



May 8, 2018

Cumberland Pharmaceuticals Reports First Quarter 2018 Financial Results

- **Caldolor® sNDA accepted by the FDA**
- **Advancing four Phase II clinical programs**

NASHVILLE, Tenn., May 8, 2018 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care, gastroenterology, and oncology supportive care today announced first quarter 2018 financial results. Net revenues for the period were \$8.6 million, resulting in a net loss of \$(2.4) million or \$(0.15) per diluted share. As of March 31, 2018, Cumberland had \$91 million in total assets, including approximately \$51 million in cash and marketable securities.



QUARTER HIGHLIGHTS:

- | Submitted supplemental New Drug Application for a Next Generation Caldolor® product
- | Released clinical publications in support of Omeclamox®-Pak and Ethyol®
- | Progressed enrollment in Phase II clinical studies for four advanced pipeline programs
- | Obtained approval for sale of Caldolor in India, with launch preparations underway
- | Entered into collaboration agreement with Louisiana State University through Cumberland Emerging Technologies

"Our goal has been to build a business that generates sustainable growth and profitability," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We continue to develop and grow the current portfolio while selectively adding new brands. Meanwhile, we are advancing a very robust clinical pipeline which includes several potential orphan drug candidates. We believe that these continued developments will help progress our goal of advancing patient care through the delivery of high-quality medicines."

KEY QUARTER DEVELOPMENTS:

Caldolor®

The FDA has accepted for filing the supplemental New Drug Application Cumberland submitted early in the year for the approval of its Next Generation Caldolor product. It features improved packaging and a new formulation. Also during the first quarter, Cumberland continued enrollment in a study evaluating Caldolor in patients ranging from newborn to six months of age. Additionally, Caldolor was approved for sale in India. Cumberland is now preparing for the launch of the brand with its international partner in that market.

Amifostine Study Publication

In January 2018, the Company announced a new publication in *Leukemia & Lymphoma*, with study results showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma. Cumberland markets branded amifostine in the U.S. under the name Ethyol.

H. Pylori Triple Therapy Publication

In March 2018, the Company announced a publication of an open access article in *Infection and Drug Resistance*, with results demonstrating an 85% eradication rate of *Helicobacter pylori* (*H. pylori*) infection using clarithromycin-based triple therapy. Cumberland markets a branded clarithromycin-based triple therapy in the U.S. under the name Omeclamox-Pak.

GEL Agreement

In March 2018, Cumberland reached agreement with Gastro-Entero-Logic LLC (GEL), to acquire the assets associated with Omeclamox-Pak including the product's FDA approved New Drug Application, trademarks and other assets. As a result of this acquisition Cumberland will no longer be obligated to provide GEL with royalty or fees for overseeing the product's manufacturing. Cumberland will become responsible for maintaining the FDA approval and for overseeing the product's packaging.

CET Collaboration Agreement

In February 2018, Cumberland Emerging Technologies (CET), Cumberland's majority-owned subsidiary, and Louisiana State University entered into an agreement, adding to CET's roster of academic collaborations which also includes Vanderbilt University, the University of Mississippi, and the University of Tennessee Research Foundation. These partnerships combine the strengths and capabilities of each organization by working together to identify, formulate, and develop attractive new biomedical products.

FINANCIAL RESULTS:

Net Revenue: For the three months ended March 31, 2018, net revenues were \$8.6 million, compared to \$9.6 million for the prior year period. Net revenue by product for the three months ended March 31, 2018, included \$3.3 million for Kristalose[®], and \$2.3 million for Ethyol[®]. Net revenue for the Company's other brands were \$1.3 million for Acetadote[®] (including the brand and Company's Authorized Generic) \$1.0 million for Caldolor[®], \$0.4 million for Totect[®], \$0.1 million for Vaprisol[®], and \$0.1 million for Omeclamox[®]-Pak.

Operating Expenses: Total operating expenses for the three months ended March 31, 2018 were \$11.0 million, compared to \$10.3 million during the prior year period. The primary reason for this increase is costs associated with the Company's Phase II clinical programs.

Earnings: Net income (loss) for the first quarter 2018 was \$(2.4) million or \$(0.15) per diluted share, compared to \$(1.3) million or \$(0.08) a share for the prior year period.

