



Cumberland Pharmaceuticals Reports First Quarter 2023 Financial Results & Company Update

May 9, 2023

NASHVILLE, Tenn., May 9, 2023 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company, today announced that the Company's product portfolio of FDA-approved brands delivered combined revenues of \$9.2 million during the first quarter of 2023. Net income for the period was \$0.2 million, or \$0.01 a share, resulting in adjusted earnings of \$1.7 million, or \$0.11 a share. The Company ended the first quarter with \$89 million in total assets, \$53 million in total liabilities, and \$36 million of shareholders' equity.



Cumberland will report its first quarter 2023 financial results and provide a company update via a conference call and live internet webcast today at 4:30 p.m. Eastern Time.

"We are pleased to announce a steady start to 2023," said Cumberland's CEO, A.J. Kazimi. "As we continue to navigate through the many issues in our operating environment – supporting our patients and their quality of life is a top priority, as our team remains dedicated to delivering and developing high- quality medicines."

RECENT COMPANY DEVELOPMENTS:

Federal NOPAIN Act

In April 2023, Cumberland announced that it expects its Caldolor[®] product will be eligible for special Medicare reimbursement under the *Non-Opioids Prevent Addiction in the Nation Act* (the "NOPAIN Act"), which was enacted as part of the Consolidated Appropriations Act of 2023.

The NOPAIN Act requires Medicare to provide separate reimbursement for non-opioid products that are used to manage pain during surgeries, conducted in outpatient hospital departments or in ambulatory surgical centers. The NOPAIN Act applies to products that are indicated to provide analgesia without acting upon the body's opioid receptors. As a result, Cumberland expects that the NOPAIN Act will affect Medicare reimbursement for Caldolor, the Company's non-opioid analgesic injection brand.

FDA Fee Waiver

In March 2023, the FDA informed Cumberland that it had granted a barrier-to-innovation waiver, which will result in a refund of nearly \$2 million that the Company had previously paid for prescription drug program fees associated with its RediTrex[®] product line.

The FDA granted the barrier-to-innovation waiver after concluding that Cumberland met the statutory criteria, based on the innovation associated with Cumberland's ifetroban clinical development programs. Cumberland's request for the waiver provided the rationale that the funds could be better used to advance its clinical programs, which are designed to address a series of unmet medical needs.

New Office Headquarters

Cumberland has relocated its international headquarters to the Broadwest campus in the Vanderbilt/West End corridor of Nashville. The new location allows Cumberland to maintain a strong presence in the Nashville healthcare community, which represents the nation's largest concentration of healthcare companies.

International Updates

During the first quarter of 2023, the Company continued to support its international partners in their efforts to register Cumberland products in their countries:

- PiSA Pharmaceutical is preparing its submission for distribution of Caldolor in Mexico.
- Tabuk Pharmaceutical is updating the approval in Saudi Arabia in order to begin introducing Vibativ into the Middle East.
- SciClone Pharmaceuticals continues to address regulatory inquiries, as it seeks approval for Vibativ in China.
- DB Pharm Korea Co. Ltd. is working towards approval of Vibativ in South Korea, where it also distribute Caldolor.

Nordic Pharma RediTrex[®] Agreement Restructured

In 2022, Cumberland restructured its agreement with Nordic Pharma, who previously provided Cumberland with the license for the U.S. rights associated with the RediTrex product line. Nordic will assume the responsibility for the product in the U.S. after June 30, 2023.

Sancuso Acquisition

During 2022, Cumberland announced its acquisition of the U.S. rights to oncology-supportive drug Sancuso[®] from the U.S. subsidiary of Kyowa Kirin, Inc., a Japan-based specialty pharmaceutical company. Sancuso is the first and only FDA-approved prescription patch that prevents nausea and

vomiting in cancer patients receiving certain types of chemotherapy treatment. Through the acquisition, Cumberland obtained full commercial responsibility for Sancuso in the U.S., including its marketing, promotion, distribution and manufacturing. In late 2022, the FDA approved moving the product's manufacturer to a new facility, which will be the source of future product supplies. The product continues to be a significant contributor to Cumberland's business.

