

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

May 09, 2011

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2011**

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

**Commission File Number: 001-33637**

**Cumberland Pharmaceuticals Inc.**

(Exact name of registrant as specified in its charter)

**Tennessee**

(State or other jurisdiction  
of incorporation or organization)

**62-1765329**

(I.R.S. Employer Identification No.)

**2525 West End Avenue, Suite 950, Nashville, Tennessee**

(Address of principal executive offices)

**37203**

(Zipcode)

**(615) 255-0068**

(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant has submitted electronically and posted on its Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at May 4, 2011
Common stock, no par value	20,487,855



**CUMBERLAND PHARMACEUTICALS INC.  
INDEX**

<u>PART I FINANCIAL INFORMATION</u>	1
<u>Item 1: Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Income</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Condensed Consolidated Statements of Equity and Comprehensive Income</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
<u>Item 3: Quantitative and Qualitative Disclosure about Market Risk</u>	13
<u>Item 4: Controls and Procedures</u>	13
<u>PART II OTHER FINANCIAL INFORMATION</u>	13
<u>Item 1a: Risk Factors</u>	13
<u>Item 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	14
<u>Item 5: Other Information</u>	14
<u>Item 6: Exhibits</u>	14
<u>SIGNATURES</u>	15
<u>Exhibit 31.1</u>	
<u>Exhibit 32.1</u>	

---

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1: Financial Statements**

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

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 65,958,844	\$ 65,893,970
Accounts receivable, net of allowances	5,145,590	5,145,494
Inventories	7,822,872	7,683,842
Other current assets	2,174,638	2,315,536
Total current assets	81,101,944	81,038,842
Property and equipment, net	1,196,516	1,220,010
Intangible assets, net	7,269,649	7,427,223
Other assets	2,006,940	2,367,979
Total assets	\$ 91,575,049	\$ 92,054,054
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 2,666,668	\$ 2,666,668
Accounts payable	2,170,929	2,124,654
Other current liabilities	3,915,542	4,436,298
Total current liabilities	8,753,139	9,227,620
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	1,999,998	2,666,665
Other long-term obligations, excluding current portion	610,221	618,343
Total liabilities	13,189,309	14,338,579
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock — no par value; 100,000,000 shares authorized; 20,468,779 and 20,338,461 shares issued and outstanding as of March 31, 2011 and December 31, 2010, respectively	70,737,856	70,778,874
Retained earnings	7,719,966	6,998,806

Total shareholders' equity	78,457,822	77,777,680
Noncontrolling interests	(72,082)	(62,205)
Total equity	78,385,740	77,715,475
Total liabilities and equity	\$ 91,575,049	\$ 92,054,054

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Net revenues	\$ 10,666,927	\$ 10,130,652
Costs and expenses:		
Cost of products sold	786,938	859,288
Selling and marketing	5,288,584	5,607,512
Research and development	1,009,673	773,868
General and administrative	1,980,391	1,881,203
Amortization of product license right	171,727	171,726
Other	21,613	26,547
Total costs and expenses	9,258,926	9,320,144
Operating income	1,408,001	810,508
Interest income	42,909	60,679
Interest expense	(216,043)	(345,952)
Income before income tax expense	1,234,867	525,235
Income tax expense	(523,584)	(211,737)
Net income	711,283	313,498
Net loss attributable to noncontrolling interests	9,877	10,080
Net income attributable to common shareholders	\$ 721,160	\$ 323,578
Earnings per share attributable to common shareholders		
- Basic	\$ 0.04	\$ 0.02
- Diluted	\$ 0.03	\$ 0.02
Weighted-average shares outstanding		
- Basic	20,445,921	20,233,267
- Diluted	20,777,666	21,395,419
See accompanying notes to unaudited condensed consolidated financial statements.		





