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): September 27, 2019 (September 24, 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)	(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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 o

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. o

Item 8.01 Other Events

On September 24, 2019, Cumberland announced U.S. Food and Drug Administration ("FDA") Orphan Drug Grant funding for a new Phase II clinical program. The Company has initiated the clinical development of ifetroban for the treatment of cardiomyopathy associated with Duchenne Muscular Dystrophy (DMD). Based on pre-clinical findings, the FDA has cleared Cumberland's application to study ifetroban in DMD patients, 7 years of age and older. In addition, Cumberland has been awarded just over $1 million in funding from the FDA through their Orphan Drug Grant program to support this Phase II DMD clinical study. It's the first DMD clinical study approved for FDA Orphan Product Development funding.

DMD is a rare, fatal, genetic neuromuscular disease and is characterized by the progressive loss of muscle which results in deterioration of the skeletal, heart and lung muscles. This deterioration leads to loss of movement and wheelchair dependency. Heart muscle disease is now the leading cause of death in patients with DMD. There is currently no universally effective treatment for the cardiomyopathy associated with DMD, and it remains an unmet need.

Ifetroban is a selective and potent thromboxane-prostanoid receptor (TPr) antagonist. Preclinical work on this molecule demonstrated that blocking TPr with ifetroban improves cardiac survival while increasing cardiac output in multiple animal models. These encouraging findings compelled Cumberland to develop a clinical program to evaluate ifetroban for the treatment of DMD cardiomyopathy.

A copy of the press release is furnished as Exhibit 99.1.

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: September 27, 2019

By: */s/ Michael Bonner*
Michael Bonner
Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated September 24, 2019

CUMBERLAND PHARMACEUTICALS ANNOUNCES

FDA ORPHAN DRUG GRANT AWARD

FOR NEW PHASE II CLINICAL PROGRAM

NASHVILLE, TENNESSEE (Tuesday, September 24, 2019) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company, today announced FDA Orphan Drug Grant funding for a new Phase II clinical program. The Company has initiated the clinical development of ifetroban for the treatment of cardiomyopathy associated with Duchenne Muscular Dystrophy (DMD). Based on pre-clinical findings, the U.S. Food and Drug Administration (FDA) has cleared Cumberland's application to study ifetroban in DMD patients, 7 years of age and older. In addition, Cumberland has been awarded just over $1 million in funding from the FDA through their Orphan Drug Grant program to support a Phase II DMD clinical study. It's the first DMD clinical study approved for FDA Orphan Product Development funding.

DMD is a rare, fatal, genetic neuromuscular disease and is characterized by the progressive loss of muscle which results in deterioration of the skeletal, heart and lung muscles. This deterioration leads to loss of movement and wheelchair dependency. It affects 1 in 3,500-5,000 male children, making it the most common childhood muscle disease. Heart muscle disease is now the leading cause of death in patients with DMD. There is currently no universally effective treatment for the cardiomyopathy associated with DMD, and it remains an unmet need.

"This new program is an excellent strategic fit for our company given our mission to develop new medicines that address unmet medical needs," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "As ifetroban may uniquely address the heart failure associated with this deadly disease, we very much appreciate the FDA grant support of our novel treatment for these critically ill patients."

Ifetroban is a selective and potent thromboxane-prostanoid receptor (TPr) antagonist. Preclinical work on this molecule demonstrated that blocking TPr with ifetroban improves cardiac survival while increasing cardiac output in multiple animal models. These encouraging findings compelled Cumberland to develop a clinical program to evaluate ifetroban for the treatment of DMD cardiomyopathy. The new Orphan Drug grant funding will support a Phase II multicenter study evaluating ifetroban for safety and efficacy in the treatment of DMD heart muscle disease while improving the quality of life in children and men with DMD. For more information about enrollment in this clinical trial please email the Company at research@cumberlandpharma.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high quality prescription brands to improve patient care. The Company develops, acquires and commercializes brands for the hospital acute care, gastroenterology and oncology market segments. These medical specialties are categorized by moderately concentrated prescriber bases that we believe can be penetrated effectively by targeted sales forces. The Company's portfolio of FDA approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole*, *clarithromycin*, *amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **Ethyol®** *(amifostine)* Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;
- **Totect®** *(dexrazoxane hydrochloride)* Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues); and
- **Vibativ®** (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

Cumberland has submitted a New Drug Application for the approval of **RediTrex™** (*methotrexate*) Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

The Company has Phase II clinical programs underway evaluating ifetroban in patients with Systemic Sclerosis ("SSc"), the deadliest autoimmune disease and in patients with a severe form of asthma, Aspirin-Exacerbated Respiratory Disease ("AERD"),

Cumberland has also completed Phase II clinical programs with ifetroban in patients with Hepatorenal Syndrome ("HRS") and patients with Portal Hypertension ("PH").

About the FDA Orphan Drug Grant Program

The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. The OOPD evaluates scientific and study data from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. The OOPD also provides incentives for sponsors developing medical products for rare diseases including the Orphan Drug Designation program, the Rare Pediatric Disease Review Priority Voucher program and the Orphan Products Grant Program. The Grant Program provides funding for clinical research aimed at evaluating the safety and efficacy of medical products in rare diseases. Cumberland's Phase II study is the first DMD clinical trial approved for FDA OPD funding.

About Ifetroban

Ifetroban is a pharmacological antagonist of the thromboxane A2 / prostaglandin endoperoxide receptor (TPR). Ifetroban exhibits high-affinity for TPRs on platelets, vascular and airway smooth muscle and certain other cell types and lacks agonistic activity. Ifetroban also displays anti-platelet, antivasospastic and antibronchospastic activities and is effective in certain preclinical models of vasospasm, thrombosis, reperfusion injury and endothelial dysfunction, including models that are insensitive to aspirin.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. Forward-looking statements include, among other things, statements regarding our intent, belief or expectations. As with any business, all phases of Cumberland's operations are subject to factors outside of its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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SOURCE: Cumberland Pharmaceuticals Inc.