Clinical Development Program

Cumberland continues to sponsor and progress three Phase II clinical programs featuring the Company's ifetroban product candidate. These studies involve patients with:

- a. *Aspirin-Exacerbated Respiratory Disease*, or AERD, a severe form of asthma;
- b. *Systemic Sclerosis*, a debilitating autoimmune disorder; and
- c. *Duchenne Muscular Dystrophy*, a genetic neuromuscular disease.

In addition, Cumberland has been designing a fourth Phase II clinical program, which will evaluate the use of ifetroban to treat patients with Progressive Fibrosing Interstitial Lung Diseases.

FINANCIAL RESULTS:

Net Revenue: For the three months ended March 31, 2023, net revenues were \$9.2 million.

Net revenue by product for the first quarter of 2023, included \$4.3 million for Kristalose[®], \$1.9 million for Sancuso[®], \$1.8 million for Vibativ[®] and \$0.9 million for Caldolor[®].

Operating Expenses: Total operating expenses for the first quarter of 2023 were \$10.8 million.

Net Income: The Net Income for the first quarter of 2023 was \$0.2 million or \$0.01 a share.

Adjusted earnings: Adjusted earnings for the first quarter of 2023 were \$1.7 million, or 0.11 per share.

The adjusted earnings calculation does not include the benefit of the \$0.2 million of Vibativ cost of goods, which were received with the product acquisition. It also does not include the benefit of the \$0.3 million of Sancuso cost of goods, which were received with that product's acquisition.

Balance Sheet: At March 31, 2023, Cumberland had \$89 million in total assets, including \$16 million in cash and cash equivalents.

Total liabilities were \$53 million, including \$16 million outstanding on the Company's revolving line of credit. Total shareholders' equity was \$36 million.

EARNINGS REPORT CALL:

A conference call will be held on May 9 at 4:30 p.m. Eastern Time, to discuss the results.

To participate in the call, please register at: <https://register.vevent.com/register/BI723fac45344448bbb1833dbb8fa667f3>.

Registered participants can dial in from their phone using a dial-in and PIN number that will be provided to them. Alternatively, they can choose a "Call Me" option to have the system automatically call them at the start of the conference.

A replay of the call will be available for one year and can be accessed via Cumberland's website or by visiting <https://edge.media-server.com/mmc/p/mpH53zt2>.

ABOUT CUMBERLAND PHARMACEUTICALS:

Cumberland Pharmaceuticals Inc. is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on the delivery of high-quality, prescription brands designed to improve patient care. The company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and oncology market segments.

The Company's portfolio of FDA-approved brands includes:

- **Acetadote[®]** (*acetylcysteine*) injection, for the treatment of acetaminophen poisoning;
- **Caldolor[®]** (*ibuprofen*) injection, for the treatment of pain and fever;
- **Kristalose[®]** (*lactulose*) oral, a prescription laxative, for the treatment of constipation;
- **Omeclamox[®]-Pak**, (*omeprazole, clarithromycin, amoxicillin*) oral, for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- **RediTrex[®]** (*methotrexate*) injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis;
- **Sancuso[®]** (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol[®]** (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **Vibativ[®]** (*telavancin*) injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections;

The Company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy

associated with Duchenne Muscular Dystrophy, Systemic Sclerosis, and Aspirin-Exacerbated Respiratory Disease.

For more information on Cumberland's approved products, including full prescribing information, please visit links to the individual product websites, 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. For full prescribing and safety 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. For full prescribing and safety 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. 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 and safety 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. For full prescribing and safety information, visit www.omeclamox.com.

