

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 07, 2011

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**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 September 30, 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**

(Zip code)

**(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. (Check one):

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 October 28, 2011
Common stock, no par value		20,177,339

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

	<b>September 30, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,074,807	\$ 65,893,970
Accounts receivable, net of allowances	4,505,411	5,145,494
Inventories	6,874,599	7,683,842
Other current assets	3,423,574	2,315,536
Total current assets	85,878,391	81,038,842
Property and equipment, net	1,198,805	1,220,010
Intangible assets, net	7,029,186	7,427,223
Other assets	1,972,284	2,367,979
Total assets	\$ 96,078,666	\$ 92,054,054
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$	\$ 2,666,668
Accounts payable	3,280,289	2,124,654
Other current liabilities	4,172,942	4,436,298
Total current liabilities	7,453,231	9,227,620
Revolving line of credit	4,575,951	1,825,951
Long-term debt, excluding current portion		2,666,665
Other long-term obligations, excluding current portion	592,427	618,343
Total liabilities	12,621,609	14,338,579
Commitments and contingencies		
Equity:		
Shareholders' equity:		

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Common stock no par value; 100,000,000 shares authorized; 20,215,910 and 20,338,461 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	71,802,068	70,778,874
Retained earnings	11,744,997	6,998,806
Total shareholders equity	83,547,065	77,777,680
Noncontrolling interests	(90,008)	(62,205)
Total equity	83,457,057	77,715,475
Total liabilities and equity	\$ 96,078,666	\$ 92,054,054

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Net revenues	\$ 13,054,278	\$ 12,190,870	\$ 38,110,946	\$ 33,061,457
Costs and expenses:				
Cost of products sold	1,341,256	909,434	3,411,354	2,632,447
Selling and marketing	5,060,546	5,692,048	16,253,574	17,147,683
Research and development	1,233,025	1,138,955	3,269,746	2,947,623
General and administrative	2,117,684	1,806,975	6,442,139	5,471,012
Amortization of product license right	171,727	171,732	515,180	515,184
Other	31,680	27,869	80,735	83,283
Total costs and expenses	9,955,918	9,747,013	29,972,728	28,797,232
Operating income	3,098,360	2,443,857	8,138,218	4,264,225
Interest income	52,459	48,675	147,628	159,688
Interest expense	(33,390)	(547,795)	(329,037)	(1,299,703)
Income before income taxes	3,117,429	1,944,737	7,956,809	3,124,210
Income tax expense	(1,278,472)	(943,141)	(3,238,421)	(1,529,339)
Net income	1,838,957	1,001,596	4,718,388	1,594,871
Net loss at subsidiary attributable to noncontrolling interests	8,455	6,648	27,803	24,255
Net income attributable to common shareholders	\$ 1,847,412	\$ 1,008,244	\$ 4,746,191	\$ 1,619,126
Earnings per share attributable to common shareholders				
- basic	\$ 0.09	\$ 0.05	\$ 0.23	\$ 0.08
- diluted	\$ 0.09	\$ 0.05	\$ 0.23	\$ 0.08
Weighted-average shares outstanding				
- basic	20,327,537	20,327,867	20,414,593	20,335,911
- diluted	20,534,647	20,803,182	20,657,567	21,135,762

See accompanying notes to unaudited condensed consolidated financial statements.



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

	<b>Nine Months Ended September</b>	
	<b>30,</b>	
	<b>2011</b>	<b>2010</b>
Cash flows from operating activities:		
Net income	\$ 4,718,388	\$ 1,594,871
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	801,483	723,687
Non-employee equity compensation	119,313	62,547
Stock-based compensation employee stock options	467,850	503,446
Excess tax benefit derived from exercise of stock options	(2,657,259)	(1,256,913)
Non-cash interest expense	131,469	328,475
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	640,083	1,384,903
Inventory	809,243	(2,823,355)
Other current assets and other assets	(1,240,700)	1,461,538
Accounts payable and other accrued liabilities	3,911,450	(840,429)
Other long-term obligations	(9,262)	(105,668)
<b>Net cash provided by operating activities</b>	<b>7,692,058</b>	<b>1,033,102</b>
Cash flows from investing activities:		
Additions to property and equipment	(241,885)	(311,301)
Additions to patents	(140,356)	(132,047)
<b>Net cash used in investment activities</b>	<b>(382,241)</b>	<b>(443,348)</b>
Cash flows from financing activities:		
Principal payments on note payable	(5,333,333)	(12,000,000)
Net borrowings on line of credit	2,750,000	
Costs of financing for long-term debt and credit facility		(82,500)
Proceeds from exercise of stock options	681,634	1,182,139
Excess tax benefit derived from exercise of stock options	2,657,259	1,256,913
Repurchase of common shares	(2,884,540)	(4,129,648)
<b>Net cash used in financing activities</b>	<b>(2,128,980)</b>	<b>(13,773,096)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>5,180,837</b>	<b>(13,183,342)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>65,893,970</b>	<b>78,701,682</b>

