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): November 29, 2019 (November 25, 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:

☐ 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

On November 25, 2019, Cumberland announced a new online publication in *Drugs - Real World Outcomes*, detailing the positive clinical outcomes that resulted from treating multiple infection types with Vibativ®, including complicated skin and skin structure infections (cSSSI), bone and joint infections, bacteremia and endocarditis, and lower respiratory tract infections (LRTI).

Vibativ® (telavancin) is a patented, FDA approved anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia. It is also approved for complicated skin and skin structure infections. It addresses a range of gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

For full prescribing information, including important safety information, visit www.vibativ.com. Information on the website is not, and will not be deemed, a part of this report or incorporated into any other filings the Company makes with the Securities and Exchange Commission.

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: November 29, 2019

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

Exhibit Index

Exhibit No.	Description
99.1	Press release dated November 25, 2019

NEW STUDY REVEALS REAL-WORLD USAGE
OF VIBATIV® IN A VARIETY OF INFECTIONS

NASHVILLE, Tenn. (Monday, November 25, 2019) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company announces a new online publication in *Drugs - Real World Outcomes*, detailing the positive clinical outcomes that resulted from treating multiple infection types with Vibativ®, including complicated skin and skin structure infections (cSSSI), bone and joint infections, bacteremia and endocarditis, and lower respiratory tract infections (LRTI).

Vibativ® (telavancin) is a patented, FDA approved anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia. It is also approved for complicated skin and skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

The *Telavancin Observational Use Registry* (TOUR™) was conducted to record population characteristics, prescription information, and real-world clinical outcomes of patients with Gram-positive infections treated with Vibativ. Data from 1,063 patients were collected from 45 US sites through retrospective medical chart review. Of the 964 (91%) patients for whom an end-of-treatment assessment was available, 78% had a positive clinical response. The overall positive clinical response rates by infection type were comparable at 74% in patients with bacteremia or endocarditis, 79% in patients with bone and joint infections, 80% in patients with cSSSI, and 67% in patients with LRTI. Results from TOUR confirm the real-world efficacy of telavancin for treatment of the approved indications and provide evidence that clinicians are successfully using telavancin to treat additional infection types.

About Vibativ®

Vibativ® (telavancin) Injection was discovered in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus (S. aureus)* and other Gram-positive bacteria, including MRSA and MSSA. Vibativ is a once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency, bactericidal activity within six hours, and penetration into target infection sites. The drug is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *S. aureus* when alternative treatments are not suitable. In addition, Vibativ is approved in the U.S. for the treatment of adult patients with complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *S. aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

The product labeling also describes the use of Vibativ in treating patients whose pneumonia or skin infection is complicated by concurrent bacteremia. The product's proven efficacy against difficult-to-treat Gram-

positive infections has been demonstrated in several large, multinational registrational studies, which involved one of the largest cohorts of patients with *S. aureus* infections studied to date. Importantly, these studies demonstrated significantly higher cure rates for Vibativ as compared to vancomycin in HABP/VABP due to any single Gram-positive pathogen or *S. aureus* with vancomycin MIC ≥1 µg/mL. Additionally, there is extensive and well-documented evidence of the drug's *in vitro* potency and *in vivo* activity against a broad collection of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant. For full prescribing information, visit www.vibativ.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 its ifetroban product candidates in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), Systemic Sclerosis ("SSc"), the deadliest autoimmune disease and in patients with a severe form of asthma, and Aspirin-Exacerbated Respiratory Disease ("AERD").

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

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.