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): October 1, 2018 (October 1, 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)	(IRS 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))

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

In February 2018, Cumberland Pharmaceuticals Inc. (the "Company" or "we") completed and filed with the U.S. Food and Drug Administration ("FDA") an application for the approval of our next generation Caldolor® (ibuprofen) injection product. The product features a new, patented formulation in a more convenient to use package. In April 2018, the FDA determined that the application was complete and notified us of their acceptance for review. There were then a number of communications with questions addressed through multiple amendments that were submitted to the application. On August 2, 2018, we received a complete response from the FDA outlining the additional information needed for the application's approval. The requests were for additional quality and nonclinical data. We held a teleconference with the FDA to discuss their additional requirements.

On September 26, 2018 the Company submitted an amendment to our application containing additional quality and nonclinical data. We now await the FDA's response and approval decision expected by late January 2019.

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 FDA-approved intravenous therapy for fever. 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: October 1, 2018

By: /s/ Michael Bonner

Name: Michael Bonner
Title: Chief Financial Officer