**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Cash flows from operating activities:		
Net income	\$ 711,283	\$ 313,498
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	262,306	231,332
Nonemployee equity compensation	19,856	3,972
Stock-based compensation employee stock options	147,207	130,915
Excess tax benefit derived from exercise of stock options	(141,080)	(206,418)
Noncash interest expense	24,010	67,380
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	(96)	2,361,638
Inventory	(139,030)	(2,583,529)
Other current assets and other assets	126,084	132,847
Accounts payable and other accrued liabilities	(23,990)	127,104
Other long-term obligations	(2,570)	(59,266)
<b>Net cash provided by operating activities</b>	<b>983,980</b>	<b>519,473</b>
Cash flows from investing activities:		
Additions to property and equipment	(34,260)	(64,085)
Additions to patents	(20,289)	
<b>Net cash used in investment activities</b>	<b>(54,549)</b>	<b>(64,085)</b>
Cash flows from financing activities:		
Principal payments on note payable	(666,667)	(4,561,973)
Costs of financing for long-term debt and credit facility		(27,500)
Proceeds from exercise of stock options	433,055	807,496
Excess tax benefit derived from exercise of stock options	141,080	206,418
Payments made in connection with repurchase of common shares	(772,025)	(1,828,697)
<b>Net cash used in financing activities</b>	<b>(864,557)</b>	<b>(5,404,256)</b>
Net increase (decrease) in cash and cash equivalents	64,874	(4,948,868)
Cash and cash equivalents at beginning of period	65,893,970	78,701,682
Cash and cash equivalents at end of period	\$ 65,958,844	\$ 73,752,814

Non-cash investing and financing activities:

Fixed asset additions not yet paid 26,689

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Common stock</b>		<b>Retained</b>	<b>Non-</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>earnings</b>	<b>controlling</b>	<b>equity</b>
				<b>interests</b>	
Balance, December 31, 2010	20,338,461	\$ 70,778,874	\$ 6,998,806	\$ (62,205)	\$ 77,715,475
Stock-based compensation nonemployees		11,340			11,340
Exercise of options and related tax benefit	261,880	574,135			574,135
Stock-based compensation employees		145,532			145,532
Repurchase of shares	(131,562)	(772,025)			(772,025)
Net and comprehensive income			721,160	(9,877)	711,283
Balance, March 31, 2011	20,468,779	\$ 70,737,856	\$ 7,719,966	\$ (72,082)	\$ 78,385,740

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**(1) BASIS OF PRESENTATION**

In the opinion of management, the accompanying unaudited condensed consolidated financial statements, or the condensed consolidated financial statements, of Cumberland Pharmaceuticals Inc. and its subsidiaries, or the Company or Cumberland, have been prepared on a basis consistent with the December 31, 2010 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly present the information set forth herein. All significant intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in accordance with the regulations of the Securities and Exchange Commission, or the SEC, and omit certain information and footnote disclosure necessary to present the statements in accordance with U.S. generally accepted accounting principles. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010. The results of operations for the first three months of 2011 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income was comprised solely of net income for the three months ended March 31, 2011 and 2010.

**Accounting Policies:**

In preparing the condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles, management must make decisions that impact the reported amounts and the related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgments based on its understanding and analysis of the relevant circumstances, historical experience, and other available information. Actual amounts could differ from those estimated at the time the condensed consolidated financial statements are prepared.

Management has evaluated events occurring subsequent to March 31, 2011 for accounting and disclosure implications.

**(2) EARNINGS PER SHARE**

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three months ended March 31, 2011 and 2010:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Numerator:		
Net income attributable to common shareholders	\$ 721,160	\$ 323,578
Denominator:		
Weighted-average shares outstanding basic	20,445,921	20,233,267
Dilutive effect of other securities	331,745	1,162,152
Weighted-average shares outstanding diluted	20,777,666	21,395,419

As of March 31, 2011 and 2010, restricted stock awards and options to purchase 1,300,895 and 541,522 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.



