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

February 19, 2025 (February 19, 2025)
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.)

1600 West End Avenue, Suite 1300 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 February 18, 2025, Cumberland Pharmaceuticals Inc. (“Cumberland”) and SciClone Pharmaceuticals (Holdings) Limited ("SciClone") announced the NMPA (National Medical Products Administration) approval of Cumberland’s Vibativ® (telavancin) injection in China. The announcement follows an agreement between the companies providing SciClone the exclusive rights to register, promote and distribute the product to patients in that country. The NMPA is the Chinese pharmaceutical regulatory authority there, equivalent to the United States’ Food and Drug Administration (FDA).

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated February 18, 2025

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: February 19, 2025

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

VIBATIV® RECEIVES MARKETING APPROVAL IN CHINA

Vibativ® is a life-saving antibiotic for pneumonia and serious skin infections

Approval in China paves the way for launch in world's second-largest market

NASHVILLE, Tennessee, U.S. and SHANGHAI, China (February 18, 2025) – Specialty pharmaceutical companies **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) and **SciClone Pharmaceuticals (Holdings) Limited** ("SciClone Pharmaceuticals" or "SciClone") today announced the NMPA (National Medical Products Administration) approval of Cumberland's Vibativ® (telavancin) injection in China. The announcement follows an agreement between the companies providing SciClone the exclusive rights to register, promote and distribute the product to patients in that country. The NMPA is the Chinese pharmaceutical regulatory authority there, equivalent to the United States' Food and Drug Administration (FDA).

Vibativ is a potent, FDA-approved injectable anti-infective that serves as a potentially life-saving treatment in patients with hospital-acquired and ventilator-associated pneumonia resulting from a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and are multidrug-resistant. Vibativ is also used for the treatment of complicated skin and skin structure infections, such as MRSA. As a once-daily dosed antibiotic, it does not require therapeutic drug monitoring, decreasing health care professionals' exposure to the patient.

While many recently introduced antibiotics are quickly losing the battle to fight the bacteria they were designed to kill because those bacteria have become drug-resistant, Vibativ was specifically designed to kill drug-resistant bacteria. Two published studies – one that tested over 24,000 clinical isolates and one that tested over 15,000 – show that Vibativ is just as potent today against difficult-to-treat and multidrug-resistant bacteria as it was when it was introduced over 10 years ago.

"Vibativ's life-saving potential for patients with certain difficult-to-treat infections makes it an important addition to our portfolio and supports our mission to provide quality medical products that improve patient care," said Zhao Hong, Executive Director, President and CEO of SciClone Pharmaceuticals. "We strongly believe in this product and look forward to providing it to patients in China."

"SciClone has a strong distribution network throughout China, and we are proud to partner with them to introduce Vibativ for the benefit of patients in their market," said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. "We are confident they will ensure the product reaches as many patients within the country as possible."

SciClone and Cumberland plan to launch Vibativ in China later this year.

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. It is a once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency, bactericidal activity within six hours and penetration into patients' target infection sites.

The drug is approved in the U.S., China and Middle East 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 for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *S. aureus* and 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.

In October 2023, Cumberland announced a new publication in *Antimicrobial Agents and Chemotherapy* detailing the results of the first clinical study investigating the safety and pharmacokinetics of Vibativ in children 2 to 17 years of age. The results of the 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.

For full prescribing information, including important safety information visit www.vibativ.com.

About SciClone Pharmaceuticals

SciClone Pharmaceuticals (Holdings) Limited ("SciClone Pharmaceuticals") is a global biopharmaceutical company with an integrated platform for the development and commercialization of innovative therapies for cancer and severe infection.

With an innovation-driven strategic transformation, SciClone Pharmaceuticals has established a product portfolio with differentiated advantages, including a number of first-in-class and best-in-class potential products / pipelines. Staying true to its original aspiration of "SciClone gives life hope," SciClone Pharmaceuticals is dedicated to improving patients' health by providing top-tier health care products and services with global standards of care.

For more information regarding SciClone Pharmaceuticals, please visit: www.sciclone.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on providing unique products that improve the quality of patient care. The company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and oncology market segments.

Cumberland's portfolio comprises six FDA-approved brands. The company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy associated with Duchenne muscular dystrophy, Systemic Sclerosis and Idiopathic Pulmonary Fibrosis.

For more information on Cumberland's approved products, including full prescribing information, please visit links to the individual product websites, which can be found on the company's website at 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. 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, 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 its control as more fully discussed in the company's most recent Form 10-K and any additional updates 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. and SciClone Pharmaceuticals

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