

# CUMBERLAND PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 03/31/17 for the Period Ending 03/31/17

Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN 37203
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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 31, 2017 (March 27, 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 March 27, 2017, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the publication of a trial providing evidence that using Caldolor in multimodal pain control strategies improves postoperative pain control and reduces opioid use in patients undergoing transsphenoidal surgery. A copy of the press release is furnished as Exhibit 99.1.

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**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 31, 2017

Cumberland Pharmaceuticals Inc.

*By: Michael Bonner*

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*Name: Michael Bonner*

*Title: Chief Financial Officer*

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 27, 2017



**CALDOLOR<sup>®</sup> DEMONSTRATES SIGNIFICANT POST SURGICAL  
PAIN REDUCTION AND DECREASE IN OPIOID USE**

*New study data supports the use of Caldolor<sup>®</sup> in controlling pain and reducing opioid use in surgical patients.*

**NASHVILLE, Tenn. (Monday, March 27, 2017)** - Cumberland Pharmaceuticals Inc. (**NASDAQ: CPIX**) today announced the publication of a trial providing evidence that using Caldolor in multimodal pain control strategies improves postoperative pain control and reduces opioid use in patients undergoing transsphenoidal surgery. The trial was conducted at the Department of Neurosurgery, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center in Phoenix, Arizona and was published in the *Journal of Neurosurgery*, March 2017.

“The United States is in the midst of an epidemic of excessive opioid use, misuse, and abuse to control chronic pain,” said AJ Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “The more we can prevent postsurgical pain from transitioning into chronic pain, the more likely we are to decrease reliance on opioids and improve the quality of life for patients long-term. We are thrilled to add this study to the growing body of literature supporting the safety and use of Caldolor in hospitalized patients.”

The trial compared outcomes in 2 groups of patients treated with multimodal pain management protocols following transsphenoidal surgery for pituitary lesions: Group 1 patients treated intraoperatively with IV Ibuprofen (Caldolor 800 mg q 8 hr), scheduled oral acetaminophen and rescue opioids, versus Group 2 patients treated with IV saline placebo q 8 hr, scheduled oral acetaminophen, and rescue opioids. The Caldolor Group 1 patients demonstrated a significant reduction of 43% mean VAS scores compared with Placebo Group 2 patients. Opioid use was also significantly different, with a 58% reduction in the Caldolor Group 1 patients compared to Placebo Group 2 patients.

The study had two aims. The primary endpoint was patient pain scores measured on a 0-10 Visual Analog Scale (VAS), and the secondary endpoint was the estimated oral morphine equivalent (OME) used for breakthrough pain in the first 48 hours after surgery. The study was terminated early because the planned interim analysis demonstrated that the primary and secondary endpoints had been reached.

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## About Caldolor<sup>®</sup>

Caldolor is indicated in adults and pediatric patients six months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with a history of asthma or other allergic-type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit [www.caldolor.com](http://www.caldolor.com).

## About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's six marketed products include Acetadote<sup>®</sup> ( *acetylcysteine* ) Injection for the treatment of acetaminophen poisoning, Caldolor<sup>®</sup> ( *ibuprofen* ) Injection, for the treatment of pain and fever, Kristalose<sup>®</sup> ( *lactulose* ) for Oral Solution, a prescription laxative, Vaprisol<sup>®</sup> ( *conivaptan* ) Injection, for the treatment of hyponatremia, Omeclamox-Pak<sup>®</sup> for the treatment of *H. pylori* infection and duodenal ulcer disease, and Ethylol<sup>®</sup> ( *amifostine* ) for Injection, for the treatment of oncology patients. Cumberland is developing Hepatoren<sup>®</sup> ( *ifetroban* ) Injection for the treatment of Hepatorenal Syndrome, Boxaban<sup>®</sup> ( *ifetroban* ) Oral Capsule for the treatment of Aspirin-Exacerbated Respiratory Disease, Vasculan<sup>™</sup> ( *ifetroban* ) Oral Capsule for the treatment of Systemic Sclerosis, and Portaban<sup>™</sup>, for the treatment of Portal Hypertension.