



May 10, 2016

## **Cumberland Pharmaceuticals Reports First Quarter 2016 Financial Results**

- Caldolor® Launched for Use in Pediatric Patients**
- Co-Promotion Underway to Support Hospital Products**

NASHVILLE, Tenn., May 10, 2016 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced first quarter 2016 financial results with Net Revenues of \$7.7 million and Adjusted Earnings of \$0.3 million or \$0.02 per share.

As of March 31, 2016, the Company had just under \$90 million in Total Assets including over \$51 million in cash and marketable securities. Total Liabilities were approximately \$14 million and Total Shareholder's Equity was just over \$75 million. Cumberland also had approximately \$43 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

"During the first quarter, we began to build upon the foundation we established in 2015," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We have already had a series of positive developments this year that we expect to make important contributions toward our goal of delivering long-term sustainable growth."

### **QUARTER HIGHLIGHTS:**

#### **Caldolor® Pediatric Launch**

Cumberland launched the promotion of Caldolor for the treatment of pain and fever in children at its National Sales Meeting in March. Caldolor has been approved for use in adults for the management of pain, as well as the reduction of fever, since 2009. The Company received pediatric approval and three year exclusivity from the FDA of Caldolor for use in children six months of age and older in November 2015. Cumberland seeks to maximize the potential of its FDA approved product line and expand the use of its products into new patient populations. The pediatric approval and launch of Caldolor for use in children is one more achievement toward supporting those objectives.

#### **Hospital Co-Promotion**

During the first quarter, Cumberland launched a co-promotion agreement with Piramal Critical Care to increase the support for our Caldolor® and Vaprisol® brands.

This collaboration provides coverage to an additional group of hospitals where Piramal's critical care sales force has existing relationships. The Company expects this new initiative to provide expanded promotional coverage and increased communication to medical professionals in support of these two brands.

### **RECENT DEVELOPMENTS:**

#### **Vasculan™ Program**

Cumberland recently announced a new clinical program to develop Vasculan™ (ifetroban) oral capsule for the treatment of systemic sclerosis. Systemic sclerosis (SSc), also called scleroderma, is a rare autoimmune disorder that affects the skin and internal organs. It is characterized by vasculopathy, inflammation, and fibrosis. This disease has a high morbidity and the highest case-specific mortality of any rheumatic disorder with 50% of patients dying or developing major internal organ complications within 3 years of diagnosis.

Although several medications are used to treat the skin disease associated with SSc, there is no universally effective treatment to improve the function of affected internal organs such as the lungs, heart, and gastrointestinal tract, hence the treatment of SSc remains an unmet need. The U.S. Food and Drug Administration has cleared Cumberland's investigational new drug application for a Phase II clinical program for Vasculan in patients with systemic sclerosis.

#### **Ethylol® Agreement**

Earlier today, the Company announced an agreement for the commercialization of Ethyol<sup>®</sup> (amifostine) in the United States. 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 agreement, Cumberland will be responsible for all marketing, promotion, and distribution of the product in the U.S.

Ethyol is an FDA approved cytoprotective drug indicated as an adjuvant therapy to reduce the incidence of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer.

## **FINANCIAL RESULTS:**

**Net Revenue:** For the three months ended March 31, 2016, net revenues were \$7.7 million, compared to \$8.7 million for the prior year period. Net revenue by product for the three months ended March 31, 2016, included \$3.6 million for Kristalose<sup>®</sup>, \$1.8 million for Acetadote<sup>®</sup>, including \$1.2 million for the Company's Authorized Generic, \$1.1 million for Caldolor<sup>®</sup>, \$0.8 million for Omeclamox<sup>®</sup>-Pak, and \$0.4 million for Vaprisol<sup>®</sup>.

**Operating Expenses:** Total operating expenses for the three months ended March 31, 2016 were \$8.2 million, compared to \$8.7 million during the prior year period, as the Company continued its efforts to maintain expenses in line with its revenues.

**Adjusted Earnings:** Adjusted Earnings for the first quarter were \$0.3 million or \$0.02 per share, compared to \$1.6 million or \$0.09 per share for the prior year period. The definition and reconciliation of Adjusted Earnings is provided in this release.

**Balance Sheet:** At March 31, 2016, Cumberland had \$51.3 million in cash and marketable securities, with approximately \$36.4 million in cash and equivalents and \$14.9 million in marketable securities. Total Assets at March 31, 2016 were \$89.2 million. Total Liabilities were \$13.9 million, including \$1.7 million outstanding on our revolving line of credit, resulting in Total Shareholder's Equity of \$75.4 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, May 10, 2016 at 4:30 p.m. Eastern Time to discuss the Company's first 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 87898815. 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 five marketed products include Acetadote<sup>®</sup> (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor<sup>®</sup> (*ibuprofen*) Injection, for the treatment of pain and fever, Kristalose<sup>®</sup> (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol<sup>®</sup> (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak<sup>®</sup> for the treatment of *H. pylori* infection and duodenal ulcer disease. Cumberland is developing Hepatoren<sup>®</sup> (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome, Boxaban<sup>®</sup> (*ifetroban*) Oral Capsule for the treatment of Aspirin-Exacerbated Respiratory Disease, and Vascular<sup>™</sup> (*ifetroban*) Oral Capsule for the treatment of systemic sclerosis. 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](http://www.cumberlandpharma.com).

## **About Acetadote<sup>®</sup> (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](http://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](http://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 hyponatremia. 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).

### **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](http://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](http://www.vaprisol.com).

