

CUMBERLAND PHARMACEUTICALS INC
Form 8-K
April 11, 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):

April 5, 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))

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Item 8.01 Other Events.

In April 2012, the United States Patent and Trademark Office issued a patent ("Patent") to Cumberland Pharmaceuticals Inc. ("Cumberland") relating to its new formulation of Acetadote (acetylcysteine) Injection. This new Patent Number 8,148,356 has now been listed in the FDA Orange Book following its issuance.

The new Acetadote formulation was developed as part of a Phase IV commitment by Cumberland in response to a request by the Food and Drug Administration ("FDA") to evaluate the reduction of Ethylene diamine tetracetic acid (EDTA) from the formulation. The new Acetadote formulation does not contain EDTA or any other stabilization and chelating agents and is free of preservatives. The new formulation was listed in the FDA Orange Book following its approval in January 2011.

Subsequent to the issuance of the Patent, Cumberland received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC. challenging the Patent. Cumberland is now evaluating the details of the notices and has 45 days from the receipt of the Paragraph IV certifications to commence a patent infringement suit against the challengers that would automatically stay, or bar, the FDA from approving the another product application for approval for two and a half years or until a district court decision that is adverse to the asserted patents, whichever is earlier.

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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.

April 11, 2012

By: *Rick S. Greene*

Name: Rick S. Greene
Title: Chief Financial Officer