**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes To Condensed Consolidated Financial Statements Continued**  
**(Unaudited)**

**(3) SEGMENT REPORTING**

We operate in one segment, specialty pharmaceutical products. Our management has chosen to organize the Company based on the type of products sold. All of the Company's assets are located in the United States. We had sales of less than \$0.1 million to non-U.S. customers during the three months ended March 31, 2011 and 2010. Our net revenues consisted of the following for the three months ended March 31, 2011 and 2010:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Products:		
Acetadote	\$ 8,544,593	\$ 7,723,273
Kristalose	2,070,381	2,309,982
Caldolor	11,954	19,305
Other	39,999	78,092
Total net revenues	\$ 10,666,927	\$ 10,130,652

**(4) INVENTORIES**

We work closely with third parties to manufacture and package finished goods for sale, takes title to the finished goods at the time of shipment from the manufacturer and warehouses such goods until distribution and sale. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method. In the fourth quarter of 2010, we purchased certain packaging materials related to the manufacture of Caldolor. As these materials are consumed as part of the manufacturing process, the costs associated with these materials will be used to offset the finished goods price from the manufacturer. As of March 31, 2011 and December 31, 2010, inventory was comprised of the following:

	<b>March 31,</b>	<b>December 31,</b>
	<b>2011</b>	<b>2010</b>
Raw materials	\$ 588,637	\$ 356,676
Finished goods	7,234,235	7,327,166
Total	\$ 7,822,872	\$ 7,683,842

**(5) SHAREHOLDERS EQUITY**

In May 2010, we announced a share repurchase program to repurchase up to \$10.0 million of our outstanding common shares pursuant to Rule 10b-18 of the Securities Act. In January 2011, our Board of Directors modified this plan to provide for the repurchase of \$10.0 million of our outstanding common shares, in addition to the amount repurchased in 2010. In the first quarter of 2011, we repurchased 111,562 shares at a weighted-average price of \$5.93 per share under this plan.

During 2011, options to purchase 261,880 shares of common stock were exercised. The exercise of these options created a tax deduction of approximately \$1.0 million. Of this amount, approximately \$0.9 million was previously recognized for book purposes, resulting in a deferred tax asset of approximately \$0.3 million at December 31, 2010. Upon exercise, the associated deferred tax asset was used to offset current income taxes payable. The incremental excess tax benefit was also used to offset the estimated tax liability arising from the results of operations for the three months ended March 31, 2011, with a corresponding increase in common stock. As of March 31, 2011, we had \$63.5 million of unrecognized federal net operating loss carryforwards created by the exercise of nonqualified options in 2009. These benefits will be recognized in the period in which they are able to reduce current taxes payable.



**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES  
Notes To Condensed Consolidated Financial Statements Continued  
(Unaudited)**

**(6) COLLABORATIVE AGREEMENTS**

We are a party to several collaborative arrangements with certain research institutions to identify and pursue promising pre-clinical pharmaceutical product candidates. We have determined these collaborative agreements do not meet the criteria for accounting under Accounting Standards Codification 808, *Collaborative Agreements*. The agreements do not specifically designate each party's rights and obligations to each other under the collaborative arrangements. Except for patent defense costs, expenses incurred by one party are not required to be reimbursed by the other party. The funding for these programs is generally provided through private sector investments or federal Small Business (SBIR/STTR) grant programs. Expenses incurred under these collaborative agreements are included in research and development expenses in the condensed consolidated statements of income. Funding received from private sector investments and grants are recorded as net revenues in the condensed consolidated statements of income.

**(7) SUBSEQUENT EVENTS**

Pursuant to the share repurchase plan, as modified by the Board of Directors in January 2011, we repurchased an additional 36,588 shares for approximately \$0.2 million for the period from April 1, 2011 to May 4, 2011.



**Table of Contents**

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion contains certain forward-looking statements which reflect management's current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We caution you that our actual results may differ significantly from the results we discuss in these forward looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; significant leverage and debt service requirements; our ability to continue to acquire branded products; product sales; and management of our growth and integration of our acquisitions. Other important factors that may cause actual results to differ materially from forward-looking statements are discussed in Risk Factors on pages 22 through 35 and Special Note Regarding Forward-Looking Statements on page 35 of our Annual Report on Form 10-K for the year ended December 31, 2010. We do not undertake to publicly update or revise any of our forward-looking statements, even in the event that experience or future changes indicate that the anticipated results will not be realized. The following presentation of management's discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes thereto included in this Form 10-Q.