Adjusted Earnings for the first quarter were \$(1.4) million or \$(0.09) per diluted share, compared to \$0.3 million or \$0.02 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 March 31, 2018, Cumberland had \$50.9 million in cash and marketable securities, including approximately \$35.3 million in cash and equivalents. Total assets at March 31, 2018 were \$91.1 million. Total liabilities were \$30.2 million, including \$12.0 million outstanding on the Company's revolving line of credit, resulting in Total shareholder's equity of \$61.1 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, May 8, 2018 at 4:30 p.m. Eastern Time to discuss the Company's first quarter 2018 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 4296607. 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:

- l **Acetadote[®]** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- l **Caldolor[®]** (*ibuprofen*) Injection, for the treatment of pain and fever;

- 1 **Kristalose**[®] (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- 1 **Omeclamox**[®]-**Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- 1 **Vaprisol**[®] (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- 1 **Ethyol**[®] (*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; and
- 1 **Totect**[®] (*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**[®] (*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**[®] (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- 1 **Vascular**[®] (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of patients with the systemic sclerosis (SSc) form of autoimmune disease;
- 1 **Portaban**[®] (*ifetroban*) Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease; and
- 1 **RediTrex**[™] (*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.

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 FDA 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 FDA 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 Totect[®] (dexrazoxane) Injection

Totect is an anthracycline extravasation agent approved by the FDA. 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.

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 release contains forward-looking statements within the meaning of the federal securities laws, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. These forward looking statements involve certain risks and uncertainties, and actual results may differ materially from them. Some important factors which may cause results to differ from expectations 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; availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; management of our growth and integration of our acquisitions, as well as other risks discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and other filings 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, 2018 | December 31, 2017 |
|--|---------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 35,262,976 | \$ 45,412,868 |
| Marketable securities | 15,610,105 | 4,672,476 |
| Accounts receivable, net of allowances | 6,301,162 | 8,395,112 |
| Inventories, net | 6,661,525 | 6,737,848 |
| Other current assets | 2,987,404 | 3,466,541 |
| Total current assets | 66,823,172 | 68,684,845 |
| Property and equipment, net | 566,907 | 528,882 |
| Intangible assets, net | 21,052,197 | 21,444,545 |
| Other assets | 2,565,354 | 2,486,830 |
| Deferred tax assets, net | 87,210 | 87,210 |
| Total assets | \$ 91,094,840 | \$ 93,232,312 |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 8,518,879 | \$ 8,979,929 |
| Other current liabilities | 7,770,977 | 8,714,814 |
| Total current liabilities | 16,289,856 | 17,694,743 |
| Revolving line of credit | 12,000,000 | 9,800,000 |
| Other long-term liabilities | 1,930,679 | 1,815,968 |
| Total liabilities | 30,220,535 | 29,310,711 |
| Commitments and contingencies | | |
| Equity: | | |
| Shareholders' equity: | | |
| Common stock—no par value; 100,000,000 shares authorized; 15,727,250 and 15,723,075 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively | 51,755,834 | 52,410,941 |
| Retained earnings | 9,329,983 | 11,709,222 |
| Total shareholders' equity | 61,085,817 | 64,120,163 |
| Noncontrolling interests | (211,512) | (198,562) |
| Total equity | 60,874,305 | 63,921,601 |
| Total liabilities and equity | \$ 91,094,840 | \$ 93,232,312 |

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

| | Three months ended March 31, | |
|-----------------------------------|-------------------------------------|--------------|
| | 2018 | 2017 |
| Net revenues | \$ 8,587,605 | \$ 9,636,755 |
| Costs and expenses: | | |
| Cost of products sold | 1,527,961 | 1,381,497 |
| Selling and marketing | 4,670,511 | 5,293,020 |
| Research and development | 1,874,939 | 898,363 |
| General and administrative | 2,330,281 | 2,110,233 |
| Amortization | 636,135 | 611,444 |
| Total costs and expenses | 11,039,827 | 10,294,557 |
| Operating income (loss) | (2,452,222) | (657,802) |
| Interest income | 82,494 | 52,535 |
| Interest expense | (18,302) | (31,715) |
| Income (loss) before income taxes | (2,388,030) | (636,982) |
| Income tax (expense) benefit | (4,159) | (656,587) |

| | | |
|---|-----------------------|-----------------------|
| Net income (loss) | (2,392,189) | (1,293,569) |
| Net loss at subsidiary attributable to noncontrolling interests | 12,950 | 19,123 |
| Net income (loss) attributable to common shareholders | <u>\$ (2,379,239)</u> | <u>\$ (1,274,446)</u> |
| Earnings (loss) per share attributable to common shareholders | | |
| - basic | \$ (0.15) | \$ (0.08) |
| - diluted | \$ (0.15) | \$ (0.08) |
| Weighted-average shares outstanding | | |
| - basic | 15,689,240 | 16,042,219 |
| - diluted | 15,689,240 | 16,042,219 |
| Comprehensive income (loss) attributable to common shareholders | (2,379,239) | (1,274,446) |
| Net loss at subsidiary attributable to noncontrolling interests | 12,950 | 19,123 |
| Total comprehensive income (loss) | <u>\$ (2,392,189)</u> | <u>\$ (1,293,569)</u> |

