

CUMBERLAND PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN, 37203
Telephone	615-255-0068
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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): March 30, 2018 (March 26, 2018)

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 March 26, 2018, Cumberland announced the publication of an open access article in *Infection and Drug Resistance*, with results demonstrating an 85% eradication rate of *Helicobacter pylori* (*H. pylori*) infection using clarithromycin-based triple therapy. Cumberland markets a branded clarithromycin-based triple therapy in the U.S. under the name Omeclamox[®]-Pak.

H. pylori has long been known as a common pathogen associated with gastric ulcers and related dyspeptic symptoms in many infected patients. If *H. pylori* is left untreated, it can damage the stomach and small intestine wall causing peptic ulcer disease, specifically duodenal ulcers. Symptoms of *H. pylori*-induced duodenal ulcers generally surface in adults and may include burning pain in the abdomen, nausea, vomiting, bloating, and weight loss.

This study, led by Devjit S. Nayar at Gastroenterology Associates of Central Jersey, evaluated the potential incidence of resistance in the New York Metropolitan region. The clinical success rate of clarithromycin-based triple therapy was evaluated by retrospectively reviewing patient data over six years. The cases of 151 patients, ranging in age from 21-76 years and receiving prescriptions for clarithromycin-based triple therapy between December 2011 and May 2017 were analyzed. The results of *H. pylori* eradication testing following completion of clarithromycin-based triple therapy revealed that 85%, or 130 of the 151, patients treated according to the standard protocol were negative for *H. pylori*.

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.

March 30, 2018

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 March 26, 2018



**NEWLY PUBLISHED DATA DEMONSTRATES
85% ERADICATION OF ULCER CAUSING BACTERIA**

Study supports use of Omeclamox[®]-Pak as first-line treatment for H. pylori

NASHVILLE, Tenn. (Monday, March 26, 2018) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company announced today the publication of an open access article in *Infection and Drug Resistance*, with results demonstrating an 85% eradication rate of Helicobacter pylori (H. pylori) infection using clarithromycin-based triple therapy. Cumberland markets a branded clarithromycin-based triple therapy in the U.S. under the name Omeclamox[®]-Pak.

H. pylori has long been known as a common pathogen associated with gastric ulcers and related dyspeptic symptoms in many infected patients. If H. pylori is left untreated, it can damage the stomach and small intestine wall causing peptic ulcer disease, specifically duodenal ulcers. Symptoms of H. pylori-induced duodenal ulcers generally surface in adults and may include burning pain in the abdomen, nausea, vomiting, bloating, and weight loss.

Currently, the use of clarithromycin-based triple therapy has the support of organizational bodies in gastroenterology. Over the last 10 years, early recommendations to use clarithromycin-based triple therapy have been challenged by some sources and based on the premise that resistance is increasing.

This study, led by Devjit S. Nayar at Gastroenterology Associates of Central Jersey, evaluated the potential incidence of resistance in the New York Metropolitan region. The clinical success rate of clarithromycin-based triple therapy was evaluated by retrospectively reviewing patient data over six years. The cases of 151 patients, ranging in age from 21-76 years and receiving prescriptions for clarithromycin-based triple therapy between December 2011 and May 2017 were analyzed. The results of H. pylori eradication testing following completion of clarithromycin-based triple therapy revealed that 85%, or 130 of the 151, patients treated according to the standard protocol were negative for H. pylori.

Despite predictions from other sources in the last decade that clarithromycin-based treatments are becoming less effective, based on the results of this study, patients with a positive diagnosis of H. pylori could expect an 85% or better eradication rate when treated with clarithromycin-based triple therapy.

About Omeclamox[®]-Pak (omeprazole, clarithromycin, amoxicillin)

Omeclamox[®]-Pak is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori. Omeprazole is an antisecretory drug, which works by decreasing the amount of acid the stomach produces. Clarithromycin and amoxicillin are antibacterial drugs, which inhibit the growth of bacteria allowing the stomach lining to heal. Omeclamox-Pak is contraindicated in patients with a history of hypersensitivity to omeprazole, any macrolide antibiotic or penicillin. The safety and effectiveness of Omeclamox-Pak in the pediatric population has not yet been established. For full prescribing information, visit www.omeclamox.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).

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 systemic sclerosis (SSc) form of autoimmune disease;
- **Portaban**® (*ifetroban*) Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease;
- **RediTrex**™ (*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

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Investor Contact:

Media Contact:

Erin Smith

Damon Maida

Corporate Relations

the Bradford Group

(615) 255-0068

(615) 515-4883