



May 13, 2014

## Cumberland Pharmaceuticals Reports First Quarter 2014 Financial Results

- Launched promotional efforts to support Omeclamox®-Pak
- Acquired and launched promotion of Vaprisol®
- Joint R&D investment with Gloria Pharmaceuticals

NASHVILLE, Tenn., May 13, 2014 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced first quarter 2014 financial results. During the quarter the Company returned to profitability, launched two new products, and continued to maintain positive cash flow from operations.



**Net Revenue:** For the three months ended March 31, 2014, net revenues were \$8.1 million, compared to \$10.3 million for the prior year period. The change in net revenues was driven by a decrease in Acetadote® revenues, partially offset by increased revenues from Kristalose® and Caldolor® and the addition of new revenues from Omeclamox-Pak and Vaprisol.

Net revenue was \$3.4 million for Kristalose, \$2.7 million for Acetadote, including \$1.3 million of authorized generic, \$1.1 million for Omeclamox, \$0.5 million for Caldolor and \$0.3 million for Vaprisol. Net revenue for Vaprisol represents one month of sales following the acquisition of the product at the end of February 2014.

**Operating Expenses:** Total operating expenses for the three months ended March 31, 2014, were \$7.7 million, compared to \$8.9 million during the prior year period. The decrease in total operating expenses was driven primarily by decreases in research and development expenses following the conclusion of clinical studies related to Caldolor and a decrease in general & administrative expenses as the Company focuses on managing expenses in line with revenues.

**Net Income:** Net income attributable to common shareholders for the three months ended March 31, 2014, was \$0.3 million, or \$0.02 per diluted share, compared to \$0.9 million or \$0.05 per diluted share during the prior period. However, first quarter net income represented a return to profitability for the Company and an increase from a net loss of \$(1.5) million or \$(0.08) per diluted share in the fourth quarter of 2013.

**Operating Cash Flow:** Operating cash flows for the three months ended March 31, 2014, were \$1.0 million, compared to \$1.7 million, for the prior year period.

**Balance Sheet:** As of March 31, 2014, Cumberland had \$52.6 million in cash and marketable securities, with approximately \$39.0 million in cash and equivalents and \$13.5 million in marketable securities. Total assets at March 31, 2014, were \$91.1 million and the Company had no debt at the end of the first quarter.

"We are very optimistic about the opportunities that Vaprisol and Omeclamox-Pak will offer Cumberland. We continue to build a diversified product portfolio while deploying our resources to sustain long-term growth," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "The joint investment with Gloria will allow us to continue to both accelerate the development of existing CET projects and pursue new product candidates."

### 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 euvolemic and hypervolemic hyponatremia. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the first and only intravenously administered 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 believes that Vaprisol, an injectable hospital product, used in the critical care setting, is an excellent strategic fit for the Company as it overlays well with the existing efforts of its sales organization. The Company began shipping Vaprisol in early March 2014 and launched active promotional efforts in early May 2014 by its hospital sales force, which also features Caldolor® and Acetadote®.

## **Omeclamox®-Pak**

### *Launch of Omeclamox-Pak*

Cumberland launched promotion and distribution efforts to support Omeclamox-Pak in January 2014. The Company's 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 contains 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. Cumberland's involvement with Omeclamox-Pak was effective October 2013, through an agreement with Pernix Therapeutics. Pernix Therapeutics 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.

## **Caldolor®**

### *Caldolor Pediatric Presentation*

Data from the Company's Caldolor pediatric fever study was presented at the Society of Pediatric Anesthesiology meeting in Ft. Lauderdale in March 2014. The presentation entitled "*A Multi-Center, Open-Label, Parallel, Active-Comparator, Multiple Dose Trial to Determine the Efficacy, Safety, and Pharmacokinetics of Intravenous Ibuprofen in Pediatric Patients*" was presented by Dr. Samia N. Khalil, M.D., Department of Anesthesiology, the University of Texas Medical School at Houston. The meeting was co-sponsored by the Society for Pediatric Anesthesia and the American Academy of Pediatrics Section on Anesthesiology and Pain Medicine.

