CUMBERLAND PHARMACEUTICALS INC
Form 8-K
August 09, 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): August 6, 2013 (August 9, 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 August 6, 2013, Cumberland Pharmaceuticals Inc. (the "Company") issued a press release announcing the operating results for the three and six months ended June 30, 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.

August 9, 2013

By: Rick S. Greene

Name: Rick S. Greene
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated August 6, 2013

CUMBERLAND PHARMACEUTICALS REPORTS
SECOND QUARTER FINANCIAL RESULTS

- Caldolor pediatric fever study completed with positive top-line results.
- New international agreements signed including South America and Pacific Rim.

NASHVILLE, TN (Tuesday, August 6, 2013) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced second quarter 2013 financial results.
Net Revenue: For the three months ended June 30, 2013, net revenue was $7.1 million compared to $12.4 million for the prior year period.
Net revenue was $4.1 million for Acetadote, $2.0 million for Kristalose and $0.6 million for Caldolor. Other revenue was $0.3 million and includes upfront payments recognized as a result of new international agreements.

For the six months ended June 30, 2013, net revenue was $17.3 million compared with $22.6 million for the six months ended June 30, 2012.
Operating Expenses: Total operating expenses for the three months ended June 30, 2013, were $8.2 million compared to $10.4 million during the prior year period.
For the six months ended June 30, 2013, operating expenses were $17.2 million compared to $20.0 million for the prior year period.
Net Income (Loss): Net income (loss) attributable to common shareholders for the three months ended June 30, 2013, was $(0.6) million, or $(0.03) per diluted share.

For the six months ended June 30, 2013, net income attributable to common shareholders was $0.2 million, or $0.01 per diluted share.
Cash Flow: Operating cash flows for the six months ended June 30, 2013, were $1.8 million, compared to $3.2 million, for the prior year period.
Balance Sheet: As of June 30, 2013, Cumberland had $69.2 million in cash and marketable securities, with approximately $49.7 million in cash and equivalents and $19.5 million in marketable securities. Total assets at June 30, 2013, were $95.5 million.

"We made considerable progress this quarter by completing our pediatric program for Caldolor, obtaining

FDA approval for new Acetadote labeling and further expanding our network of international partners," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are fortunate to have a strong balance sheet through this transition period as we manage Acetadote's life cycle and work to add new products to our portfolio."

Product Highlights
Caldolor®

Caldolor Pediatric Fever Study
Today, Cumberland announced top-line results from a clinical pediatric fever study evaluating the safety and efficacy of Caldolor (ibuprofen) Injection compared to acetaminophen in treating fever (greater than or equal to 101.0ºF) in hospitalized patients ranging from birth to 16 years old. One hundred and three patients were enrolled in this multi-center, randomized, open-label active comparator study. The pediatric patients received either 10 mg/kg intravenous ibuprofen (not to exceed 400 mg per dose) or 10 mg/kg acetaminophen (not to exceed 650 mg per dose). The primary endpoint of the study was to assess the area under the change in temperature versus time curve from baseline to 2 hours after the start of the initial dose of study drug. In the two hours following dosing, pediatric patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen, p= 0.012; therefore meeting the primary endpoint of the study.

After a single dose, significantly more patients receiving intravenous ibuprofen (93%) were considered to no longer be febrile (temperature less than 100.4ºF) compared to patients receiving acetaminophen (78%), p=0.036.

Patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen upon all temperature assessments during the four hours after dosing with reductions reaching statistical significance by ninety minutes post-dose.

No safety concerns were identified in the study, as the incidence of adverse events was similar across the treatment groups.

Acetadote®
Acetadote Updated Labeling
In June 2013, Cumberland announced that the U.S. Food and Drug Administration ("FDA") approved updated labeling for Acetadote (acetylcysteine) Injection. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations. The new indication states, "Acetadote is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen." The product's previous indication included the qualifying phrase, "administered intravenously within 8 to 10 hours," which was originally

intended to impress the urgency for early treatment. This phrase has been removed due to potential confusion concerning efficacy when administration within that time period is not possible.
In addition, specific dosing guidance is now included for patients weighing over 100 kg. New language has also been added to alert health care providers that in certain clinical situations, therapy should be extended for some patients.
Acetadote does not contain Ethylene diamine tetracetic acid (EDTA) or any other stabilization or chelating agents and is free of preservatives. The product's formulation was developed as part of our Phase IV commitment in response to a request by the FDA to evaluate the reduction of EDTA. The new formulation's 30 month shelf life is longer than the shelf life of the previous formulation.

International Licensing Agreements
During the second quarter of 2013, Cumberland entered into two new agreements for the registration and commercialization of Caldolor outside the United States. The first agreement is with the Spanish-based company, Laboratorios Grifols, S.A, for a territory that includes Spain, Portugal, Argentina, Chile, Brazil, Ecuador, Peru, and Uruguay. The second agreement is with PT. SOHO Industri Pharmasi an Indonesian-based company and includes a territory of Singapore, Thailand, Vietnam, Cambodia, Laos, Brunei and the Philippines.
Also during the second quarter, Cumberland amended the agreement with Harbin Gloria Pharmaceuticals for the registration and commercialization of Caldolor and Acetadote in China by extending the territory to include Hong Kong and Macau.
The agreements entered into during 2013 provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, will handle ongoing distribution and sales in the respective international territories. Cumberland maintains responsibility for the intellectual property, product formulations, development and manufacturing, and will provide finished product for sale. Under the licensing agreements, Cumberland is entitled to receive upfront and milestone payments upon the achievement of defined regulatory approvals and sales milestones.

