CUMBERLAND PHARMACEUTICALS INC
Form 8-K
March 04, 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): March 1, 2013 (February 28, 2013)

Cumberland Pharmaceuticals Inc.
_____
(Exact name of registrant as specified in its charter)

Tennessee (State or other jurisdiction of incorporation)	001-33637 (Commission File Number)	62-1765329 (I.R.S. Employer Identification No.)
2525 West End Avenue, Suite 950, Nashville, Tennessee (Address of principal executive offices)		37203 (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 February 28, 2013, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the operating results for the three months and year ended December 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.

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.

March 1, 2013

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated February 28, 2013

CUMBERLAND PHARMACEUTICALS REPORTS
2012 ANNUAL FINANCIAL RESULTS

- Net income increased nearly 100% in fourth quarter.
- New Caldolor® pilot study top-line results provide favorable comparison.
- International agreements now include Indonesia and India.

NASHVILLE, TN (February 28, 2013) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced fourth quarter and annual 2012 financial results.

Net Revenue: For the three months ended December 31, 2012, net revenue was $13.7 million, up from $13.0 million in the prior year period.

For the year ended December 31, 2012, net revenues were $48.9 million, compared with $51.1 million for 2011.

Operating Expenses: Total operating expenses for the three months ended December 31, 2012 were $10.4 million compared to $11.3 million the prior year period. During the fourth quarter of 2012, operating expenses included $0.7 million of non-recurring expenses associated with the realignment of our sales organization.

For the year ended December 31, 2012, total operating expenses were approximately $40.0 million compared with $41.3 million for 2011.

Net Income: Net income attributable to common shareholders for the three months ended December 31, 2012, was $1.8 million, or $0.09 per diluted share, compared to $0.9 million, or $0.04 per diluted share, for the same period in 2011. This increase resulted from quarter- over-quarter sales growth along with reduced expenses.

Net income attributable to common shareholders for the year ended December 31, 2012 increased to $5.8 million, or $0.30 per diluted share, compared to $5.7 million, or $0.28 per diluted share, for 2011. After excluding the one-time sales realignment expenses, adjusted diluted earnings per share were $0.32.[(1)]

Balance Sheet: As of December 31, 2012, Cumberland had $71.0 million in cash and marketable securities, compared to $70.6 million at the end of 2011. Total assets at December 31, 2012, were

FOR IMMEDIATE DISTRIBUTION

$98.6 million compared to $95.5 million in 2011. At December 31, 2012, Cumberland had total loans of $4.4 million, down from $4.9 million at the end of 2011. Shareholders' equity increased to $85.7 million at the end of 2012 from $82.9 million for the prior period.

"We are pleased with the progress we made in 2012 as highlighted by our financial results, as well as several product milestones, including the expansion of our international presence, the completion of four Caldolor studies, and the allowance of two new Acetadote patents," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "As we move into 2013, we will continue to maximize our near term opportunities while laying the foundation for the long term expansion, diversification and success of our business."

Product Highlights

Acetadote®

In November 2012, Cumberland received a Notice of Allowance from the United States Patent and Trademark Office for a second patent relating to the new formulation of Acetadote. The new patent will include claims regarding the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose and will expire in August 2025.

Cumberland also entered into a Settlement Agreement with Paddock Laboratories, LLC and Perrigo Company in November to resolve the challenges and pending litigation between the Company and each of Paddock and Perrigo involving the Acetadote patent. Under the Settlement Agreement, Paddock and Perrigo admit that the Acetadote patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the Acetadote patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the Acetadote patent through its expiration currently scheduled for May 2026.

The Company has also entered into a License and Supply Agreement with Paddock and Perrigo. Under the terms of the License and Supply Agreement, if a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party has made such generic version available for purchase in commercial quantities in the United States, the Company will supply Perrigo with an authorized generic version of the Company's Acetadote product.

In January 2013, Perrigo announced initial distribution of Cumberland's authorized generic acetylcysteine injection product.

Caldolor®

Cumberland is pleased to announce new 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.

Fifty-one patients were enrolled at The Ohio State Medical Center. Compared to patients receiving ketorolac, patients receiving intravenous ibuprofen experienced less postoperative pain prior to

(1)Refer to Reconciliation of Net Income Attributable to Common Shareholders to Adjusted Net Income Attributable to Common Shareholders and Adjusted Earnings Per Share Attributable to Common Shareholders herein.

Cumberland Pharmaceuticals Reports 2012 Annual Financial Results

discharge. Patients receiving Caldolor also needed less 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.
These positive results follow the February release of two recent studies affirming the safety and efficacy of Caldolor in treating pain and fever in adult patients when administered over a shortened infusion time. Top-line results from these two registry studies involved 450 patients who received Caldolor at 34 leading medical centers throughout the United States.
The Company continued to expand the international market for Caldolor through strategic partnerships. In December 2012, the application for regulatory approval of Caldolor for fever in Australia by Cumberland's partner Phebra Pty Ltd., was approved.
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.

Company Update
In November 2012, Cumberland completed a realignment of its national sales organization to more efficiently cover key targets in support of all three marketed products, Caldolor, Acetadote and Kristalose, in the United States.

Conference Call and Webcast
A conference call and live Internet webcast will be held on Thursday, February 28, 2013 at 4:30 p.m. Eastern Time to discuss the Company's fourth 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 97366269. 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.

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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.

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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)
December 31, 2012 and 2011

	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$54,349,381	$70,599,146
Marketable securities	16,686,136	—
Accounts receivable, net of allowances	6,017,201	7,082,890
Inventories	6,218,355	5,774,694
Prepaid and other current assets	1,671,091	1,627,455
Deferred tax assets	2,290,078	2,223,882
Total current assets	87,232,242	87,308,067
Property and equipment, net	1,188,914	1,119,339
Intangible assets, net	9,476,798	7,023,064
Deferred tax assets	50,411	—
Other assets	645,366	67,846
Total assets	$98,593,731	$95,518,316
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$2,790,554	$1,513,548
Accrued liabilities	5,264,806	5,086,400
Total current liabilities	8,055,360	6,599,948
Revolving line of credit	4,359,951	4,859,951
Deferred tax liability	—	645,029
Other long-term liabilities	611,933	578,119
Total liabilities	13,027,244	12,683,047
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock – no par value; 100,000,000 shares authorized; 18,937,107 and 20,020,535 shares issued and outstanding as of December 31, 2012 and 2011, respectively	67,197,167	70,272,155
Retained earnings	18,499,154	12,656,662
Total shareholders' equity	85,696,321	82,928,817
Noncontrolling interests	(129,834)	(93,548)
Total equity	85,566,487	82,835,269
Total liabilities and equity	$98,593,731	$95,518,316

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

	Three months ended December 31,		Years ended December 31,	
	2012	2011	2012	2011
Revenues:				
Net product revenue	$13,637,333	$12,782,848	$47,944,031	$50,893,794