



August 5, 2014

## Cumberland Pharmaceuticals Reports Second Quarter 2014 Financial Results

- Revenues up 38% from prior year period
- New line of credit established with SunTrust Bank

NASHVILLE, Tenn., Aug. 5, 2014 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced second quarter 2014 financial results.



**SUMMARY FINANCIAL RESULTS:** During the second quarter 2014, net revenues were \$9.8 million, up nearly 38% from the prior year period. Operating cash flow was \$1.8 million for the six months as the Company managed expenses in line with its revenue during the first half of the year. Cumberland returned to profitability in 2014 with \$1.0 million in net income during the first half of the year or \$0.06 per diluted share.

As of June 30, 2014, the Company had nearly \$54 million in cash and investments, \$94 million in total assets and no debt. Cumberland also had approximately \$43 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

### **SUMMARY QUARTER HIGHLIGHTS:**

- In May 2014, Cumberland launched promotional efforts to support Vaprisol<sup>®</sup> following the brand's acquisition from Astellas in February.
- The launch of Omeclamox<sup>®</sup>-Pak and a new marketing strategy for Kristalose<sup>®</sup> also contributed to the Company's second quarter growth.
- During the quarter, Cumberland announced a new research and development initiative with its Chinese partner, Gloria Pharmaceuticals, with each company contributing \$1.0 million to Cumberland Emerging Technologies.
- Cumberland also entered into a new three year line of credit with SunTrust Bank providing up to \$20 million in debt financing availability to support the Company's growth and acquisition initiatives.

"The launch of our two new products, Vaprisol and Omeclamox-Pak, has diversified our business and has contributed to our return to profitability in 2014," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We were also pleased to expand our relationship with SunTrust and extend our access to this important source of capital."

### **FINANCIAL RESULTS:**

**Net Revenue:** For the three months ended June 30, 2014, net revenue was \$9.8 million, compared to \$7.1 million for the prior year period.

Net revenue was \$3.6 million for Kristalose, \$3.1 million for Acetadote<sup>®</sup>, including \$1.8 million for the Company's Authorized Generic, \$1.3 million for Omeclamox-Pak, \$1.1 million for Vaprisol and \$0.6 million for Caldolor<sup>®</sup>.

For the six months ended June 30, 2014, net revenue was \$17.8 million compared with \$17.3 million for the six months ended June 30, 2013.

Net revenue for the six months ended June 30, 2014, was \$6.9 million for Kristalose, \$5.8 million for Acetadote, including \$3.2 million for the Company's Authorized Generic, \$2.5 million for Omeclamox-Pak, \$1.4 million for Vaprisol and \$1.1 million for Caldolor.

**Operating Expenses:** Total operating expenses for the three months ended June 30, 2014, were \$8.5 million, compared to

\$8.2 million during the prior year period.

For the six months ended June 30, 2014, operating expenses were \$16.2 million compared to \$17.2 million for the prior year period. The decrease in operating expenses continues to be from the Company's efforts to manage expenses in line with its revenues.

**Net Income:** Net income attributable to common shareholders for the three months ended June 30, 2014, was \$0.7 million, or \$0.04 per diluted share, compared to a loss of \$(0.6) million or \$(0.03) per diluted share during the prior year period.

For the six months ended June 30, 2014, net income attributable to common shareholders was \$1.0 million, or \$0.06 per diluted share compared to net income of \$0.2 million, or \$0.01 per diluted share during the prior year period.

**Operating Cash Flow:** Operating cash flows for the six months ended June 30, 2014, was \$1.8 million, similar to the prior year period.

**Balance Sheet:** As of June 30, 2014, Cumberland had \$53.9 million in cash and marketable securities, with approximately \$39.1 million in cash and equivalents and \$14.8 million in marketable securities. Total assets at June 30, 2014, were \$93.5 million and the Company had no debt at the end of the second quarter.

## **QUARTER HIGHLIGHTS**

### **Vaprisol®**

#### *Acquisition and Launch of Vaprisol*

In February 2014, Cumberland acquired certain product rights, intellectual property and related assets for Vaprisol from Astellas Pharma US, Inc. Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvoletic and hypervolemic hyponatremia. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the first and only intravenously administered branded treatment.

Hyponatremia, an imbalance of serum sodium to body water, is the most common electrolyte disorder among hospitalized patients. These electrolyte disturbances occur when the sodium ion concentration in the plasma is lower than normal and are often associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia. Vaprisol raises serum sodium to appropriate levels and promotes free water secretion.

Cumberland re-launched active promotion of the brand in early May 2014, utilizing the Company's hospital sales force, which also features its Caldolor and Acetadote products.