Conference Call and Webcast
A conference call and live Internet webcast will be held on Tuesday, August 6, 2013 at 4:30 p.m. Eastern Time to discuss the Company's second quarter 2013 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 24879662. 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 is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. 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.

Investor Contact:
Elizabeth Davis
Corporate Relations
(615) 255-0068

Media Contact:
Rebecca Kirkham
Lovell Communications
(615) 297-7766

SOURCE: Cumberland Pharmaceuticals Inc.

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

	June 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$49,664,762	$54,349,381
Marketable securities	19,513,639	16,686,136
Accounts receivable, net of allowances	3,970,942	6,017,201
Inventories	6,094,294	6,218,355
Other current assets	3,197,594	3,961,169
Total current assets	82,441,231	87,232,242
Property and equipment, net	1,055,677	1,188,914
Intangible assets, net	10,649,164	9,476,798
Other assets	1,319,538	695,777
Total assets	$95,465,610	$98,593,731
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$3,094,071	$2,790,554
Other current liabilities	3,000,549	5,264,806
Total current liabilities	6,094,620	8,055,360
Revolving line of credit	5,859,951	4,359,951
Other long-term liabilities	637,671	611,933
Total liabilities	12,592,242	13,027,244
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 18,306,364 and 18,937,107 shares issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	64,311,576	67,197,167
Retained earnings	18,714,845	18,499,154
Total shareholders' equity	83,026,421	85,696,321
Noncontrolling interests	(153,053)	(129,834)
Total equity	82,873,368	85,566,487
Total liabilities and equity	$95,465,610	$98,593,731

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

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Net revenues	$7,081,088	$12,366,940	$17,339,220	$22,623,152
Costs and expenses:				
Cost of products sold	1,154,833	1,103,005	2,263,468	1,951,555
Selling and marketing	3,542,049	5,491,964	7,215,988	10,472,517
Research and development	1,386,904	1,553,343	2,835,622	2,957,365
General and administrative	1,855,201	2,147,518	4,430,940	4,412,543
Amortization	282,645	131,179	407,695	243,226
Total costs and expenses	8,221,632	10,427,009	17,153,713	20,037,206
Operating (loss) income	(1,140,544)	1,939,931	185,507	2,585,946
Interest income	48,982	76,074	141,359	148,355
Interest expense	(20,700)	(16,720)	(38,435)	(39,147)
(Loss) income before income taxes	(1,112,262)	1,999,285	288,431	2,695,154
Income tax benefit (expense)	463,408	(263,031)	(95,959)	(545,059)
Net (loss) income	(648,854)	1,736,254	192,472	2,150,095
Net loss at subsidiary attributable to noncontrolling interests	9,836	8,036	23,219	17,403
Net (loss) income attributable to common shareholders	$(639,018)	$1,744,290	$215,691	$2,167,498
Earnings (loss) per share attributable to common shareholders				
- basic	$(0.03)	$0.09	$0.01	$0.11
- diluted	$(0.03)	$0.09	$0.01	$0.11
Weighted-average shares outstanding				
- basic	18,405,522	19,771,167	18,580,891	19,889,583
- diluted	18,405,522	19,996,805	18,756,691	20,117,246
Comprehensive (loss) income	$(648,854)	$1,736,254	$192,472	$2,150,095

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

	Six months ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net income	$192,472	$2,150,095
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	610,052	441,199
Deferred tax expense	65,413	—
Share-based compensation	305,199	390,788
Excess tax benefit derived from exercise of stock options	(15,288)	(854,988)
Noncash interest expense	12,038	12,038
Noncash investment (gains) losses	62,323	(34,604)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,046,259	2,091,278
Inventory	124,061	(1,541,912)
Other current assets and other assets	59,877	(173,889)
Accounts payable and other current liabilities	(1,707,560)	1,362,385
Other long-term liabilities	37,479	(596,911)
Net cash provided by operating activities	1,792,325	3,245,479
Cash flows from investing activities:		
Additions to property and equipment	(69,119)	(178,886)
Purchases of marketable securities	(4,371,508)	(18,356,482)
Proceeds from sale of marketable securities	1,481,682	145,646
Additions to intangible assets	(1,829,693)	(519,719)
Net cash used in investment activities	(4,788,638)	(18,909,441)
Cash flows from financing activities:		
Net borrowings (repayments) on line of credit	1,500,000	(500,000)
Exercise of stock options	(41,292)	545,601
Excess tax benefit derived from exercise of stock options	15,288	854,988
Repurchase of common shares	(3,162,302)	(3,562,381)
Net cash used in financing activities	(1,688,306)	(2,661,792)
Net decrease in cash and cash equivalents	(4,684,619)	(18,325,754)
Cash and cash equivalents at beginning of period	54,349,381	70,599,146
Cash and cash equivalents at end of period	$49,664,762	$52,273,392
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Net change in unpaid additions to intangibles, property and equipment	$249,633	$73,457