,316	693,564
EBITDA	**$ 7,480,145**	**$ 6,593,134**

Conference Call and Webcast

A conference call and live Internet webcast will be held on Tuesday, March 8, 2011 at 5:00 p.m. Eastern Time to discuss the Company's 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 45026812. 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 product portfolio 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 on Cumberland, 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 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.

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 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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
December 31, 2010 and 2009

ASSETS	**2010**	**2009**
Current assets:		
Cash and cash equivalents	$ 65,893,970	$ 78,701,682
Accounts receivable, net of allowances	5,145,494	6,176,585
Inventories	7,683,842	4,822,873
Prepaid and other current assets	1,336,765	2,746,259
Deferred tax assets	978,771	726,196
Total current assets	81,038,842	93,173,595
Property and equipment, net	1,220,010	918,412
Intangible assets, net	7,427,223	7,956,009
Deferred tax assets	2,265,192	1,306,514
Other assets	102,787	369,790
Total assets	$ 92,054,054	$ 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	24,692	144,828
Accounts payable	2,124,654	5,632,796
Other accrued liabilities	4,411,606	3,784,777
Total current liabilities	9,227,620	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	2,666,665	8,938,027
Other long-term obligations, excluding current portion	618,343	184,632
Total liabilities	14,338,579	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; 20,338,461 and 20,180,486 (1) shares issued and outstanding as of December 31, 2010 and 2009, respectively	70,778,874	67,711,746
Retained earnings	6,998,806	4,542,126
Total shareholders' equity	77,777,680	72,253,872
Noncontrolling interests	(62,205)	(32,536)
Total equity	77,715,475	72,221,336
Total liabilities and equity	$ 92,054,054	$ 103,724,320

(1) Number of shares issued and outstanding represents total shares of common stock regardless of classification on the consolidated balance sheet. The number of shares of redeemable common stock as of December 31, 2009 was 142,016.

Condensed Consolidated Statements of Income
Three Months and Years ended December 31, 2010, 2009

	Three months ended December 31,		Year ended December 31,	
	2010	2009	2010	2009
Net revenues	$ 12,814,914	$ 10,714,306	$ 45,876,371	$ 43,537,278
Costs and expenses:				
Cost of products sold	954,199	865,178	3,586,646	4,136,541
Selling and marketing	5,526,822	5,582,278	22,674,505	20,194,074
Research and development	1,379,862	951,559	4,327,485	4,993,278
General and administrative	2,519,210	2,424,145	7,990,222	7,643,070
Amortization of product license right	171,727	171,726	686,911	686,904
Other	25,572	25,985	108,855	106,776
Total costs and expenses	10,577,392	10,020,871	39,374,624	37,760,643
Operating income	2,237,522	693,435	6,501,747	5,776,635
Interest income	40,519	37,322	200,207	79,363
Interest expense	(123,820)	(342,720)	(1,423,523)	(772,927)
Income before income taxes	2,154,221	388,037	5,278,431	5,083,071
Income tax expense	(1,322,081)	(104,836)	(2,851,420)	(2,024,192)
Net income	832,140	283,201	2,427,011	3,058,879
Net loss at subsidiary attributable to noncontrolling interests	5,414	6,116	29,669	32,536
Net income attributable to common shareholders	$ 837,554	$ 289,317	$ 2,456,680	$ 3,091,415
Earnings per share attributable to common shareholders				
- basic	$ 0.04	$ 0.01	$ 0.12	$ 0.22
- diluted	$ 0.04	$ 0.01	$ 0.12	$ 0.17
Weighted-average shares outstanding				
- basic	20,328,058	20,139,020	20,333,932	14,199,479
- diluted	20,827,084	21,456,162	21,058,577	18,234,171

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
Years ended December 31, 2010 and 2009

	2010	2009
Cash flows from operating activities:		
Net income	$ 2,427,011	$ 3,058,879
Adjustments to reconcile net income to net cash provided by operating activities:		
Gain on early extinguishment of other long-term obligations	-	-
Depreciation and amortization expense	978,398	816,499
Deferred tax (benefit) expense	(332,349)	(525,467)

Nonemployee stock granted for services received	37,121	210,740
Nonemployee stock option grant expense	43,101	845,661
Stock-based compensation — employee stock options	688,408	606,395
Excess tax benefit derived from exercise of stock options	(3,874,966)	(3,968,894)
Noncash interest expense	352,484	128,800
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	1,031,091	(3,047,238)
Inventory	(2,860,969)	(3,060,097)
Prepaid, other current assets and other assets	1,342,032	(721,464)
Accounts payable and other accrued liabilities	201,725	6,572,098
Other long-term obligations	313,575	(510,942)
Net cash provided by operating activities	346,662	404,970
Cash flows from investing activities:		
Additions to property and equipment	(577,159)	(601,802)
Additions to trademarks and patents	(191,483)	(110,541)
Net cash used in investing activities	(768,642)	(712,343)
Cash flows from financing activities:		
Proceeds from initial public offering of common stock	-	85,000,000
Costs of initial public offering	-	(7,479,011)
Proceeds from borrowings on long-term debt	-	18,000,000
Principal payments on note payable	(12,666,667)	(5,000,000)
Net borrowings on line of credit	-	-
Payment of other long-term obligations	-	-
Costs of financing for long-term debt and credit facility	(110,000)	(189,660)
Payments made in connection with repurchase of common shares	(4,846,791)	(27,295,808)
Proceeds from exercise of stock options	1,362,760	175,089
Excess tax benefit derived from exercise of stock options	3,874,966	3,968,894
Net cash (used in) provided by financing activities	(12,385,732)	67,179,504
Net (decrease) increase in cash and cash equivalents	(12,807,712)	66,872,131
Cash and cash equivalents, beginning of year	78,701,682	11,829,551
Cash and cash equivalents, end of year	$ 65,893,970	$ 78,701,682
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$ 814,373	$ 677,387
Income taxes	52,136	196,187
Noncash investing and financing activities:		
Reclass of redeemable common stock to (from) equity	1,930,000	(1,930,000)
Deferred financing costs	-	335,075

SOURCE Cumberland Pharmaceuticals Inc.