

# **Cumberland Pharmaceuticals Reports Second Quarter 2011 Financial Results**

- Net revenue grows 34% over prior year period
- Phase II study for new pipeline candidate Hepatoren™ underway
- Caldolor® licensed for new Asian markets, application for approval submitted in Canada

NASHVILLE, Tenn., Aug. 4, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology markets, today announced second quarter 2011 financial results.

**Net Revenue:** For the three months ended June 30, 2011, net revenue was \$14.4 million, up 34% from \$10.7 million in the prior year period. The growth in revenue was due to an increase in sales volume for Acetadote following the Company's introduction of the new formulation for that product.

For the six months ended June 30, 2011, net revenue was \$25.1 million, up 20% compared with \$20.9 million for the six months ended June 30, 2010. This increase was largely attributable to the growth in net revenue during the second quarter of 2011.

**Operating Expenses:** Total operating expenses for the three months ended June 30, 2011, were \$10.8 million compared with \$9.7 million for the prior year period. The difference related primarily to increases in cost of products sold during the quarter as well as increases in general and administrative expenses. For the six months ended June 30, 2011, total operating expenses were \$20.0 million compared with \$19.1 million for the six months ended June 30, 2010.

**EBITDA:** Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) for the three months ended June 30, 2011, were \$3.9 million, up from \$1.2 million for the prior year period. EBITDA for the six months ended June 30, 2011, grew to \$5.6 million, up from \$2.3 million for the prior year period. The increase was primarily due to net revenue growth in the second quarter of 2011.

**Net Income:** Net income attributable to common shareholders for the three months ended June 30, 2011, was \$2.2 million, or \$0.11 per diluted share, up 658% from \$0.3 million, or \$0.01 per diluted share, for the prior year period.

For the six months ended June 30, 2011, net income attributable to common shareholders was \$2.9 million, or \$0.14 per diluted share, compared with \$0.6 million, or \$0.03 per diluted share, for the same period in 2010.

**Balance Sheet:** As of June 30, 2011, cash and cash equivalents grew to \$69.8 million, compared to \$66.0 million at March 31, 2011, due to strong operating cash flow during the quarter. Total assets at June 30, 2011, grew to \$94.6 million. Cumberland's total debt as of June 30, 2011, was \$5.8 million, including a current portion of \$4.0 million, compared to \$6.5 million in total debt at March 31, 2011. Following the end of the quarter, the Company repaid its term loan in full. Cumberland also increased its revolving line of credit to \$10 million, which is expandable to \$20 million and incorporated reduced pricing terms.

"We are very pleased with the Company's performance during the second quarter, having accomplished several key objectives for the year and delivering strong growth in revenue, income and cash flow," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Our team's execution of the launch of the new Acetadote formulation, the addition of a key pipeline candidate and growth in our network of international commercial partners are a few highlights from the quarter. From a historical performance perspective, this quarter also trends nicely with our consistent quarter-over-quarter growth in net revenue, EBITDA, operating income and net income."

Based on its second quarter performance, Cumberland is raising its full year 2011 revenue guidance to \$51 - \$55 million. This guidance represents the Company's best estimate of future results, which may be affected by factors described below in "Forward-Looking Statements."

# **Company Highlights**

**Acetadote®** 

New Formulation

In January 2011, the U.S. Food and Drug Administration (FDA) approved Cumberland's supplemental new drug application (sNDA) for a new formulation of Acetadote, which was the result of a phase IV commitment the Company made to the FDA upon receipt of initial marketing approval of the product. The new formulation does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. Cumberland launched the next generation product, which replaced the previously marketed formulation, in the first quarter of 2011 and during the second quarter worked to ensure widespread distribution and transition to the next generation product.

In July 2011, Cumberland filed a response with the U.S. Patent and Trademark Office for its patent application to protect proprietary discoveries related to the new Acetadote formulation. This formulation patent was allowed and issued in China in April 2011. The Company also recently filed a second U.S. patent application related to the safety profile of the new formulation.

sNDA for Non-Acetaminophen Induced Acute Liver Failure

In the first quarter of 2010, Cumberland submitted an application to the FDA for use of Acetadote in patients with non-acetaminophen acute liver failure. This sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that early-stage acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant and that these patients can also survive a significant number of days longer without transplant. In December 2010, the FDA issued a Complete Response Letter indicating that it had identified additional items that must be addressed prior to any approval.

Cumberland has been in discussions with the FDA to determine a pathway forward for the potential new indication. The Company recently identified and is currently analyzing additional patient data to support the application, and plans to present the new information to the FDA.