The pediatric study met its primary endpoint demonstrating that Caldolor was associated with a statistically significant reduction in temperature within the first 2 hours of dosing when compared to acetaminophen. Equally important, no safety concerns were observed during the study. During the study, febrile hospitalized children ranging in age from less than 1 year to 16 years, were administered Caldolor (*ibuprofen*) injection or oral or rectal acetaminophen as a single or multiple dose therapy for up to five days. One hundred and three patients were enrolled in this multi-center, randomized, open-label active comparator study. The pediatric patients received either 10 mg/kg intravenous ibuprofen (not to exceed 400 mg per dose) or 10 mg/kg acetaminophen (not to exceed 650 mg per dose).

## **International Agreement**

As announced last week, Cumberland received approximately \$1 million from Harbin Gloria Pharmaceuticals, Ltd. ("Gloria") for their 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 will be used to accelerate the development of CET product candidates. CET was founded through a partnership between Cumberland, Vanderbilt University and the state of Tennessee.

## **Conference Call and Webcast**

A conference call and live Internet webcast will be held on Tuesday, May 13, 2014 at 4:30 p.m. Eastern Time to discuss the Company's first 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 34342681. 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 euvoletic 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,<br>2014    | December 31, 2013    |
|--|----------------------|----------------------|
| <b>ASSETS</b>  |                      |                      |
| Current assets:  |                      |                      |
| Cash and cash equivalents  | \$ 39,047,959        | \$ 40,869,457        |
| Marketable securities  | 13,531,808           | 14,019,761           |
| Accounts receivable, net of allowances   | 5,417,093            | 4,530,424            |
| Inventories  | 7,422,145            | 5,722,882            |
| Other current assets   | 3,847,125            | 3,537,191            |
| Total current assets   | 69,266,130           | 68,679,715           |
| Property and equipment, net  | 809,227              | 880,647              |
| Intangible assets, net   | 18,473,434           | 15,498,819           |
| Other assets   | 2,557,341            | 2,554,557            |
| Total assets   | <u>\$ 91,106,132</u> | <u>\$ 87,613,738</u> |
| <b>LIABILITIES AND EQUITY</b>  |                      |                      |
| Current liabilities:   |                      |                      |
| Accounts payable   | \$ 4,724,873         | \$ 2,035,853         |
| Other current liabilities  | 6,624,983            | 5,509,917            |
| Total current liabilities  | 11,349,856           | 7,545,770            |
| Revolving line of credit   | —                    | —                    |
| Other long-term liabilities  | 795,837              | 776,125              |
| Total liabilities  | <u>12,145,693</u>    | <u>8,321,895</u>     |
| Commitments and contingencies  |                      |                      |
| Equity:  |                      |                      |
| Shareholders' equity:  |                      |                      |
| Common stock—no par value; 100,000,000 shares authorized;<br>17,807,317 and 17,985,503 shares issued and outstanding as of<br>March 31, 2014 and December 31, 2013, respectively | 62,467,355           | 63,073,941           |
| Retained earnings  | 16,680,860           | 16,394,540           |
| Total shareholders' equity   | 79,148,215           | 79,468,481           |
| Noncontrolling interests   | (187,776)            | (176,638)            |
| Total equity   | <u>78,960,439</u>    | <u>79,291,843</u>    |
| Total liabilities and equity   | <u>\$ 91,106,132</u> | <u>\$ 87,613,738</u> |