About RediTrex® (methotrexate) Injection

RediTrex is a single-dose prefilled syringe containing prescription methotrexate. RediTrex is used to treat adults with severe, active rheumatoid arthritis and children with active polyarticular juvenile idiopathic arthritis, after treatment with other medicines including non-steroidal anti-inflammatory drugs (NSAIDs) have been used and did not work well. Methotrexate can control the symptoms of severe, resistant, disabling psoriasis in adults when other types of treatment have failed. For full prescribing and safety information, visit www.reditrex.com

About Sancuso® (granisetron) Transdermal System

Sancuso is the only skin patch approved by the U.S. Food and Drug Administration for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately and/or highly emetogenic chemotherapy. When applied 24 to 48 hours before receiving chemotherapy, the SANCUSO patch slowly and continuously releases the medicine contained in the adhesive through clean and intact skin areas into the patient's bloodstream. It can be worn for up to seven days in a row for chemotherapy regimens of up to five consecutive days. For full prescribing and safety information, visit www.sancuso.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 is contraindicated in patients with hypovolemic hyponatremia. The coadministration of Vaprisol with potent CYP3A inhibitors, such as ketoconazole, itraconazole, clarithromycin, ritonavir, and indinavir, is contraindicated. For full prescribing and safety information, including boxed warning, visit www.vaprisol.com.

About Vibativ® (telavancin) for Injection

Vibativ is a patented, FDA approved injectable anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia and complicated skin and skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant. Intravenous unfractionated heparin sodium is contraindicated with Vibativ administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after Vibativ administration. Vibativ is contraindicated in patients with a known hypersensitivity to telavancin. For more information, please visit www.vibativ.com.

ABOUT CUMBERLAND EMERGING TECHNOLOGIES:

Cumberland Emerging Technologies, Inc. (www.cet-fund.com) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and WinHealth. 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 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. Forward-looking statements include, among other things, statements regarding the company's intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate," "look forward" and other comparable terms or the negative thereof. 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 operation results. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis, failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, natural disasters, public health epidemics, maintaining an effective sales and marketing infrastructure, and other events beyond the company's control as more fully discussed in its most recent 10-K as filed with the U.S. Securities and Exchange Commission ("SEC"), as well as the Company's other filings with the SEC from time to time. 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,386,166	\$ 19,757,970
Accounts receivable, net	14,529,133	13,163,681
Inventories, net	10,180,002	9,863,581
Prepaid and other current assets	2,715,498	3,084,978
Total current assets	43,810,799	45,870,210
Non-current inventories	7,534,303	7,527,167
Property and equipment, net	354,857	284,039
Intangible assets, net	29,390,195	30,590,678
Goodwill	914,000	914,000
Operating lease right-of-use assets	4,919,057	5,218,403
Other assets	2,545,424	2,520,661
Total assets	\$ 89,468,635	\$ 92,925,158
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 11,222,333	\$ 10,819,011
Operating lease current liabilities	158,369	172,910
Other current liabilities	14,326,712	17,587,911
Total current liabilities	25,707,414	28,579,832
Revolving line of credit	16,072,286	16,200,000
Operating lease non-current liabilities	4,549,150	4,586,301
Other long-term liabilities	7,091,298	7,585,019
Total liabilities	53,420,148	56,951,152
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 14,430,047 and 14,366,316 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	47,377,168	47,474,973
Retained earnings (deficit)	(11,016,657)	(11,208,841)
Total shareholders' equity	36,360,511	36,266,132
Noncontrolling interests	(312,024)	(292,126)
Total equity	36,048,487	35,974,006
Total liabilities and equity	\$ 89,468,635	\$ 92,925,158

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

	Three months ended March 31,	
	2023	2022
Net revenues	\$ 9,224,638	\$ 11,175,045

Costs and expenses:		
Cost of products sold	1,250,264	2,211,885
Selling and marketing	4,277,318	4,614,429
Research and development	1,499,670	1,745,136
General and administrative	2,498,993	2,302,349
Amortization	1,230,071	1,593,245
Total costs and expenses	10,756,316	12,467,044
Operating income (loss)	(1,531,678)	(1,291,999)
Interest income	50,190	16,041
Other income	1,847,065	—
Interest expense	(186,353)	(119,575)
Income (loss) before income taxes	179,224	(1,395,533)
Income tax (expense) benefit	(6,938)	(6,900)
Net income (loss)	172,286	(1,402,433)
Net (income) loss at subsidiary attributable to noncontrolling interests	19,898	17,180
Net income (loss) attributable to common shareholders	\$ 192,184	\$ (1,385,253)

