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): July 10, 2017 (July 10, 2017)

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 July 10, 2017, Clinigen Group plc and Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the FDA approval of Totect ® (dexrazoxane hydrochloride) in the U.S. 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.

Cumberland Pharmaceuticals Inc.

July 10, 2017

By: Michael Bonner

Name: Michael Bonner
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated July 10, 2017

Clinigen and Cumberland Pharmaceuticals obtain FDA approval for Totect ® in the U.S.

Clinigen Group plc (AIM: CLIN, 'Clinigen' or the 'Group'), the global pharmaceutical and services company and Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX, 'Cumberland'), a U.S. specialty pharmaceutical company, today announce they have obtained FDA approval of Totect ® (dexrazoxane hydrochloride) in the U.S.

Totect is an 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.

In January 2017, Clinigen and Cumberland entered an exclusive U.S. agreement to commercialize Totect, the second such agreement under their Strategic Alliance, established in 2015. The FDA approval of Totect is an important milestone in the preparation for the U.S. launch of the product this year.

Totect was acquired by Clinigen's Specialty Pharmaceuticals (SP) division in March 2016 to expand its dexrazoxane portfolio for the U.S. market. Clinigen SP continues to commercialise its existing dexrazoxane products, Savene ® and Cardioxane ®, in Europe and other territories outside of the U.S.

Shaun Chilton, Chief Executive Officer of Clinigen said:

"Totect is the second SP product that we have exclusively licensed to Cumberland as part of the Strategic Alliance, and the FDA approval of Totect is an important milestone in its revitalisation strategy.

"Approval paves the way for launch, which will enable patients to access this vital FDA-approved emergency support therapy."

A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals said:

"We are delighted by the FDA approval of Totect for the United States, and we are looking forward to expanding the number of patients that will benefit from this important oncolgy support product.

"This is a significant next step for Cumberland as we build our position in Oncology supportive care and further strengthen our Strategic Alliance with our partner, Clinigen."

About Totect® (dexrazoxane)
Totect is the only agent approved by the United States Food and Drug Administration to treat anthracycline extravasation. 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. Untreated extravasations can lead to an interruption in needed anti-cancer therapy.

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 products.

For more information, please visit www.clinigengroup.com.

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 .

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.