

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): May 29, 2020 (May 26, 2020)

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 May 26, 2020, Cumberland announced a new publication in *Drugs - Real World Outcomes*, detailing the positive clinical outcomes with Vibativ® in treating patients with bacteremia or endocarditis.

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. This publication assessed 151 patients in TOUR™ with endocarditis and/or bacteremia with a known or unknown primary source.

A copy of the press release is furnished as [Exhibit 99.1](#).



**NEW PUBLICATION REVEALS REAL-WORLD USAGE
OF VIBATIV® IN PATIENTS WITH
BACTEREMIA OR ENDOCARDITIS**

NASHVILLE, Tenn. (Tuesday, May 26 2020) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company, announces a new publication in *Drugs - Real World Outcomes*¹, detailing the positive clinical outcomes with Vibativ® in treating patients with bacteremia or endocarditis.

Vibativ® (telavancin) is a potent, FDA-approved anti-infective for the treatment of 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. This publication assessed 151 patients in TOUR™ with endocarditis and/or bacteremia with a known or unknown primary source.

Of the 132 patients with an available assessment at the end of telavancin therapy, a positive clinical response was achieved in 74.2%, while 10.6% failed therapy and 15.2% had an indeterminant outcome. There was no change in creatinine clearance for 75.3% patients with values recorded at the beginning and the end of telavancin therapy.

This sub analysis suggests telavancin is a promising and viable option for patients with bacteremia or endocarditis, including those with MRSA or another *S. aureus* pathogen.

1. Reilly, Joseph et al. "Clinical Experience with Telavancin for the Treatment of Patients with Bacteremia and Endocarditis: Real-World Results from the Telavancin Observational Use Registry (TOUR™)." *Drugs - real world outcomes*, 10.1007/s40801-020-00191-x. 5 May. 2020, doi:10.1007/s40801-020-00191-x

<https://link.springer.com/article/10.1007%2Fs40801-020-00191-x>

About Vibativ®

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 $\mu\text{g/mL}$. 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 and gastroenterology market segments. 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;
- **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;
- **RediTrex**[®] (*methotrexate*) Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

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.

The Company also has a series of 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"), Hepatorenal Syndrome ("HRS") and 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. 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, natural disasters, public health epidemics, and other events beyond our control, as more fully discussed in the Company's most recent Form 10-K and subsequent 10-Qs 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.

SOURCE: Cumberland Pharmaceuticals Inc.

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