

CUMBERLAND PHARMACEUTICALS INC

Form 8-K

February 26, 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 21, 2013 (February 25, 2013)

Cumberland Pharmaceuticals Inc.

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(Exact name of registrant as specified in its charter)

Tennessee

(State or other jurisdiction of  
incorporation)

001-33637

(Commission File Number)

62-1765329

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

2525 West End Avenue, Suite 950,  
Nashville, Tennessee

(Address of principal executive  
offices)

37203

(Zip Code)

Registrant's telephone number, including area code:

(615) 255-0068

Not Applicable

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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))

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Item 8.01 Other Events.

On February 21, 2013, Cumberland Pharmaceuticals Inc. issued a press release announcing that it has entered into an exclusive agreement with Sandor Medicaids Pvt. Ltd., an India-based pharmaceutical company, for the commercialization of Caldolor® (ibuprofen) Injection in India. A copy of the press release is attached as Exhibit 99.1.

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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.

February 25, 2013

Cumberland Pharmaceuticals Inc.

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 21, 2013

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FOR IMMEDIATE DISTRIBUTION

CUMBERLAND PHARMACEUTICALS LICENSES  
CALDOLOR® (IBUPROFEN) INJECTION TO SANDOR MEDICAIDS PVT. LTD.  
FOR COMMERCIALIZATION IN INDIA

Nashville, Tenn. (February 21, 2013) - Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX) today announced that it has entered into an exclusive agreement with Sandor Medicais Pvt. Ltd., an India-based pharmaceutical company, for the commercialization of Caldolor® (ibuprofen) Injection in India.

Under the terms of the agreement, Sandor Medicais Pvt. Ltd. is responsible for seeking regulatory approval for Caldolor and, following approval, would handle ongoing distribution and sales in the territory. Cumberland maintains responsibility for product formulation, development and manufacturing, and will provide finished product for sale. In exchange for the license to the product, Cumberland will receive upfront and milestone payments, a transfer price and royalties on future sales of Caldolor.

"We believe Caldolor can fill an unmet need in the hospital market in India, and look forward to communicating its benefits to the medical community here," said Rajeev Sindhi, Managing Director for Sandor Medicais Pvt. Ltd. "Cumberland's strong clinical data and profile for use of the product should help facilitate regulatory approval and encourage widespread hospital use in our country."

Used primarily in hospitalized patients who are unable to receive oral therapies, Caldolor is expected to be the first and only injectable ibuprofen product available in India for the treatment of pain and fever, featuring analgesic, antipyretic and anti-inflammatory properties.

"We are very pleased to expand our network of international partners for Caldolor with this new agreement," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Sandor has an established infrastructure to handle commercialization of hospital pharmaceutical products, and we look forward to working with them to make Caldolor available to a larger population of patients."

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

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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](http://www.caldolor.com).

#### Sandor Medicais

Sandor Medicais Pvt. Ltd is a medical and drug distribution firm. Since its establishment in 1995 at Hyderabad, the company focuses on providing high technology biomedical and biotechnology products to the Indian patient. Sandor is recognized as a pioneer in bringing in "Point of Care" concept in the Indian Health Care Industry. Sandor's marketing and distribution team is comprised of experienced professionals from the Health Care Industry across the country. They ensure the products of our partners reach the customers at the Right Time, to the Right Place, in the Right form and for the Right Price.

A sub- network of 15 distribution centers ably supports Sandor's existing efficient and effective COLD CHAIN DISTRIBUTION network in the 16 major cities of the country. The entire network is centrally monitored from the Sandor Head Office at Hyderabad Sandor offers a complete range of Logistics & Distribution management, Regulatory services to manufactures in speciality drugs, medical devices and hospital supplies industries.

#### 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 product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning; Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever available 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, please visit the company website at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

#### Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to 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, among other things, market conditions, intense competition from existing and new products, an inability of manufacturers to produce Acetadote on a timely basis or a failure of manufacturers 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 only limited protection from competition, and other factors related to the Company 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 the results or developments 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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