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

October 13, 2023 (October 13, 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.)

2525 West End Avenue, Suite 950 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 October 10, 2023, Cumberland Pharmaceuticals Inc. announced a new publication in *Antimicrobial Agents and Chemotherapy* detailing the results of the first reported clinical study investigating the safety and pharmacokinetics of Vibativ® (*telavancin)* injection in children 2 to 17 years of age. This publication describes results of an open-label study aimed at characterizing a single 10 mg/kg dose of Vibativ in children 2 to 17 years of age who required systemic antibiotics for the treatment of a known or suspected bacterial infection.

Vibativ is an intravenous antibiotic approved by the FDA for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) as well as complicated skin and skin structure infections (cSSSIs) caused by certain gram-positive bacteria in adults.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated October 10, 2023

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 13, 2023

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

NEW VIBATIV® PEDIATRIC PUBLICATION
HIGHLIGHTS ITS SAFETY
IN PATIENTS 2 TO 17 YEARS OF AGE

NASHVILLE, Tenn. (October 10, 2023) – Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX) announced today a new publication in *Antimicrobial Agents and Chemotherapy*[1] detailing the results of the first clinical study investigating the safety and pharmacokinetics of Vibativ® (*telavancin)* injection in children 2 to 17 years of age. Vibativ is an intravenous antibiotic approved by the FDA for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) as well as complicated skin and skin structure infections (cSSSIs) caused by certain gram-positive bacteria in adults[2]. This is the first reported study evaluating Vibativ in pediatric patients.

“Methicillin-resistant Staphylococcus aureus (MRSA) continues to be a problem for children. New, effective and safe therapy, particularly once-daily therapy, will be welcomed by those who care for children with serious MRSA infections requiring intravenous therapy,” said first author Dr. John Bradley, Distinguished Professor of Pediatrics, University of California San Diego School of Medicine and Medical Director of Infectious Disease at Rady Children’s Hospital of San Diego.

This publication describes results of an open-label study aimed at characterizing a single 10 mg/kg dose of Vibativ in children 2 to 17 years of age who required systemic antibiotics for the treatment of a known or suspected bacterial infection. Of the 22 patients treated in the study, 14 were 12 to 17 years of age, 7 were 6 to 11 years of age and one was 2 years of age. The study found a single 10 mg/kg dose of Vibativ was safe with no serious adverse events or renal concerns. Drug exposure to Vibativ was lower in children compared with observations in adult patients[3].

“Antimicrobial resistance poses a significant challenge in the treatment of bacterial infections, necessitating the development of new antibiotic therapies. The results of this study suggest that a single dose of Vibativ is safe in children and they experience reduced exposure to Vibativ, compared with the same body weight-based dosing in adults,” said corresponding author Dr. Antonio Arrieta, Professor of Pediatrics, University of California Irvine and Medical Director of Pediatric Infectious Disease, Children’s Hospital of Orange County.

For full prescribing and important safety information, please see the brand’s website at www.vibativ.com.

1. Bradley JS, Goldman JL, James, LP, Kaelin B, Gibson BHY, Arrieta A. Pharmacokinetics and Safety of a Single Dose of Telavancin in Pediatric Subjects Aged 2 to 17 Years of Age. *Antimicrob Agents Chemother.* October 10, 2023.
2. Vibativ® (telavancin) [Package Insert]. Cumberland Pharmaceuticals Inc. Nashville, TN; 2020.
3. Worboys PD, Wong SL, Barriere SL. Pharmacokinetics of intravenous telavancin in healthy subjects with varying degrees of renal impairment. *Eur J Clin Pharmacol.* 2015 Jun 1;71(6):707–14.

About Vibativ® (telavancin) for Injection

Vibativ is a patented, FDA-approved injectable anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia and 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. Intravenous unfractionated heparin sodium is contraindicated with Vibativ administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after Vibativ administration. Vibativ is contraindicated in patients with a known hypersensitivity to telavancin. For more information please 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 rheumatology 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 constipation;
- **Omeclamox®-Pak**, (*omeprazole*, *clarithromycin*, *amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Sancuso®** (*granisetron)* transdermal system, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **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.

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") and Systemic Sclerosis ("SSc").

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.

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 the company's intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate" and other comparable terms or the negative thereof. 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 operation results. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis, failure of

manufacturers to comply with regulations applicable to pharmaceutical manufacturers, natural disasters, public health epidemics, maintaining an effective sales and marketing infrastructure, and other events beyond the company's control as more fully discussed in its most recent 10-Q 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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