CUMBERLAND PHARMACEUTICALS INC
Form 8-K
November 13, 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): November 12, 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.

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 Paddock Laboratories, LLC ("Paddock") and Perrigo Company ("Perrigo") challenging the Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, the Company responded to the Paddock Paragraph IV certification notice and contested the challenge by filing a lawsuit for infringement of the Acetadote Patent in the United States District Court for the District of Delaware. On August 9, 2012, the Company responded to the Perrigo Paragraph IV certification notice and contested the challenge by filing a lawsuit for infringement of the Acetadote Patent the in the United States District Court for the Northern District of Illinois, Eastern Division.

On November 12, 2012, the Company entered into a Settlement Agreement (the "Settlement Agreement") with Paddock and Perrigo to resolve the challenges and the pending litigation between the Company and each of Paddock and Perrigo involving the Acetadote Patent. Under the Settlement Agreement, Paddock and Perrigo admit that the Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the Acetadote Patent. In addition Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the Acetadote Patent through its expiration currently scheduled for May 2026. The Settlement Agreement provides, among other things, that (i) within three days of execution, the parties will file with the respective Illinois and Delaware courts all necessary papers required to dismiss without prejudice all claims and counterclaims, motions and petitions asserted in the above referenced lawsuits; (ii) within three days of the date of the Settlement Agreement, Paddock will withdraw its ANDA for a generic Acetadote product and (iii) within ten days of the date of the Settlement Agreement, the parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Settlement Agreement also contains customary releases, confidentiality provisions and representations and warranties of the parties.

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, the Company will supply Perrigo with an authorized generic version of the Company's Acetadote product (the "Authorized Generic"). Perrigo agrees to sell the Authorized Generic and that it would share with the Company the net sales revenues derived by Perrigo from the sale of such Authorized Generic. Subject to certain exceptions, Perrigo is required to exclusively purchase the supply of the authorized generic directly from the Company and is not permitted to sublicense or transfer its appointment to any unaffiliated third party. The License and Supply Agreement also provides for certain other customary provisions, including indemnification, insurance, termination, confidentiality, and representations and warranties of the parties.

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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.

November 13, 2012

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer