CUMBERLAND PHARMACEUTICALS INC
Form 8-K
May 24, 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 18, 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)	(IRS 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 (see General Instruction A.2. below):

¨ 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 5.02

Cumberland Pharmaceuticals Inc. (Cumberland) has adopted a Supplemental Executive Retirement and Savings Plan (SERP). The SERP is an unfunded nonqualified deferred compensation plan designed to provide tax-deferred compensation for a select group of Cumberland s employees, independent contractors, and non-employee directors chosen by the Compensation Committee of Cumberland s Board of Directors.

The SERP is intended to provide participants with a retirement benefit that is competitive with industry practices when combined with their other employer-funded retirement benefits. The SERP gives Cumberland the discretion to make a specific annual nonqualified deferred compensation contribution to the account of each of the participants. Whether an annual deferred compensation contribution will be made to the account balance of a participant, as well as the amount of the contribution, is and shall remain discretionary on the part of Cumberland s compensation committee. The participants are permitted to make individual contributions to their SERP accounts.

Cumberland s contribution vests upon a participant reaching age 65 or upon the tenth anniversary of participation in the plan. All initial SERP participants must remain a Cumberland employee for at least 5 years, regardless of age, for vesting to occur. Each participant s account balance is generally payable in either lump sum or in annual installments over a period of up to 10 years beginning at a separation of service, including for death or disability.

The preceding summary of the SERP is qualified in its entirety by reference to Exhibit 10.30 filed with this report, and such exhibit is here incorporated by reference.

Item 8.01

Conclusion of Option Exchange Program

The Offer to Exchange expired at 11:59 P.M. Eastern Daylight Time on May 21, 2012. Pursuant to the Offer to Exchange, 424,475 eligible stock options were tendered, representing 83% of the total Eligible Option Grants in the Offer to Exchange. On May 22, 2012, the Company granted an aggregate of 147,828 shares of Restricted Stock in exchange for Eligible Option Grants surrendered in the Offer to Exchange. As of May 21, 2012, the market value of each share of Restricted Stock issued in the Offer to Exchange was $6.41, the closing price of the Company s common stock on May 21, 2012 as reported by the NASDAQ.

Patent Challenge Update

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 Acetedote 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). On May 18, 2012 the Company received a Paragraph IV certification notice from Sagent Agila LLC challenging the Acetadote Patent. As of the date of this report, the Company has not filed a patent infringement suit against Sagent Agila LLC. The Company intends to vigorously defend and protect its Acetadote product and related intellectual property rights.

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.

Item 9.01 Financial Statements and Exhibits

10.30 Supplemental Executive Retirement and Savings Plan

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 24, 2012

By: Rick S. Greene
Name: Rick S. Greene
Title: CFO