

CUMBERLAND PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN, 37203
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CIK	0001087294
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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): February 2, 2018 (January 30, 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 January 30, 2018, Cumberland announced a new publication in *Leukemia & Lymphoma*, with study results showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma. Cumberland markets branded amifostine in the U.S. under the name Ethyol[®].

The investigator study, led by Ehsan Malek, MD at Case Western Reserve University, assessed multiple myeloma patients receiving high dose melphalan followed by auto-HTC. It consisted of patients at University Hospitals Seidman Cancer Center in Cleveland, OH and the MD Anderson Cancer Center in Houston, TX. It evaluated the effect amifostine has on this method of treatment.

Amifostine is used to reduce the side effects of certain chemotherapy agents and radiation treatment. It is known as a cytoprotective agent, protecting the body from some of the potentially serious side effects of treatment.

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.

February 2, 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 January 30, 2018



NEWLY PUBLISHED DATA DEMONSTRATES
AMIFOSTINE REDUCES GASTRO-INTESTINAL TOXICITY
FOR MULTIPLE MYELOMA PATIENTS

Amifostine may prevent gastro-intestinal toxicities in certain cancer patients.

NASHVILLE, Tenn. (Tuesday, January 30, 2018) - 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 a new publication in *Leukemia & Lymphoma* , with study results showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma. Cumberland markets branded amifostine in the U.S. under the name **Ethyol[®]** .

Multiple myeloma remains incurable, despite the significant improvement in treatment over the past 10 years. Data predicts that there will be over a 57% increase in the number of multiple myeloma patients by 2030 as a result of achieving longer survival for these patients and the population aging. Gastrointestinal (GI) toxicities such as nausea, vomiting, diarrhea and ulcers in mouth are a major limitation to the use of autologous hematopoietic cell transplantation (auto-HTC), especially in the elderly population which constitutes a significant proportion of multiple myeloma patients. Preventing GI toxicities for these patients without compromising efficacy of transplant is an important goal that could lead to an expansion of transplant eligibility criteria to older patients.

The study, led by Ehsan Malek, MD at Case Western Reserve University, assessed multiple myeloma patients receiving high dose melphalan followed by auto-HTC. It consisted of patients at University Hospitals Seidman Cancer Center in Cleveland, OH and the MD Anderson Cancer Center in Houston, TX. It evaluated the impact of amifostine on reducing GI toxicities among multiple myeloma patients undergoing transplant.

Amifostine is used to reduce the side effects of certain chemotherapy agents and radiation treatment. It is known as a cytoprotective agent, protecting the body from some of the potentially serious side effects of treatment. One hundred and seven patients participated in this study. Amifostine 740 mg was administered at 24 hours and 15 min before high-dose melphalan. The study concluded that amifostine therapy decreased GI toxicity without any significant adverse effects while preserving the anti-myeloma efficacy of high-dose melphalan and auto-HTC.