CUMBERLAND PHARMACEUTICALS INC
Form 8-K
May 03, 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): May 3, 2013 (May 2, 2013)

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))

Item 2.02 Results of Operations and Financial Condition

On May 2, 2013, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the operating results for the three months ended March 31, 2013. 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.

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, 2013

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated May 2, 2013

CUMBERLAND PHARMACEUTICALS REPORTS
FIRST QUARTER FINANCIAL RESULTS

- Diluted earnings per share increased 150% to $0.05

NASHVILLE, TN (Thursday, May 2, 2013) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced first quarter 2013 financial results.

Net Revenue: For the three months ended March 31, 2013, net revenue was $10.3 million, in line with net revenues from the first quarter of 2012.

Operating Expenses: Total operating expenses for the three months ended March 31, 2013, were $8.9 million compared to $9.6 million during the prior year period. This decrease was driven primarily by the realignment of the sales force in late 2012.

Net Income: Net income attributable to common shareholders for the three months ended March 31, 2013, was $0.9 million, or $0.05 per diluted share, compared to $0.4 million, or $0.02 per diluted share, for the same period in 2012.

Cash Flow: Operating cash flows for the three months ended March 31, 2013, were $1.7 million, compared to $2.6 million, for the prior year period.

Balance Sheet: As of March 31, 2013, Cumberland had $70.2 million in cash and marketable securities, with approximately $51.2 million in cash and equivalents and $19.0 million in marketable securities. Total assets at March 31, 2013, were $98.3 million.

"Our progress during the first quarter included top line results from three new Caldolor studies and new international partnerships for India and Indonesia," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We were also pleased with the first quarter financial results maintaining revenues from the prior year quarter, while significantly increasing our net income through the efficient management of our expenses."

Product Highlights

Acetadote®

In January 2013, Cumberland initiated shipments of the Company's Authorized Generic version of Acetadote distributed by Perrigo Company. The Authorized Generic resulted from a License and Supply Agreement with Perrigo and a related Settlement Agreement with Paddock Laboratories, LLC and Perrigo Company signed in November 2012.

On March 19, 2013, the United States Patent and Trademark Office issued U.S. Patent number 8,399,445. The claims of this second Acetadote patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. On April 8, 2013, the new Acetadote patent was listed in the FDA "Orange Book" and it is scheduled to expire in August 2025.

Caldolor®

In February 2013, Cumberland announced the top-line results from two registry studies evaluating the safety and efficacy of Caldolor (ibuprofen) Injection administered over a shortened infusion time in treating pain and fever in adult patients. The studies involved 450 patients receiving Caldolor at 34 leading medical centers throughout the United States.

The first of two registry studies was a phase IV multi-center, open-label surveillance clinical study to assess the safety and efficacy of ibuprofen administered intravenously over five to ten minutes to adult patients in the hospital setting with temperature fever (>101ºF) and/or pain (visual analog scale (VAS) assessment >3). Eligible patients were enrolled to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24- hour dosing period. One hundred fifty patients from 13 clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The second of two registry studies was a phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from 21clinical sites were enrolled in this study. The shortened infusion time was well tolerated.
In February 2013, Cumberland also announced favorable top line results from a pilot clinical study evaluating the safety and analgesic efficacy of Caldolor (ibuprofen) Injection compared to ketorolac injection in treating pain following knee arthroscopy procedures in adult patients. The study was conducted at the Ohio State University Medical Center. The study enrolled fifty-one patients and the results indicate, compared to patients receiving ketorolac, patients receiving intravenous ibuprofen experienced less postoperative pain prior to discharge. Patients receiving Caldolor also needed fewer narcotics and were less likely to require narcotics prior to discharge. This data supports the benefits of using Caldolor in a pre-emptive model of multimodal analgesia.

International Agreements
In January 2013, Cumberland entered into agreements with India's Sandor Medicaids Pvt. Ltd. and Indonesia's PT. SOHO Industri Pharmasi (a SOHO Group company) for the commercialization of Caldolor in those countries. Cumberland also entered into an agreement with GerminMED W.L.L. for the commercialization of Acetadote, Caldolor and Kristalose in the Arabian Peninsula.

