



November 1, 2016

Cumberland Pharmaceuticals Reports Third Quarter & Year To Date 2016 Financial Results

- **Launched Ethyol® in the United States**
- **New Portaban™ Development Program Initiated**
- **Revenues up 11% Over Prior Year Period**

NASHVILLE, Tenn., Nov. 1, 2016 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced third quarter 2016 financial results with Net Revenues of \$8.8 million and Adjusted Earnings of \$1.0 million or \$0.06 per share. Earnings prior to adjustments were \$0.1 million or \$0.01 per share.



As of September 30, 2016, the Company had approximately \$91 million in Total Assets including \$50 million in cash and marketable securities. Total Liabilities were approximately \$17 million and Total Shareholder's Equity was just under \$75 million. Cumberland also had approximately \$43 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

QUARTER HIGHLIGHTS:

- ┆ Launched Ethyol®, an FDA approved cytoprotective drug and Cumberland's first oncology product, in the United States.
- ┆ Initiated a fourth ifetroban clinical program, with FDA clearance for an IND - to develop Portaban™ for the treatment of portal hypertension.
- ┆ Welcomed Caroline Young, former president of the Nashville Health Care Council, to the Company's Board of Directors.

"We have been busy putting the pieces in place to build our sales momentum while expanding our clinical pipeline and maintaining a strong financial position," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We entered the second half of 2016 with renewed excitement and remain focused on our key operating objectives which we believe will take the company to the next level."

RECENT DEVELOPMENTS:

Ethyol®

Cumberland launched Ethyol® (amifostine) for Injection in the United States at a National Meeting of the Company's sales organization in September. Ethyol is an FDA approved hospital product used to support the care of oncology patients. It is a cytoprotective drug indicated to support select patients undergoing radiation treatment as well as those undergoing chemotherapy for certain cancers. At the National Sales Meeting, Cumberland's hospital sales organization was trained and prepared to reintroduce branded amifostine to a new generation of oncologists. For the last several years, no company has been educating physicians on the benefits of this product for their patients.

This is the first product to be licensed by Cumberland from Clinigen Group plc under the Strategic Alliance entered into last year and also Cumberland's first oncology product. Under the terms of the Ethyol license agreement, Cumberland is responsible for all distribution, marketing, promotion, and medical support of the product in the U.S.

Portaban™

Cumberland announced its fourth clinical development program for ifetroban to develop Portaban™, an oral form of ifetroban, for the treatment of portal hypertension associated with liver disease. Portal hypertension, a complication of liver cirrhosis, is an increase in the blood pressure within the portal venous system. This increased pressure in the portal veins may lead to the development of large, swollen veins which can rupture and bleed, resulting in potentially life-threatening complications. Preclinical studies have shown that ifetroban can reduce portal pressure, inflammation, and fibrosis in multiple models of liver injury.

The U.S. Food and Drug Administration has cleared Cumberland's investigational new drug application, or IND, for a Phase II clinical study of Portaban. The Company is in the process of preparing for the study, expected to begin later this fall.

FINANCIAL RESULTS:

Net Revenue: For the three months ended September 30, 2016, net revenues were \$8.8 million, compared to \$7.9 million for the prior year period. Net revenue by product for the three months ended September 30, 2016, included \$3.7 million for Kristalose®, \$1.8 million for Acetadote®, including \$1.2 million for the Company's Authorized Generic, \$1.4 million for Caldolor®, \$0.8 million for Omeclamox®-Pak, \$0.5 million for Vaprisol®, and \$0.5 million for Ethyol®.

For the nine months ended September 30, 2016, net revenues were \$23.9 million compared to \$25.5 million for the nine months ended September 30, 2015.

Operating Expenses: Total operating expenses for the three months ended September 30, 2016 were \$8.7 million, compared to \$7.6 million during the prior year period. Total operating expenses for the first nine months of 2016 were \$24.4 million similar to \$24.5 million for 2015.

Earnings: Net income for the third quarter of 2016 was \$0.1 million and \$0.01 per diluted share, similar to the prior year period. Adjusted Earnings for the third quarter were \$1.0 million or \$0.06 per share, compared to \$0.7 million or \$0.04 per share for the prior year period. The definition and reconciliation of Adjusted Earnings to net income is provided in this release.