### **Omeclamox®-Pak**

#### *Launch of Omeclamox-Pak*

Cumberland launched our promotion and distribution efforts to support Omeclamox-Pak in early 2014. Our field sales force promotes Omeclamox-Pak to the gastroenterologist segment, which accounts for the largest component of the prescriber base for this product. Omeclamox-Pak is a branded prescription product used for the treatment of *Helicobacter pylori* (*H. pylori*) infection and duodenal ulcer disease. This innovative product combines three well-known and widely prescribed medications: omeprazole, clarithromycin, and amoxicillin. Omeclamox-Pak is the first FDA approved triple therapy combination medication to contain omeprazole as the proton pump inhibitor, which works to decrease the amount of acid the stomach produces. Clarithromycin and amoxicillin are both antibiotic agents which hinder the growth of *H. pylori*. Interaction of these agents allows the stomach lining to heal effectively. The medications are packaged together on convenient daily dosing cards, making it simple to follow the twice a day dosing before meals.

While there are competing products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the competing branded products, Omeclamox-Pak has the lowest pill burden, fewest days of therapy and the lowest cost. Our involvement with Omeclamox-Pak was effective October 2013, through an agreement with Pernix Therapeutics ("Pernix"). Pernix continues to promote the product through its specialty sales force focusing on select primary care physicians. Cumberland is responsible for the marketing, sale and distribution of the product.

## **International Agreement**

In April 2014, Cumberland received approximately \$1.0 million from Harbin Gloria Pharmaceuticals., Ltd. ("Gloria") for its participation in Cumberland Emerging Technologies Inc. ("CET"). As part of this transaction Gloria will have the first right to

negotiate a license to CET products for the Chinese market. The funds from this new investment are being used to support and accelerate the development of CET product candidates. CET was founded through a partnership between Cumberland, Vanderbilt University and the state of Tennessee.

## **Caldolor®**

### *Caldolor Pediatric Pain Study Published*

Data from the Company's Caldolor (*ibuprofen*) pediatric pain study was published in the May 2014 edition of *Pediatric Anesthesia*. The study was a multi-center, randomized, double-blind placebo-controlled, single dose trial of the safety and efficacy of intravenous ibuprofen for treatment of pain in pediatric patients undergoing tonsillectomy. The objective of the study was to determine whether administration of Caldolor prior to pediatric tonsillectomy surgery can significantly decrease the number of doses of narcotic following surgery when compared with placebo.

During the study a total of 161 pediatric patients undergoing tonsillectomy, ranging in age from 6 years to 17 years, were randomized to receive either a single dose of Caldolor or placebo prior to surgery. Postoperative pain was managed with intravenous narcotic on an as needed basis based on the visual analog scale (VAS) as well as deemed appropriate by the recovery room nurses and physicians. The primary endpoint was the number of doses and amount of narcotic administered following surgery.

The pediatric study indicated that there was a significant reduction in the number of postoperative doses and the amount of narcotic administered after surgery in the group that was administered Caldolor compared with the placebo group. There were no differences in the time to the first analgesia request or the number of patients who required analgesia after surgery. There were no significant differences in the incidence of serious adverse events. The study concluded that the administration of Caldolor significantly reduced narcotic use in pediatric tonsillectomy patients.

### *Caldolor Patents*

On May 27, 2014, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,735,452 (the "452 Caldolor Patent") which is assigned to Cumberland. The claims of the 452 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 452 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

On June 23, 2014, Cumberland received a Notice of Allowance from the USPTO for a patent relating to methods of treating pain using intravenous ibuprofen and which is scheduled to expire in September 2029. Cumberland also has additional patent applications relating to Caldolor which are pending with the USPTO and may or may not be issued.

## **Conference Call and Webcast**

A conference call and live Internet webcast will be held on Tuesday, August 5, 2014, at 4:30 p.m. Eastern Time to discuss the Company's second quarter 2014 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 77335881. The live webcast and rebroadcast can be accessed via Cumberland's website at <http://investor.shareholder.com/cpix/events.cfm>.

