

# CUMBERLAND PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

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Address	2525 WEST END AVENUE SUITE 950 NASHVILLE,, TN 37203
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Industry	Pharmaceuticals
Sector	Healthcare

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):

February 3, 2017 (January 30, 2017)

Cumberland Pharmaceuticals Inc.

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(Exact name of registrant as specified in its charter)

Tennessee

001-33637

62-1765329

(State or other jurisdiction of incorporation)

(Commission File Number)

(I.R.S. Employer Identification No.)

2525 West End Avenue, Suite 950, Nashville,  
Tennessee

37203

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(Address of principal executive offices)

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(Zip Code)

Registrant's telephone number, including area code: (615) 255-0068

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))
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**Item 8.01 Other Events.**

On January 30, 2017, the Company issued a press release announcing the Appeals Court ruling in favor of Cumberland in a patent case associated with its Acetadote product. A copy of the press release is furnished as Exhibit 99.1 as well as the Company's updated risk disclosure related to Acetadote at Exhibit 99.2.

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**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.

*February 3, 2017*

*By: Michael Bonner*

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*Name: Michael Bonner*

*Title: Chief Financial Officer*



## U.S. COURT OF APPEALS AFFIRMS CUMBERLAND PHARMACEUTICALS'

### VICTORY IN PATENT LITIGATION CASE

**NASHVILLE, Tenn . (Monday, January 30, 2017)** - Cumberland Pharmaceuticals Inc. (NASDAQ:CPIX) , a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced that on January 26, 2017, the U.S. Court of Appeals for the Federal Circuit ruled in favor of Cumberland in a patent case associated with its Acetadote<sup>®</sup> product.

The Appeals Court ruling affirmed the September 30, 2015 decision reached by the United States District Court for the Northern District of Illinois upholding Cumberland's patent and expressly rejecting Mylan Inc. and Mylan Institutional LLC's challenge of patent validity.

Cumberland developed, registered, and launched Acetadote, which is now a standard of care for the leading cause of poisoning in the U.S. The patent that was challenged has claims associated with Cumberland's next-generation formulation of Acetadote that is free of EDTA or any other preservative, chelating, or stabilizing agent. Through this new formulation of Acetadote, Cumberland has been able to retain a significant market share in spite of generic competition that utilizes the old formulation of the product. By ruling in Cumberland's favor, the Appeals Court upheld the validity of the patent which encompasses Cumberland's EDTA-Free formulation and has a term until August 2025.

"We are very pleased with this outcome," said A.J. Kazimi, Cumberland CEO. "We look forward to continuing the supply of this potentially life-saving product in support of the healthcare professionals who administer it, and especially the patients who need it. Meanwhile, we will also continue to protect and defend Cumberland's intellectual property."

The Company continues to seek additional patent claims to protect its intellectual property associated with Acetadote and has additional patent applications related to Acetadote<sup>®</sup> pending with the US Patent Trademark Office (USPTO).

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## About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of high-quality products that improve the quality of care for patients. The Company has a diverse product portfolio with a focus in the areas of hospital acute care and gastroenterology.

Cumberland's marketed products include Acetadote<sup>®</sup> ( *acetylcysteine* ) Injection for the treatment of acetaminophen poisoning, Caldolor<sup>®</sup> ( *ibuprofen* ) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose<sup>®</sup> ( *lactulose* ) for Oral Solution, a prescription laxative, Vaprisol<sup>®</sup> ( *conivaptan* ) Injection, for the treatment of hyponatremia, Omeclamox-Pak<sup>®</sup> for the treatment of *H. pylori* and duodenal ulcer disease, and Ethyol<sup>®</sup> ( *amifostine* ) for Injection, for the prevention of treatment-related adverse reactions in oncology patients. Cumberland is also dedicated to developing innovative products that address unmet medical needs.

The Company's product candidates in clinical development include: Hepatoren<sup>®</sup> ( *ifetroban* ) Injection for the treatment of hepatorenal syndrome, Boxaban<sup>®</sup> ( *ifetroban* ) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, Vasculan<sup>™</sup> ( *ifetroban* ) Oral Capsule for the treatment of systemic sclerosis and Portaban<sup>™</sup> ( *ifetroban* ) Oral Capsule for the treatment of portal hypertension.

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

## About Acetadote<sup>®</sup> (acetylcysteine) Injection

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma or where there is a history of bronchospasm. The total volume administered should be adjusted for patients weighing less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure, and death. For full prescribing information, visit [www.acetadote.com](http://www.acetadote.com).

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A new formulation of Acetadote<sup>®</sup> (*acetylcysteine*) Injection was developed by Cumberland Pharmaceuticals Inc. (the "Company" or "Cumberland") as part of a Phase IV commitment by the Company in response to a request by the Food and Drug Administration ("FDA") to evaluate the reduction of ethylene diamine tetraacetic acid ("EDTA") from the product's formulation. Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. The new Acetadote formulation does not contain EDTA or any other chelating or stabilization agent and is free of preservatives. The new formulation was listed in the FDA Orange Book following its FDA approval in January 2011. In April 2012, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,148,356 (the "356 Acetadote Patent") which is assigned to Cumberland. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

Following the issuance of the 356 Acetadote Patent, the Company received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC ("Paddock") and Mylan Institutional LLC challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, Cumberland responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the 356 Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. ("Mylan") in the United States District Court for the Northern District of Illinois, Eastern Division. The second lawsuit was filed against InnoPharma, Inc. in the United States District Court for the District of Delaware. The third lawsuit was also filed in the United States District Court for the District of Delaware against Paddock and Perrigo Company ("Perrigo"). On May 20, 2012, the Company received a Paragraph IV certification notice from Sagent Agila LLC challenging the 356 Acetadote Patent. On June 26, 2012, the Company filed a lawsuit for infringement of the 356 Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. ("Sagent") in the United States District Court for the District of Delaware. On July 9, 2012, Cumberland received a Paragraph IV certification notice from Perrigo. On August 9, 2012, the Company filed a lawsuit for infringement of the 356 Acetadote Patent against Perrigo in the United States District Court for the Northern District of Illinois, Eastern Division.

