
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 13, 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 2.02 Results of Operations and Financial Condition.

On May 13, 2010, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the operating results for the three months ended March 31, 2010. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated May 13, 2010.

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 14, 2010

By: David L. Lowrance

*Name: David L. Lowrance
Title: Chief Financial Officer*

Exhibit Index

Exhibit No.	Description
99.1	Press release dated May 13, 2010.



CUMBERLAND PHARMACEUTICALS REPORTS FIRST QUARTER 2010 EARNINGS

- *Acetadote sNDA for acute liver failure accepted for review by FDA*

— *Caldolor now available for compassionate use in Australia*

NASHVILLE, TN (May 13, 2010) — Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company focused on the hospital acute care and gastroenterology markets, today announced first quarter 2010 financial results.

“We remain focused on gaining widespread hospital formulary approval for Caldolor and our efforts are producing meaningful results” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “We will continue to extend our products into new markets and seek expanded labeling where new indications warrant. Our balance sheet remains strong following our initial public offering in 2009, and we are actively pursuing opportunities to selectively build our product portfolio.”

Net Revenue: For the three months ended March 31, 2010, net revenue was \$10.1 million, an increase of \$0.7 million over the same period in 2009. Net revenue by product was \$7.7 million for Acetadote[®] (acetylcysteine) Injection and \$2.3 million for Kristalose[®] (lactulose) for Oral Solution. Net revenue attributable to Caldolor[®] (ibuprofen) Injection, which was launched in September 2009, was \$19,000.

Operating Expenses: Total operating expenses for the three months ended March 31, 2010 were \$9.3 million, compared with \$7.3 million for the same period in 2009. This increase was due primarily to sales and marketing expense associated with the expansion of the Company’s hospital sales force in connection with the launch of Caldolor.

Net Income: Net income for the three months ended March 31, 2010, was \$0.3 million, or \$0.02 per diluted share, compared to \$1.2 million, or \$0.08 per diluted share, for the same period in 2009. The decrease in earnings per share was due to the increase in costs associated with the Company’s hospital sales force expansion and was also impacted by an increase in shares outstanding as a result of the Company’s initial public offering. Weighted-average diluted shares outstanding at March 31, 2010 was 21.4 million, up from 16.1 million at March 31, 2009.

EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) for the three months ended March 31, 2010 was \$1.0 million compared with \$2.3 million for the same period in the prior year. Excluding \$0.1 million and \$0.2 million in non-cash stock compensation expense for the three months ended March 31, 2010 and 2009, respectively, adjusted EBITDA was \$1.2 million and \$2.5 million, respectively.

Balance Sheet: As of March 31, 2010, Cumberland had \$73.8 million in cash and cash equivalents, compared to \$78.7 million as of December 31, 2009. Total assets as of March 31, 2010 were \$98.7 million compared with \$103.7 million at December 31, 2009. The decreases in cash and total assets were primarily related to scheduled debt repayments. A large majority of proceeds from the Company’s initial public offering remain available for planned expansion of the Company’s product portfolio and further product development support.

QUARTER HIGHLIGHTS

Supplemental New Drug Application for Acetadote

In March 2010, Cumberland 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 induced 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. This data also indicates that patients can survive a significant number of days longer without transplant, providing those who require transplant increased time for a donor organ to become available.

RECENT DEVELOPMENTS

FDA Accepts Acetadote sNDA for Review

In May 2010, the FDA officially accepted the Company’s aforementioned sNDA for Acetadote and granted a priority review. In addition to expanded labeling for Acetadote, the Company has requested additional exclusivity for the product. If approved, Cumberland expects to begin marketing Acetadote for the new indication in 2011.

International Markets

License Agreement for Caldolor in Canada

In April 2010, Cumberland entered into an exclusive agreement with Alveda Pharmaceuticals Inc., a Toronto-based specialty pharmaceutical company, for the commercialization of Caldolor in Canada. Under the agreement, Alveda will seek Canadian regulatory approval for Caldolor and, upon approval, will handle ongoing regulatory requirements as well as product marketing, distribution and sales throughout Canada. Cumberland will maintain responsibility for product formulation, development and manufacturing. In exchange for the license to the product, Cumberland will receive royalties on future sales of Caldolor in addition to upfront and milestone payments as well as a transfer price.