**OVERVIEW**

**Our Business**

We are a profitable and growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology, which are characterized by concentrated physician bases that we believe can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients.

Our marketed product portfolio includes 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. In April 2011, we also acquired rights to a late-stage product candidate that we intend to develop under the brand name Hepatoren (ifetroban) Injection for the treatment of Hepatorenal Syndrome. We market and sell our approved products through our hospital and field sales forces in the United States and are working with partners to reach international markets.

We have both product development and commercial capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, commercialization and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Cumberland's product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our products are manufactured by third parties, which are overseen and managed by our quality control and manufacturing group. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our third party distribution partner to ensure availability and delivery of our products.

We became profitable in 2004, and since then have generated sufficient cash flows to fund our development and marketing programs. In 2009, we completed an initial public offering of our common stock to help facilitate further growth.

## **Table of Contents**

### **Growth Strategy**

Our growth strategy involves maximizing the potential of our existing products and continuing to build a portfolio of new, differentiated products. Specifically, we expect to grow by executing the following plans:

We market our products in the United States through a comprehensive marketing and promotional effort, and we are working to bring our products to select international markets with our first international launch occurring in the third quarter of 2010.

We look for opportunities to expand into additional patient populations with new product indications, whether through our own development work or by supporting promising investigator-initiated studies at research institutions.

We actively pursue opportunities to acquire additional late-stage development product candidates as well as marketed products in our target medical specialties.

We supplement the aforementioned growth strategy with the early-stage drug development activities of Cumberland Emerging Technologies, Inc., or CET, our majority-owned subsidiary. CET partners with university research centers to identify and cost-effectively develop promising early-stage product candidates, which Cumberland Pharmaceuticals has the opportunity to commercialize. Our acquisition of Hepatoren in April 2011 represents the first development candidate to emerge from CET as an addition to Cumberland's portfolio.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our website address is [www.cumberlandpharma.com](http://www.cumberlandpharma.com). We make available through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments, as well as other documents, as soon as reasonably practicable after their filing with the SEC. These filings are also available to the public through the Internet by the SEC at [www.sec.gov](http://www.sec.gov).

### **Recent Developments**

#### **Acetadote®**

##### *FDA Approval and Launch of New Formulation of Acetadote*

In October 2010, we submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for approval of a new formulation of Acetadote, which was the result of a phase IV commitment Cumberland made to the FDA upon receipt of initial marketing approval of the product. In January 2011, the FDA approved the new formulation, which does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. We have completed the U.S. launch activities for this next generation product, which replaced the previously marketed formulation, which will no longer be manufactured. We have filed and are prosecuting a patent application with the U.S. Patent and Trademark Office to protect our discoveries associated with this new formulation.

##### *Supplemental New Drug Application for Acetadote*

In March 2010, we submitted an application to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. This sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that early-stage acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant and that these patients can also survive a significant number of days longer without transplant. In December, the FDA issued a Complete Response Letter indicating that it had completed its review of the application and identified additional items that must be addressed prior to approval of the potential new indication. We have initiated discussions with the FDA to better understand and determine whether we can address the additional requirements for that approval.

**Table of Contents**

**Caldolor®**

In June 2009, the FDA approved Caldolor, our intravenous formulation of ibuprofen, for marketing in the United States following a priority review. In September 2009, we initiated the launch of Caldolor in the U.S. through our sales organization. Caldolor is stocked at wholesalers serving hospitals nationwide, available in both 400mg and 800mg vials.

In 2010, we focused our sales efforts primarily on securing formulary approval and stocking nationally for Caldolor. Caldolor is being stocked in a growing number of U.S. medical centers, and in the first quarter of 2011 we began the shift to a pull-through strategy with an emphasis on the activities required to build volume and help many more patients in the centers that have already stocked this product.

