

CUMBERLAND PHARMACEUTICALS INC  
Form 8-K  
May 18, 2012

---

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 17, 2012

Cumberland Pharmaceuticals Inc.

(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

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(615) 255-0068

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))



**Top of the Form**

**Item 8.01 Other Events.**

A new formulation of Acetadote (acetylcysteine) Injection was developed by Cumberland Pharmaceuticals, Inc. (the "Company") 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. 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 "Acetadote Patent") which is assigned to the Company. The claims of the Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the Acetadote Patent was listed in the FDA Orange Book. The Acetadote Patent is scheduled to expire in May 2026 which time period includes a 270-day patent term adjustment granted by the USPTO. The Company also has additional patent applications relating to the uses of Acetadote which are pending with the USPTO.

Following the issuance of the Acetadote Patent, the Company received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the Acetadote Patent on the basis of non-infringement and/or invalidity (the "Paragraph IV Challenges"). On May 17, 2012, the Company responded to the Paragraph IV Challenges by filing three separate lawsuits for infringement of the Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. 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 Laboratories, LLC and Perrigo Company (collectively, the "Infringement Lawsuits"). The Company intends to vigorously defend and protect its Acetadote product and related intellectual property rights.

As previously disclosed, 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 May 18, 2012, the Company requested the aforementioned bar or stay in connection with the filing of the Infringement Lawsuits. The aforementioned bar or stay may or may not be available to the Company with respect to the Infringement Lawsuits.

On May 18, 2012, the Company also submitted a Citizen Petition (the "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.

---

**Top of the Form**

**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.

*May 18, 2012*

*By: Rick S. Greene*

---

*Name: Rick S. Greene*

*Title: CFO*