Caldolor Launched for Compassionate Use in Australia

In December 2009, Cumberland entered into an exclusive agreement with Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, for distribution of Caldolor in Australia and New Zealand. In April 2010, Phebra made the product available in Australia for compassionate use. The Therapeutics Goods Administration (TGA), which regulates drugs and medical devices in Australia, operates compassionate use programs that allow patients with critical clinical need to access products not yet approved through their medical practitioner. Phebra is also planning to submit an application to the TGA for regulatory approval of Caldolor.

Acetadote Approved for Marketing in Australia

In April 2010, the Therapeutic Goods Administration approved Acetadote for marketing in Australia. Cumberland previously granted an exclusive license to Phebra Pty Ltd. to commercialize Acetadote in Australia. Phebra is now preparing for the Australian launch of the product, which it expects to commence this year.

Under their agreement, Phebra is responsible for ongoing regulatory requirements, marketing, distribution and sales of Acetadote in Australia, New Zealand and the Asia Pacific while Cumberland maintains responsibility for product formulation, development and manufacturing. Cumberland receives milestone payments, a transfer price and royalties on future sales in exchange for the product license.

Share Repurchase Program

In May 2010, Cumberland's Board of Directors approved a share repurchase program that authorizes the Company to repurchase up to \$10 million of its outstanding common shares. Purchases will be made from time-to-time, at the Company's discretion, on the open market over a period of several months. Any share repurchases will be funded by excess cash flow. The Board believes the repurchase program demonstrates its confidence in Cumberland's long-term potential and that the Company's shares are currently undervalued, and as such that the shares represent an attractive investment alternative.

SUPPLEMENTAL FINANCIAL INFORMATION

The following table presents a reconciliation of Cumberland's net income to EBITDA and adjusted EBITDA. The Company defines EBITDA as net income plus interest, income tax, depreciation and amortization, and presents these measures to assist investors in evaluating Cumberland's operating performance and comparing the Company's results with those of other companies. EBITDA and adjusted EBITDA should not be considered in isolation from or as a substitute for net income.

	Three Months Ended March 31,	
	2010	2009
Net income	\$ 313,498	\$1,205,851
Income tax expense	211,737	831,059
Depreciation & amortization	231,332	196,059
Interest expense, net	285,273	80,115
EBITDA	1,041,840	2,313,084
Adjustments:		
Non-cash stock compensation	135,899	157,062
Adjusted EBITDA	\$1,177,739	\$2,470,146

CONFERENCE CALL AND WEBCAST

A conference call and live webcast will be held on Thursday, May 13, 2010, at 5:00 p.m. Eastern Time to discuss the Company's first quarter 2010 financial results. To participate on the call, please dial 877-303-1298 (for U.S. callers) or 253-237-1032 (for international callers). A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 800-642-1687 (for U.S. callers) or 706-645-9291 (for international callers). The Conference ID for the rebroadcast is 72042780. The live webcast and rebroadcast can be accessed via Cumberland Pharmaceuticals' website at <http://investor.shareholder.com/cpix/events.cfm>.

ABOUT CUMBERLAND PHARMACEUTICALS

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever available in the United

States, and Kristalose[®] (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit the Company's website at www.cumberlandpharma.com.

ABOUT CALDOLOR

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever in adults. It is the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

ABOUT ACETADOTE

Acetadote is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose, the leading cause of poisonings presenting in emergency departments in the country¹. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine

¹ National Poison Data System, American Association of Poison Control Centers

intravenously. Acetadote should be used with caution in patients with asthma, or where there is a history of bronchospasm. The total volume administered should be adjusted for patients less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure, and death. For full prescribing information, visit www.acetadote.net.

ABOUT KRISTALOSE

Kristalose is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia and hypernatremia. Nausea and vomiting have been reported. Use with caution in diabetics. Kristalose is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. For full prescribing information, visit www.kristalose.com.

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of Cumberland's operations are subject to factors outside its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or a failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in Cumberland's Form 10-K filed with the SEC on March 19, 2010. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

SOURCE: Cumberland Pharmaceuticals Inc.

