

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): August 23, 2019 (August 23, 2019)

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 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 New Drug Application (“NDA”) for its methotrexate product line. These products are designed for the treatment of adult and pediatric patients with rheumatoid arthritis, as well as adults with psoriasis.

In January 2018, the FDA determined that the application was complete and notified us of their acceptance for its review, setting September 2019 as the Prescription Drug User Fee (“PDUFA”) action date for an approval decision. Since that time, the Company has had a number of communications with the FDA and addressed their questions through multiple amendments that were submitted to the application.

On August 22, 2019, the FDA sent us a goal extension letter in order to allow them additional time to review the application. They set a new PDUFA action date of early December 2019.

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: August 23, 2019

By:

/s/ Michael Bonner

Michael Bonner

Chief Financial Officer