CUMBERLAND PHARMACEUTICALS INC
Form 8-K
February 21, 2013

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): February 19, 2013 (February 21, 2013)

Cumberland Pharmaceuticals Inc.
_____
(Exact name of registrant as specified in its charter)

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| Tennessee<br>(State or other jurisdiction of incorporation) | 001-33637<br>(Commission File Number) | 62-1765329<br>(I.R.S. Employer Identification No.) |
| 2525 West End Avenue, Suite 950,<br>Nashville, Tennessee<br>(Address of principal executive offices) | | 37203<br>(Zip Code) |

Registrant's telephone number, including area code: (615) 255-0068
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))

Item 8.01 Other Events.

On February 19, 2013, Cumberland Pharmaceuticals Inc. issued a press release announcing top-line results from two registry studies evaluating the safety and efficacy of Caldolor® (ibuprofen) Injection administered over a shortened infusion time in treating pain and fever in adult patients. The studies involved 450 patients receiving Caldolor at 35 leading medical centers throughout the United States. A copy of the press release is attached as Exhibit 99.1.

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.

Cumberland Pharmaceuticals Inc.

February 21, 2013

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

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Exhibit Index

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated February 19, 2013 |

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FOR IMMEDIATE DISTRIBUTION

CALDOLOR® REDUCES PAIN AND FEVER IN ADULT PATIENTS
-Studies support shortened Caldolor infusion time
- Studies conducted at 35 leading medical centers

Nashville, Tenn. - February 19, 2013 - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX) today announced top-line results from two registry studies evaluating the safety and efficacy of Caldolor® (ibuprofen) Injection administered over a shortened infusion time in treating pain and fever in adult patients. The studies involved 450 patients receiving Caldolor at 35 leading medical centers throughout the United States.

The first of two registry studies was a phase IV multi-center, open-label surveillance clinical study to assess the safety and efficacy of ibuprofen administered intravenously over five to ten minutes to adult patients in the hospital setting with temperature fever (>101ºF) and/or pain (visual analog scale (VAS) assessment >3). Eligible patients were enrolled to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from 13 clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The second of two registry studies was a phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from 21clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

"We are pleased to complete these two important studies supporting the safety of a shortened Caldolor infusion time," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “We remain committed to the ongoing development of our brands and expanding the patient safety database for our products."

SOURCE: Cumberland Pharmaceuticals Inc.

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, including boxed warning, visit www.caldolor.com.

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's marketed products include Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (lactulose) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information, visit the Company's website at www.cumberlandpharma.com.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views on future events, based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include market conditions, competition from existing and new products, an inability or failure of manufacturers to produce the Company's products on a timely basis or to comply with stringent regulations applicable to drug manufacturers, maintaining and building an effective sales and marketing infrastructure, government regulation, the possibility that patent rights may provide limited protection from competition, and other factors including those under the headings “Risk factors” and “Management's discussion and analysis of financial condition and results of operations” in Cumberland's Form 10-K filed with the SEC on March 7, 2012. There can be no assurance that results anticipated by Cumberland will be realized or, if realized, 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. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof.

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