**Hepatoren**

In April 2011, we entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. We have initiated clinical development under the brand name Hepatoren (ifetroban) Injection and are evaluating this candidate for the treatment of critically ill hospitalized patients suffering from Hepatorenal Syndrome, or HRS. HRS is a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment. Approximately 450,000 patients in the United States suffer from medical conditions that make them susceptible to cirrhosis and a subset of these patients develop HRS every year.

Our acquisition of the rights to the ifetroban program included rights to an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property. Ifetroban, an active thromboxane receptor antagonist, was initially developed by Bristol-Myers Squibb, or BMS, for significant cardiovascular indications. BMS conducted extensive preclinical and clinical studies, including seven Phase II trials, for its own target indications and eventually donated the entire program to Vanderbilt University. Researchers at Vanderbilt identified ifetroban as a potentially valuable compound in treating patients for several niche indications. We acquired the rights to the ifetroban program from Vanderbilt through CET, assuming responsibility for development and commercialization of the product.

We have received clearance from the FDA for our investigational new drug (IND) submission associated with the product. We plan to develop ifetroban for a series of indications, initially focusing on the treatment of HRS for the hospital acute care market. In addition to commencing manufacturing, we have initiated a Phase II clinical study for Hepatoren and intend to develop the product as an Orphan Drug for which we will pursue seven years of marketing exclusivity. Patent applications have also been filed to protect intellectual property related to the product. We believe this new product is an excellent strategic fit for us given our established presence in the hospital acute care market.

**New Board Director**

In January 2011, Joey Jacobs joined our Board of Directors. He is the former Chairman, President and Chief Executive Officer of Psychiatric Solutions, which he co-founded in 1997 and grew into a \$2 billion healthcare provider. Mr. Jacobs has more than 30 years of experience in the healthcare industry, including 21 years at Hospital Corporation of America (HCA). We believe his hospital expertise and experience building a public healthcare company make him a valuable addition to Cumberland's board. After Mr. Jacobs appointment, he was elected to serve as a Class I Director until 2014 by the shareholders at our 2011 annual meeting.

**Table of Contents**

**CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES**

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 43 through 46 in Management's Discussion and Analysis of our Annual Report on Form 10-K for the year ended December 31, 2010.

**Accounting Estimates and Judgments**

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. We base our estimates on past experience and on other factors we deem reasonable given the circumstances. Past results help form the basis of our judgments about the carrying value of assets and liabilities that are not determined from other sources. Actual results could differ from these estimates. These estimates, judgments and assumptions are most critical with respect to our accounting for revenue recognition, provision for income taxes, stock-based compensation, research and development accounting and intangible assets.

**RESULTS OF OPERATIONS**

**Three months ended March 31, 2011 compared to the three months ended March 31, 2010**

*Net revenues.* Net revenues for the three months ended March 31, 2011 totaled approximately \$10.7 million, representing an increase of approximately \$0.5 million over the same period in 2010. Net revenue for Acetadote increased approximately \$0.8 million, with volume remaining consistent between the periods. Kristalose net revenue decreased approximately \$0.1 million, primarily due to a decrease in sales volume. During the first quarter of 2011, we experienced delays in receiving some deliveries of Kristalose from our manufacturer, resulting in a decrease in net revenues.

*Cost of products sold.* Cost of products sold as a percentage of net revenues decreased from 8.5% for the three months ended March 31, 2010 to 7.4% for the same period in 2011, and was primarily due to a change in the sales mix between the two periods.

*Selling and marketing.* Selling and marketing expense for the three months ended March 31, 2011 totaled approximately \$5.3 million, representing a decrease of approximately \$0.3 million, or 5%, over the same period in 2010. The decrease was primarily due to cost-savings related to the conversion of our field sales force from contract employees to Cumberland employees and lower royalty expense for Acetadote, partially offset by increases in marketing, advertising and promotional expenses.

