



May 7, 2015

## Cumberland Pharmaceuticals Reports First Quarter 2015 Financial Results

- **Caldolor® sNDA submitted and accepted for review by FDA**
- **Phase II clinical trial for Boxaban™ enrollment progressing**
- **Favorable top line data from Hepatoren® study**

NASHVILLE, Tenn., May 7, 2015 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced first quarter 2015 financial results with Adjusted Earnings up 72% to \$1.6 million or \$0.09 per share. Net revenues were \$8.7 million, compared to \$8.1 million for the prior year period.



As of March 31, 2015 the Company had \$53 million in cash and investments, approximately \$92 million in total assets, and no debt. Cumberland also had \$44 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

### QUARTER HIGHLIGHTS:

- Received FDA acceptance to review the Caldolor® *supplemental New Drug Application* (sNDA) requesting a label update with pediatric information.
- Announced the addition of Boxaban™, in Phase II development, for the treatment of asthma patients with *Aspirin Exacerbated Respiratory Disease* (AERD).
- Provided encouraging top line results from the Phase II Hepatoren® study first patient cohort.

"Our first quarter was successful on many fronts," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are building on the positive momentum generated in 2014. Our goal remains to maximize the value of our existing products and invest in new product opportunities that will drive sustainable long-term growth."

### FINANCIAL RESULTS:

**Net Revenue:** For the three months ended March 31, 2015, net revenue was \$8.7 million, compared to \$8.1 million for the prior year period. Net revenue by product for the three months ended March 31, 2015, included \$4.1 million for Kristalose®, \$1.5 million for Acetadote®, including \$0.5 million for the Company's Authorized Generic, \$1.2 million for Caldolor®, \$1.0 million for Vaprisol® and \$0.8 million for Omeclamox®-Pak. Authorized Generic sales were impacted by a temporary product backorder.

**Operating Expenses:** Total operating expenses for the three months ended March 31, 2015 were \$8.7 million, compared to \$7.7 million during the prior year period. Operating expenses for the first quarter were impacted by a \$1.2 million FDA filing fee associated with the supplemental New Drug Application for Caldolor.

**Adjusted Earnings:** Adjusted Earnings for the first quarter were \$1.6 million or \$0.09 per share, up 72% from \$0.9 million or \$0.05 per share for the prior year period. The definition and reconciliation of Adjusted Earnings is provided in this release.

**Balance Sheet:** At March 31, 2015, Cumberland had \$52.9 million in cash and marketable securities, with approximately \$39.0 million in cash and equivalents and \$13.9 million in marketable securities. Total assets at March 31, 2015 were \$92.2 million, and the Company had no debt at the end of the first quarter. Cumberland also had \$44.2 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

### RECENT DEVELOPMENTS

## **Caldolor®**

Cumberland completed a series of Phase IV studies for Caldolor in more than 1,000 patients in over 30 leading medical centers across the U.S. These studies included evaluation of the product in both children and adults. Following the completion of these Phase IV programs, the Company submitted a supplemental new drug application (sNDA) to the FDA for the product during the first quarter of 2015. This submission requested changes to the package insert to include pediatric data from Cumberland's post-marketing pediatric development program.

Additionally, in January 2015, *Clinical Therapeutics, The International Peer-Reviewed Journal of Drug Therapy*, published two articles with data from two Caldolor (*ibuprofen*) registry studies. These two studies evaluated the tolerability and efficacy of a shortened infusion time for Caldolor.

One study entitled, "*A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety and Efficacy*" provided for eligible enrolled patients to receive one of two dose strengths of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from thirteen clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The other registry study entitled "*A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety*" was a Phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg of intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from twenty-one clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

## **Hepatoren®**

Cumberland is developing Hepatoren as a potential treatment for Hepatorenal Syndrome (HRS) - a life threatening condition with a high mortality rate and no approved pharmaceutical therapy in this country. There is an ongoing sixty-four patient study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study is designed to evaluate escalating dose levels of Hepatoren in Type II patients. Progression to higher dose levels is reviewed and approved by an independent safety committee. The study is stratified into Type I or Type II patients with HRS based upon the progression of their disease.

The Company has completed enrollment of the Type II patients. Top line results from these patients indicate that Hepatoren was overall well tolerated with no safety concerns noted. Furthermore, the patients receiving the higher dose levels of Hepatoren were more likely to experience increases in urine output, a signal of improved kidney function, compared to patients who received placebo.

Enrollment of the remaining patients in the Type I HRS cohort is underway. Next steps include further analysis of the data set received from the Type II patient study, completion of enrollment for the Type I patients, and design of a follow-up study based on these findings.

## **Boxaban™**

Cumberland recently announced an expansion of its pipeline with a new Phase II development program. The Company has begun the clinical development of Boxaban for the treatment of Aspirin-Exacerbated Respiratory Disease (AERD). AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin. It is characterized by sharp increases in inflammatory mediators and platelet activity within the respiratory system. Ifetroban, an active thromboxane receptor antagonist, may interfere with these pathways to modify the disease and provide symptomatic relief.

Cumberland completed manufacturing of the Boxaban oral capsules and has made progress in enrolling patients in a Phase II clinical study to evaluate Boxaban in those suffering with AERD. The study is designed to gather initial safety and tolerability data on ifetroban in AERD patients. It is a multicenter study of sixteen patients with enrollment well underway at several U.S. medical centers.