#### Caldolor®

In June 2009, the FDA approved Caldolor, the Company's intravenous formulation of ibuprofen, for marketing in the United States through a priority review. In late 2009, Cumberland launched the product in the U.S. and Caldolor is stocked at wholesalers serving hospitals nationwide.

In 2010, the Company focused its sales and marketing efforts primarily on securing formulary approval nationally for Caldolor. Early in the second quarter of 2011, Cumberland implemented a strategic shift to begin focusing on pull-through activities necessary to build volume of use and bring Caldolor to a larger population of patients in facilities stocking the product.

During the second quarter of 2011, Cumberland also progressed four clinical studies to further evaluate Caldolor in patients. Two of these trials are designed to support pediatric use, including a pediatric fever study to evaluate safety, efficacy and pharmacokinetics of Caldolor in hospitalized children as well as a pediatric pain study. Two new registry studies will gather additional data in adults, including a study evaluating Caldolor in treating pain and fever in a wide range of hospitalized patients and another evaluating the product for management of pain in surgical patients.

#### Hepatoren™

In April 2011, Cumberland entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. The Company has initiated clinical development under the brand name Hepatoren \*\*Mf\(\epsilon\) troban) Injection and is evaluating the product for treatment of critically ill hospitalized patients suffering from hepatorenal syndrome (HRS), a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment.

Ifetroban was initially developed extensively by a large pharmaceutical company for certain cardiovascular indications. The development program was eventually donated to Vanderbilt University, where researchers identified ifetroban as a potentially valuable compound in treating patients for several other niche indications. Cumberland acquired the rights to the ifetroban program from Vanderbilt through Cumberland Emerging Technologies and intends to develop it for several potential indications, including as an Orphan Drug for HRS for which it will pursue seven years of marketing exclusivity.

The FDA has cleared the Company's IND for this product candidate and Cumberland has initiated a Phase II dose escalation study to evaluate Hepatoren for the treatment of HRS. The Company has commenced manufacturing and filed patent applications to protect intellectual property related to the new indication. Cumberland believes Hepatoren is an excellent strategic fit given the Company's established presence in the hospital acute care market.

### International Markets

During the second quarter, Cumberland executed agreements with partners for commercialization of Caldolor and Acetadote in Malaysia and Taiwan. In Malaysia, the Company is partnering with Insanbakti and in Taiwan with Harvest & Health Co., Ltd.

These agreements are part of a larger initiative to secure distribution of Cumberland's products in Asian markets, and are in addition to a recent license agreement with DB Pharm Korea for Caldolor in South Korea.

The application for regulatory approval of Caldolor in Canada was recently submitted by Cumberland's Canadian partner, Alveda Pharma. Review of the application for regulatory approval of Caldolor in Australia is underway and Cumberland is working to identify additional arrangements for commercialization of its products in other markets as well.

# **Supplemental Financial Information**

The following table presents a reconciliation of Cumberland's net income to EBITDA. The Company defines EBITDA as net income plus interest, income tax, depreciation and amortization, and presents these measures to assist investors in evaluating Cumberland's operating performance and comparing the Company's results with those of other companies. EBITDA should not be considered in isolation from or as a substitute for net income.

| Three Months Ended June 30, |           |  |  |  |
|-----------------------------|-----------|--|--|--|
|                             | 2011      | 2010   |  |  |
| \$                          | 2,177,619 | \$   | 287,304                                  |  |
|                             | 1,436,365 |  | 374,461                                  |  |
|                             | 264,995   |  | 232,344                                  |  |
|                             | 27,344    |  | 355,622                                  |  |
| \$ 3,906,323 \$ 1,249       |           | 1,249,731                                      |  |  |
|                             | \$        | \$ 2,177,619<br>1,436,365<br>264,995<br>27,344 | \$ 2,177,619 \$ 1,436,365 264,995 27,344 |  |

|  | Six Months Ended June 30, |           |           |         |  |
|--|---------------------------|-----------|-----------|---------|--|
|  | 2011                      |           |           | 2010    |  |
|  |                           |           |           |         |  |
| Net income attributable to common shareholders | \$                        | 2,898,779 | \$        | 610,882 |  |
| Income tax expense                             |                           | 1,959,949 |           | 586,198 |  |
| Depreciation & amortization                    |                           | 527,301   |           | 463,676 |  |
| Interest expense, net                          |                           | 200,478   |           | 640,895 |  |
| EBITDA   | \$ 5,586,507 \$ 2,301,0   |           | 2,301,651 |         |  |

#### **Conference Call and Webcast**

A conference call and live Internet webcast will be held on Thursday, August 4, 2011 at 5:00 p.m. Eastern Time to discuss the Company's second quarter 2011 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 83958714. The live webcast and rebroadcast can be accessed via Cumberland's website at <a href="http://investor.shareholder.com/cpix/events.cfm">http://investor.shareholder.com/cpix/events.cfm</a>.

