

CUMBERLAND PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 09/29/17 for the Period Ending 09/29/17

Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN, 37203
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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): September 29, 2017 (September 25, 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 September 25, 2017, Cumberland announced the promotional launch of Totect[®] (dexrazoxane hydrochloride) in the United States.

Totect is an FDA-approved hospital based emergency oncology intervention drug, 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.

In preparation for the Totect launch, Cumberland has completed the training of its sales and medical organization, stocked the product at wholesalers serving hospitals nationwide, and recently introduced the product website. Totect will be supported by Cumberland's hospital sales force.

Totect is Cumberland's second oncology support product and complements its current portfolio of specialty pharmaceuticals.

A copy of the press release is furnished 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.

September 29, 2017

Cumberland Pharmaceuticals Inc.

By: Michael Bonner

Name: Michael Bonner

Title: Chief Financial Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated September 25, 2017



CUMBERLAND PHARMACEUTICALS LAUNCHES

PROMOTION OF TOTECT[®] IN THE U.S.

FOR EMERGENCY ONCOLOGY INTERVENTION

Nashville, Tenn., and Burton on Trent, UK, September 25, 2017 - Cumberland Pharmaceuticals Inc. (NASDAQ:CPIX, 'Cumberland') and Clinigen Group plc (AIM:CLIN, 'Clinigen') , announced today the promotional launch of Totect[®] (dexrazoxane hydrochloride), in the U.S.

Totect is an FDA-approved hospital based emergency oncology intervention drug, 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.

In preparation for the Totect launch, Cumberland has completed the training of its sales and medical organization, stocked the product at wholesalers serving hospitals nationwide, and recently introduced the product website. Totect will be supported by Cumberland's hospital sales force.

“This is a significant next step for Cumberland as we build our position in oncology supportive care while improving the quality of care for patients in the U.S.,” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals.

Totect is Cumberland’s second oncology support product and complements its current portfolio of specialty pharmaceuticals. Cumberland entered into an exclusive agreement with Clinigen to commercialize Totect in the U.S. earlier this year. Cumberland is managing all marketing, promotion, and distribution of the product in the U.S. Clinigen is responsible for manufacturing, regulatory, and clinical management of the product.

Totect was acquired by Clinigen in March 2016 to expand its dexrazoxane portfolio and enter the U.S. market. Clinigen will continue to commercialize its existing dexrazoxane products, Savene[®] and Cardioxane[®] , in Europe and other territories outside of the U.S.

“The commercial launch of Totect in the U.S. is an important milestone in the dexrazoxane revitalization strategy at Clinigen,” said Simon Clayton, Commercial Director, Specialty Pharmaceuticals Clinigen Group. “It will ensure that patients in the U.S. can access this vital FDA-approved emergency support therapy.”

About Totect[®] (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.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. The Company develops, acquires, and commercializes brands for the hospital acute care, gastroenterology, and oncology market segments.

The Company's portfolio of FDA approved brands includes:

- **Acetadote[®]** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
 - **Caldolor[®]** (*ibuprofen*) Injection, for the treatment of pain and fever;
 - **Kristalose[®]** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
 - **Omeclamox[®] -Pak** , (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
 - **Vaprisol[®]** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
 - **Ethyol[®]** (*amifostine*) Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;
 - **Totect[®]** (*dexrazoxane hydrochloride*) Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).
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Cumberland's pipeline of product candidates includes:

- **Hepatoren**[®] (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- **Boxaban**[®] (*ifetroban*) oral capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- **Vasculan**[™] (*ifetroban*) oral capsules, a Phase II candidate for the treatment of patients with the systemic sclerosis (SSc) form of autoimmune disease;
- **Portaban**[™] (*ifetroban*) oral formulation, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease;
- **Methotrexate** (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psoriasis.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing access to medicines. Its mission is to deliver the right medicine to the right patient at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

For more information, please visit www.clinigengroup.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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