



November 7, 2017

## Cumberland Pharmaceutical Reports 27% Revenue Growth In The Third Quarter

- Launched Totect® in the United States
- Implemented Kristalose® Co-Promotion Agreement

NASHVILLE, Tenn., Nov. 7, 2017 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care, gastroenterology, and oncology supportive care today announced third quarter 2017 financial results with Net Revenues of \$11.2 million, up 27% over the prior year quarter. It was the fifth consecutive quarter of year over year revenue growth for the Company, and during the first nine months of 2017 Net Revenues increased 23% over the prior year period.



### QUARTER HIGHLIGHTS:

- l Initiated distribution, sales and promotion of Totect®, Cumberland's branded dexrazoxane and second oncology support drug, in the United States.
- l Launched a new co-promotion agreement for Kristalose®, more than doubling the number of physicians called on in support of the brand.
- l Continued to progress Phase II clinical studies for the four advanced pipeline programs.

"Over the past year, we have dramatically expanded our product portfolio and reach, through a series of successful business development initiatives. As a result, we are now marketing seven FDA-approved brands," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "This diversified strategy has driven our double-digit top-line growth over the last year, and our momentum is strong. Our goal remains the same - deliver sustainable revenue growth and profitability through the delivery of high quality medicines."

### KEY QUARTER DEVELOPMENTS:

#### **Totect®**

In late July 2017, Cumberland Pharmaceuticals initiated distribution and sale of Totect (dexrazoxane hydrochloride) in the United States. This followed the FDA approval of the updated labeling and product manufacturer for the product. In late September 2017, Cumberland announced the launch of sales promotional support for Totect in the United States.

Totect is an FDA-approved hospital based emergency oncology intervention drug, indicated to treat the toxic effects of anthracycline chemotherapy. It treats anthracycline extravasation that occurs when the injected medication escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications. Totect can limit such damage without the need for additional surgeries or procedures and enables patients to continue their essential anti-cancer treatment.

In preparation for the Totect promotional launch, the Company completed the training of its sales and medical organization, stocked the product at select wholesalers serving hospitals, and introduced the brand's website. Totect is supported by Cumberland's hospital sales force. Totect was launched during a national shortage of dexrazoxane, resulting in strong initial demand for the product. It's Cumberland's second oncology support product licensed through a Strategic Alliance with Clinigen Group plc.

#### **Kristalose®**

During the third quarter 2017, Cumberland fully implemented the co-promotion arrangements with Poly Pharmaceuticals,

Inc. ("Poly") following a multi-year agreement signed in April 2017.

Poly is a privately held U.S. specialty pharmaceutical company that is featuring Kristalose to an expanded number of physicians. Poly's sales organization is more than doubling the number of nationwide physicians called upon with Kristalose bringing the brand's message to thousands of additional medical professionals. Cumberland continues to manage the national marketing, distribution, and regulatory activities associated with the product.

## **FINANCIAL RESULTS:**

**Net Revenue:** For the three months ended September 30, 2017, net revenues were \$11.2 million, a 27% increase compared to \$8.8 million for the prior year period. Net revenue by product for the three months ended September 30, 2017, included \$2.9 million for Totect<sup>®</sup>, \$2.7 million for Kristalose<sup>®</sup> and \$2.6 million for Ethyol<sup>®</sup>. Net revenue for the Company's other brands totaled \$2.8 million for the third quarter with \$1.3 million for Acetadote<sup>®</sup> (including the brand and Company's Authorized Generic) \$0.9 million for Caldolor<sup>®</sup>, \$0.4 million for Vaprisol<sup>®</sup>, and \$0.2 million for Omeclamox<sup>®</sup>-Pak.

**Operating Expenses:** Total operating expenses for the three months ended September 30, 2017 were \$12.0 million, compared to \$8.7 million during the prior year period. The primary reasons for this increase were the additional cost of goods sold and royalty expenses associated with the growth in sales.

**Earnings:** Net income (loss) for the third quarter 2017 was \$(0.7) million or \$(0.05) per diluted share, compared to \$0.1 million or \$0.01 a share for the prior year period.

Adjusted Earnings for the third quarter were \$0.1 million or \$0.01 per diluted share, compared to \$1.0 million or \$0.06 per diluted share for the prior year period. The definition and reconciliation of Adjusted Earnings to net income is provided in this release.

**Balance Sheet:** At September 30, 2017, Cumberland had \$50.1 million in cash and marketable securities, including approximately \$42.0 million in cash and equivalents. Total Assets at September 30, 2017 were \$90.4 million. Total Liabilities were \$25.4 million, including \$8.0 million outstanding on the Company's revolving line of credit, resulting in Total Shareholder's Equity of \$65.1 million.

Cumberland also has approximately \$44 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

## **Conference Call and Webcast**

A conference call and live Internet webcast will be held on Tuesday, November 7, 2017 at 4:30 p.m. Eastern Time to discuss the Company's third quarter 2017 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 48389040. 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 delivery of high-quality prescription brands to improve patient care. The Company develops, acquires, and commercializes brands for the hospital acute care, gastroenterology, and oncology market segments.