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Cash and cash equivalents at end of period	\$ 71,074,807	\$ 65,518,340
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Supplemental disclosure of cash flow information:

Non-cash investing and financing activities:

Common shares repurchased during period but not paid as of the end of the period

\$ 22,207

See accompanying notes to unaudited condensed consolidated financial statements.

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**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	9,144	103,224			103,224
Exercise of options and related tax benefit	376,850	3,338,893			3,338,893
Stock-based compensation - employees		465,617			465,617
Repurchase of shares	(508,545)	(2,884,540)			(2,884,540)
Net and comprehensive income			4,746,191	(27,803)	4,718,388
Balance, September 30, 2011	20,215,910	\$ 71,802,068	\$ 11,744,997	\$ (90,008)	\$ 83,457,057

See accompanying notes to unaudited condensed consolidated financial statements.

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**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 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 nine 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 and nine months ended September 30, 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 September 30, 2011 for accounting and disclosure implications.

**(2) EARNINGS PER SHARE**

The following tables reconcile the numerator and denominator used to calculate diluted earnings per share for the three and nine months ended September 30, 2011 and 2010:

	<b>Three Months Ended September</b>	
	<b>30,</b>	
	<b>2011</b>	<b>2010</b>
Numerator:		
Net income attributable to common shareholders	\$ 1,847,412	\$ 1,008,244
Denominator:		
Weighted-average shares outstanding basic	20,327,537	20,327,867
Dilutive effect of other securities	207,110	475,315
Weighted-average shares outstanding diluted	20,534,647	20,803,182

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**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to condensed consolidated financial statements continued**  
**(unaudited)**

	<b>Nine Months Ended September</b>	
	<b>30,</b>	
	<b>2011</b>	<b>2010</b>
Numerator:		
Net income attributable to common shareholders	\$ 4,746,191	\$ 1,619,126
Denominator:		
Weighted-average shares outstanding basic	20,414,593	20,335,911
Dilutive effect of other securities	242,974	799,851
Weighted-average shares outstanding diluted	20,657,567	21,135,762

As of September 30, 2011 and 2010, restricted stock awards and options to purchase 1,082,309 and 1,200,017 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

**(3) SEGMENT REPORTING**

We operate in one segment, specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. All of our assets are located in the United States. We had sales to non-U.S. customers of \$0 and \$0.1 million during the three months ended September 30, 2011 and 2010, respectively. We had sales of \$0.1 million to non-U.S. customers during each of the nine months ended September 30, 2011 and 2010. The Company's net revenues consisted of the following for the three and nine months ended September 30, 2011 and 2010:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Products:				
Acetadote	\$ 10,882,342	\$ 9,600,427	\$ 31,594,237	\$ 25,632,260
Kristalose	2,077,310	2,506,894	6,249,662	7,088,294
Caldolor	47,966	14,103	145,947	79,184
Other	46,660	69,446	121,100	261,719
Total net revenues	\$ 13,054,278	\$ 12,190,870	\$ 38,110,946	\$ 33,061,457

**(4) INVENTORIES**

We work closely with third parties to manufacture and package finished goods for sale. We take title to the finished goods at the time of shipment from the manufacturer and warehouse 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. As of September 30, 2011, some portion of our inventory may be in excess of our current inventory requirements based on the recent level of sales and projections. As of September 30, 2011 and December 31, 2010, we have recognized a reserve for potential obsolescence for our marketed products of approximately \$1.0 million and \$0.1 million, respectively. 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 September 30, 2011 and December 31, 2010, inventory was comprised of the

following:

	<b>September 30, 2011</b>	<b>December 31, 2010</b>
Raw materials	\$ 588,637	\$ 356,676
Finished goods	6,285,962	7,327,166
Total	\$ 6,874,599	\$ 7,683,842

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**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to condensed consolidated financial statements continued**  
**(unaudited)**

**(5) DEBT**

In July 2011, we paid in full the outstanding term debt balance of \$4.0 million. We did not incur any prepayment or other fees associated with the payoff. In connection with the repayment, we wrote-off the unamortized debt issue costs associated with the term debt of approximately \$0.1 million during the second quarter of 2011. These costs are included in interest expense in the condensed consolidated statement of income for the nine months ended September 30, 2011.

