



August 4, 2015

Cumberland Pharmaceuticals Reports Second Quarter & Year To Date 2015 Financial Results

- Hepatoren® and Boxaban® Clinical Studies Enrollment Progressing - sNDA for Caldolor® Pediatric Label Update Advances

NASHVILLE, Tenn., Aug. 4, 2015 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced second quarter 2015 financial results with Net Revenues of \$8.9 million and Adjusted Earnings of \$1.6 million or \$0.09 per share. Net Revenues for the first six months of 2015 were \$17.6 million with Adjusted Earnings of \$3.2 million or \$0.18 per share.



As of June 30, 2015 the Company had approximately \$93 million in total assets including \$53 million in cash and investments. Total Liabilities were \$14.2 million and Total Shareholder's Equity was \$78.7 million. Cumberland also had nearly \$44 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

QUARTER HIGHLIGHTS:

- Progressing with the Caldolor® *supplemental New Drug Application* (sNDA) requesting a label update with pediatric information.
- Patient enrollment well underway with the Company's late stage product candidates, Boxaban® and Hepatoren®, with Phase II studies expected to finish by the end of 2015.
- *Cumberland Emerging Technologies (CET)*, which is providing the Company with a long term pipeline of new product candidates, renewed collaboration agreements with the University of Mississippi School of Pharmacy and the University of Tennessee Research Foundation, and expanded activities with Vanderbilt University.

"We continued to make progress in the second quarter towards our goal of building a company that offers long-term, sustainable growth," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We remain in a strong financial position with a solid balance sheet and profitable operations. We are working to maximize the potential of our five commercial products and actively pursuing the addition of new brands to our portfolio."

FINANCIAL RESULTS:

Net Revenue: For the three months ended June 30, 2015, net revenues were \$8.9 million, compared to \$9.8 million for the prior year period. Net revenue by product for the three months ended June 30, 2015, included \$4.1 million for Kristalose®, \$2.8 million for Acetadote®, including \$1.8 million for the Company's Authorized Generic, \$0.9 million for Omeclamox®-Pak, \$0.5 million for Caldolor®, and \$0.5 million for Vaprisol®.

For the six months ended June 30, 2015, net revenues were \$17.6 million compared to \$17.8 million for the six months ended June 30, 2014.

Operating Expenses: Total operating expenses for the three months ended June 30, 2015 were \$8.2 million, compared to \$8.5 million during the prior year period.

Total operating expenses for the first six months of 2015 were just under \$17 million, compared to \$16.2 million for 2014. These expenses include a \$1.2 million FDA fee during the first quarter associated with the submission of the Caldolor pediatric data and request to update that product's label.

Adjusted Earnings: Adjusted Earnings for the second quarter were \$1.6 million or \$0.09 per share, compared to \$1.8 million

or \$0.10 per share for the prior year period.

Adjusted Earnings for the six months ended June 30, 2015 were \$3.2 million, or \$0.18 per share compared to \$2.7 million, or \$0.15 a share in 2014. The definition and reconciliation of Adjusted Earnings is provided in this release.

Balance Sheet: At June 30, 2015, Cumberland had \$53.1 million in cash and marketable securities, with approximately \$38.9 million in cash and equivalents and \$14.1 million in marketable securities. Total assets at June 30, 2015 were \$92.9 million. Total Liabilities were \$14.2 million including \$1.7 million outstanding on our revolving line of credit, resulting in Total Shareholder's Equity of \$78.7 million. Cumberland also had \$43.9 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 that evaluated the product in both children and adults. Following the completion of these Phase IV studies, 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.

Cumberland is making progress with the FDA regarding the review of the sNDA and anticipates receiving a decision about these requested updates toward the end of this year.

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 study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study is stratified into Type I or Type II patients with HRS based upon the progression of their disease.

The Company completed enrollment of the Type II patients and previously announced favorable top line results from that study. Enrollment of the remaining patients in the Type I HRS cohort is well underway and is expected to finish by the end of 2015.

Boxaban®

The Company is developing 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. No approved pharmaceutical treatment currently exists for AERD in this country.

Cumberland 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. Enrollment is well underway in this multi-center study. The Company looks forward to announcing findings from this study later this year.

Cumberland Emerging Technologies (CET)

During the second quarter, Cumberland Emerging Technologies renewed collaboration agreements with the University of Mississippi School of Pharmacy and the University of Tennessee Research Foundation, while expanding activities with Vanderbilt University. CET also announced a major expansion in the tenant footprint at the CET Life Sciences Center with the arrival of InvisionHeart, Inc. which now occupies nearly 4,400 square feet of office and manufacturing space.

CET was formed to identify biopharmaceutical innovation at regional academic research centers and team with the scientists to advance their research and provide a long term pipeline of new product candidates. The Life Sciences Center has a growing number of successful tenants and graduates and provides laboratory and office space, equipment and infrastructure to early-stage biomedical ventures.