## **Conference Call and Webcast**

A conference call and live Internet webcast will be held on Thursday, May 7, 2015 at 4:30 p.m. Eastern Time to discuss the Company's first quarter 2015 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 34386261. The live webcast and rebroadcast can be accessed via Cumberland's website at

## **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 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 and Boxaban<sup>™</sup> (*ifetroban*) Oral Capsule for treatment of Aspirin-Exacerbated Respiratory Disease. 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<sup>®</sup> (ibuprofen) Injection**

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](http://www.caldolor.com).

### **About Kristalose<sup>®</sup> (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](http://www.kristalose.com).

### **About Omeclamox<sup>®</sup>-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<sup>®</sup> (conivaptan hydrochloride) Injection**

Vaprisol 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).

## 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 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)

	March 31, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 39,044,749	\$ 39,866,037
Marketable securities	13,865,122	14,841,418
Accounts receivable, net of allowances	5,174,866	5,504,728
Inventories	4,634,065	5,600,319
Other current assets	4,826,271	5,002,469
Total current assets	67,545,073	70,814,971
Property and equipment, net	685,188	651,030
Intangible assets, net	21,551,175	21,568,541
Other assets	2,408,399	2,370,572
Total assets	<u>\$ 92,189,835</u>	<u>\$ 95,405,114</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,371,184	\$ 3,242,713
Other current liabilities	8,523,418	10,506,769
Total current liabilities	11,894,602	13,749,482
Revolving line of credit	—	—
Other long-term liabilities	950,699	902,841
Total liabilities	<u>12,845,301</u>	<u>14,652,323</u>
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,935,764 and 17,118,993 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively	60,507,641	61,942,410
Retained earnings	18,864,544	18,818,263
Total shareholders' equity	79,372,185	80,760,673
Noncontrolling interests	(27,651)	(7,882)
Total equity	<u>79,344,534</u>	<u>80,752,791</u>
Total liabilities and equity	<u>\$ 92,189,835</u>	<u>\$ 95,405,114</u>

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

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net revenues	\$ 8,686,774	\$ 8,093,244
Costs and expenses:		
Cost of products sold	1,161,841	1,053,717
Selling and marketing	3,530,915	3,613,931
Research and development	1,859,012	826,373
General and administrative	1,644,141	1,897,217
Amortization	486,749	293,955
Total costs and expenses	8,682,658	7,685,193
Operating income	4,116	408,051
Interest income	56,402	67,343
Interest expense	(15,550)	(12,203)
Income before income taxes	44,968	463,191
Income tax expense	(18,456)	(188,009)
Net income	26,512	275,182
Net loss at subsidiary attributable to noncontrolling interests	19,769	11,138
Net income attributable to common shareholders	\$ 46,281	\$ 286,320
Earnings per share attributable to common shareholders		
- basic	\$ —	\$ 0.02
- diluted	\$ —	\$ 0.02
Weighted-average shares outstanding		
- basic	17,012,852	17,907,848
- diluted	17,405,019	18,161,680
Comprehensive income attributable to common shareholders	46,281	286,320
Net loss at subsidiary attributable to noncontrolling interests	19,769	11,138
Total comprehensive income	\$ 26,512	\$ 275,182

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

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Cash flows from operating activities:		
Net income	\$ 26,512	\$ 275,182
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	561,248	395,135
Share-based compensation	246,475	125,758
Excess tax benefit derived from exercise of stock options	(18,558)	(188,008)
Noncash interest expense	8,051	6,019
Noncash investment (gains) losses	(20,818)	141,920
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:		
Accounts receivable	329,862	(886,669)
Inventory	966,254	(289,263)
Other current assets and other assets	130,321	(319,506)
Accounts payable and other current liabilities	(251,261)	1,696,229
Other long-term liabilities	55,735	25,775
Net cash provided by operating activities	2,033,821	982,572
Cash flows from investing activities:		
Additions to property and equipment	(108,658)	(29,760)
Purchases of marketable securities	(1,500,000)	(750,000)
Proceeds from sale of marketable securities	2,497,114	1,096,033

Cash paid for acquisitions	—	(2,000,000)
Additions to intangible assets	(2,062,321)	(388,768)
Net cash used in investing activities	(1,173,865)	(2,072,495)
Cash flows from financing activities:		
Exercise of stock options	12,000	—
Excess tax benefit derived from exercise of stock options	18,558	188,008
Repurchase of common shares	(1,711,802)	(919,583)
Net cash used in financing activities	(1,681,244)	(731,575)
Net decrease in cash and cash equivalents	(821,288)	(1,821,498)
Cash and cash equivalents at beginning of period	39,866,037	40,869,457
Cash and cash equivalents at end of period	\$ 39,044,749	\$ 39,047,959

#### CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

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

	Three months ended March 31, 2015		Three months ended March 31, 2014	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
<b>Net income attributable to common shareholders</b>	\$ 46,281	\$ —	\$ 286,320	\$ 0.02
Less: Net loss at subsidiary attributable to noncontrolling interests	19,769	—	11,138	—
Net income	26,512	—	275,182	0.02
Adjustments to net income				
Income tax expense	18,456	—	188,009	0.01
Depreciation and amortization expense	561,248	0.03	395,135	0.02
Share-based compensation expense (a)	246,475	0.01	125,758	0.01
Product label expansion fees (b)	1,167,600	0.07	—	—
Gain on contingent consideration (c)	(381,037)	(0.02)	—	—
Interest income	(56,402)	—	(67,343)	—
Interest expense	15,550	—	12,203	—
<b>Adjusted Earnings and Adjusted Diluted Earnings Per Share</b>	<b>\$ 1,598,402</b>	<b>\$ 0.09</b>	<b>\$ 928,944</b>	<b>\$ 0.05</b>
Diluted weighted-average common shares outstanding:		17,405,019		18,161,680

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 expense 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 gain on contingent consideration 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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