

CUMBERLAND PHARMACEUTICALS INC

Form 8-K

January 14, 2019

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):

January
11, 2019
(January
11, 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) (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. ☐
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Item 8.01 Other Events

On January 4, 2019, the U.S. Food and Drug Administration ("FDA") accepted for review the New Drug Application ("NDA") for the approval of our methotrexate product line, which is designed to treat adult and pediatric patients with arthritis and adults with psoriasis. The NDA was accepted for filing with a PDUFA action date projected for November 2019.

The application was submitted to the FDA in November 2018 and its submission follows two meetings held with the FDA to discuss the approval pathway and requirements for the submission. We remitted a payment of \$1.3 million to the FDA for the PDUFA Application Fee associated with this methotrexate product line application.

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: January 11, 2019 By: /s/ Michael Bonner

Name: Michael Bonner
Title: Chief Financial Officer