CUMBERLAND PHARMACEUTICALS INC
Form 8-K
June 14, 2013

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): June 14, 2013 (June 10, 2013)

Cumberland Pharmaceuticals Inc.
_____
(Exact name of registrant as specified in its charter)

Tennessee (State or other jurisdiction of incorporation)	001-33637 (Commission File Number)	62-1765329 (I.R.S. Employer Identification No.)
2525 West End Avenue, Suite 950, Nashville, Tennessee (Address of principal executive offices)		37203 (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))

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 "356 Acetadote Patent") which is assigned to the Company. 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, the Company 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. 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 ("Perrigo"). On May 20, 2012, the Company received a fourth 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. in the United States District Court for the District of Delaware. On July 9, 2012, the Company 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, 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 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, the Company will supply Perrigo with an authorized generic version of the Company's Acetadote product (the "Authorized Generic").

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 three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to the Company with respect to the remaining lawsuits.

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. The Company 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, the Company brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of Cumberland's Citizen Petition and acceptance for review and approval of any InnoPharma 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 Cumberland's authorized generic acetylcysteine injection product.

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 received separate Paragraph IV certification notices from Perrigo and Sagent Pharmaceuticals, Inc. challenging the 445 Acetadote Patent on the basis of non-infringement.

The Company also has additional patent applications relating to Acetadote which are pending with the USPTO.

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. The Company intends to continue to vigorously defend and protect its Acetadote product and related intellectual property rights.

On June 10, 2013, the Company 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. A copy of the announcement is attached as Exhibit 99.1.

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.

June 14, 2013

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated June 10, 2013