



## **Cumberland Pharmaceuticals Reports First Quarter 2024 Financial Results & Company Update**

**NASHVILLE, TENNESSEE (Tuesday, May 7, 2024)** – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company, today announced that its product portfolio of FDA-approved brands delivered combined revenues of \$8.5 million during the first quarter of 2024. The company ended the quarter with \$82 million in total assets, \$54 million in total liabilities and \$27 million of shareholders' equity.

“It has been a steady start to 2024 – and despite some challenges the biopharmaceutical sector is facing in the financial markets amid stubborn inflation and stalled interest rate cuts, we remain optimistic about our industry’s fundamentals and future,” said Cumberland’s CEO, A.J. Kazimi. “We continue to build our portfolio of innovative and differentiated products here at Cumberland, and our resulting, diversified product line has enabled us to weather external challenges while our team remains responsive to the evolving market. We look forward to sharing an update on our brands, pipeline and partnerships, including a number of growth opportunities.”

### **Recent company developments include:**

#### **Caldolor® Special Report**

In March 2024, a Special Report was published in *Anesthesiology News*, *General Surgery News* and *Pharmacy Practice News* presenting the growing amount of clinical data supporting the use of Cumberland’s Caldolor (ibuprofen) injection as a standard of care for the treatment of pain and fever in adults, children and infants as young as 3 months of age.

Takeaways from the Special Report include:

- Intravenous ibuprofen results in significant reduction in temperature compared with placebo in adults and with acetaminophen in pediatric patients.
- Administration of the product prior to surgery leads to patients waking up in significantly less postsurgical pain, while also lessening or even eliminating the need for opioids.
- The use of intravenous ibuprofen in the hospital emergency department for acute pain can minimize opioid requirements while achieving significant pain control.
- Caldolor should be considered a foundation for any multimodal pain regimen.

Pain management has become one of the most common health care problems. As this Special Report states, comprehensive multimodal pain regimens have become key in preventing pain and optimizing pain control, while minimizing the need for opioids. A non-steroidal anti-inflammatory drug, such as Caldolor, can provide a cornerstone for many treatment paradigms.

## **Federal NOPAIN Act**

Cumberland expects Caldolor 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 and more favorable reimbursement for non-opioid products used to manage pain during surgeries conducted in hospital outpatient departments or in ambulatory surgical centers. The NOPAIN Act applies, in part, to products that are indicated to provide analgesia without acting upon the body’s opioid receptors.

The Centers for Medicare & Medicaid Services (“CMS”) requested that manufacturers with potentially applicable non-opioid products submit comments and supporting clinical evidence regarding products that should be eligible for separate payment. Cumberland submitted a comment letter along with the requisite clinical information to the CMS in September 2023 explaining why Caldolor should be included and separately reimbursed. The company now awaits information from CMS regarding the reimbursement status and price for the product.

The Act is scheduled to go into effect in early 2025 and will initially apply to products that are furnished between January 1, 2025 and January 1, 2028.

## **New Manufacturing & Supplies of Sancuso®**

After acquiring U.S. rights to Sancuso, Cumberland successfully completed the transition from Kyowa Kirin in 2023, including the NDA transfer. A new facility was approved by the FDA for Sancuso and, during the first quarter of 2024, Cumberland completed the manufacturing of Cumberland-packaged product there. The company will launch these new supplies this year. Meanwhile, it continues to support the product through its expanded oncology sales division to help cancer patients by addressing certain side effects associated with their chemotherapy treatments.

## **Vaprisol® Supply Update**

Cumberland’s new manufacturing and distribution partner for Vaprisol is providing a special supply of compounded product in support of critically ill patients. The companies await FDA approval for the facility in order to relaunch the brand.

Vaprisol is the first and only intravenously administered vasopressin receptor antagonist. It is used to raise serum sodium levels in hospitalized patients with hyponatremia, the most common electrolyte disorder among such patients.

## **Clinical Development Pipeline**

Cumberland has been evaluating its ifetroban product candidate, a selective thromboxane-prostanoid receptor antagonist, in a series of clinical studies. It has now been dosed in nearly 1,400 subjects and has been found to be safe and well tolerated in healthy volunteers and various patient populations.

Cumberland has initiated its newest clinical program in medical centers across the country and enrollment has now begun in patients with *Idiopathic Pulmonary Fibrosis*, the most common form of progressive fibrosing interstitial lung disease. This FIGHTING FIBROSIS trial is designed to enroll 128 patients in over 20 medical centers of excellence across the United States. Recent studies have shown ifetroban can both prevent and enhance resolution of lung fibrosis in multiple preclinical models.

