UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

September 9, 2009

Cumberland Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Tennessee

001-33637

(Commission

File Number)

(State or other jurisdiction of incorporation)

2525 West End Avenue, Suite 950, Nashville, Tennessee

(Address of principal executive offices)

Registrant's telephone number, including area code:

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

62-1765329

(I.R.S. Employer Identification No.)

37203

(Zip Code)

(615) 255-0068

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Item 8.01 Other Events.

On September 9, 2009, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the commerical launch of Caldolor, our intravenous formulation of ibuprofen. A copy of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated September 9, 2009 announcing commercial launch of Caldolor

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

September 9, 2009

Cumberland Pharmaceuticals Inc.

By: /s/ David L. Lowrance

Name: David L. Lowrance Title: Chief Financial Officer Exhibit Index

Exhibit No.

Description

99.1

Press release dated September 9, 2009 announcing commercial launch of Caldolor



CUMBERLAND PHARMACEUTICALS LAUNCHES CALDOLOR[®] IN THE UNITED STATES FOR TREATMENT OF PAIN AND FEVER

* First and only IV ibuprofen for pain and fever
* Caldolor offers increased pain control while reducing narcotic use
* Conference Call and webcast at 11:00 a.m. ET today to discuss U.S. introduction of Caldolor

NASHVILLE, TN, September 9, 2009 – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX) announced today that it has successfully implemented the U.S. launch of Caldolor[®], an intravenous formulation of ibuprofen, designed primarily for use in the hospital setting. Caldolor is the first and only injectable product available in the United States for the treatment of pain and fever. Cumberland received U.S. Food and Drug Administration marketing approval for Caldolor in June 2009. The product is now fully stocked at the wholesalers serving hospitals nationwide, and is available in both 400mg and 800mg vials.

"We are pleased to introduce Caldolor ahead of schedule, offering a new level of patient care as ibuprofen advances to IV," said A.J. Kazimi, Cumberland's Chief Executive Officer. "We have worked diligently over the past year to prepare for the introduction of Caldolor to physicians and patients as the only injectable product available in the United States for reduction of fever, and as an important alternative for single-agent and multi-modal pain management."

In preparation for the product launch, Cumberland conducted comprehensive market research, prepared a full package of educational materials, optimized hospital coverage and recently launched the product website. Caldolor will be supported by 113 experienced sales professionals across the country, comprised of Cumberland's recently expanded hospital sales force of 77 representatives and managers as well as its field sales force of 36 representatives and managers. Cumberland has also expanded its professional affairs group to handle medical inquiries about the product.

"The introduction of IV ibuprofen (Caldolor) should allow anesthesiologists to achieve improved pain control with less opioid analgesic medication, thereby improving patient satisfaction," said Dr. Paul F. White, Professor and holder of the McDermott Distinguished Chair of Anesthesiology & Pain Management at the University of Texas Southwestern Medical Center at Dallas and visiting scientist at Cedars Sinai Medical Center in Los Angeles. "The use of IV ibuprofen can help reduce opioid-related side effects, and Caldolor is the first IV analgesic with antipyretic and anti-inflammatory properties."

Until now, the only injectable drugs available to reduce pain were opioids, such as morphine and meperdine, and the non-steroidal anti-inflammatory drug ketorolac. Opioids can cause sedation, nausea, vomiting, cognitive impairment and respiratory depression, and ketorolac has been associated with side effects such as increased risk of bleeding as well as gastrointestinal and renal complications. Caldolor is the first new injectable product available in the United States in 20 years for IV pain treatment, and provides safe and effective relief from both pain and fever. Caldolor also offers reliable IV delivery of ibuprofen, which has a long history of safe and effective use as an oral formulation.

"We are greatly encouraged by the medical community's favorable early reception for Caldolor, particularly the rate at which hospitals are adding the product to their formularies," Mr. Kazimi added. "Moreover, with the imminent onset of the flu season, we envision Caldolor as becoming an important new treatment for high fever often seen in hospitalized flu patients."

Hospitals and other healthcare institutions interested in obtaining product supplies should contact their wholesalers. Medical inquiries should be directed to Cumberland's Professional Affairs group at 877-484-2700. For more product information about Caldolor, please visit <u>www.caldolor.com</u>.

Caldolor is the third drug in Cumberland's portfolio and the second for which Cumberland has completed development and secured FDA approval. The Company also markets Acetadote[®], the first injectable drug to treat acetaminophen overdose, which is a leading cause of poisoning in the United States, and Kristalose^O, a prescription laxative product designed to enhance patient compliance and acceptance.

Conference Call and Webcast

A conference call and live webcast will be held on Wednesday, September 9, 2009, at 11:00 a.m. Eastern Time to discuss the Company's detailed launch plans for Caldolor. To participate on the call, please dial 888-634-7543 (for U.S. callers) or 719-457-2731 (for international callers). A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 888-203-1112 (for U.S. callers) or 719-457-0820 (for international callers). The passcode for the rebroadcast is 5439189. The live webcast and rebroadcast can be accessed via Cumberland Pharmaceuticals' website at http://investor.shareholder.com/cpix/events.cfm.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland markets Acetadote[®] for the treatment of acetaminophen poisoning and Kristalose[®], a prescription laxative. The Company also recently received FDA approval for Caldolor[®], the first injectable treatment for pain and fever available in the United States, and has now completed the commercial launch of that product. Cumberland is dedicated to providing innovative products which improve quality of care for patients. The Company recently completed the initial public offering of its common stock.

For more information on Cumberland Pharmaceuticals, please visit www.cumberlandpharma.com.

About Caldolor

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever in adults. It is the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or 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, visit www.caldolor.com.

About Acetadote

Acetadote is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose, the leading cause of poisonings presenting in emergency departments in the country¹. 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 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 <u>www.acetadote.net</u>.

About Kristalose

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 <u>www.kristalose.com</u>.

Important Note Regarding Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements reflect Cumberland's current views with respect to future events, based on what it believes are reasonable assumptions. No assurance can be given, however, that these events will occur. As with any business, all phases of Cumberland's operations are subject to influences outside its control. Any one, or a combination, of these risk factors could materially affect the results of the Cumberland's operations. These factors include among other things, market conditions, the commercialization of Caldolor, Cumberland's dependence on Acetadote and Kristalose to generate almost all of its revenues, intense competition from existing and new products, which could diminish the commercial potential of Cumberland's products, an inability of manufacturers to produce Cumberland's products on a timely basis or a failure of manufacturers to comply with stringent regulations applicable to pharmaceutical drug manufacturers, maintaining and building an effective sales and marketing infrastructure, Cumberland's ability to identify and acquire rights to products, government regulation, the possibility that Cumberland's marketing exclusivity and patent rights may provide only limited protection from competition, and other factors discussed in our Registration Statement declared effective by the SEC on August 10, 2009. There can be no assurance that the results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business and operations. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

SOURCE: Cumberland Pharmaceuticals Inc.

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 $^{1}\;$ National Poison Data System, American Association of Poison Control Centers