The Company's portfolio of FDA approved brands includes:

- 1 **Acetadote<sup>®</sup>** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- 1 **Caldolor<sup>®</sup>** (*ibuprofen*) Injection, for the treatment of pain and fever;
- 1 **Kristalose<sup>®</sup>** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- 1 **Omeclamox<sup>®</sup>-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- 1 **Vaprisol<sup>®</sup>** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- 1 **Ethyol<sup>®</sup>** (*amifostine*) Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative

radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;

- 1 **Totect**<sup>®</sup> (*dexrazoxane hydrochloride*) Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).

Cumberland's pipeline of product candidates includes:

- 1 **Hepatoren**<sup>®</sup> (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- 1 **Boxaban**<sup>®</sup> (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- 1 **Vasculan**<sup>®</sup> (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of patients with the systemic sclerosis (SSc) form of autoimmune disease;
- 1 **Portaban**<sup>™</sup> (*ifetroban*) Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease;
- 1 **Methotrexate** (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psoriasis.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

### **About Acetadote<sup>®</sup> (acetylcysteine) Injection**

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma or where there is a history of bronchospasm. The total volume administered should be adjusted for patients weighing less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure and death. For full prescribing information, visit [www.acetadote.com](http://www.acetadote.com).

### **About Caldolor<sup>®</sup> (ibuprofen) Injection**

Caldolor is indicated in adults and pediatric patients 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. 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 a history of asthma or other allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit [www.caldolor.com](http://www.caldolor.com).

### **About Kristalose<sup>®</sup> (lactulose) Oral Solution**

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

Kristalose is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. For full prescribing information, visit [www.kristalose.com](http://www.kristalose.com).

### **About Omeclamox<sup>®</sup>-Pak (omeprazole, clarithromycin, amoxicillin)**

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

### **About Vaprisol® (conivaptan hydrochloride) Injection**

Vaprisol is an intravenous treatment for hyponatremia used in the critical care setting. Hyponatremia is an electrolyte disturbance in which sodium ion concentration in blood plasma is lower than normal. This can be associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia. The product is a vasopressin receptor antagonist that raises serum sodium levels and promotes free water secretion. Vaprisol was approved by the U.S. Food and Drug Administration in 2005 for euvolemic hyponatremia and in 2007 for hypervolemic hyponatremia. For full prescribing information, visit [www.vaprisol.com](http://www.vaprisol.com).

### **About Ethyol® (amifostine) Injection**

Ethyol is indicated to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. It is indicated to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands.

### **About Totect® (dexrazoxane) Injection**

Totect is an anthracycline extravasation agent approved by the United States Food and Drug Administration. Anthracyclines are used to treat many types of cancer and are among the most common cancer therapies.

Anthracycline extravasation occurs when there is accidental leaking of the intravenously-administered medication into the surrounding tissues. Anthracycline extravasation can result in serious complications for cancer patients including tissue necrosis with skin ulceration. In addition to tissue damage, an anthracycline extravasation may cause damage to the nerves, tendons, muscle, and joints. For more information please visit [www.totect.com](http://www.totect.com).

### **About Cumberland Emerging Technologies (CET)**

Cumberland Emerging Technologies, Inc. ([www.cet-fund.com](http://www.cet-fund.com)) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and Gloria Pharmaceuticals. The mission of CET is to advance biomedical technologies and products conceived at Vanderbilt University and other regional research centers towards 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, provides laboratory space, equipment and infrastructure for CET's activities and other early-stage life sciences ventures.

### **Forward-Looking Statements**

This announcement 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 Annual Report on Form 10-K and subsequent reports on Form 10-Q 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.

	September 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 42,018,953	\$ 34,510,330
Marketable securities	8,055,017	15,622,111
Accounts receivable, net of allowances	7,205,378	7,330,127
Inventories, net	5,857,468	5,371,729
Other current assets	2,945,999	2,710,967
Total current assets	66,082,815	65,545,264
Property and equipment, net	474,748	464,454
Intangible assets, net	21,540,316	22,154,176
Other assets	2,253,178	2,120,742
Deferred tax assets, net	—	3,119,930
Total assets	<u>\$ 90,351,057</u>	<u>\$ 93,404,566</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,921,600	\$ 8,036,611
Other current liabilities	7,876,491	6,755,652
Total current liabilities	15,798,091	14,792,263
Revolving line of credit	8,000,000	4,100,000
Other long-term liabilities	1,634,936	1,391,484
Total liabilities	25,433,027	20,283,747
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 15,781,736 and 16,074,176 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	52,585,566	54,643,268
Retained earnings	12,509,767	18,604,931
Total shareholders' equity	65,095,333	73,248,199
Noncontrolling interests	(177,303)	(127,380)
Total equity	64,918,030	73,120,819
Total liabilities and equity	<u>\$ 90,351,057</u>	<u>\$ 93,404,566</u>