Conference Call and Webcast

A conference call and live Internet webcast will be held on Tuesday, August 4, 2015 at 4:30 p.m. Eastern Time to discuss the Company's second 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

73155393. The live webcast and rebroadcast can be accessed via Cumberland's website at <http://investor.shareholder.com/cpix/events.cfm>.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's five marketed products include Acetadote[®] (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor[®] (*ibuprofen*) Injection, for the treatment of pain and fever, 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* infection and duodenal ulcer disease. Cumberland is developing Hepatoren[®] (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome and Boxaban[®] (*ifetroban*) Oral Capsule for the 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.

About Acetadote[®] (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.

About Caldolor[®] (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.

About Kristalose[®] (lactulose) Oral Solution

Kristalose is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia and 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.

About Omeclamox[®]-Pak (omeprazole, clarithromycin, amoxicillin)

Omeprazole is an antisecretory drug, which works by decreasing the amount of acid the stomach produces. Clarithromycin and amoxicillin are antibacterial drugs, which inhibit the growth of bacteria allowing the stomach lining to heal. Omeclamox-Pak is contraindicated in patients with a history of hypersensitivity to omeprazole, any macrolide antibiotic or penicillin. The safety and effectiveness of Omeclamox-Pak in the pediatric population has not yet been established. Omeclamox-Pak was approved by the U.S. Food and Drug Administration in 2011. For full prescribing information, visit www.omeclamox.com.

About Vaprisol[®] (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.

About Cumberland Emerging Technologies (CET)

Cumberland Emerging Technologies, Inc. (www.cet-fund.com) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and Gloria Pharmaceuticals. The mission of CET is to bring biomedical technologies and products conceived at Vanderbilt University and other regional research centers to the marketplace. CET helps manage the development and commercialization process for select projects, and provides expertise on intellectual property, regulatory, manufacturing and marketing issues that are critical to successful new biomedical products. CET's Life Sciences Center, located in Nashville, Tennessee, provides laboratory space, equipment and infrastructure to early-stage life sciences companies.

Forward-Looking Statements

This 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)

	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 38,940,681	\$ 39,866,037
Marketable securities	14,136,925	14,841,418
Accounts receivable, net of allowances	5,808,014	5,504,728
Inventories	4,795,543	5,600,319
Other current assets	4,519,796	5,002,469
Total current assets	68,200,959	70,814,971
Property and equipment, net	568,759	651,030
Intangible assets, net	21,760,085	21,568,541
Other assets	2,386,924	2,370,572
Total assets	<u>\$ 92,916,727</u>	<u>\$ 95,405,114</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 4,110,082	\$ 3,242,713
Other current liabilities	7,437,924	10,506,769
Total current liabilities	11,548,006	13,749,482
Revolving line of credit	1,700,000	—
Other long-term liabilities	966,829	902,841
Total liabilities	<u>14,214,835</u>	<u>14,652,323</u>
Commitments and contingencies		
Equity:		

Shareholders' equity:

Common stock—no par value; 100,000,000 shares authorized;
16,703,493 and 17,118,993 shares issued and outstanding as of June
30, 2015 and December 31, 2014, respectively

Retained earnings

Total shareholders' equity

Noncontrolling interests

Total equity

Total liabilities and equity

59,470,701	61,942,410
19,270,542	18,818,263
78,741,243	80,760,673
(39,351)	(7,882)
78,701,892	80,752,791
\$ 92,916,727	\$ 95,405,114

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Net revenues	\$ 8,909,741	\$ 9,750,168	\$ 17,596,515	\$ 17,843,412
Costs and expenses:				
Cost of products sold	1,237,001	1,298,816	2,398,842	2,352,533
Selling and marketing	3,505,486	3,930,082	7,036,401	7,544,013
Research and development	828,070	861,154	2,687,082	1,687,527
General and administrative	2,153,562	2,140,249	3,797,703	4,037,466
Amortization	511,691	304,258	998,440	598,213
Total costs and expenses	8,235,810	8,534,559	16,918,468	16,219,752
Operating income	673,931	1,215,609	678,047	1,623,660
Interest income	57,846	29,544	114,248	96,887
Interest expense	(18,489)	(12,278)	(34,039)	(24,481)
Income before income taxes	713,288	1,232,875	758,256	1,696,066
Income tax expense	(318,990)	(523,339)	(337,446)	(711,348)
Net income	394,298	709,536	420,810	984,718
Net loss at subsidiary attributable to noncontrolling interests	11,700	13,034	31,469	24,172
Net income attributable to common shareholders	\$ 405,998	\$ 722,570	\$ 452,279	\$ 1,008,890
Earnings per share attributable to common shareholders				
- basic	\$ 0.02	\$ 0.04	\$ 0.03	\$ 0.06
- diluted	\$ 0.02	\$ 0.04	\$ 0.03	\$ 0.06
Weighted-average shares outstanding				
- basic	16,820,725	17,743,395	16,916,193	17,825,174
- diluted	17,184,345	18,025,913	17,294,087	18,093,391
Comprehensive income attributable to common shareholders	405,998	722,570	\$ 452,279	\$ 1,008,890
Net loss at subsidiary attributable to noncontrolling interests	11,700	13,034	31,469	24,172
Total comprehensive income	\$ 394,298	\$ 709,536	\$ 420,810	\$ 984,718

