

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): October 18, 2019 (October 15, 2019)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Tennessee

(State or other jurisdiction of incorporation)

001-33637

(Commission File Number)

62-1765329

(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 October 15, 2015, Cumberland announced a new publication in *Infectious Diseases and Therapy*, showing numerically superior cure rates of telavancin compared to vancomycin within a subset of patients who were enrolled in phase 3 ATTAIN trials and had hospital-acquired pneumonia caused by bacteria with low susceptibility to vancomycin. Cumberland manufactures and distributes telavancin under the brand name Vibativ®.

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: October 18, 2019

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

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release dated October 15, 2019</u>



**NEW STUDY REVEALS SUPERIORITY OF VIBATIV®
OVER VANCOMYCIN IN SELECT PATIENTS
WITH BACTERIAL PNEUMONIA**

NASHVILLE, Tenn. (Tuesday, October 15, 2019) – Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company announces a new publication in *Infectious Diseases and Therapy*, showing numerically superior cure rates of telavancin compared to vancomycin within a subset of patients who were enrolled in phase 3 ATTAIN trials and had hospital-acquired pneumonia caused by bacteria with low susceptibility to vancomycin. Cumberland manufactures and distributes telavancin under the brand name Vibativ®.

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.

Hospital-acquired pneumonia and ventilator-associated pneumonia (HAP/VAP) occurs in 5 to >20 cases per 1000 hospital admissions and 2-16 episodes per 1000 ventilator days, respectively. Alternative treatment options are needed for HAP/VAP patients with *S. aureus* infections that test with high vancomycin minimum inhibitory concentration (MIC) and patients unable to tolerate vancomycin or linezolid.

The study, led by Michael S. Niederman, MD at Weill Cornell Medicine in New York, assessed a subset of the ATTAIN microbiologically evaluable patients with hospital-acquired monomicrobial *S. aureus* infections with vancomycin MIC ≥ 1.0 ug/mL to determine the efficacy and safety of telavancin. Of the 1,503 patients treated in ATTAIN, 194 microbiologically evaluable patients had monomicrobial respiratory *S. aureus* infections with vancomycin MIC ≥ 1.0 ug/mL; 89 patients were treated with telavancin, and 105 with vancomycin. The overall clinical cure rate for telavancin was 85.4% versus 74.3% for vancomycin with a 95% confidence interval 11.1% (- 0.002%, 22.2). In addition, several other sub-group analyses also demonstrated where telavancin was numerical superiority over vancomycin, including patients age ≥ 65 , patients with APACHE II ≥ 20 , and patients with VAP. Renal function changes and or other AEs were comparable between treatment groups. In settings where organisms with vancomycin MIC ≥ 1.0 ug/mL are prevalent, telavancin is an alternative to vancomycin for empiric or specific coverage of MRSA in patients with HAP/VAP.

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; 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 also 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.

Additionally, 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"), and 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").

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.