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Net revenues	\$ 11,196,961	\$ 8,791,753	\$ 29,500,843	\$ 23,944,120
Costs and expenses:				
Cost of products sold	2,166,353	1,973,948	5,216,776	4,353,148
Selling and marketing	6,226,438	3,614,714	16,174,391	10,585,955
Research and development	943,162	644,662	2,921,951	2,029,914
General and administrative	2,090,785	1,865,575	6,554,158	5,817,943
Amortization	609,572	562,722	1,811,589	1,632,920
Total costs and expenses	12,036,310	8,661,621	32,678,865	24,419,880
Operating income (loss)	(839,349)	130,132	(3,178,022)	(475,760)
Interest income	94,833	51,636	216,849	160,248
Interest expense	(8,902)	(29,088)	(70,646)	(77,777)
Income (loss) before income taxes	(753,418)	152,680	(3,031,819)	(393,289)
Income tax (expense) benefit	(3,822)	(57,192)	(4,196,192)	159,282
Net income (loss)	(757,240)	95,488	(7,228,011)	(234,007)
Net loss at subsidiary attributable to noncontrolling interests	14,209	10,678	49,923	39,018
Net income (loss) attributable to common shareholders	<u>\$ (743,031)</u>	<u>\$ 106,166</u>	<u>\$ (7,178,088)</u>	<u>\$ (194,989)</u>
Earnings (loss) per share attributable to common shareholders				
- basic	\$ (0.05)	\$ 0.01	\$ (0.45)	\$ (0.01)

- diluted	\$ (0.05)	\$ 0.01	\$ (0.45)	\$ (0.01)
Weighted-average shares outstanding				
- basic	15,867,159	16,217,442	15,973,737	16,268,579
- diluted	15,867,159	16,504,568	15,973,737	16,268,579
Comprehensive income (loss) attributable to common shareholders	(743,031)	106,166	(7,178,088)	(194,989)
Net loss at subsidiary attributable to noncontrolling interests	14,209	10,678	49,923	39,018
Total comprehensive income (loss)	<u>\$ (757,240)</u>	<u>\$ 95,488</u>	<u>\$ (7,228,011)</u>	<u>\$ (234,007)</u>

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

	<b>Nine months ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
Cash flows from operating activities:		
Net income (loss)	\$ (7,228,011)	\$ (234,007)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization expense	1,974,194	1,785,057
Deferred tax expense	4,293,963	662,689
Share-based compensation	849,198	623,504
Excess tax (benefit) expense derived from exercise of stock options	(91,109)	907,270
Noncash interest expense	60,708	61,224
Noncash investment gains	(48,084)	(69,140)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	124,748	(595,180)
Inventories	(485,739)	(713,084)
Other current assets and other assets	(428,176)	(1,241,372)
Accounts payable and other current liabilities	640,453	(1,705,007)
Other long-term liabilities	239,703	267,730
Net cash used in operating activities	<u>(98,152)</u>	<u>(250,316)</u>
Cash flows from investing activities:		
Additions to property and equipment	(172,899)	(98,275)
Purchases of marketable securities	(2,029,414)	(3,643,894)
Proceeds from sale of marketable securities	9,644,592	3,676,745
Additions to intangible assets	(841,647)	(1,554,410)
Net cash provided by (used in) investing activities	<u>6,600,632</u>	<u>(1,619,834)</u>
Cash flows from financing activities:		
Net borrowings on line of credit	3,900,000	2,000,000
Excess tax expense derived from exercise of stock options	—	(907,270)
Repurchase of common shares	(2,893,857)	(1,879,395)
Net cash provided by (used in) financing activities	<u>1,006,143</u>	<u>(786,665)</u>
Net increase (decrease) in cash and cash equivalents	7,508,623	(2,656,815)
Cash and cash equivalents at beginning of period	34,510,330	38,203,059
Cash and cash equivalents at end of period	<u>\$ 42,018,953</u>	<u>\$ 35,546,244</u>

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

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

	<b>Three months ended</b>		<b>Three months ended</b>	
	<b>September 30, 2017</b>		<b>September 30, 2016</b>	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact

<b>Net income (loss) attributable to common shareholders</b>	\$ (743,031)	\$ (0.05)	\$ 106,166	\$ 0.01
Less: Net loss at subsidiary attributable to noncontrolling interests	14,209	—	10,678	—
Net income (loss)	(757,240)	(0.05)	95,488	0.01
Adjustments to net income (loss)				
Income tax	3,822	—	57,192	—
Depreciation and amortization	659,901	0.04	613,620	0.04
Share-based compensation (a)	297,943	0.02	215,278	0.01
Interest income	(94,833)	(0.01)	(51,636)	—
Interest expense	8,902	—	29,088	—
<b>Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share</b>	<u>\$ 118,495</u>	<u>\$ 0.01</u>	<u>\$ 959,030</u>	<u>\$ 0.06</u>
Diluted weighted-average common shares outstanding:		<u>16,280,883</u>		<u>16,504,568</u>

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:

- 1 **Adjusted Earnings (loss):** net income (loss) adjusted for the impact of income taxes, depreciation and amortization expense, share-based compensation and interest income and interest expense.
  - (a) Represents the share-based compensation of Cumberland.
- 1 **Adjusted Diluted Earnings (loss) Per Share:** Adjusted Earnings (loss) divided by diluted weighted-average common shares outstanding.

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