CUMBERLAND PHARMACEUTICALS INC
Form 8-K
July 22, 2010

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): July 21, 2010

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 March 2010, we submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA includes data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. These patients can also survive a significant number of days longer without transplant, providing patients requiring transplant increased time for a donor organ to become available.

Acute liver failure is associated with a high mortality rate and frequent need for liver transplantation. Approximately half of acute liver failure cases are caused by acetaminophen poisoning while the other half result from a variety of causes including hepatitis and alcohol. Currently, transplantation of the liver is the only treatment for patients with liver failure not caused by acetaminophen overdose.

In May 2010, the FDA officially accepted the sNDA and granted a priority review, with a Prescription Drug User Fee Act date of September 10, 2010. In addition to expanded labeling for Acetadote, we have requested additional exclusivity for the product. If approved, we expect to begin marketing Acetadote with the new indication in 2011.

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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.

July 21, 2010

By: David L. Lowrance

Name: David L. Lowrance
Title: CFO