CUMBERLAND PHARMACEUTICALS INC
Form 8-K
May 03, 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 3, 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 2.02 Results of Operations and Financial Condition.

On May 3, 2012, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the operating results for the three months ended March 31, 2012. A copy of the press release is furnished as Exhibit 99.1.

This information is furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, unless specifically incorporated by reference in a document filed under the Securities Act of 1933, as amended, or the Exchange Act. By filing this report on Form 8-K and furnishing this information, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by Item 2.02.

Item 8.01 Other Events.

A new formulation of Acetadote (acetylcysteine) Injection 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 tetraacetic acid ("EDTA") from the product's formulation. The new Acetadote formulation does not contain EDTA or any other chelating or stabilization or 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 Cumberland. 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.

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 Patent on the basis of non-infringement and/or invalidity (the "Paragraph IV Challenges"). The Company is currently reviewing the Paragraph IV Challenges, and analyzing its options and intends to vigorously defend and protect its Acetadote product and related intellectual property rights. As of the date of this report, the Company has not filed a patent infringement lawsuit against any of the challengers.

As a result of these developments, the Company updated the risk factor related to our strategy to secure and extend marketing exclusivity or patent rights may provide only limited protection from competition. The updated risk factor is as follows:

Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited protection from competition.

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product 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. 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 us. The claims of the Acetadote Patent encompass the new Acetadote formulation. 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. We also have additional patent applications relating to the uses of Acetadote which are pending with the USPTO and may or may not be issued.

Following the issuance of the Acetadote Patent, we 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"). We are currently reviewing the Paragraph IV Challenges. By statute, where the Paragraph IV certification is to a patent timely listed before an ANDA is filed, a company has 45 days to institute a patent infringement lawsuit, during which period 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. The aforementioned bar or stay may or may not be available to us in the event it does file a patent infringement lawsuit. We are currently analyzing our options and intend to vigorously defend and protect our Acetadote product and related intellectual property rights. If we are unsuccessful in protecting our Acetadote intellectual property rights, our competitors may be able to introduce products into the

marketplace that reduce the sales and market share of our Acetadote product which may require us to take measures such as reducing prices or increasing our marketing expense, any of which may result in a material adverse effect our financial condition and results of operations.

We have a U.S. patent for Caldolor, and some related international patents, which are directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor—ibuprofen—is in the public domain, and if a competitor were to develop a sufficiently distinct formulation, it could develop and seek FDA approval for another ibuprofen product that competes with Caldolor. Upon receipt of FDA approval in June 2009, we received three years of marketing exclusivity for Caldolor. Upon the expiration of our marketing exclusivity, a competitor with a generic form of injectable ibuprofen could enter the market.

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

Item 9.01 Financial Statements and Exhibits.

(d)

99.1 Press release dated May 3, 2012.

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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.

May 3, 2012

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Press release dated May 3, 2012.