



May 15, 2017

Cumberland Pharmaceuticals Reports Revenue Growth Of 25% In First Quarter 2017

- Acquired exclusive U.S. Rights to Totect®
- Successfully defended Acetadote® patent

NASHVILLE, Tenn., May 15, 2017 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced first quarter 2017 financial results with Net Revenues of \$9.6 million and Adjusted Earnings of \$0.3 million or \$0.02 per share. As of March 31, 2017, the Company had approximately \$92 million in Total Assets including \$50 million in cash and marketable securities.



QUARTER HIGHLIGHTS:

- | Announced the acquisition of exclusive U.S. rights to Totect® through an agreement with the Clinigen Group plc.
- | Two new Caldolor® study manuscripts published, adding to the growing body of literature supporting the product.
- | Successfully defended Acetadote® patent in Federal Appeals Court.
- | Welcomed Kenneth Krogulski, President and Chief Executive Officer of Berkshire Asset Management LLC, to the Company's Board of Directors.

"We are off to a fast start in 2017," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We have already had a series of positive developments this year that will make important contributions toward our goal of delivering long-term sustainable growth."

KEY DEVELOPMENTS:

Totect®

Cumberland announced an agreement with the Clinigen Group plc to acquire exclusive U.S. rights to the FDA approved oncology support drug, Totect®. This is the second product Clinigen has licensed to Cumberland under a strategic alliance entered into between the companies.

Totect is an FDA-approved emergency oncology intervention which is indicated to reverse the toxic effects of extravasation associated with anthracycline chemotherapy. Extravasation occurs when an injected medicine escapes from the blood vessels and circulates into surrounding tissues in the body causing severe damage and serious complications. Totect can reverse such damage without the need for additional surgeries and procedures, enabling patients to continue their essential anti-cancer treatment.

Under the terms of the agreement, Cumberland will be responsible for all marketing, promotion, and distribution of the product in the United States. Clinigen will retain responsibility for manufacturing and regulatory management of the product. The U.S. launch of Totect is currently expected in late 2017.

Caldolor®

Early in the first quarter, Cumberland announced the publication of a multicenter clinical study demonstrating that Caldolor® delivered significant fever reduction in hospitalized children.

The study evaluated the efficacy and safety of intravenous ibuprofen in pediatric patients, six months and older, with fever. Results from the study demonstrated that a single 10 mg/kg dose of intravenous ibuprofen provided a significant reduction

of temperature in the pediatric patients and provides an effective option for reducing fever in children. This pivotal data published in the British BMC Pediatrics Journal supported the FDA approval of Caldolor for use in this pediatric patient population.

In March 2017, the Company announced the publication of a trial providing evidence that using Caldolor in multimodal pain control strategies improves postoperative pain control and reduces opioid use in patients undergoing surgery.

The trial compared outcomes in two groups of patients treated with multimodal pain management protocols following transsphenoidal surgery for pituitary lesions: Group 1 patients treated intraoperatively with IV Ibuprofen (Caldolor 800 mg.), scheduled oral acetaminophen and rescue opioids, versus Group 2 patients treated with IV saline placebo, scheduled oral acetaminophen, and rescue opioids. The patients receiving Caldolor demonstrated a significant reduction of 43% in their mean pain scores compared with those receiving placebo. Opioid use was also significantly impacted with a 58% reduction in the Caldolor Group patients compared to Placebo Group patients.

The trial was conducted at the Department of Neurosurgery, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center in Phoenix, Arizona. The study results were published in the Journal of Neurosurgery, March 2017.

Acetadote®

In January 2017, a Federal Appeals Court affirmed the District Court ruling in the Company's favor in its lawsuit for infringement of its Acetadote Patent. The Appeals Court opinion affirmed the District Court's ruling, expressly rejecting validity challenges, and upholding Cumberland's Patent. Since 2012, the USPTO has a series of patents associated with Acetadote, Cumberland's injectable formulation of N-Acetylcysteine ("NAC") for the treatment of acetaminophen overdose.