In August 2011, we entered into the Fifth Amended and Restated Loan Agreement, or the Agreement, for our revolving credit facility with Bank of America, N.A., or the Bank, to provide for up to \$10 million of credit. The credit facility may be increased up to \$20 million, upon the satisfaction of certain conditions. The interest rate is the BBA LIBOR Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement. In addition, we must pay 0.25% per annum on the unused line of credit. The credit facility was extended to expire on December 31, 2014. Interest is payable quarterly. Borrowings are collateralized by substantially all of our assets. Under the Agreement, we are subject to certain financial covenants including, but not limited to, maintaining a Leverage Ratio and Interest Coverage Ratio, as those terms are defined in the Agreement, that are determined on a quarterly basis, and other restrictive covenants.

Furthermore, the Bank may terminate the Agreement and require us to repay all outstanding amounts under certain conditions, as described in the Agreement, including, but not limited to: (1) cross-default on any other credit agreement with an outstanding principal amount in excess of \$500,000, (2) material adverse change in our business condition, operations or properties, (3) violation of any covenant or (4) a change in control of the Company. We did not incur any additional fees in connection with the execution of the Amendment.

**(6) 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 nine months of 2011, we repurchased 508,545 shares for \$2.9 million.

During 2011, options to purchase 437,544 shares of common stock were exercised, of which 60,694 shares were used in settlement of the exercise price. The exercise of these options created a tax deduction of approximately \$1.4 million. Of this amount, approximately \$1.0 million was previously recognized for book purposes, resulting in a deferred tax asset of approximately \$0.4 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 and nine months ended September 30, 2011, with a corresponding increase in common stock. As of September 30, 2011, we had approximately \$56.5 million of unrecognized federal net operating loss carryforwards created by the exercise of nonqualified options. These benefits will be recognized in the period in which they are able to reduce current taxes payable.

**(7) INCOME TAXES**

During the second quarter of 2011, we were notified by the Internal Revenue Service that our 2009 federal tax return was selected for examination. We expect the examination to be completed in the fourth quarter of 2011.

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**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to condensed consolidated financial statements continued**  
**(unaudited)**

**(8) COLLABORATIVE AGREEMENTS**

We are a party to several collaborative arrangements with certain research institutions to identify and pursue promising pre-clinical pharmaceutical product candidates. The Company has 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.

**(9) SUBSEQUENT EVENTS**

Pursuant to the share repurchase plan, as modified by the Board of Directors in January 2011, we repurchased an additional 46,271 shares for approximately \$0.3 million for the period from October 1, 2011 to October 28, 2011.



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**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; 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. We are 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 early 2011, we 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. Our 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 distribution partner to supply our products to our customers.

We have been profitable and have generated positive cash flow since 2004, and in 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange.

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### **Growth Strategy**

Our growth strategy involves maximizing 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 campaign to support each of our approved brands.

We are working to bring our products to select international markets with our first international launch occurring in 2010 with the introduction of Acetadote into the Australian market.

We look for opportunities to expand the use of our approved products into additional patient populations with new data and product indications. These initiatives include our own development work and our support of promising investigator-initiated studies at research institutions.

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

We supplement the aforementioned growth strategy with the earlier-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 we have the opportunity to commercialize. Hepatoren represents the first development candidate to emerge from CET as an addition to our 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 following their filing with the SEC. These filings are also available to the public by the SEC at [www.sec.gov](http://www.sec.gov).

### **Quarter Highlights and Recent Developments**

Acetadote®

#### *New Formulation*

In January 2011, the U.S. Food and Drug Administration, or FDA, approved our supplemental new drug application, or sNDA, for our new formulation of Acetadote, which was the result of a phase IV commitment we made to the FDA upon receipt of initial marketing approval of the product. The new formulation does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. We launched the next generation product, which replaced the previously marketed formulation, in the first quarter of 2011 and during the second and third quarters of 2011 continued to support the transition to this new product.