#### **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 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, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information, please visit the Company's website at <a href="https://www.cumberlandpharma.com">www.cumberlandpharma.com</a>.

## **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.

#### **About Acetadote**

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 the only injectable product approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. 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 <a href="https://www.acetadote.net">www.acetadote.net</a>.

#### **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 <a href="https://www.kristalose.com">www.kristalose.com</a>.

# **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 Form 10-K filed with the SEC on March 11, 2011. 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)

|  | June 30,<br>2011 | December 31,<br>2010 |
|--|------------------|----------------------|
| ASSETS                                 |                  |                      |
| Current assets:                        |                  |                      |
| Cash and cash equivalents              | \$ 69,832,030    | \$ 65,893,970        |
| Accounts receivable, net of allowances | 4,819,734        | 5,145,494            |
| Inventories                            | 7,453,251        | 7,683,842            |
| Other current assets                   | 2,238,864        | 2,315,536            |
| Total current assets                   | 84,343,879       | 81,038,842           |
| Property and equipment, net            | 1,195,924        | 1,220,010            |
| Intangible assets, net                 | 7,116,260        | 7,427,223            |
| Other assets                           | 1,924,992        | 2,367,979            |

| Total assets  | \$ 94,581,055 | \$ 92,054,054 |
|---|---------------|---------------|
| LIABILITIES AND EQUITY                                      |               |               |
| Current liabilities:  |               |               |
| Current portion of long-term debt                           | \$ 3,999,999  | \$ 2,666,668  |
| Accounts payable  | 2,302,058     | 2,124,654     |
| Other current liabilities                                   | 4,425,873     | 4,436,298     |
| Total current liabilities                                   | 10,727,930    | 9,227,620     |
| Revolving line of credit                                    | 1,825,951     | 1,825,951     |
| Long-term debt, excluding current portion                   | -             | 2,666,665     |
| Other long-term obligations, excluding current portion      | 602,099       | 618,343       |
| Total liabilities   | 13,155,980    | 14,338,579    |
| Commitments and contingencies                               |               |               |
| Equity:   |               |               |
| Shareholders' equity:                                       |               |               |
| Common stock - no par value; 100,000,000 shares authorized; |               |               |
| 20,400,085 and 20,338,461 shares issued and outstanding     |               |               |
| as of June 30, 2011 and December 31, 2010, respectively     | 71,609,043    | 70,778,874    |
| Retained earnings   | 9,897,585     | 6,998,806     |
| Total shareholders' equity                                  | 81,506,628    | 77,777,680    |
| Noncontrolling interests                                    | (81,553)      | (62,205)      |
| Total equity  | 81,425,075    | 77,715,475    |
| Total liabilities and equity                                | \$ 94,581,055 | \$ 92,054,054 |

# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Statements of Income (Unaudited)

|                                       | Three months ended June 30, |               | Six months e  | nded June 30, |
|---------------------------------------|-----------------------------|---------------|---------------|---------------|
|                                       | 2011                        | 2010          | 2011          | 2010          |
| Net revenues                          | \$ 14,389,741               | \$ 10,739,935 | \$ 25,056,668 | \$ 20,870,587 |
| Costs and expenses:                   |                             |               |               |               |
| Cost of products sold                 | 1,283,160                   | 863,725       | 2,070,098     | 1,723,013     |
| Selling and marketing                 | 5,904,444                   | 5,848,123     | 11,193,028    | 11,455,635    |
| Research and development              | 1,027,048                   | 1,034,800     | 2,036,721     | 1,808,668     |
| General and administrative            | 2,344,064                   | 1,782,834     | 4,324,455     | 3,664,037     |
| Amortization of product license right | 171,726                     | 171,726       | 343,453       | 343,452       |
| Other                                 | 27,442                      | 28,867        | 49,055        | 55,414        |
| Total costs and expenses              | 10,757,884                  | 9,730,075     | 20,016,810    | 19,050,219    |
| Operating income                      | 3,631,857                   | 1,009,860     | 5,039,858     | 1,820,368     |