Board of Directors Appointment

In January 2017, Cumberland announced the addition of Kenneth J. Krogulski, CFA to the Company's Board of Directors. Mr. Krogulski is the President and Chief Executive Officer of Berkshire Asset Management LLC. He is also the Chief Investment Officer of Berkshire, an SEC-registered investment advisory firm. Mr. Krogulski has over 38 years of experience in security analysis and portfolio management. Under his leadership, Berkshire's assets under supervision have grown from \$600 million in 2006 to over \$1.7 billion in 2017.

FINANCIAL RESULTS:

Net Revenue: For the three months ended March 31, 2017, net revenues were \$9.6 million, compared to \$7.7 million for the prior year period. Net revenue by product for the three months ended March 31, 2017, included \$3.7 million for Ethylol®, \$2.4 million for Kristalose®, \$1.3 million for Acetadote® (including \$0.9 million for the Company's Authorized Generic) \$0.8 million for Caldolor®, \$0.7 million for Vaprisol® and \$0.6 million for Omeclamox®-Pak.

Operating Expenses: Total operating expenses for the three months ended March 31, 2017 were \$10.3 million, compared to \$8.2 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 first quarter of 2017 was \$(1.3) million or \$(0.08) per diluted share, compared to \$(0.3) million or \$(.02) a share for the prior year period. This difference was impacted by a non-cash charge to taxes associated with an increase in the valuation allowance for prior Research and Development tax credits. Adjusted Earnings for the first quarter were \$0.3 million or \$0.02 per diluted share, similar to the prior year period. The definition and reconciliation of Adjusted Earnings to net income (loss) is provided in this release.

Balance Sheet: At March 31, 2017, Cumberland had \$50.5 million in cash and marketable securities, including approximately \$35.0 million in cash and equivalents. Total Assets at March 31, 2017 were \$91.9 million. Total Liabilities were \$19.6 million, including \$4.1 million outstanding on the Company's revolving line of credit, resulting in Total Shareholder's Equity of \$72.4 million.

Cumberland also has approximately \$44 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options. As part of the adoption of the recent Stock Compensation standard, these tax net operating loss carryforwards resulted in the addition of a new tax asset to the balance sheet along with a significant allowance. The net change in deferred tax assets was an increase of \$0.41 million for the first quarter.

Conference Call and Webcast

A conference call and live Internet webcast will be held on Monday, May 15, 2017 at 4:30 p.m. Eastern Time to discuss the Company's first 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 11376419. 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 acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's six 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, and Ethyol[®] (amifostine) for Injection, for the treatment of oncology patients. Cumberland is developing Hepatoren[®] (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome, Boxaban[®] (*ifetroban*) Oral Capsule for the treatment of Aspirin-Exacerbated Respiratory Disease, Vasculan[™] (*ifetroban*) Oral Capsule for the treatment of systemic sclerosis, and Portaban[™], for the treatment of portal hypertension. 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 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.

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 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.

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 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 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 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, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 34,974,242	\$ 34,510,330
Marketable securities	15,478,547	15,622,111
Accounts receivable, net of allowances	4,934,779	7,330,127
Inventories, net	5,646,904	5,371,729

Other current assets	2,507,876	2,710,967
Total current assets	63,542,348	65,545,264
Property and equipment, net	538,358	464,454
Intangible assets, net	22,079,180	22,154,176
Other assets	2,164,236	2,120,742
Deferred tax assets, net	3,537,483	3,119,930
Total assets	91,861,605	93,404,566
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 7,269,644	\$ 8,036,611
Other current liabilities	6,801,185	6,755,652
Total current liabilities	14,070,829	14,792,263
Revolving line of credit	4,100,000	4,100,000
Other long-term liabilities	1,478,623	1,391,484
Total liabilities	19,649,452	20,283,747
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,065,301 and 16,074,176 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	53,945,247	54,643,268
Retained earnings	18,413,409	18,604,931
Total shareholders' equity	72,358,656	73,248,199
Noncontrolling interests	(146,503)	(127,380)
Total equity	72,212,153	73,120,819
Total liabilities and equity	\$ 91,861,605	\$ 93,404,566