Balance Sheet: At September 30, 2016, Cumberland had \$50.1 million in cash and marketable securities, with approximately \$35.5 million in cash and equivalents and \$14.6 million in marketable securities. Total Assets at September 30, 2016 were \$91.1 million. Total Liabilities were \$16.7 million, including \$3.7 million outstanding on our revolving line of credit, resulting in Total Shareholder's Equity of \$74.5 million. Cumberland also had approximately \$43 million in off-balance sheet tax net operating loss carryforwards, resulting from the prior exercise of stock options.

Conference Call and Webcast

A conference call and live Internet webcast will be held on Tuesday, November 1, 2016 at 4:30 p.m. Eastern Time to discuss the Company's third quarter 2016 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 99386514. 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 acquisition, development, and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's six marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, for the treatment of pain and fever, Kristalose® (*lactulose*) Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak® for the treatment of *H. pylori* infection and duodenal ulcer disease, and Ethyol® (amifostine) for Injection, for the treatment of oncology patients.

Cumberland is developing Hepatoren® (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome, Boxaban® (*ifetroban*) Oral Capsule for the treatment of Aspirin-Exacerbated Respiratory Disease, Vasculan™ (ifetroban) Oral Capsule for the treatment of systemic sclerosis, and Portaban™, for the treatment of portal hypertension.

Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information on

Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

About Acetadote® (acetylcysteine) Injection

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 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.com.

About Caldolor® (ibuprofen) Injection

Caldolor is indicated in adults and pediatric patients 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. 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 a history of asthma or other 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 Kristalose® (lactulose) Oral Solution

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.

About Omeclamox®-Pak (omeprazole, clarithromycin, amoxicillin)

Omeprazole is an antisecretory drug, which works by decreasing the amount of acid the stomach produces. Clarithromycin and amoxicillin are antibacterial drugs, which inhibit the growth of bacteria allowing the stomach lining to heal. Omeclamox-Pak is contraindicated in patients with a history of hypersensitivity to omeprazole, any macrolide antibiotic or penicillin. The safety and effectiveness of Omeclamox-Pak in the pediatric population has not yet been established. Omeclamox-Pak was approved by the U.S. Food and Drug Administration in 2011. For full prescribing information, visit www.omeclamox.com.

About Vaprisol® (conivaptan hydrochloride) Injection

Vaprisol is an intravenous treatment for hyponatremia used in the critical care setting. Hyponatremia is an electrolyte disturbance in which sodium ion concentration in blood plasma is lower than normal. This can be associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia.

The product is a vasopressin receptor antagonist that raises serum sodium levels and promotes free water secretion. Vaprisol was approved by the U.S. Food and Drug Administration in 2005 for euvolemic hyponatremia and in 2007 for hypervolemic hyponatremia. For full prescribing information, visit www.vaprisol.com.

About Ethyol® (amifostine) Injection

Ethyol is indicated to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. It is indicated to reduce the incidence of moderate to severe xerostomia in patients undergoing

post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands.

About Cumberland Emerging Technologies (CET)

Cumberland Emerging Technologies, Inc. (www.cet-fund.com) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and Gloria Pharmaceuticals. The mission of CET is to bring biomedical technologies and products conceived at Vanderbilt University and other regional research centers to the marketplace. CET helps manage the development and commercialization process for select projects and provides expertise on intellectual property, regulatory, manufacturing and marketing issues that are critical to successful new biomedical products. CET's Life Sciences Center, located in Nashville, Tennessee, provides laboratory space, equipment, and infrastructure to early-stage life sciences companies.