In July, we filed a response with the U.S. Patent and Trademark Office for a patent to protect our proprietary discoveries related to the new Acetadote formulation. This formulation patent was allowed and issued in China in April 2011. We also recently filed a second U.S. patent application related to the safety profile of the new formulation.

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

In the first quarter of 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 2010, 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. Since then, we have been in discussions with the FDA to determine whether we can address the additional requirements for that approval. We recently identified new data to support this application and are analyzing it before presenting it to the FDA.



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### **Caldolor®**

In late 2009, we initiated the launch of Caldolor, our intravenous formulation of ibuprofen, in the U.S. through our marketing and sales organization. In 2010, we focused our sales efforts primarily on securing formulary approval and stocking nationally for Caldolor. In the second quarter of 2011, we changed our focus and implemented a pull-through strategy for Caldolor, with an emphasis on activities required to build volume and use in centers that have already stocked the product.

We are currently enrolling patients in four clinical studies designed to support marketing of Caldolor. Two of these clinical trials are designed to support pediatric use, including a pediatric fever study to evaluate safety, efficacy and pharmacokinetics of Caldolor in hospitalized children as well as a pediatric pain study. Two registry studies with Caldolor are also underway and are designed to gather additional safety and efficacy data on use of the product in adults. The first of these studies is evaluating Caldolor in treating pain and fever in a wide range of hospitalized patients and the second evaluates the product for management of pain in surgical patients.

### **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, a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment.

Our acquisition of the rights to the ifetroban program includes an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property. Ifetroban was initially developed by Bristol-Myers Squibb, or BMS, for significant cardiovascular indications. BMS conducted extensive preclinical and clinical studies 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 and intend to develop it for several potential indications, including as an Orphan Drug for HRS for which we will pursue seven years of marketing exclusivity.

The FDA has cleared our Investigational New Drug application for this product candidate and we have initiated a Phase II dose escalation clinical study to evaluate Hepatoren for the treatment of HRS. We have commenced manufacturing and have filed patent applications to protect intellectual property related to the new indication. We believe this product candidate is an excellent strategic fit for us given our established presence in the hospital acute care market.

We are also working to identify and progress additional late-stage development opportunities.

### **Kristalose®**

In November 2011, we reached an agreement to acquire the remaining rights associated with the Kristalose brand. We previously operated under a license to the assets and are now acquiring all rights, including the trademark and the FDA registration for the product. This will allow us to streamline the supply chain for Kristalose. As consideration we will provide a royalty on product sales in exchange for these assets.

### **Development Programs**

CET entered into a new collaboration agreement with Washington University in St. Louis to co-develop promising biomedical technologies. Washington University is a national leader in medical research and ranks among the top U.S. institutions in funding by the National Institutes of Health. This collaboration represents the fourth major university partnership for CET, which has similar arrangements with Vanderbilt University, the University of Tennessee and the University of Mississippi.

These agreements allow us to play an important role in fostering and shaping early-stage biomedical research to improve patient care and provide CET and Cumberland with access to promising pipeline candidates such as Hepatoren.



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### **International Markets**

The application for regulatory approval of Caldolor in Canada was recently submitted by our partner Alveda Pharma. Review of the application for approval of Caldolor in Australia submitted by our partner Phebra Pty Ltd is under review by the Australian regulatory authorities. We are also currently working to identify appropriate arrangements for the registration and commercialization of our products in other markets.

### **Company Update**

Effective October of 2011, we named Rick S. Greene as Chief Financial Officer. He had previously been serving as the interim Vice President of Finance and Accounting since April 2011. Mr. Greene has over 20 years of experience in financial management and reporting. Prior to joining us, he supported the accounting activities associated with our Initial Public Offering and the ongoing preparation of our quarterly financial information following out stock exchange listing.

### **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 condensed 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, inventory reserves, stock-based compensation, research and development accounting and intangible assets.

### **Inventories**

We provide valuation reserves for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market value based upon assumptions about remaining shelf life, future demand and market conditions. The reserve for estimated inventory obsolescence was calculated based upon specific review of the inventory expiration dates and the quantity on-hand at September 30, 2011 in comparison to our expected inventory usage. The amount of actual inventory obsolescence and unmarketable inventory could differ (either higher or lower) in the near term from the amounts accrued. Changes in our estimates would be recorded in the income statement in the period of the change.