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

	Three months ended March 31,	
	2017	2016
Net revenues	\$ 9,636,755	\$ 7,737,532
Costs and expenses:		
Cost of products sold	1,381,497	1,223,939
Selling and marketing	5,293,020	3,698,962
Research and development	898,363	706,472
General and administrative	2,110,233	2,077,972
Amortization	611,444	530,770
Total costs and expenses	10,294,557	8,238,115
Operating income (loss)	(657,802)	(500,583)
Interest income	52,535	77,129
Interest expense	(31,715)	(20,442)
Income (loss) before income taxes	(636,982)	(443,896)
Income tax (expense) benefit	(656,587)	175,339
Net income (loss)	(1,293,569)	(268,557)
Net loss at subsidiary attributable to noncontrolling interests	19,123	15,446
Net income (loss) attributable to common shareholders	\$ (1,274,446)	\$ (253,111)
Earnings (loss) per share attributable to common shareholders		
- basic	\$ (0.08)	\$ (0.02)
- diluted	\$ (0.08)	\$ (0.02)
Weighted-average shares outstanding		
- basic	16,042,219	16,341,481
- diluted	16,042,219	16,341,481
Comprehensive income (loss) attributable to common shareholders	(1,274,446)	(253,111)
Net loss at subsidiary attributable to noncontrolling interests	19,123	15,446
Total comprehensive income (loss)	\$ (1,293,569)	\$ (268,557)

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

	Three months ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	\$ (1,293,569)	\$ (268,557)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	661,485	582,093
Deferred tax expense	758,112	204,067
Share-based compensation	254,585	174,778
Excess tax (benefit) expense derived from exercise of stock options	(92,741)	427,993
Noncash interest expense	26,778	13,933
Noncash investment gains	(4,807)	(46,577)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,395,348	1,254,320
Inventories	(275,175)	196,454
Other current assets and other assets	132,819	(534,621)
Accounts payable and other current liabilities	(1,216,345)	(1,483,998)
Other long-term liabilities	92,881	78,602
Net cash provided by operating activities	<u>1,439,371</u>	<u>598,487</u>
Cash flows from investing activities:		
Additions to property and equipment	(123,945)	(73,057)
Purchases of marketable securities	(792,716)	(1,166,218)
Proceeds from sale of marketable securities	941,087	910,692
Additions to intangible assets	(453,961)	(624,898)
Net cash used in investing activities	<u>(429,535)</u>	<u>(953,481)</u>
Cash flows from financing activities:		
Excess tax expense derived from exercise of stock options	—	(427,993)
Repurchase of common shares	(545,924)	(979,293)
Net cash used in financing activities	<u>(545,924)</u>	<u>(1,407,286)</u>
Net increase (decrease) in cash and cash equivalents	463,912	(1,762,280)
Cash and cash equivalents at beginning of period	34,510,330	38,203,059
Cash and cash equivalents at end of period	<u>\$ 34,974,242</u>	<u>\$ 36,440,779</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)

	Three months ended March		Three months ended March	
	31, 2017		31, 2016	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income (loss) attributable to common shareholders	\$ (1,274,446)	\$ (0.08)	\$ (253,111)	\$ (0.02)
Less: Net loss at subsidiary attributable to noncontrolling interests	19,123	—	15,446	—
Net income (loss)	<u>(1,293,569)</u>	<u>(0.08)</u>	<u>(268,557)</u>	<u>(0.02)</u>
Adjustments to net income (loss)				
Income tax	656,587	0.04	(175,339)	(0.01)
Depreciation and amortization	661,485	0.04	582,093	0.04
Share-based compensation (a)	254,585	0.02	174,778	0.01
Interest income	(52,535)	—	(77,129)	—

Interest expense	31,715	—	20,442	—
Adjusted Earnings and Adjusted Diluted Earnings Per Share	<u>\$ 258,268</u>	<u>\$ 0.02</u>	<u>\$ 256,288</u>	<u>\$ 0.02</u>
Diluted weighted-average common shares outstanding:		<u>16,455,943</u>		<u>16,341,481</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:** 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 Per Share:** Adjusted Earnings divided by diluted weighted-average common shares outstanding.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-reports-revenue-growth-of-25-in-first-quarter-2017-300457641.html>

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media