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

June 7, 2023 (June 2, 2023)
Date of Report (date of earliest event reported)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Tennessee	**001-33637**	**62-1765329**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1600 West End Avenue, Suite 1300 Nashville, Tennessee 37203
(Address of Principal Executive Offices)
(615) 255-0068
Registrant's telephone number, including area code

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 (see General Instruction A.2. below):

☐ 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:

Title of each class	Trading Symbol(s)	Name of each exchange 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

On June 2, 2023, the U.S. Food and Drug Administration (the “FDA” or the “agency”) informed Cumberland Pharmaceuticals Inc. (“Cumberland” or the “Company”) that it had granted a barrier-to-innovation waiver, which will result in a refund of approximately $1.2 million that the Company previously paid for prescription drug program fees associated with its RediTrex® product line.

The FDA granted the barrier-to-innovation waiver after concluding that the Company met the statutory criteria, based on the innovation associated with Cumberland’s ifetroban clinical development programs which are designed to address a series of unmet medical needs.

The FDA’s decision was in response to a request for reconsideration that Cumberland provided, through its attorney, on April 3, 2023. Cumberland paid the FDA the fiscal year 2023 RediTrex prescription drug program fees in the amount of approximately $1.2 million on or about December 28, 2022. The fees were assessed under the Prescription Drug User Fee Act.

The FDA informed Cumberland on June 2, 2023, that the agency’s Office of Financial Management had been asked to provide a refund of the fees, which is expected within 45 days.

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: June 7, 2023

By: */s/ John Hamm*
John Hamm
Chief Financial Officer