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): September 10, 2019 (September 10, 2019)

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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Class	Trading Symbol	Name of exchanged on which registered
Common stock, no par value	CPIX	NASDAQ Global Select Market

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 ☐

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. ☐

Item 8.01 Other Events

Cumberland Pharmaceuticals Inc. (“we” “our” or "the Company") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products.

In November 2018, the Company completed and filed with the U.S. Food and Drug Administration ("FDA"), a submission to provide an update to our Caldolor® New Drug Application approval. Aiming to further expand the product’s label, we provided data generated from our clinical studies regarding an optimal infusion time, additional safety information, as well as geriatric and pediatric administration. The proposed revised label would also include a class label update on the use of non-steroidal anti-inflammatory drugs ("NSAIDs" or "NSAID") with aspirin.

In early September 2019, the FDA informed us that our submission was not accepted for their review because of the number of new claims. The FDA recommended splitting up the submission into several separate submissions, each containing a single proposed labeling claim or group of related labeling claims, with additional data in support of each claim. We are evaluating the FDA’s response. They have offered a Type A meeting to discuss their recommendations, which we intend to schedule.

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first injectable product approved by the FDA for fever. It was also the first NSAID approved for pain and fever in pediatric patients six months of age and older.

For full prescribing instructions, including important safety information, visit www.caldolor.com. Information on the website is not, and will not be deemed, a part of this report or incorporated into any other filings the Company makes with the Securities and Exchange Commission.

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.

Dated: September 10, 2019

By: */s/ Michael Bonner*
Michael Bonner
Chief Financial Officer