### **RESULTS OF OPERATIONS**

#### **Three months ended September 30, 2011 compared to the three months ended September 30, 2010**

*Net revenues.* Net revenues for the three months ended September 30, 2011 totaled approximately \$13.1 million, representing an increase of approximately \$0.9 million over the same period in 2010. The increase was primarily due to an increase in Acetadote revenue, partially offset by slightly lower Kristalose revenue. The increase in Acetadote revenue was primarily due to an increase in our selling price, along with increased volume from the continued acceptance of the new formulation of Acetadote and a shortage of the oral form of acetylcysteine in 2011. The increase in Caldolor revenue was due to increased volume, while Kristalose revenue decreased due to increased generic competition.

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*Cost of products sold.* Cost of products sold as a percentage of net revenues increased from approximately 8% for the three months ended September 30, 2010 to 10% for the same period in 2011. The increase in cost of products sold as a percentage of net revenues was impacted by the change in our sales mix during the periods, with Acetadote comprising more of our net revenues during the three months ended September 30, 2011 as compared to the same period in 2010 offset by the recognition in 2011 of approximately \$0.5 million of product inventory reserves. We continuously monitor our inventory levels and may take additional reserves in the future, if needed.

*Selling and marketing.* Selling and marketing expense for the three months September 30, 2011 totaled approximately \$5.1 million, representing a decrease of approximately \$0.6 million over the same period in 2010. The decrease was primarily due to (1) a decrease in royalty expense due to the Acetadote royalty agreement expiring in January 2011 and (2) decreased sales force and related expenses as a result of converting our field sales force in September 2010 from contract employees to Cumberland employees, partially offset by increased marketing and advertising expenses associated with refreshing our promotional literature and branding of our products. We expect selling and marketing expense to remain consistent for the remainder of the year.

*General and administrative.* General and administrative expense for the three months ended September 30, 2011 totaled approximately \$2.1 million, representing an increase of approximately \$0.3 million over the same period in 2010. The increase was primarily due to increased charitable contribution expenses of approximately \$0.3 million associated with a donation of inventory to charitable contributions for humanitarian needs throughout the world.

*Interest expense.* Interest expense for the three months ended September 30, 2011 totaled less than \$0.1 million, representing a decrease of approximately \$0.5 million as compared to the same period in 2010. The decrease is primarily attributable to the decrease in our average term debt balance in 2011 as compared to 2010. In July 2011, we paid in full the outstanding balance of our term debt (\$4.0 million at June 30, 2011).

In August 2011, we entered into the Fifth Amended and Restated Loan Agreement, or the Agreement, for our revolving credit facility with Bank of America, N.A. to provide for up to \$10 million of credit. The interest rate is the BBA LIBOR Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement. In connection with the Agreement, we reduced our Applicable Margin from the prior amendments. We continuously monitor our working capital needs, and will draw on the line of credit as needed. Future interest expense will be based on amounts drawn on our line of credit.

*Income tax expense.* Income tax expense for the three months ended September 30, 2011 totaled approximately \$1.3 million, representing an increase of \$0.3 million over the same period in 2010. As a percentage of net income before income taxes, income tax expense decreased from 48.5% for the three months ended September 30, 2010 to 41% for the three months ended September 30, 2011. The decrease, in percentage of net income before income taxes, was due to an increase in our projected pre-tax income for 2011 without a corresponding increase in our permanent tax differences.

During 2009 and continuing thru September 2011, significant stock options were exercised that resulted in an excess tax benefit to us. As of September 30, 2011, we have approximately \$56.5 million of these tax deductions available to us that will be used to offset future income tax liabilities. In accordance with current accounting pronouncements, these deductions have not been recognized in the condensed consolidated balance sheet as of September 30, 2011. We will recognize the tax benefits in future periods when they are used to offset taxes payable. We expect our cash outflow related to income tax payments to be minimal during 2011 and 2012.

**Nine months ended September 30, 2011 compared to the nine months ended September 30, 2010**

*Net revenues.* Net revenues for the nine months ended September 30, 2011 totaled approximately \$38.1 million, representing an increase of approximately \$5.0 million over the same period in 2010. The increase in net revenues is primarily due to increased Acetadote and Caldolor revenue partially offset by a decrease in Kristalose revenue. The increase in Acetadote revenue was primarily due to an increase in volume from the factors previously noted, as well as an increase in our selling price between the two periods. The increase in Acetadote volume was attributable to (1) the continued acceptance of the new formulation of Acetadote and (2) a shortage of the oral form of acetylcysteine during. The increase in Caldolor revenue was due to increased volume as we continue to penetrate our target market. The decrease in Kristalose revenue was primarily due to increased generic competition.