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

	Six months ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net income	\$ 420,810	\$ 984,718
Adjustments to reconcile net income to net cash provided by operating activities:		

Depreciation and amortization expense	1,143,002	800,231
Deferred tax benefit	23,593	—
Share-based compensation	549,603	325,344
Excess tax benefit derived from exercise of stock options	(313,955)	(711,348)
Noncash interest expense	19,782	12,038
Noncash investment (gains) losses	(44,870)	181,950
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:		
Accounts receivable	(303,286)	(1,484,052)
Inventory	804,776	136,039
Other current assets and other assets	422,946	(701,604)
Accounts payable and other current liabilities	1,265,725	2,165,828
Other long-term liabilities	79,742	109,244
Net cash provided by operating activities	<u>2,448,885</u>	<u>1,818,388</u>
Cash flows from investing activities:		
Additions to property and equipment	(62,291)	(48,239)
Purchases of marketable securities	(4,046,142)	(3,254,903)
Proceeds from sale of marketable securities	4,795,505	2,267,082
Cash paid for acquisitions	—	(2,000,000)
Additions to intangible assets	(2,740,001)	(732,072)
Net cash used in investing activities	<u>(2,052,929)</u>	<u>(3,768,132)</u>
Cash flows from financing activities:		
Net borrowings on line of credit	1,700,000	—
Exercise of stock options	21,366	—
Excess tax benefit derived from exercise of stock options	313,955	711,348
Cash settlement of contingent consideration	(1,618,983)	—
Sale of subsidiary shares to noncontrolling interest	—	1,000,005
Repurchase of common shares	(3,356,633)	(1,580,225)
Net cash (used in) provided by financing activities	<u>(1,321,312)</u>	<u>131,128</u>
Net decrease in cash and cash equivalents	(925,356)	(1,818,616)
Cash and cash equivalents at beginning of period	<u>39,866,037</u>	<u>40,869,457</u>
Cash and cash equivalents at end of period	<u>\$ 38,940,681</u>	<u>\$ 39,050,841</u>

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 June 30, 2015		Three months ended June 30, 2014	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income attributable to common shareholders	\$ 405,998	\$ 0.02	\$ 722,570	\$ 0.04
Less: Net loss at subsidiary attributable to noncontrolling interests	11,700	—	13,034	—
Net income	<u>394,298</u>	<u>0.02</u>	<u>709,536</u>	<u>0.04</u>
Adjustments to net income				
Income tax expense	318,990	0.02	523,339	0.03
Depreciation and amortization expense	581,754	0.03	405,096	0.02
Share-based compensation expense (a)	303,128	0.02	199,586	0.01
Interest income	(57,846)	—	(29,544)	—
Interest expense	18,489	—	12,278	—
Adjusted Earnings and Adjusted Diluted Earnings Per Share	<u>\$ 1,558,813</u>	<u>\$ 0.09</u>	<u>\$ 1,820,291</u>	<u>\$ 0.10</u>
Diluted weighted-average common shares outstanding:		<u>17,184,345</u>		<u>18,025,913</u>

	Six months ended June 30, 2015		Six months ended June 30, 2014	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income attributable to common shareholders	\$ 452,279	\$ 0.03	\$ 1,008,890	\$ 0.06
Less: Net loss at subsidiary attributable to noncontrolling				

interests	31,469	—	24,172	—
Net income	420,810	0.02	984,718	0.05
Adjustments to net income				
Income tax expense	337,446	0.02	711,348	0.04
Depreciation and amortization expense	1,143,002	0.07	800,231	0.04
Share-based compensation expense (a)	549,603	0.03	325,344	0.02
Product label expansion fees (b)	1,167,600	0.07	—	—
Gain on contingent consideration (c)	(381,037)	(0.02)	—	—
Interest income	(114,248)	(0.01)	(96,887)	(0.01)
Interest expense	34,039	—	24,481	—
Adjusted Earnings and Adjusted Diluted Earnings Per Share	\$ 3,157,215	\$ 0.18	\$ 2,749,235	\$ 0.15
Diluted weighted-average common shares outstanding:		17,294,087		18,093,391

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.

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

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-reports-second-quarter--year-to-date-2015-financial-results-300123395.html>

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media