

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 6, 2018 (November 1, 2018)

CUMBERLAND PHARMACEUTICALS INC.

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(Exact name of registrant as specified in its charter)

Tennessee

(State or other jurisdiction of incorporation)

001-33637

(Commission File Number)

62-1765329

(IRS 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

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(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))

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 1.01 Entry into a Material Definitive Agreement

On November 6, 2018, Cumberland Pharmaceuticals Inc. (the “Company” or “Cumberland”) announced a definitive agreement to acquire VIBATIV® from Theravance Biopharma. Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. Theravance Biopharma is a diversified pharmaceutical organization with the core purpose of helping improve the lives of patients suffering from serious illness.

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 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.

Under the terms of the agreement with Theravance Biopharma, Cumberland will assume full responsibility for the product including its marketing, distribution, manufacturing and regulatory activities. Cumberland will support VIBATIV in the United States through its established hospital sales organization. The Company expects to selectively expand its sales force, medical science liaison and corporate teams to ensure the needed support of VIBATIV as well as its oncology and acute care brands.

The financial terms include a \$20 million payment to Theravance Biopharma upon closing, a \$5 million additional payment in early 2019, and tiered royalties up to 20% on future U.S. net product sales. The agreement is expected to close in mid-November 2018, pending customary closing conditions.

## Item 7.01 Regulation FD Disclosure

On November 6, 2018, Cumberland Pharmaceuticals Inc. Cumberland issued a press release announcing the agreement. A copy of the press release is attached as Exhibit 99.1 and is incorporated by reference in this Item 7.01.

This information is being furnished under Item 7.01 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

## Item 9.01 Financial Statements and Exhibits

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u>  |
|--------------------|---|
| 99.1               | <a href="#"><u>Press release dated November 6, 2018</u></a> |

## 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 6, 2018

*By: /s/ Michael Bonner*

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Name: Michael Bonner

Title: Chief Financial Officer



**CUMBERLAND PHARMACEUTICALS  
TO ACQUIRE VIBATIV®**

*FDA approved injectable anti-infective with life-saving potential*

**Nashville, Tennessee, (November 6, 2018) - Cumberland Pharmaceuticals Inc.** (NASDAQ:CPIX) announced today that it has entered into a definitive agreement to acquire VIBATIV® from Theravance Biopharma. Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. Theravance Biopharma, Inc. is a diversified pharmaceutical organization with the core purpose of helping improve the lives of patients suffering from serious illness.

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 and complicated skin & skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Under the terms of the agreement, Cumberland will assume full responsibility for the product including its marketing, distribution, manufacturing and regulatory activities. Cumberland will support VIBATIV in the United States through its established hospital sales organization. The Company expects to selectively expand its sales force, medical science liaison and corporate teams to ensure the needed support of VIBATIV as well as its oncology and acute care brands.

The financial terms include a \$20 million payment to Theravance Biopharma upon closing, a \$5 million additional payment in early 2019, and tiered royalties of up to 20% on future US net product sales. Cumberland expects that the addition of VIBATIV will be accretive to the Company's earnings.

"VIBATIV is a lifesaving product for certain difficult to treat infections, and we are honored to be selected to acquire and transition the brand to our existing hospital acute care infrastructure," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Our immediate plan for VIBATIV is to ensure a smooth transition of the product supply and medical support to current users of the brand. We will then launch our hospital promotion and medical initiatives to help ensure that the product is available to the patients who need it. We are very optimistic about the opportunity that VIBATIV will offer Cumberland."

"Following an extensive process involving discussions with several interested parties, we determined that Cumberland was best positioned to optimize the value of the VIBATIV brand and ensure the product's important therapeutic benefits reach as many patients as possible," said Rick E. Winningham, chairman and chief executive officer of Theravance Biopharma. "We believe that Cumberland's track record of successfully

marketing and selling hospital-based products, combined with VIBATIV's existing base of hospital formulary inclusions, positions the company to drive commercial success for VIBATIV as a flagship product."

The transaction is expected to close in mid-November, pending satisfaction of customary closing conditions. Cumberland will provide additional remarks on its upcoming third quarter 2018 earnings call.

### **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  $\geq 1$   $\mu\text{g/mL}$ . 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](http://www.vibativ.com).

### **About Cumberland Pharmaceuticals Inc.**

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.

For more information, please visit [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

### **About Theravance Biopharma, Inc.**

Theravance Biopharma, Inc. is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness. The company's research efforts are focused in the areas of inflammation and immunology, with the goal of designing localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from this research focus on immunology and localized treatments is an oral, gut-selective pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. The company's pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

For more information, please visit [www.theravance.com](http://www.theravance.com).

## Forward-Looking Statements

This release contains forward-looking statements within the meaning of the federal securities laws, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. These forward-looking statements involve certain risks and uncertainties, and actual results may differ materially from them. Some important factors which may cause results to differ from expectations 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; availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; management of our growth and integration of our acquisitions; our ability to close the transaction, as well as other risks discussed in the “Risk Factors” section of the Company's most recent Annual Report on Form 10-K, and other filings 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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|--------------------------|-----------------------|
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