Conference Call and Webcast

A conference call and live Internet webcast will be held on Thursday, May 2, 2013 at 4:30 p.m. Eastern Time to discuss the Company's first quarter 2012 financial results. To participate in 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 855-859-2056 (for U.S. callers) or 404-537-3406 (for international callers). The Conference ID for the rebroadcast is 46598348. The live webcast and rebroadcast can be accessed via Cumberland's website at http://investor.shareholder.com/cpix/events.cfm.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a 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 marketed products include Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (lactulose) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information, please visit the Company's website at www.cumberlandpharma.com.

About Acetadote

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. 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 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 weighing 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.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 was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticarial, 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 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 of 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 failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent
10-Q's as filed with the SEC. 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.

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SOURCE: Cumberland Pharmaceuticals Inc.

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$51,209,544	$54,349,381
Marketable securities	18,958,810	16,686,136
Accounts receivable, net of allowances	5,967,631	6,017,201
Inventories	5,992,031	6,218,355
Other current assets	3,892,239	3,961,169
Total current assets	86,020,255	87,232,242
Property and equipment, net	1,153,426	1,188,914
Intangible assets, net	10,403,974	9,476,798
Other assets	700,095	695,777
Total assets	$98,277,750	$98,593,731
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$3,427,256	$2,790,554
Other current liabilities	4,808,531	5,264,806
Total current liabilities	8,235,787	8,055,360
Revolving line of credit	4,359,951	4,359,951
Other long-term liabilities	652,371	611,933
Total liabilities	13,248,109	13,027,244
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 18,549,749 and 18,937,107 shares issued and outstanding as of March 31, 2013 and December 31, 2012, respectively	65,818,995	67,197,167
Retained earnings	19,353,863	18,499,154
Total shareholders' equity	85,172,858	85,696,321
Noncontrolling interests	(143,217)	(129,834)
Total equity	85,029,641	85,566,487
Total liabilities and equity	$98,277,750	$98,593,731

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

	Three months ended March 31,	
	2013	2012
Net revenues	$10,258,132	$10,256,212
Costs and expenses:		
Cost of products sold	1,108,635	848,550
Selling and marketing	3,673,939	4,980,553
Research and development	1,448,718	1,404,022
General and administrative	2,575,739	2,265,025
Amortization	125,050	112,047
Total costs and expenses	8,932,081	9,610,197
Operating income	1,326,051	646,015
Interest income	92,377	72,281
Interest expense	(17,735)	(22,427)
Income before income taxes	1,400,693	695,869
Income tax expense	(559,367)	(282,028)
Net income	841,326	413,841
Net loss at subsidiary attributable to noncontrolling interests	13,383	9,367
Net income attributable to common shareholders	$854,709	$423,208
Earnings per share attributable to common shareholders		
- basic	$0.05	$0.02
- diluted	$0.05	$0.02
Weighted-average shares outstanding		
- basic	18,758,383	20,007,998
- diluted	18,925,165	20,234,438
Comprehensive income	$841,326	$413,841

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

	Three months ended March 31,	
	2013	2012
Cash flows from operating activities:		
Net income	$841,326	$413,841
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	290,508	217,263
Deferred tax expense	65,413	—
Share-based compensation	128,625	214,381
Excess tax benefit derived from exercise of stock options	(478,698)	(191,081)
Noncash interest expense	6,019	6,019
Noncash investment gains (losses)	10,571	(8,800)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	49,570	2,619,523
Inventory	226,324	(230,784)
Other current assets and other assets	(8,298)	(324,954)
Accounts payable and other current liabilities	492,983	(282,862)
Other long-term liabilities	46,308	178,120
Net cash provided by operating activities	1,670,651	2,610,666
Cash flows from investing activities:		
Additions to property and equipment	(60,911)	(32,800)
Purchases of marketable securities	(2,970,000)	(15,992,822)
Proceeds from sale of marketable securities	686,755	—
Additions to intangible assets	(961,013)	(180,787)
Net cash used in investment activities	(3,305,169)	(16,206,409)
Cash flows from financing activities:		
Net borrowings on line of credit	—	250,000
Proceeds from exercise of stock options	(41,292)	545,601
Excess tax benefit derived from exercise of stock options	478,698	191,081
Repurchase of common shares	(1,942,725)	(2,346,524)
Net cash used in financing activities	(1,505,319)	(1,359,842)
Net decrease in cash and cash equivalents	(3,139,837)	(14,955,585)
Cash and cash equivalents at beginning of period	54,349,381	70,599,146
Cash and cash equivalents at end of period	$51,209,544	$55,643,561
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Net change in unpaid additions to intangibles, property and equipment	$160,272	$82,696