Forward-Looking Statements

This announcement 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 most recent Form 10-K and subsequent 10-Q's as filed with the SEC. 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)

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,546,244	\$ 38,203,059
Marketable securities	14,600,404	14,564,115
Accounts receivable, net of allowances	6,672,300	6,077,120
Inventories	4,983,227	4,270,143
Other current assets	5,160,817	3,997,637
Total current assets	66,962,992	67,112,074
Property and equipment, net	482,591	536,450
Intangible assets, net	21,172,570	21,168,596
Other assets	2,456,118	3,101,839
Total assets	<u>\$ 91,074,271</u>	<u>\$ 91,918,959</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 6,658,196	\$ 2,877,479
Other current liabilities	5,027,735	9,534,268
Total current liabilities	11,685,931	12,411,747
Revolving line of credit	3,700,000	1,700,000
Other long-term liabilities	1,265,725	987,429
Total liabilities	<u>16,651,656</u>	<u>15,099,176</u>
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,195,631 and 16,379,501 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	55,175,133	57,338,294

Retained earnings	19,354,625	19,549,614
Total shareholders' equity	74,529,758	76,887,908
Noncontrolling interests	(107,143)	(68,125)
Total equity	74,422,615	76,819,783
Total liabilities and equity	\$ 91,074,271	\$ 91,918,959

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Income (loss)
(Unaudited)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Net revenues	\$ 8,791,753	\$ 7,885,048	\$ 23,944,120	\$ 25,481,563
Costs and expenses:				
Cost of products sold	1,973,948	980,176	4,353,148	3,379,018
Selling and marketing	3,614,714	3,608,828	10,585,955	10,645,229
Research and development	644,662	757,442	2,029,914	3,444,524
General and administrative	1,865,575	1,794,279	5,817,943	5,591,982
Amortization	562,722	473,439	1,632,920	1,471,879
Total costs and expenses	<u>8,661,621</u>	<u>7,614,164</u>	<u>24,419,880</u>	<u>24,532,632</u>
Operating income (loss)	130,132	270,884	(475,760)	948,931
Interest income	51,636	64,072	160,248	178,320
Interest expense	(29,088)	(19,815)	(77,777)	(53,854)
Income (loss) before income taxes	152,680	315,141	(393,289)	1,073,397
Income tax (expense) benefit	(57,192)	(193,439)	159,282	(530,885)
Net income (loss)	95,488	121,702	(234,007)	542,512
Net loss at subsidiary attributable to noncontrolling interests	10,678	4,911	39,018	37,780
Net income (loss) attributable to common shareholders	<u>\$ 106,166</u>	<u>\$ 126,613</u>	<u>\$ (194,989)</u>	<u>\$ 580,292</u>
Earnings (loss) per share attributable to common shareholders				
- basic	\$ 0.01	\$ 0.01	\$ (0.01)	\$ 0.03
- diluted	\$ 0.01	\$ 0.01	\$ (0.01)	\$ 0.03
Weighted-average shares outstanding				
- basic	16,217,442	16,604,682	16,268,579	16,811,360
- diluted	16,504,568	16,996,376	16,268,579	17,193,854
Comprehensive income (loss) attributable to common shareholders	106,166	126,613	\$ (194,989)	\$ 580,292
Net loss at subsidiary attributable to noncontrolling interests	10,678	4,911	39,018	37,780
Total comprehensive income (loss)	<u>\$ 95,488</u>	<u>\$ 121,702</u>	<u>\$ (234,007)</u>	<u>\$ 542,512</u>

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

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Cash flows from operating activities:		
Net income (loss)	\$ (234,007)	\$ 542,512
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	1,785,057	1,677,906
Deferred tax benefit	662,689	43,991
Share-based compensation	623,504	426,651
Excess tax expense (benefit) derived from exercise of stock options	907,270	(470,584)
Noncash interest expense	61,224	33,001
Noncash investment gains	(69,140)	(80,321)
Net changes in assets and liabilities affecting operating activities:		