On November 12, 2012, Cumberland entered into a Settlement Agreement (the "Settlement Agreement") with Paddock and Perrigo to resolve the challenges and the pending litigation with each of Paddock and Perrigo involving the 356 Acetadote Patent. Under the Settlement Agreement, Paddock and Perrigo admit that the 356 Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, the Company entered into a License and Supply Agreement with Paddock and Perrigo (the "License and Supply Agreement"). Under the terms of the License and Supply Agreement, if a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party has made such generic version available for purchase in commercial quantities in the United States, Cumberland will supply Perrigo with an Authorized Generic version of the Company's Acetadote product (the "Authorized Generic").

On May 18, 2012, the Company also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that Cumberland evaluate the reduction or removal of EDTA from its original Acetadote formulation. On November 7, 2012, the FDA responded to the Citizen Petition denying the Company's request and stating that ANDAs referencing Acetadote that contain EDTA may be accepted and approved provided they meet all applicable requirements. Cumberland believes this response contradicts the FDA's request to evaluate the reduction or removal of EDTA. On November 8, 2012, the Company learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. On November 13, 2012, Cumberland brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of the Company's Citizen Petition and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law.

The Company found during the resulting legal proceedings that the FDA initially concluded that the original Acetadote formulation was withdrawn for safety reasons and no generic versions should be approved. The FDA later reversed its position based on the possibility of drug shortages and the presence of EDTA in other formulations. At the same time, the FDA noted that exclusively marketing a non-EDTA containing product would be preferable because it would eliminate the potential risk of EDTA.

On January 7, 2013, Perrigo announced initial distribution of the Company's Authorized Generic acetylcysteine injection product.

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On March 19, 2013, the USPTO issued U.S. Patent number 8,399,445 (the “445 Acetadote Patent”) which is also assigned to the Company. The claims of the 445 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. On April 8, 2013, the 445 Acetadote Patent was listed in the FDA Orange Book. The 445 Acetadote Patent is scheduled to expire in August 2025. Following the issuance of the 445 Acetadote Patent, the Company has received separate Paragraph IV certification notices from Perrigo, Sagent, and Mylan challenging the 445 Acetadote Patent on the basis of non-infringement, unenforceability and/or invalidity.

On June 10, 2013, the Company became aware of a Paragraph IV certification notice from Akorn, Inc. challenging the 445 Acetadote Patent and the 356 Acetadote Patent on the basis of non-infringement. On July 12, 2013, the Company filed a lawsuit for infringement of the 356 Acetadote Patent against Akorn, Inc. in the United States District Court for the District of Delaware.

On June 10, 2013, Cumberland announced that the FDA approved updated labeling for Acetadote. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations.

On September 30, 2013, the United States District Court for the District of Columbia filed an opinion granting a Summary Judgment in favor of the FDA regarding Cumberland’s November 13, 2012 suit. On November 1, 2013, the United States District Court for the District of Delaware filed opinions granting Sagent’s and InnoPharma’s motions to dismiss the Company’s May 2012 and June 2012 suits.

On February 18, 2014, the USPTO issued U.S. Patent number 8,653,061 (the “061 Acetadote Patent”) which is assigned to the Company. The claims of the 061 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. Following its issuance, the 061 Acetadote Patent was listed in the FDA Orange Book. The 061 Acetadote Patent is scheduled to expire in August 2025.

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the “738 Acetadote Patent”) which is assigned to Cumberland. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, the Company became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

By statute, where the Paragraph IV certification is to a patent timely listed before an Abbreviated New Drug Application (“ANDA”) is filed, a company has 45 days to institute a patent infringement lawsuit during which period the FDA may not approve another application. In addition, such a lawsuit for patent infringement filed within such 45-day period may stay, or bar, the FDA from approving another product application for two and a half years or until a district court decision that is adverse to the asserted patents, whichever is earlier.

On February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the “065 Acetadote Patent”) which is assigned to Cumberland. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division (“District Court”) ruled in favor of Cumberland in its lawsuit against Mylan for infringement of Cumberland's 445 Acetadote Patent. The opinion upheld the 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to Cumberland for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On November 17, 2015, the District Court entered an order enjoining Mylan and its affiliates from selling or using its generic version of Acetadote until August 2025, the date of expiration of the 445 Acetadote Patent. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the “Appeals Court”).

On May 3, 2016, the USPTO issued U.S. Patent number 9,327,028 (the “028 Acetadote Patent”) which is assigned to us. The claims of the 028 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 028 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in July 2031.

On January 26, 2017, the Appeals Court affirmed the District Court ruling in the Company's favor in its lawsuit against Mylan for infringement of the 445 Acetadote Patent. The Appeals Court opinion affirmed the District Court’s ruling upholding Cumberland's 445 Acetadote Patent and expressly rejected Mylan's validity challenge.

The Company also has additional patent applications relating to Acetadote which are pending with the USPTO and may or may not be issued. Cumberland intends to continue to vigorously defend and protect the Company’s Acetadote product and related intellectual property rights.