

CUMBERLAND PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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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): January 13, 2017 (January 9, 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 January 9, 2017, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing it has entered into an agreement with Clinigen Group plc to acquire exclusive rights to commercialize the FDA approved oncology support drug, Totect[®] (dexrazoxane hydrochloride) in the United States. 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.

January 13, 2017

Cumberland Pharmaceuticals Inc.

By: Michael Bonner

Name: Michael Bonner

Title: Chief Financial Officer



**CUMBERLAND PHARMACEUTICALS AND CLINIGEN ENTER EXCLUSIVE
U.S. COMMERCIALIZATION AGREEMENT FOR TOTECT[®]**

Nashville, Tenn., January 9, 2017 - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX) , a U.S. specialty pharmaceutical company and **Clinigen Group plc (AIM: CLIN, 'Clinigen')** , the global pharmaceutical and services company, announce an exclusive agreement to commercialize the oncology support drug, Totect[®] (dexrazoxane hydrochloride) in the U.S.

This is the second product Clinigen has licensed to Cumberland under the strategic alliance established in 2015, following the launch of Ethyol[®] (amifostine) in the U.S. in September 2016.

Totect is an FDA-approved emergency oncology intervention which is indicated to reverse 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 reverse such damage without the need for additional surgeries and procedures, enabling patients to continue their essential anti-cancer treatment.

Under the terms of the agreement, Cumberland has been granted an exclusive U.S. license and will manage all marketing, promotion, and distribution of Totect in the US. Clinigen will retain responsibility for manufacturing, regulatory and clinical management of the product. Preparations are now underway for the U.S. launch of Totect later this year.

Totect was acquired by Clinigen's Specialty Pharmaceuticals (SP) division in 2016 to expand its dexrazoxane portfolio and enter the U.S. market. Clinigen SP will continue to commercialize its existing dexrazoxane products, Savene[®] and Cardioxane[®] , in Europe and other territories outside of the U.S.

"It's good to see another product emerge from our strategic partnership with Clinigen, as we continue to selectively expand our line of marketed hospital brands," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are keen to help yet another group of oncology patients with Totect, which reflects our mission of delivering products that help improve patients' quality of care."

Shaun Chilton, Chief Executive Officer of Clinigen Group, added, "This agreement marks an important milestone for Clinigen. Totect is the second Specialty Pharmaceuticals product that we have exclusively licensed to Cumberland as part of the strategic alliance signed in 2015. Cumberland is a valuable partner, providing us with the opportunity to expand our dexrazoxane portfolio into the sizable U.S. market and enabling patients to 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.

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® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia, Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease, and Ethyol® (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® (*ifetroban*) Injection for the treatment of hepatorenal syndrome, Boxaban® (*ifetroban*) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, Vasculan™ (*ifetroban*) Oral Capsule for the treatment of systemic sclerosis and Portaban™ (*ifetroban*) Oral Capsule for the treatment of portal hypertension.

For more information on Cumberland Pharmaceuticals Inc., please visit 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. The Group consists of five synergistic businesses focused in three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

Clinigen Clinical Trial Services is the global market leader in the management and supply of commercial medicines for clinical trials.

The Group is also the trusted global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need, through three of its divisions: Idis Managed Access runs early access programs for innovative new medicines. Idis Global Access and Link Healthcare work directly with healthcare professionals to enable compliant access to unlicensed medicines on a global basis and niche essential licensed and generic medicines across Australasia, Africa and Asia (AAA region).

Clinigen Specialty Pharmaceuticals acquires global rights, revitalises and markets its own portfolio of niche hospital commercial products.

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.