UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

# FORM 8-K

**CURRENT REPORT**
**PURSUANT TO SECTION 13 OF 15(D)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of Earliest Event Reported): April 13, 2018 (April 9, 2018)

# 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)

**(615) 255-0068**
(Registrant's telephone number, including area code)

**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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

The information contained in this Current Report on Form 8-K (including the exhibit hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 7.01 Regulation FD Disclosure.**

On April 9, 2018, Cumberland Pharmaceuticals Inc. (the "Company") announced that it has expanded its medical specialties to include oncology-related medications. The Company’s entry into the oncology specialty includes two initial supportive care medications: Ethyol® (amifostine) injection and Totect® (dexrazoxane hydrochloride) injection. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01.

**Item 9.01. Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated April 9, 2018 |

**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.**

April 13, 2018

By: Michael Bonner

Name: Michael Bonner

Title: Chief Financial Officer

**CUMBERLAND PHARMACEUTICALS EXPANDS**

**INTO ONCOLOGY SUPPORT**

*FDA-approved Ethyol® and Totect® address harmful effects of cancer treatment to help improve the quality of life for oncology patients*

NASHVILLE, Tenn., April 9, 2018 - Cumberland Pharmaceuticals - announced today that it has expanded its medical specialties to include oncology-related medications. The company's entry into the oncology specialty includes two initial supportive care medications: Ethyol® (amifostine) injection and Totect® (dexrazoxane hydrochloride) injection.

"Since the company's founding, Cumberland has endeavored to deliver high quality medicines to improve patient care," said CEO AJ Kazimi. "Our strategy has been to focus on select medical specialties that we can support nationally and make a significant impact. Oncology is a particularly rewarding and valuable field, and we are delighted to be able to help patients as they undergo their cancer treatments."

There were 1,688,780 new cases of cancer diagnosed in the U.S. in 2017, and advances in treatment have resulted in the average patient now living longer after initial diagnosis. As a result, quality of life becomes of paramount concern - and Cumberland's focus is on supporting cancer patients during their treatment, with the goal of improving their ongoing quality of life.

"The overarching goal of supportive care is to help patients tolerate and continue their cancer treatments," said Kazimi. "Our oncology medications enable us to target the side effects of patients' cancer treatments and help address the psychological or social problems that might result from those complications. We're grateful for the opportunity to contribute to the welfare of cancer patients, and help improve their quality of life."

Cumberland entered into an exclusive U.S. license to distribute and market both Ethyol and Totect with the Clinigen Group plc, a British specialty pharmaceutical and services company following a Strategic Alliance established between the companies.

Ethyol and Totect can offer significant benefits to cancer patients as noted in the following:

**ETHYOL® (AMIFOSTINE)**

- Ethyol, Cumberland's first oncology supportive care product, has two FDA-approved indications.
- The product is used to protect kidneys in women who are receiving cisplatin, a chemotherapy treatment for ovarian cancer, as well as for the treatment of dry mouth (xerostomia) that can occur in patients receiving radiation treatment for head and neck cancer.
- Due to the greater likelihood of positive survival outcomes and length of life, xerostomia is of great concern impacting the patient's ability to eat, chew, and swallow for the rest of their life. Xerostomia occurs in up to 80 percent of patients undergoing radiotherapy.
- More specifically, health care providers are concerned with toxicity levels in patients as a result of cumulative radiation and cisplatin. These toxicity levels can prevent treatment in the future, particularly toxicity to the kidneys (nephrotoxicity) caused by cisplatin. The use of Ethyol results in significantly fewer patients experiencing treatment-limiting nephrotoxicity when compared to patients who did not receive Ethyol treatment.

For more information, including full prescribing instructions, please visit www.ethyol.com

**TOTECT® (DEXRAZOXANE)**

- Totect, Cumberland's second oncology supportive care product, is an FDA-approved hospital-based emergency oncology intervention drug.
- The product is indicated to treat the toxic effects of extravasation which is the leakage associated with anthracycline chemotherapy. 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. Anthracyclines are a class of drugs that includes doxorubicin, epirubicin, and daunorubicin which are used to treat many cancers. The incidence of anthracycline extravasation has been reported to be up to 6.0 percent, although it is widely acknowledged to be both underreported and undertreated.
- Totect can limit the damage caused by extravasation without the need for surgery and enable patients to continue their essential anti-cancer treatment. It is the only FDA approved antidote to this dangerous and debilitating problem that can occur when administering anthracyclines. Even with advances in medicine, anthracyclines are still a first line treatment for most solid tumors. In clinical trials, Totect eliminated the need for surgery in 98 percent of patients with anthracycline extravasation.

For more information, including full prescribing instructions, 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).

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)* 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.

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