

# CUMBERLAND PHARMACEUTICALS INC

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

Filed 08/01/17 for the Period Ending 08/01/17

Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN 37203
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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): August 1, 2017 (July 31, 2017)

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 July 31, 2017, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the Company began distributing dexrazoxane, sold under the brand name Totect<sup>®</sup>, to U.S. wholesalers. Totect is an FDA-approved emergency oncology intervention indicated to treat the toxic effects of anthracycline chemotherapy in case of extravasation. Extravasation occurs when an injected medicine escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications. Totect can limit such damage without the need for additional surgeries and procedures and enable patients to continue their essential anti-cancer treatment.

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.

August 1, 2017

Cumberland Pharmaceuticals Inc.

*By: Michael Bonner*

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*Name: Michael Bonner*

*Title: Chief Financial Officer*

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated July 31, 2017



## **CUMBERLAND PHARMACEUTICALS BEGIN U.S. SHIPMENTS OF DEXRAZOXANE FOR ONCOLOGY PATIENT SUPPORT**

**Nashville, Tenn., July 31, 2017 - Cumberland Pharmaceuticals Inc. (NASDAQ:CPIX)**, a specialty pharmaceutical company focused on the development of innovative treatments for underserved patient populations, will begin distributing dexrazoxane, sold under the brand name Totect<sup>®</sup>, to U.S. wholesalers today. Totect is an FDA-approved emergency oncology intervention indicated to treat the toxic effects of anthracycline chemotherapy in case of extravasation. Extravasation occurs when an injected medicine escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications. Totect can limit such damage without the need for additional surgeries and procedures and enable patients to continue their essential anti-cancer treatment.

“We are delighted to make Totect (dexrazoxane) available for oncology patients throughout the U.S.,” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “We look forward to continuing to expand our activities into oncology while working to deliver products that improve the quality of care for patients.”

Totect is Cumberland’s second oncology support product and complements its current portfolio of specialty pharmaceuticals. It is also the second product Clinigen has licensed to Cumberland under the Strategic Alliance the two companies signed. Under the terms of the agreement, Cumberland is managing all marketing, promotion, and distribution of Totect in the U.S.

### **About Totect<sup>®</sup> (dexrazoxane)**

Totect is an anthracycline extravasation agent approved by the United States Food and Drug Administration. Anthracyclines are used to treat many types of cancer and are among the most common cancer therapies.

Anthracycline extravasation occurs when there is accidental leaking of the intravenously-administered medication into the surrounding tissues. Anthracycline extravasation can result in serious complications for cancer patients including tissue necrosis with skin ulceration. In addition to tissue damage, an anthracycline extravasation may cause damage to the nerves, tendons, muscle, and joints.

For more information please visit [www.totect.com](http://www.totect.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 the prevention of treatment-related adverse reactions in 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> (ifetroban) Oral Capsule for the treatment of portal hypertension.

For more information on Cumberland Pharmaceuticals Inc., please visit [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

## 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: Cumberland Pharmaceuticals Inc.

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