

CUMBERLAND PHARMACEUTICALS INC
Form 8-K
February 01, 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 1, 2013 (January 29, 2013)

Cumberland Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Tennessee	001-33637	62-1765329
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2525 West End Avenue, Suite 950, Nashville, Tennessee	37203
(Address of principal executive offices)	(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 January 29, 2013 Cumberland Pharmaceuticals Inc. issued a press release announcing it has entered into an exclusive agreement with Indonesia's PT. SOHO Industri Pharmasi (a SOHO Group company) for the registration and commercialization of Caldolor® (ibuprofen) Injection, which is used to treat pain and fever in the hospital setting. 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 1, 2013

By: Rick S. Greene

Name: Rick S. Greene

Title: Chief Financial Officer

Exhibit Index

Exhibit No.

Description

99.1

Press release dated January 29, 2013

FOR IMMEDIATE DISTRIBUTION

CUMBERLAND PHARMACEUTICALS AND PT. SOHO INDUSTRI PHARMASI
ENTER INTO exclusive licensing AGREEMENT
for CALDOLOR IN INDONESIA

-Indonesia has the World's Fourth Largest Population

Nashville, Tenn., (January 29, 2013) - Cumberland Pharmaceuticals Inc. (NASDAQ:CPIX) today announced it has entered into an exclusive agreement with Indonesia's PT. SOHO Industri Pharmasi (a SOHO Group company) for the registration and commercialization of Caldolor® (ibuprofen) Injection, which is used to treat pain and fever in the hospital setting.

Under the terms of the agreement, SOHO receives an exclusive license to Caldolor for the Indonesian market. SOHO will be responsible for seeking regulatory approval, ongoing regulatory reporting, product marketing, distribution and sales in the territory following approval. Cumberland maintains responsibility for the intellectual property, product formulation, manufacturing and other supported activities. In exchange for the license to the product, Cumberland will receive upfront and milestone licensing payments, as well as transfer prices on future sales of the drug.

“We are delighted to partner with SOHO to introduce our product in Indonesia and to help support the quality of care available to hospitalized patients in that country,” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “Expanding into new international markets is a key component of our growth strategy, and this partnership represents an important milestone in achieving that strategy and establishing a strong presence in Asia.”

While Cumberland focuses its proprietary commercial efforts on the United States, the Company has significantly expanded its international network of partners in recent years. In addition to its arrangement with SOHO, Cumberland has licensed rights for Caldolor to partners in China, South Korea, Malaysia, Dubai, Canada, Australia and New Zealand.

“There is a significant and growing body of research that supports the safety and efficacy of Caldolor,” said Marcus Pitt, President, Director and CEO of SOHO Group (a holding company of PT. SOHO Industri Pharmasi). “Due to Caldolor's attributes and strong performance in clinical trials in the United States, we are excited to share this innovative product with physicians and patients throughout Indonesia.”

Following regulatory approval, SOHO will use its existing sales force to promote Caldolor throughout Indonesia. The product features analgesic, antipyretic and anti-inflammatory properties and is designed for the treatment of pain and fever, primarily in hospitalized patients who are unable to receive oral

therapies. In clinical trials, Caldolor has demonstrated significant reductions in post-operative pain when compared with opioids alone while significantly reducing opioid requirements.

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 SOHO Group

SOHO Group is one of Indonesia's leading pharmaceutical and healthcare corporations in manufacturing, distributing, and providing quality health products and services.

The corporation consists of 3 synergy business under SOHO Group: SOHO Group PHARMA (Prescription market: Branded Generics, Natural & TCM Product, Low Price Medicine, Medical Device, and Alliance Business), SOHO Group COSTUMER HEALTH (OTC Product, Consumer Health Product, Hezzel Farm Product and Unihealth MLM Product), SOHO Group DISTRIBUTION (Distribution arm of SOHO Group & Other Principal, Raw Material Trading Business, and Retail Business "Apotek Harmony").

They focus on manufacturing - including under-licensed - herbal products (immunomodulator, antioxidant, anti diarrhea, anti laxantia) and synthetic products (antibiotic, cephalosporin, injection preparation, antiemetic, analgesic, musculoskeletal, vitamin, obgyn, gastro, neuro, and rheumatology products). SOHO distributes pharmaceutical and healthcare products for their companies, and other pharmaceutical and consumer goods manufacturers. For more information, please visit www.sohogroup.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 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.

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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