Accounts receivable	(595,180)	(293,665)
Inventory	(713,084)	1,394,280
Other current assets and other assets	(1,241,372)	(239,484)
Accounts payable and other current liabilities	(1,705,007)	1,457,656
Other long-term liabilities	267,730	61,553
Net cash (used in) provided by operating activities	<u>(250,316)</u>	<u>4,553,496</u>
Cash flows from investing activities:		
Additions to property and equipment	(98,275)	(96,768)
Purchases of marketable securities	(3,643,894)	(5,201,240)
Proceeds from sale of marketable securities	3,676,745	5,684,149
Additions to intangible assets	(1,554,410)	(2,392,477)
Net cash used in investing activities	<u>(1,619,834)</u>	<u>(2,006,336)</u>
Cash flows from financing activities:		
Net borrowings on line of credit	2,000,000	1,700,000
Exercise of stock options	—	21,366
Excess tax (expense) benefit derived from exercise of stock options	(907,270)	470,584
Cash settlement of contingent consideration	—	(1,618,983)
Repurchase of common shares	(1,879,395)	(4,669,873)
Net cash used in financing activities	<u>(786,665)</u>	<u>(4,096,906)</u>
Net decrease in cash and cash equivalents	(2,656,815)	(1,549,746)
Cash and cash equivalents at beginning of period	38,203,059	39,866,037
Cash and cash equivalents at end of period	<u>\$ 35,546,244</u>	<u>\$ 38,316,291</u>

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Reconciliation of Net Income (Loss) Attributable to Common Shareholders to Adjusted Earnings and Adjusted Diluted Earnings Per Share
(Unaudited)

	Three months ended September 30, 2016		Three months ended September 30, 2015	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income attributable to common shareholders	\$ 106,166	\$ 0.01	\$ 126,613	\$ 0.01
Less: Net loss at subsidiary attributable to noncontrolling interests	10,678	—	4,911	—
Net income	95,488	0.01	121,702	0.01
Adjustments to net income				
Income tax expense	57,192	—	193,439	0.01
Depreciation and amortization expense	613,620	0.04	534,904	0.03
Share-based compensation (a)	215,278	0.01	(122,952)	(0.01)
Interest income	(51,636)	—	(64,072)	—
Interest expense	29,088	—	19,815	—
Adjusted Earnings and Adjusted Diluted Earnings Per Share	<u>\$ 959,030</u>	<u>\$ 0.06</u>	<u>\$ 682,836</u>	<u>\$ 0.04</u>
Diluted weighted-average common shares outstanding:		<u>16,504,568</u>		<u>16,996,376</u>

The Company provided the above adjusted supplemental financial performance measures, which are considered "non-GAAP" financial measures under applicable Securities and Exchange Commission rules and regulations. These financial measures should be considered supplemental to, and not as a substitute for, financial information prepared in accordance with Generally Accepted Accounting Principles ("GAAP"). The definition of these supplemental measures may differ from similarly titled measures used by others.

Because these supplemental financial measures exclude the effect of items that will increase or decrease the Company's reported results of operations, management strongly encourages investors to review the Company's consolidated financial statements and publicly filed reports in their entirety. A reconciliation of the supplemental financial measures to the most directly comparable GAAP financial measures is included in the tables accompanying this release.

Cumberland's management believes these supplemental financial performance measures are important as they are used by management, along with financial measures in accordance with GAAP, to evaluate the Company's operating performance.

In addition, Cumberland believes that they will be used by certain investors to measure the Company's operating results. Management believes that presenting these supplemental measures provides useful information about the Company's underlying performance across reporting periods on a consistent basis by excluding items that Cumberland does not believe are indicative of its core business performance or reflect long-term strategic activities. Certain of these items are not settled through cash payments and include: depreciation, amortization, share-based compensation expense and income taxes. Cumberland utilizes its net operating loss carryforwards to pay minimal income taxes. In addition, the use of these financial measures provides greater transparency to investors of supplemental information used by management in its financial and operational decision-making, including the evaluation of the Company's operating performance.

The Company defines these supplemental financial measures as follows:

- | **Adjusted Earnings:** net income adjusted for the impact of income taxes, depreciation and amortization expense, share-based compensation expense and other income and interest expense.
 - (a) Represents the share-based compensation of Cumberland.
 - (b) Represents Cumberland's fee paid to the FDA in connection with a request for expanded pediatric labeling for Caldolor.
 - (c) Represents Cumberland's reduction in contingent liabilities as the result of a reduction in the cost of the Vaprisol acquisition.
- | **Adjusted Diluted Earnings Per Share:** Adjusted Earnings divided by diluted weighted-average common shares outstanding.

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To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-reports-third-quarter--year-to-date-2016-financial-results-300355206.html>

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