Patient enrollment is already well underway in its two other company-sponsored Phase II clinical programs evaluating ifetroban in patients with: 1) *Systemic Sclerosis*, or scleroderma, a debilitating autoimmune disorder characterized by diffuse fibrosis of the skin and internal organs and 2) cardiomyopathy associated with *Duchenne Muscular Dystrophy*, a rare, fatal, genetic neuromuscular disease results in deterioration of the skeletal, heart and lung muscles.

Cumberland's plan going forward is to complete each of its company-sponsored studies, analyze their final data, announce top-line results and decide on the best development path for the registration of ifetroban, which the company continues to believe has the potential to benefit many patients with orphan diseases that represent unmet medical needs.

## **FINANCIAL RESULTS:**

**Net Revenue:** For the three months ended March 31, 2024, net revenues were \$8.5 million.

Net revenue by product for the first quarter of 2024 included \$3.2 million for Kristalose<sup>®</sup>, \$1.8 million for Sancuso<sup>®</sup>, \$1.6 million for Vibativ<sup>®</sup> and \$1.5 million for Caldolor<sup>®</sup>.

**Operating Expenses:** Total operating expenses for the first quarter were \$10.4 million.

**Net Income:** The net loss for the first quarter of 2024 was \$1.9 million, or \$0.14 a share.

**Adjusted Earnings:** Adjusted earnings for the first quarter of 2024 were a loss of \$0.6 million, or \$0.05 per share. The adjusted earnings calculation does not include the benefit of the \$0.5 million cost of goods for Vibativ and Sancuso during the quarter, which were received as part of each product's acquisition.

**Balance Sheet:** At March 31, 2024, Cumberland had \$82 million in total assets, including \$19 million in cash and cash equivalents.

Total liabilities were \$54 million, including \$16 million outstanding on the company's revolving line of credit. Total shareholders' equity was \$27 million at the end of the quarter.

## **EARNINGS REPORT CALL:**

A conference call will be held on May 7, 2024, at 4:30 p.m. Eastern Time to provide a company update and discuss the financial results. To participate in the call, please register at: <https://register.vevent.com/register/BIbb2d35bc9570474dabf8b2e3d2e4ca72>.

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/uqsbkw9t>.

## **ABOUT CUMBERLAND PHARMACEUTICALS:**

**Cumberland Pharmaceuticals Inc.** is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on providing unique products that improve the quality of 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**<sup>®</sup> (*acetylcysteine*) injection, for the treatment of acetaminophen poisoning;
- **Caldolor**<sup>®</sup> (*ibuprofen*) injection, for the treatment of pain and fever;
- **Kristalose**<sup>®</sup> (*lactulose*) oral, a prescription laxative, for the treatment of constipation;
- **Sancuso**<sup>®</sup> (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol**<sup>®</sup> (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **Vibativ**<sup>®</sup> (*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 Idiopathic Pulmonary Fibrosis.

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](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. For full prescribing and safety 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. For full prescribing and safety information, including boxed warning, visit [www.caldolor.com](http://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](http://www.kristalose.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](http://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](http://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](http://www.vibativ.com).

### **ABOUT CUMBERLAND EMERGING TECHNOLOGIES:**

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 WinHealth. The mission of CET is to advance biomedical technologies and products conceived at Vanderbilt University and other regional research centers toward 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 macroeconomic conditions, including rising interest rates and inflation, 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 annual report on Form 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.

SOURCE: Cumberland Pharmaceuticals Inc.

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**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**

	<b>March 31, 2024</b>	<b>December 31, 2023</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,548,485	\$ 18,321,624
Accounts receivable, net	10,647,267	9,758,176
Inventories, net	4,327,526	4,609,362
Prepaid and other current assets	2,682,673	3,025,248
Total current assets	36,205,951	35,714,410
Non-current inventories	12,915,896	12,804,529
Property and equipment, net	369,499	367,903
Intangible assets, net	21,522,441	22,607,918
Goodwill	914,000	914,000
Operating lease right-of-use assets	6,521,088	6,674,394
Other assets	3,060,643	2,692,921
Total assets	\$ 81,509,518	\$ 81,776,075
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 13,075,764	\$ 14,037,629
Operating lease current liabilities	362,244	348,092
Other current liabilities	12,987,372	13,596,528
Total current liabilities	26,425,380	27,982,249
Revolving line of credit	16,084,144	12,784,144
Operating lease non-current liabilities	5,200,148	5,296,247
Other long-term liabilities	6,610,294	6,453,566
Total liabilities	54,319,966	52,516,206
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 14,159,954 and 14,121,833 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	46,923,757	47,091,602
Accumulated deficit	(19,434,424)	(17,488,161)
Total shareholders' equity	27,489,333	29,603,441
Noncontrolling interests	(299,781)	(343,572)
Total equity	27,189,552	29,259,869
Total liabilities and equity	\$ 81,509,518	\$ 81,776,075