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

| | <u>Three months ended March 31,</u> | |
|--|-------------------------------------|----------------------|
| | <u>2018</u> | <u>2017</u> |
| Cash flows from operating activities: | | |
| Net income (loss) | \$ (2,392,189) | \$ (1,293,569) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Depreciation and amortization expense | 692,991 | 661,485 |
| Deferred tax expense | — | 758,112 |
| Share-based compensation | 339,209 | 254,585 |
| Excess tax (benefit) expense derived from exercise of stock options | — | (92,741) |
| Noncash interest expense | 18,303 | 26,778 |
| Noncash investment gains | (43,338) | (4,807) |
| Net changes in assets and liabilities affecting operating activities: | | |
| Accounts receivable | 2,093,950 | 2,395,348 |
| Inventories | 76,323 | (275,175) |
| Other current assets and other assets | 600,884 | 132,819 |
| Accounts payable and other current liabilities | (1,254,535) | (1,216,345) |
| Other long-term liabilities | 103,991 | 92,881 |
| Net provided by operating activities | <u>235,589</u> | <u>1,439,371</u> |
| Cash flows from investing activities: | | |
| Additions to property and equipment | (94,881) | (123,945) |
| Purchases of marketable securities | (15,151,948) | (792,716) |
| Proceeds from sale of marketable securities | 4,257,657 | 941,087 |
| Additions to intangible assets | (532,954) | (453,961) |
| Net cash used in investing activities | <u>(11,522,126)</u> | <u>(429,535)</u> |
| Cash flows from financing activities: | | |
| Borrowings on line of credit | 12,000,000 | — |
| Repayments on line of credit | (9,800,000) | — |
| Sales of shares of common stock, net of offering costs | 200,909 | — |
| Payments of deferred offering costs | (248,108) | — |
| Repurchase of common shares | (1,016,156) | (545,924) |
| Net cash provided by (used in) financing activities | <u>1,136,645</u> | <u>(545,924)</u> |
| Net increase (decrease) in cash and cash equivalents | (10,149,892) | 463,912 |
| Cash and cash equivalents at beginning of period | 45,412,868 | 34,510,330 |
| Cash and cash equivalents at end of period | <u>\$ 35,262,976</u> | <u>\$ 34,974,242</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 | | Three months ended | |
|--|---------------------------|------------------------------|---------------------------|------------------------------|
| | March 31, 2018 | | March 31, 2017 | |
| | Earnings impact | Earnings per share impact | Earnings impact | Earnings per share impact |
| Net income (loss) attributable to common shareholders | \$ (2,379,239) | \$ (0.15) | \$ (1,274,446) | \$ (0.08) |
| Less: Net loss at subsidiary attributable to noncontrolling interests | 12,950 | — | 19,123 | — |
| Net income (loss) | <u>(2,392,189)</u> | <u>(0.15)</u> | <u>(1,293,569)</u> | <u>(0.08)</u> |
| Adjustments to net income (loss) | | | | |
| Income tax expense | 4,159 | — | 656,587 | 0.04 |
| Depreciation and amortization | 692,991 | 0.04 | 661,485 | 0.04 |
| Share-based compensation (a) | 339,209 | 0.02 | 254,585 | 0.02 |
| Interest income | (82,494) | (0.01) | (52,535) | — |
| Interest expense | 18,302 | — | 31,715 | — |
| Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share | <u>\$ (1,420,022)</u> | <u>\$ (0.09)</u> | <u>\$ 258,268</u> | <u>\$ 0.02</u> |
| Diluted weighted-average common shares outstanding: | | <u>15,689,240</u> | | <u>16,455,943</u> |

(a) Represents the share-based compensation of Cumberland.

The Company provided the above adjusted supplemental financial performance measures, which are considered "non-GAAP" financial measures under applicable SEC 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 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.
- 1 **Adjusted Diluted Earnings (loss) Per Share:** Adjusted Earnings (loss) divided by diluted weighted-average common shares outstanding.

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