*Research and development.* Research and development expense for the three months ended March 31, 2011 totaled approximately \$1.0 million, representing an increase of approximately \$0.2 million, or 31%, over the same period in 2010. The increase was primarily due to (1) increased expenses associated with continuing Caldolor pediatric fever and Acetadote studies, (2) increased expenses associated with annual FDA fees for our products and (3) increased salary and related expenses due to additional personnel. We expect research and development expenses to increase throughout 2011 as we continue our new Caldolor and Acetadote studies, as well as the start-up of studies associated with Hepatoren™ (iftetroban) injection.

*General and administrative.* General and administrative expense for the three months ended March 31, 2011 totaled approximately \$2.0 million, representing an increase of approximately \$0.1 million, or 5%, over the same period in 2010. The increase was primarily due to (1) increased salary and related costs, (2) increased rent expense and (3) increased depreciation expense. These increases reflect the continued expansion of our infrastructure to support our growth.

*Interest expense.* Interest expense for the three months ended March 31, 2011 totaled approximately \$0.2 million, representing a decrease of approximately \$0.1 million as compared to the same period in 2010. Included in interest expense for 2011 is approximately \$0.1 million of non-recurring deferred loan issue costs associated with the modification of our term debt in September 2010. Excluding these loan fees, our interest expense decreased \$0.2 million for the three months ended March 31, 2011 as compared to the same period in 2010, due primarily to the decrease in our outstanding debt balance.



**Table of Contents**

*Income tax expense.* Income tax expense for the three months ended March 31, 2011 totaled approximately \$0.5 million, representing an increase of approximately \$0.3 million over the same period in 2010. As a percentage of income before income taxes, income tax expense increased from 40.3% for the three months ended March 31, 2010 to 42.4% for the three months ended March 31, 2011. The increase in the percentage was primarily due to increases in our state tax rates.

**LIQUIDITY AND CAPITAL RESOURCES****Working Capital**

Our primary sources of liquidity are cash flows provided by our operations, our borrowings and the cash proceeds from our initial public offering of common stock that was completed in August 2009. We believe that our internally generated cash flows, amounts available under our credit facilities and cash on hand will be adequate to service existing debt, finance internal growth and fund capital expenditures. As of March 31, 2011 and December 31, 2010, cash and cash equivalents was \$66.0 million and \$65.9 million, respectively, working capital (current assets minus current liabilities) was \$72.3 million and \$71.8 million, respectively, and our current ratio (current assets to current liabilities) was 9.3x and 8.8x, respectively. As of March 31, 2011, we had an additional \$4.2 million available to us on our line of credit.

The following table summarizes our net changes in cash and cash equivalents for the three months ended March 31, 2011 and 2010:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 984	\$ 519
Investing activities	(55)	(64)
Financing activities	(865)	(5,404)
Net increase (decrease) in cash and cash equivalents <sup>(1)</sup>	\$ 65	\$ (4,949)

(1) The sum of the individual amounts may not agree due to rounding.

The net increase in cash and cash equivalents for the three months ended March 31, 2011 was primarily due to our net income, adjusted for non-cash depreciation and amortization expense, offset by cash used in financing activities.

During the first quarter of 2011, our cash flows from financing activities included (1) scheduled principal payments of approximately \$0.7 million on our term debt and (2) payments made in connection with the repurchase of our common shares of approximately \$0.8 million, offset by \$0.6 million of cash provided from the exercise of stock options.

The net decrease in cash and cash equivalents of \$4.9 million for the three months ended March 31, 2010 was primarily due to cash used in financing activities, which included (1) principal payments on our term debt of approximately \$4.6 million and (2) the repurchase of common stock of approximately \$1.8 million, offset by (i) proceeds from the exercise of stock options of approximately \$0.8 million and (ii) the excess tax benefit derived from the exercise of nonqualified options of approximately \$0.2 million.

**OFF-BALANCE SHEET ARRANGEMENTS**

During the three months ended March 31, 2011 and 2010, we did not engage in any off-balance sheet arrangements.