| Interest income  | 52,260          |    | 50,334     | 95,169          |    | 111,013    |
|--|-----------------|----|------------|-----------------|----|------------|
| Interest expense                                       | <br>(79,604)    |    | (405,956)  | <br>(295,647)   |    | (751,908)  |
| Net income before income taxes                         | 3,604,513       |    | 654,238    | 4,839,380       |    | 1,179,473  |
| Income tax expense                                     | (1,436,365)     |    | (374,461)  | (1,959,949)     |    | (586,198)  |
| Net income   | 2,168,148       |    | 279,777    | 2,879,431       |    | 593,275    |
| Net loss at subsidiary attributable to                 |                 |    |            |                 |    |            |
| noncontrolling interests                               | <br>9,471       |    | 7,527      | <br>19,348      |    | 17,607     |
| Net income attributable to                             |                 |    |            |                 |    |            |
| common shareholders                                    | \$<br>2,177,619 | \$ | 287,304    | \$<br>2,898,779 | \$ | 610,882    |
|  |                 |    |            |                 |    |            |
| Earnings per share attributable to common shareholders |                 |    |            |                 |    |            |
| - basic  | \$<br>0.11      | \$ | 0.01       | \$<br>0.14      | \$ | 0.03       |
| - diluted  | \$<br>0.11      | \$ | 0.01       | \$<br>0.14      | \$ | 0.03       |
| Weighted-average shares outstanding                    |                 |    |            |                 |    |            |
| - basic  | 20,471,621      | 2  | 20,445,560 | 20,458,842      | 2  | 20,340,000 |
| - diluted  | 20,661,719      | 2  | 21,207,645 | 20,719,714      | 2  | 21,302,119 |

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

|   | Six Months Ended June 30, |             |    |             |
|---|---------------------------|-------------|----|-------------|
|   | 2011                      |             |    | 2010        |
| Cash flows from operating activities:                                 |                           |             |    |             |
| Net income  | \$                        | 2,879,431   | \$ | 593,275     |
| Adjustments to reconcile net income to net cash provided by           |                           |             |    |             |
| operating activities:   |                           |             |    |             |
| Depreciation and amortization expense                                 |                           | 527,301     |    | 463,676     |
| Non-employee equity compensation                                      |                           | 44,574      |    | 45,554      |
| Stock-based compensation - employee stock options                     |                           | 315,513     |    | 318,139     |
| Excess tax benefit derived from exercise of stock options             |                           | (1,516,569) |    | (462,814)   |
| Non-cash interest expense   |                           | 123,654     |    | 132,866     |
| Net changes in assets and liabilities affecting operating activities: |                           |             |    |             |
| Accounts receivable   |                           | 325,760     |    | 2,216,456   |
| Inventory   |                           | 230,591     |    | (3,144,216) |
| Other current assets and other assets                                 |                           | 704         |    | 349,777     |
| Accounts payable and other accrued liabilities                        |                           | 2,009,529   |    | 337,995     |
| Other long-term obligations   |                           | (5,141)     |    | (95,541)    |
| Net cash provided by operating activities                             |                           | 4,935,347   |    | 755,167     |
| Cash flows from investing activities:                                 |                           |             |    |             |
| Additions to property and equipment                                   |                           | (105,838)   |    | (126,315)   |
| Additions to patents  |                           | (46,344)    |    | (80,734)    |
| Net cash used in investing activities                                 |                           | (152,182)   |    | (207,049)   |
| Cash flows from financing activities:                                 |                           |             |    |             |
| Principal payments on note payable                                    |                           | (1,333,334) |    | (6,061,973) |
| Costs of financing for long-term debt and credit facility             |                           | -           |    | (55,000)    |

| Proceeds from exercise of stock options                      | 523,507       | 979,292       |
|--|---------------|---------------|
| Excess tax benefit derived from exercise of stock options    | 1,516,569     | 462,814       |
| Payments made in connection with repurchase of common shares | (1,551,847)   | (3,079,628)   |
| Net cash used in financing activities                        | (845,105)     | (7,754,495)   |
| Net increase (decrease) in cash and cash equivalents         | 3,938,060     | (7,206,377)   |
| Cash and cash equivalents at beginning of period             | 65,893,970    | 78,701,682    |
| Cash and cash equivalents at end of period                   | \$ 69,832,030 | \$ 71,495,305 |
| Supplemental disclosure of cash flow information:            |               |               |
| Non-cash investing and financing activities:                 |               |               |
| Common shares repurchased during period but not paid         |               |               |
| as of the end of the period                                  | -             | 203,802       |
| Additions to property and equipment not paid as of           |               |               |
| the end of the period  | 40,070        | -             |

SOURCE Cumberland Pharmaceuticals Inc.

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