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 26, 2023 (June 26, 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 30, 2023, Cumberland Pharmaceuticals Inc. ("Cumberland" or "Company") presented results from an interim analysis for the FIGHT DMD™ trial at the 29th annual *Parent Project Muscular Dystrophy Conference* in Dallas, Texas. The interim analysis was conducted on data from 25 patients with Duchenne muscular dystrophy ("DMD") who completed six of the twelve total months of treatment and assessments. Both doses of ifetroban were reported well-tolerated in DMD participants ages 7 years of age or older. There was also a positive trend in leg muscle strength, but no statistically significant differences were yet identified at this early time point.

Cumberland is developing ifetroban – a new chemical entity for series of indications that address unmet medical needs. Ifetroban is a potent and selective thromboxane-prostanoid receptor (TPr) antagonist. Ifetroban exhibits high affinity for TPr on many cell types including platelets, vascular and airway smooth muscle, and fibroblasts, and lacks agonistic activity. Ifetroban also displays anti-platelet, antivasospastic, antifibrotic, and antibronchospastic activities and is effective in certain preclinical models of vasospasm, thrombosis, reperfusion injury, cardiac fibrosis, lung fibrosis and endothelial dysfunction, including models that are insensitive to aspirin.

Cumberland is sponsoring the FIGHT DMD™ trial, a multicenter, randomized, placebo-controlled Phase II study evaluating the safety, pharmacokinetics and efficacy of two doses of oral ifetroban for the treatment of the cardiomyopathy associated DMD, a rare and fatal genetic disorder.

This trial is evaluating 12 months of oral ifetroban in 24 subjects with early-stage cardiomyopathy and 24 subjects with advance stage heart disease across 10 U.S. centers that specialize in DMD cardiomyopathy. The safety and efficacy endpoints include left ventricular ejection fraction using cardiac MRI, pulmonary function, quantitative muscle strength, daily activity, and quality of life measures.

The U.S. Food and Drug Administration Orphan Product Division awarded Cumberland $1 million in funding under its orphan products grants program to support this trial. This was the first DMD trial awarded such funding.

The Company plans to complete each of its ifetroban sponsored studies, analyze data, announce top-line results, and then decide on the best development path for the registration of ifetroban, which has the potential to benefit many patients with orphan diseases that represent unmet medical needs.

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 30, 2023

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