### **About Cumberland Emerging Technologies (CET)**

Cumberland Emerging Technologies, Inc. ([www.cet-fund.com](http://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)**

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 36,440,779	\$ 38,203,059
Marketable securities	14,866,218	14,564,115
Accounts receivable, net of allowances	4,822,800	6,077,120
Inventories	4,073,689	4,270,143
Other current assets	4,719,427	3,997,637
Total current assets	64,922,913	67,112,074
Property and equipment, net	558,184	536,450
Intangible assets, net	21,027,967	21,168,596
Other assets	2,696,670	3,101,839
Total assets	<u>\$ 89,205,734</u>	<u>\$ 91,918,959</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,067,318	\$ 2,877,479
Other current liabilities	7,070,818	9,534,268
Total current liabilities	11,138,136	12,411,747
Revolving line of credit	1,700,000	1,700,000
Other long-term liabilities	1,048,880	987,429
Total liabilities	13,887,016	15,099,176
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,296,778 and 16,379,501 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	56,105,786	57,338,294
Retained earnings	19,296,503	19,549,614
Total shareholders' equity	75,402,289	76,887,908
Noncontrolling interests	(83,571)	(68,125)
Total equity	75,318,718	76,819,783
Total liabilities and equity	<u>\$ 89,205,734</u>	<u>\$ 91,918,959</u>

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

	<b>Three months ended March 31, 2016</b>	<b>2015</b>
Net revenues	\$ 7,737,532	\$ 8,686,774
Costs and expenses:		

Cost of products sold	1,223,939	1,161,841
Selling and marketing	3,698,962	3,530,915
Research and development	706,472	1,859,012
General and administrative	2,077,972	1,644,141
Amortization	530,770	486,749
Total costs and expenses	8,238,115	8,682,658
Operating income (loss)	(500,583)	4,116
Interest income	77,129	56,402
Interest expense	(20,442)	(15,550)
Income (loss) before income taxes	(443,896)	44,968
Income tax (expense) benefit	175,339	(18,456)
Net income (loss)	(268,557)	26,512
Net loss at subsidiary attributable to noncontrolling interests	15,446	19,769
Net income (loss) attributable to common shareholders	<u>\$ (253,111)</u>	<u>\$ 46,281</u>
Earnings (loss) per share attributable to common shareholders		
- basic	\$ (0.02)	\$ —
- diluted	\$ (0.02)	\$ —
Weighted-average shares outstanding		
- basic	16,341,481	17,012,852
- diluted	16,341,481	17,405,019
Comprehensive income (loss) attributable to common shareholders	\$ (253,111)	\$ 46,281
Net loss at subsidiary attributable to noncontrolling interests	15,446	19,769
Total comprehensive income (loss)	<u>\$ (268,557)</u>	<u>\$ 26,512</u>

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

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Cash flows from operating activities:		
Net income (loss)	\$ (268,557)	\$ 26,512
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	582,093	561,248
Deferred tax benefit	204,067	—
Share-based compensation	174,778	246,475
Excess tax expense (benefit) derived from exercise of stock options	427,993	(18,558)
Noncash interest expense	13,933	8,051
Noncash investment gains	(46,577)	(20,818)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	1,254,320	329,862
Inventory	196,454	966,254
Other current assets and other assets	(534,621)	130,321
Accounts payable and other current liabilities	(1,483,998)	(251,261)
Other long-term liabilities	78,602	55,735
Net cash provided by operating activities	<u>598,487</u>	<u>2,033,821</u>
Cash flows from investing activities:		
Additions to property and equipment	(73,057)	(108,658)
Purchases of marketable securities	(1,166,218)	(1,500,000)
Proceeds from sale of marketable securities	910,692	2,497,114
Additions to intangible assets	(624,898)	(2,062,321)
Net cash used in investing activities	<u>(953,481)</u>	<u>(1,173,865)</u>
Cash flows from financing activities:		
Exercise of stock options	—	12,000
Excess tax (expense) benefit derived from exercise of stock options	(427,993)	18,558
Repurchase of common shares	(979,293)	(1,711,802)
Net cash used in financing activities	<u>(1,407,286)</u>	<u>(1,681,244)</u>
Net decrease in cash and cash equivalents	(1,762,280)	(821,288)
Cash and cash equivalents at beginning of period	38,203,059	39,866,037

Cash and cash equivalents at end of period

\$ 36,440,779	\$ 39,044,749
---------------	---------------

**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 March 31, 2016		Three months ended March 31, 2015	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
<b>Net income (loss) attributable to common shareholders</b>	\$ (253,111)	\$ (0.02)	\$ 46,281	\$ —
Less: Net loss at subsidiary attributable to noncontrolling interests	15,446	—	19,769	—
Net income (loss)	(268,557)	(0.02)	26,512	—
Adjustments to net income (loss)				
Income tax expense (benefit)	(175,339)	(0.01)	18,456	—
Depreciation and amortization expense	582,093	0.04	561,248	0.03
Share-based compensation (a)	174,778	0.01	246,475	0.01
Product label expansion fees (b)	—	—	1,167,600	0.07
Gain on contingent consideration (c)	—	—	(381,037)	—
Interest income	(77,129)	—	(56,402)	—
Interest expense	20,442	—	15,550	—
<b>Adjusted Earnings and Adjusted Diluted Earnings Per Share</b>	<b>\$ 256,288</b>	<b>\$ 0.02</b>	<b>\$ 1,598,402</b>	<b>\$ 0.09</b>
Diluted weighted-average common shares outstanding:		16,341,481		17,405,019

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.

1 **Adjusted Diluted Earnings Per Share:** Adjusted Earnings divided by diluted weighted-average common shares outstanding.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-reports-first-quarter-2016-financial-results-300265818.html>

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media