Earnings (loss) per share attributable to common shareholders

- basic	\$ 0.01	\$ (0.09)
- diluted	\$ 0.01	\$ (0.09)
Weighted-average shares outstanding		
- basic	14,359,322	14,691,623
- diluted	14,587,843	14,691,623

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

	Three months ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	\$ 172,286	\$ (1,402,433)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	1,255,675	1,653,746
Share-based compensation	90,156	159,901
Decrease (increase) in non-cash contingent consideration	(267,637)	370,464
Decrease (increase) in cash surrender value of life insurance policies over premiums paid	(30,799)	222,209
Gain on receivable of FDA fees	(1,847,065)	—
Noncash interest expense	4,296	2,183
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	481,613	(7,758,089)
Inventories	(323,557)	2,271,484
Other current assets and other assets	682,958	239,862
Accounts payable and other current liabilities	(1,105,263)	4,461,389
Other long-term liabilities	(530,872)	(371,214)
Net cash used in operating activities	(1,418,209)	(150,498)
Cash flows from investing activities:		
Additions to property and equipment	(107,260)	(26,986)
Cash paid for acquisitions	—	(13,500,000)
Additions to intangibles	(67,193)	(14,912)
Net cash used in investing activities	(174,453)	(13,541,898)
Cash flows from financing activities:		
Borrowings on line of credit	8,000,000	20,000,000
Repayments on line of credit	(8,127,714)	(15,000,000)
Cash payment of contingent consideration	(1,464,311)	(501,505)
Repurchase of common shares	(187,117)	(580,130)

Net cash provided by (used in) financing activities	(1,779,142)	3,918,365
Net decrease in cash and cash equivalents	(3,371,804)	(9,774,031)
Cash and cash equivalents at beginning of period	\$ 19,757,970	\$ 27,040,816
Cash and cash equivalents at end of period	\$ 16,386,166	\$ 17,266,785

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Reconciliation of Net Income (loss) Attributable to Common Shareholders to
Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share
(Unaudited)

	Three months ended March 31, 2023		Three months ended March 31, 2022	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income (loss) attributable to common shareholders	\$ 192,184	\$ 0.01	\$ (1,385,253)	\$ (0.09)
Less: Net (income) loss at subsidiary attributable to noncontrolling interests	19,898	—	17,180	—
Net income (loss)	172,286	0.01	(1,402,433)	(0.09)
Adjustments to net income (loss)				
Income tax expense (benefit)	6,938	—	6,900	—
Depreciation and amortization	1,255,675	0.09	1,653,746	0.11
Share-based compensation ^(a)	90,156	0.01	159,901	0.01
Interest income	(50,190)	—	(16,041)	—
Interest expense	186,353	0.01	119,575	0.01
Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share^(b)	\$ 1,661,218	\$ 0.11	\$ 521,648	\$ 0.03
Diluted weighted-average common shares outstanding:		<u>14,587,843</u>		15,038,148

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:

- **Adjusted Earnings (loss):** net income (loss) adjusted for the impact of income taxes, depreciation and amortization expense, share-based compensation, nonrecurring gains and interest income and interest expense.

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

(b) Adjusted Earnings includes a gain on the refund of 2022 FDA fees in the amount of \$1,847,065. Cumberland has applied to the FDA for a similar refund of 2023 FDA fees which is expected to be approved within twelve to twenty-four months.

- **Adjusted Diluted Earnings (loss) Per Share:** Adjusted Earnings (loss) divided by diluted weighted-average common shares outstanding.

SOURCE Cumberland Pharmaceuticals Inc.

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