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

	Three months ended March 31,	
	2024	2023
Net revenues	\$ 8,497,701	\$ 9,224,638
Costs and expenses:		
Cost of products sold	1,575,542	1,250,264
Selling and marketing	4,154,588	4,277,318
Research and development	1,158,253	1,499,670
General and administrative	2,367,907	2,498,993
Amortization	1,110,661	1,230,071
Total costs and expenses	10,366,951	10,756,316
Operating loss	(1,869,250)	(1,531,678)
Interest income	96,746	50,190
Other income	—	1,847,065
Interest expense	(118,526)	(186,353)
Income (loss) before income taxes	(1,891,030)	179,224
Income tax expense	(11,442)	(6,938)
Net income (loss)	(1,902,472)	172,286
Net loss at subsidiary attributable to noncontrolling interests	(43,791)	19,898
Net income (loss) attributable to common shareholders	\$ (1,946,263)	\$ 192,184
Earnings (loss) per share attributable to common shareholders		
- basic	\$ (0.14)	\$ 0.01
- diluted	\$ (0.14)	\$ 0.01
Weighted-average shares outstanding		
- basic	14,098,022	14,359,322
- diluted	14,098,022	14,587,843



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

	<b>Three months ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ (1,902,472)	\$ 172,286
<b>Adjustments to reconcile net loss to net cash provided by operating activities:</b>		
Depreciation and amortization expense	1,150,685	1,255,675
Amortization of operating lease right-of-use assets	285,184	172,209
Share-based compensation	78,754	90,156
Decrease in non-cash contingent consideration	(230,430)	(267,637)
Increase in cash surrender value of life insurance policies over premiums paid	(129,217)	(30,799)
Increase in noncash interest expense	3,810	4,296
Gain on receivable of FDA fees	—	(1,847,065)
<b>Net changes in assets and liabilities affecting operating activities:</b>		
Accounts receivable	(1,066,410)	481,613
Inventories	170,469	(323,557)
Other current assets and other assets	205,619	383,612
Operating lease liabilities	(213,825)	127,137
Accounts payable and other current liabilities	(645,542)	(1,105,263)
Other long-term liabilities	156,728	(530,872)
Net cash used in operating activities	<u>(2,136,647)</u>	<u>(1,418,209)</u>
<b>Cash flows from investing activities:</b>		
Additions to property and equipment	(41,621)	(107,260)
Additions to intangible assets	(16,565)	(67,193)
Net cash used in investing activities	<u>(58,186)</u>	<u>(174,453)</u>
<b>Cash flows from financing activities:</b>		
Borrowings on line of credit	11,000,000	8,000,000
Payments on line of credit	(7,700,000)	(8,127,714)
Cash settlement of contingent consideration	(630,701)	(1,464,311)
Payments made in connection with repurchase of common shares	(247,605)	(187,117)
Net cash provided by (used in) financing activities	<u>2,421,694</u>	<u>(1,779,142)</u>
Net increase (decrease) in cash and cash equivalents	226,861	(3,371,804)
Cash and cash equivalents at beginning of period	\$ 18,321,624	\$ 19,757,970
Cash and cash equivalents at end of period	<u>\$ 18,548,485</u>	<u>\$ 16,386,166</u>

## 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,		Three months ended March 31,	
	2024	2024	2023	2023
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
<b>Net income (loss) attributable to common shareholders</b>	\$ (1,946,263)	\$ (0.14)	\$ 192,184	\$ 0.01
Less: Net loss at subsidiary attributable to noncontrolling interests	(43,791)	—	19,898	—
Net income (loss)	(1,902,472)	(0.13)	172,286	0.01
Adjustments to net loss				
Income tax expense	11,442	—	6,938	—
Depreciation and amortization	1,150,685	0.08	1,255,675	0.09
Share-based compensation <sup>(a)</sup>	78,754	0.01	90,156	0.01
Interest income	(96,746)	(0.01)	(50,190)	—
Interest expense	118,526	0.01	186,353	0.01
<b>Adjusted Earnings (Loss) and Adjusted Diluted Earnings (Loss) Per Share</b>	<b>\$ (639,811)</b>	<b>\$ (0.05)</b>	<b>\$ 1,661,218</b>	<b>\$ 0.11</b>
Diluted weighted-average common shares outstanding:		<u>14,098,022</u>		<u>14,587,843</u>

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, interest income and interest expense. The definition of Adjusted Earnings has been changed to include all gains and losses, as gains are occurring more frequently for the Company.
  - (a) Represents the share-based compensation of Cumberland.
- **Adjusted Diluted Earnings (loss) Per Share:** Adjusted Earnings (loss) divided by diluted weighted-average common shares outstanding.