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MORE

(Unaudited)

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$73,752,814	\$ 78,701,682
Accounts receivable, net of allowances	3,814,947	6,176,585
Inventories	7,406,402	4,822,873
Other current assets	3,369,809	3,472,455
Total current assets	88,343,972	93,173,595
Property and equipment, net	948,580	918,412
Intangible assets, net	7,818,394	7,956,009
Other assets	1,578,723	1,676,304
Total assets	<u>\$98,689,669</u>	<u>\$103,724,320</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 6,000,000	\$ 9,061,973
Current portion of other long-term obligations	88,739	144,828
Accounts payable	6,813,974	5,632,796
Other accrued liabilities	2,556,585	3,784,777
Total current liabilities	15,459,298	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	7,438,027	8,938,027
Other long-term obligations, excluding current portion	181,455	184,632
Total liabilities	<u>24,904,731</u>	<u>29,572,984</u>
Commitments and contingencies		
Redeemable common stock	100,000	1,930,000
Equity:		
Shareholders' equity:		
Common stock — no par value; 100,000,000 shares authorized; 20,413,605 ⁽¹⁾ and 20,180,486 ⁽¹⁾ shares issued and outstanding as of March 31, 2010 and December 31, 2009, respectively	68,861,850	67,711,746
Retained earnings	4,865,704	4,542,126
Total shareholders' equity	<u>73,727,554</u>	<u>72,253,872</u>
Noncontrolling interests	(42,616)	(32,536)
Total equity	<u>73,684,938</u>	<u>72,221,336</u>
Total liabilities and equity	<u>\$98,689,669</u>	<u>\$103,724,320</u>

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Income
(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Net revenues	\$10,130,652	\$ 9,404,599
Costs and expenses:		
Cost of products sold	859,288	733,218
Selling and marketing	5,607,512	4,140,187
Research and development	773,868	770,117
General and administrative	1,881,203	1,444,863
Amortization of product license right	171,726	171,726
Other	26,547	27,463
Total costs and expenses	<u>9,320,144</u>	<u>7,287,574</u>
Operating income	810,508	2,117,025
Interest income	60,679	17,596
Interest expense	<u>(345,952)</u>	<u>(97,711)</u>
Income before income tax expense	525,235	2,036,910
Income tax expense	<u>(211,737)</u>	<u>(831,059)</u>
Net income	313,498	1,205,851
Net loss attributable to noncontrolling interests	<u>10,080</u>	<u>12,239</u>
Net income attributable to common shareholders	<u>\$ 323,578</u>	<u>\$ 1,218,090</u>

Earnings per share attributable to common shareholders		
- Basic	\$ 0.02	\$ 0.12
- Diluted	\$ 0.02	\$ 0.08
Weighted-average shares outstanding		
- Basic	20,233,267	10,321,175
- Diluted	21,395,419	16,127,240

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Cash flows from operating activities:		
Net income	\$ 313,498	\$ 1,205,851
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	231,332	196,059
Nonemployee equity compensation	3,972	37,760
Stock-based compensation — employee stock options	130,915	143,902
Excess tax benefit derived from exercise of stock options	(206,418)	(2,842,825)
Noncash interest expense	67,380	14,256
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,361,638	(267,892)
Inventory	(2,583,529)	415,948
Other current assets and other assets	132,847	955,169
Accounts payable and other accrued liabilities	127,104	(1,187,558)
Other long-term obligations	(59,266)	(405,801)
Net cash provided by (used in) operating activities	<u>519,473</u>	<u>(1,735,131)</u>
Cash flows from investing activities:		
Additions to property and equipment	(64,085)	(15,601)
Additions to patents	—	(16,345)
Net cash used in investment activities	<u>(64,085)</u>	<u>(31,946)</u>
Cash flows from financing activities:		
Costs of initial public offering	—	(114,428)
Principal payments on note payable	(4,561,973)	—
Costs of financing for long-term debt and credit facility	(27,500)	(15,475)
Proceeds from exercise of stock options	807,496	4,296
Excess tax benefit derived from exercise of stock options	206,418	2,842,825
Payments made in connection with repurchase of common shares	(1,828,697)	(2,707,419)
Net cash (used in) provided by financing activities	<u>(5,404,256)</u>	<u>9,799</u>
Net decrease in cash and cash equivalents	(4,948,868)	(1,757,278)
Cash and cash equivalents at beginning of period	<u>78,701,682</u>	<u>11,829,551</u>
Cash and cash equivalents at end of period	<u><u>\$73,752,814</u></u>	<u><u>\$10,072,273</u></u>
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$ 276,288	\$ 33,517
Income taxes	12,376	80,000
Non-cash investing and financing activities:		
Increase in accounts payable and accrued expenses of initial public offering	—	5,311

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