**Condensed Consolidated Statements of Operations and Comprehensive Income  
(Unaudited)**

|   | <b>Three months ended March 31,</b> |               |
|---|-------------------------------------|---------------|
|   | <b>2014</b>                         | <b>2013</b>   |
| Net revenues  | \$ 8,093,244                        | \$ 10,258,132 |
| Costs and expenses:   |                                     |               |
| Cost of products sold   | 1,053,717                           | 1,108,635     |
| Selling and marketing   | 3,613,931                           | 3,673,939     |
| Research and development  | 826,373                             | 1,448,718     |
| General and administrative                                      | 1,897,217                           | 2,575,739     |
| Amortization  | 293,955                             | 125,050       |
| Total costs and expenses  | 7,685,193                           | 8,932,081     |
| Operating income  | 408,051                             | 1,326,051     |
| Interest income   | 67,343                              | 92,377        |
| Interest expense  | (12,203)                            | (17,735)      |
| Income before income taxes                                      | 463,191                             | 1,400,693     |
| Income tax expense  | (188,009)                           | (559,367)     |
| Net income  | 275,182                             | 841,326       |
| Net loss at subsidiary attributable to noncontrolling interests | 11,138                              | 13,383        |
| Net income attributable to common shareholders                  | \$ 286,320                          | \$ 854,709    |
| Earnings per share attributable to common shareholders          |                                     |               |
| - basic   | \$ 0.02                             | \$ 0.05       |
| - diluted   | \$ 0.02                             | \$ 0.05       |
| Weighted-average shares outstanding                             |                                     |               |
| - basic   | 17,907,848                          | 18,758,383    |
| - diluted   | 18,161,680                          | 18,925,165    |
| Comprehensive income  | \$ 275,182                          | \$ 841,326    |

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

|  | <b>Three months ended March 31,</b> |             |
|--|-------------------------------------|-------------|
|  | <b>2014</b>                         | <b>2013</b> |
| Cash flows from operating activities:  |                                     |             |
| Net income   | \$ 275,182                          | \$ 841,326  |
| Adjustments to reconcile net income to net cash provided by operating activities:                            |                                     |             |
| Depreciation and amortization expense  | 395,135                             | 290,508     |
| Deferred tax expense   | —                                   | 65,413      |
| Share-based compensation   | 125,758                             | 128,625     |
| Excess tax benefit derived from exercise of stock options  | (188,008)                           | (478,698)   |
| Noncash interest expense   | 6,019                               | 6,019       |
| Noncash investment losses  | 141,920                             | 10,571      |
| Net changes in assets and liabilities affecting operating activities, net of effect of business combination: |                                     |             |
| Accounts receivable  | (886,669)                           | 49,570      |
| Inventory  | (289,263)                           | 226,324     |
| Other current assets and other assets  | (319,506)                           | (8,298)     |
| Accounts payable and other current liabilities   | 1,696,229                           | 492,983     |
| Other long-term liabilities  | 25,775                              | 46,308      |
| Net cash provided by operating activities  | 982,572                             | 1,670,651   |
| Cash flows from investing activities:  |                                     |             |
| Additions to property and equipment  | (29,760)                            | (60,911)    |
| Purchases of marketable securities   | (750,000)                           | (2,970,000) |
| Proceeds from sale of marketable securities  | 1,096,033                           | 686,755     |
| Cash paid for acquisitions   | (2,000,000)                         | —           |
| Additions to intangible assets   | (388,768)                           | (961,013)   |
| Net cash used in investment activities   | (2,072,495)                         | (3,305,169) |
| Cash flows from financing activities:  |                                     |             |
| Exercise of stock options  | —                                   | (41,292)    |
| Excess tax benefit derived from exercise of stock options  | 188,008                             | 478,698     |

|  |               |               |
|--|---------------|---------------|
| Repurchase of common shares                      | (919,583)     | (1,942,725)   |
| Net cash used in financing activities            | (731,575)     | (1,505,319)   |
| Net decrease in cash and cash equivalents        | (1,821,498)   | (3,139,837)   |
| Cash and cash equivalents at beginning of period | 40,869,457    | 54,349,381    |
| Cash and cash equivalents at end of period       | \$ 39,047,959 | \$ 51,209,544 |

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