

# CUMBERLAND PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 11/21/16 for the Period Ending 11/21/16

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CIK	0001087294
Symbol	CPIX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare

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): November 21, 2016 (November 16, 2016)

Cumberland Pharmaceuticals Inc.

(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

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 November 16, 2016, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing it has entered into an Agreement to acquire the exclusive U.S. rights to Nordic Group B.V.'s injectable methotrexate product line. A copy of the press release is furnished 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.

November 21, 2016

Cumberland Pharmaceuticals Inc.

*By: Michael Bonner*

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*Name: Michael Bonner*

*Title: Chief Financial Officer*



**CUMBERLAND PHARMACEUTICALS ACQUIRES U.S. RIGHTS TO  
NORDIC GROUP'S METHOTREXATE INJECTION PRODUCTS**

*Methotrexate Injectors designed for use in patients with active rheumatoid arthritis*

**Nashville, Tenn., November 16, 2016 - Cumberland Pharmaceuticals (NASDAQ: CPIX)**, a U.S. specialty pharmaceutical company has entered into an Agreement to acquire the exclusive U.S. rights to **Nordic Group B.V.'s innovative injectable methotrexate product line**. The products are designed for the treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, severe psoriatic arthritis, and severe disabling psoriasis. The product line is approved for patient use in various European countries. Cumberland will register and commercialize the methotrexate products in the United States.

Under the terms of the Agreement, Cumberland will be responsible for the products' FDA submission and registration. The regulatory submission, expected to occur during the first half of 2017, will be based on the dossier provided by Nordic. Following registration, Cumberland will be responsible for product launch and commercialization, including all marketing, promotion, and distribution of the products in the U.S. Cumberland projects building to \$40 million in annual sales over time for the product line. As consideration for the license, Cumberland will provide Nordic a series of payments tied to the products' FDA approval and achievement of certain sales milestones. Nordic will be responsible for manufacture and will receive a transfer price on supplies of the products.

Nordic has successfully developed and registered the product line in Europe. "We have worked to deliver innovative, patient friendly, and cost effective treatments for arthritis patients" said Drs. Hans Schram, Chief Executive Officer of the Nordic Group. "These products have been successfully launched in Europe in 2016 and our agreement with Cumberland, and the upcoming U.S. launch, will be another significant step in their geographic expansion."

"We continue to be very selective in the brands we choose to bring into our portfolio," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We believe that these innovative products from Nordic will be an excellent fit for our field based commercial division and their ongoing support of office

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based physicians. We look forward to bringing these Nordic products into the U.S. in order to better address the care of arthritis patients here."

### **About injectable Methotrexate**

Methotrexate, the active ingredient in Nordic's product, is approved in the U.S. as a treatment for diseases like arthritis. Methotrexate is recognized as the "anchor drug" of such auto-immune diseases and is the reference treatment used as first line therapy. Methotrexate has been shown to reduce inflammation and slow the progression of disease by interfering with the growth of certain cells of the body.

The rationale for considering the administration of methotrexate using subcutaneous route has been driven by the need to increase the therapeutic dose, ensure the maximum bioavailability, reduce symptomatic side effects for some patients, and improve treatment compliance. The subcutaneous route of administration seems to be the best treatment option from the outset, in terms of risk-benefit ratio, compared with the oral route.

Using an innovative injection device, like Nordic's, offers patients with reduced dexterity the option for self-injection with secured handling, more autonomy and better disease management.

This results in increased efficacy, greater continuation rates, and less discomfort for patients.

### **About Nordic Group B.V.**

Nordic Group B.V. is a privately-owned European specialty pharmaceutical company with a direct presence in 17 countries. The company focuses on the development and commercialization of niche hospital and orphan products, aiming to address unmet medical needs in rheumatology, gynecology and critical care. Nordic focuses on the development and sales of its own products, while exploring product opportunities throughout the various stages of product development.

The Nordic Group has always maintained a tradition of developing successful partnerships with third parties, in addition to supporting internal development projects. Nordic also offers U.S., Japanese, and other non-European companies the opportunity to take advantage of Nordic's intricate understanding of the European markets by forging broad partnerships to develop, register, and commercialize their products in Europe. Find more information at [www.nordicpharmagroup.com](http://www.nordicpharmagroup.com)

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## **About Cumberland Pharmaceuticals**

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of high-quality products that improve the quality of care for patients. The Company has a diverse product portfolio with a focus in the areas of hospital acute care and gastroenterology.

Cumberland's marketed products include Acetadote<sup>®</sup> (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor<sup>®</sup> (ibuprofen) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose<sup>®</sup> (lactulose) for Oral Solution, a prescription laxative, Vaprisol<sup>®</sup> (conivaptan) Injection, for the treatment of hyponatremia, Omeclamox-Pak<sup>®</sup> for the treatment of H. pylori and duodenal ulcer disease, and Ethyol<sup>®</sup> (amifostine) for Injection, for use by oncology patients. Cumberland is also dedicated to developing innovative products that address unmet medical needs. The Company's product candidates in clinical development include: Hepatoren<sup>®</sup> (ifetroban) Injection for the treatment of hepatorenal syndrome, Boxaban<sup>®</sup> (ifetroban) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, Vasculan<sup>™</sup> (ifetroban) Oral Capsule for the treatment of systemic sclerosis, and Portaban<sup>™</sup>, for the treatment of portal hypertension. For more information on Cumberland Pharmaceuticals Inc., please visit [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

## **Important Note Regarding 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. 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 results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure, and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. 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: Nordic Group B.V. and Cumberland Pharmaceuticals Inc.

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## **Contact Details**

### **Nordic Group B.V.**

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