## **About Cumberland Pharmaceuticals Inc.**

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's marketed products include 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, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease. 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 [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

## **About Acetadote**

Acetadote is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. 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**

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**

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-Pak**

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**

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 does not require dilution and has a well-defined daily dose of 10 mg, 20 mg, or 40 mg. 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)**

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 39,050,841	\$ 40,869,457
Marketable securities	14,825,632	14,019,761
Accounts receivable, net of allowances	6,014,477	4,530,424
Inventories	6,996,843	5,722,882
Other current assets	3,744,244	3,537,191
Total current assets	70,632,037	68,679,715
Property and equipment, net	726,868	880,647
Intangible assets, net	19,073,458	15,498,819
Other assets	3,036,301	2,554,557
Total assets	<u>\$ 93,468,664</u>	<u>\$ 87,613,738</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,220,194	\$ 2,035,853
Other current liabilities	7,642,960	5,509,917
Total current liabilities	11,863,154	7,545,770
Revolving line of credit	—	—
Other long-term liabilities	873,246	776,125
Total liabilities	12,736,400	8,321,895
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 17,660,367 and 17,985,503 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively	63,529,644	63,073,941
Retained earnings	17,403,430	16,394,540
Total shareholders' equity	80,933,074	79,468,481
Noncontrolling interests	(200,810)	(176,638)
Total equity	80,732,264	79,291,843
Total liabilities and equity	<u>\$ 93,468,664</u>	<u>\$ 87,613,738</u>

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

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net revenues	\$ 9,750,168	\$ 7,081,088	\$ 17,843,412	\$ 17,339,220
Costs and expenses:				
Cost of products sold	1,298,816	1,154,833	2,352,533	2,263,468
Selling and marketing	3,930,082	3,542,049	7,544,013	7,215,988
Research and development	861,154	1,386,904	1,687,527	2,835,622
General and administrative	2,140,249	1,855,201	4,037,466	4,430,940
Amortization	304,258	282,645	598,213	407,695
Total costs and expenses	8,534,559	8,221,632	16,219,752	17,153,713
Operating income (loss)	1,215,609	(1,140,544)	1,623,660	185,507
Interest income	29,544	48,982	96,887	141,359
Interest expense	(12,278)	(20,700)	(24,481)	(38,435)
Income (loss) before income taxes	1,232,875	(1,112,262)	1,696,066	288,431
Income tax (expense) benefit	(523,339)	463,408	(711,348)	(95,959)
Net income (loss)	709,536	(648,854)	984,718	192,472

Net loss at subsidiary attributable to noncontrolling interests	13,034	9,836	24,172	23,219
Net income (loss) attributable to common shareholders	<u>\$ 722,570</u>	<u>\$ (639,018)</u>	<u>\$ 1,008,890</u>	<u>\$ 215,691</u>
Earnings (loss) per share attributable to common shareholders				
- basic	\$ 0.04	\$ (0.03)	\$ 0.06	\$ 0.01
- diluted	\$ 0.04	\$ (0.03)	\$ 0.06	\$ 0.01
Weighted-average shares outstanding				
- basic	17,743,395	18,405,522	17,825,174	18,580,891
- diluted	18,025,913	18,405,522	18,093,391	18,756,691
Comprehensive income (loss)	<u>\$ 709,536</u>	<u>\$ (648,854)</u>	<u>\$ 984,718</u>	<u>\$ 192,472</u>

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

	<b>Six months ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
Cash flows from operating activities:		
Net income	\$ 984,718	\$ 192,472
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	800,231	610,052
Deferred tax expense	—	65,413
Share-based compensation	325,344	305,199
Excess tax benefit derived from exercise of stock options	(711,348)	(15,288)
Noncash interest expense	12,038	12,038
Noncash investment losses	181,950	62,323
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:		
Accounts receivable	(1,484,052)	2,046,259
Inventory	136,039	124,061
Other current assets and other assets	(701,604)	59,877
Accounts payable and other current liabilities	2,165,828	(1,707,560)
Other long-term liabilities	109,244	37,479
Net cash provided by operating activities	<u>1,818,388</u>	<u>1,792,325</u>
Cash flows from investing activities:		
Additions to property and equipment	(48,239)	(69,119)
Purchases of marketable securities	(3,254,903)	(4,371,508)
Proceeds from sale of marketable securities	2,267,082	1,481,682
Cash paid for acquisitions	(2,000,000)	—
Additions to intangible assets	(732,072)	(1,829,693)
Net cash used in investment activities	<u>(3,768,132)</u>	<u>(4,788,638)</u>
Cash flows from financing activities:		
Net borrowings on line of credit	—	1,500,000
Exercise of stock options	—	(41,292)
Excess tax benefit derived from exercise of stock options	711,348	15,288
Sale of subsidiary shares to noncontrolling interest	1,000,005	—
Repurchase of common shares	(1,580,225)	(3,162,302)
Net cash provided by (used in) financing activities	<u>131,128</u>	<u>(1,688,306)</u>
Net decrease in cash and cash equivalents	<u>(1,818,616)</u>	<u>(4,684,619)</u>
Cash and cash equivalents at beginning of period	40,869,457	54,349,381
Cash and cash equivalents at end of period	<u>\$ 39,050,841</u>	<u>\$ 49,664,762</u>

Logo - <http://photos.prnewswire.com/prnh/20140505/84325>

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