**Table of Contents**

**Item 3: Quantitative and Qualitative Disclosure about Market Risk**

**Interest Rate Risk**

We are exposed to market risk related to changes in interest rates on our revolving credit facility and our term note payable. We do not utilize derivative financial instruments or other market risk-sensitive instruments to manage exposure to interest rate changes. The main objective of our cash investment activities is to preserve principal while maximizing interest income through low-risk investments.

The interest rate related to borrowings under our revolving credit facility and term debt is a variable rate of LIBOR plus an applicable margin, as defined in the debt agreement (4.75% at March 31, 2011). As of March 31, 2011, we had outstanding borrowings of approximately \$6.5 million under our revolving credit facility and term debt combined. If interest rates increased by 1.0%, our annual interest expense on our borrowings would increase by approximately \$0.1 million.

**Exchange Rate Risk**

While we operate primarily in the United States, we are exposed to foreign currency risk. One of our supply agreements for Caldolor is denominated in Australian dollars. Additionally, some of our research and development is performed abroad. As of March 31, 2011, our outstanding payables denominated in a foreign currency were less than \$0.1 million.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms, with much of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange gains and losses were not significant for the three months ended March 31, 2011 and 2010. Neither a 10% increase nor decrease from current exchange rates would have a significant effect on our operating results or financial condition.

**Item 4: Controls and Procedures**

Our principal executive and financial officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2011. Based on that evaluation, our disclosure controls and procedures are considered effective to ensure that material information relating to us and our consolidated subsidiaries is made known to officers within these entities in order to allow for timely decisions regarding required disclosure.

In April 2011, we expanded our accounting staff with the addition of an experienced accounting manager who holds a CPA designation in the State of Tennessee. In addition, we appointed a new vice president, finance and accounting, to replace the individual who formerly held this position and departed to pursue other interests. We do not expect these changes to have an adverse impact on our internal controls over financial reporting.

**PART II OTHER FINANCIAL INFORMATION**

**Item 1a: Risk Factors**

Information regarding risk factors appears on pages 22 through 35 in our Annual Report on Form 10-K for the year ended December 31, 2010 under the section titled Risk Factors. There have been no material changes from the risk factors previously discussed therein.

**Table of Contents****Item 2: Unregistered Sales of Equity Securities and Use of Proceeds**  
**Purchases of Equity Securities**

The following table summarizes the purchase of equity securities by us during the three months ended March 31, 2011:

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plan or Programs <sup>(1)</sup>
January 1 - January 31	46,858	\$ 6.06	46,858	\$ 7,139,698
February 1 - February 28	25,591	6.16	25,591	6,982,119
March 1 - March 31	59,113 <sup>(2)</sup>	5.58	39,113	9,986,783
Total	131,562		111,562	

- (1) In May 2010, we announced a share repurchase program to purchase up to \$10 million of our common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, our Board of Directors modified the existing repurchase program to provide for the repurchase of \$10 million of our common stock, in addition to the amount repurchased in 2010. The modified plan was effective March 21, 2011.
- (2) Of this amount, 20,000 shares were repurchased directly from a shareholder at the fair market value on the close of business on March 24, 2011.

**Item 5: Other Information**

During the first quarter of 2011, we were notified by Bayer HealthCare, LLC of its intent to discontinue the production of human pharmaceuticals at their Kansas manufacturing facility over the next several years and focus that operation on animal health production. Our current manufacturing agreement will expire in February 2013. Bayer is one of two suppliers of Caldolor and Acetadote. We are evaluating alternative manufacturing facilities available to us after the expiration of the contract, including alternate Bayer facilities outside of the United States.

**Item 6: Exhibits**

No.	Description
31.1	Certification of Chief Executive and Principal Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	



Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

Certification of Chief Executive and Principal Financial Officer Pursuant to 18 U.S.C.  
Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**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 thereunto duly authorized.

Cumberland Pharmaceuticals Inc.

Dated: May 9, 2011

By: */s/ A. J. Kazimi*  
A. J. Kazimi  
Chief Executive and  
Principal Financial Officer