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*Cost of products sold.* Cost of products sold as a percentage of net revenues increased from 8% for the nine months ended September 30, 2010 to 9% for the same period in 2011. The sales mix changed between the periods, with Acetadote comprising a higher percentage in 2011 than 2010, which would ordinarily result in the percentage decreasing. However, as previously discussed, we recognized product inventory reserves of approximately \$1.0 million during the first nine months of 2011 that offset the impact of the change in the sales mix.

*Selling and marketing.* Selling and marketing expense for the nine months ended September 30, 2011 totaled approximately \$16.3 million, representing a decrease of approximately \$0.9 million over the same period in 2010. The decrease was primarily due to (1) a decrease in royalty expense due to the Acetadote royalty agreement expiring in January 2011 and (2) decreased sales force and related expenses as a result of converting our field sales force in September 2010 from contract employees to Cumberland employees, partially offset by increased marketing and advertising expenses as we rolled out new advertising campaigns in 2011.

*Research and development.* Research and development expense for the nine months ended September 30, 2011 totaled approximately \$3.3 million, representing an increase of approximately \$0.3 million over the same period in 2010. The increase was primarily due to (1) increased salary and related expenses as we build our infrastructure to support our development efforts and (2) costs related to the annual FDA product and establishment fees for our products. We expect research and development expenses to increase as we begin our development efforts for Hepatoren, as well as continue our studies for existing and new indications of Acetadote and Caldolor.

*General and administrative.* General and administrative expense for the nine months ended September 30, 2011 totaled approximately \$6.4 million, representing an increase of approximately \$1.0 million over the same period in 2010. The increase was primarily due to increased consulting and charitable contribution expenses offset by a decrease in legal, accounting and tax professional fees.

*Interest expense.* Interest expense for the nine months ended September 30, 2011 totaled approximately \$0.3 million, representing a decrease of approximately \$1.0 million as compared to the same period in 2010. The decrease is primarily attributable to the decrease in our average term debt balance in 2011 as compared to 2010. Offsetting this decrease was an increase in interest expense in 2011 associated with the deferred financing costs that was accelerated due to the early payment of our term debt in July 2011.

*Income tax expense.* Income tax expense for the nine months ended September 30, 2011 totaled approximately \$3.2 million, representing an increase of approximately \$1.7 million, over the same period in 2010. As a percentage of net income before income taxes, income tax expense decreased from 49.0% for the nine months ended September 30, 2010 to 40.7% for the nine months ended September 30, 2011. The decrease, in percentage of net income before income taxes, was due to an increase in our projected pre-tax income for 2011 without a corresponding increase in our permanent tax differences.

**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 September 30, 2011 and December 31, 2010, cash and cash equivalents was \$71.1 million and \$65.9 million, respectively, working capital (current assets minus current liabilities) was \$78.4 million and \$71.8 million, respectively, and our current ratio (current assets to current liabilities) was 11.5x and 8.8x, respectively. As of September 30, 2011, we had an additional \$5.4 million available to us on our line of credit.

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In July 2011, we repaid all amounts owed under our term debt agreement with Bank of America. In August, 2011, we entered into the Fifth Amended and Restated Loan Agreement, or the Agreement, for our revolving credit facility with Bank of America, N.A., or the Bank, to provide for up to \$10 million of credit. The credit facility may be increased up to \$20 million, upon the satisfaction of certain conditions. The interest rate is the BBA LIBOR Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement. We reduced the Applicable Margin from our prior amendments. The credit facility was extended to expire on December 31, 2014. Interest is payable quarterly. Borrowings are collateralized by substantially all of our assets. The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2011 and 2010:

	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 7,692	\$ 1,033
Investing activities	(382)	(443)
Financing activities	(2,129)	(13,773)
Net increase (decrease) in cash and cash equivalents <sup>(1)</sup>	\$ 5,181	\$ (13,183)

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

The net increase in cash and cash equivalents of \$5.2 million for the nine months ended September 30, 2011 was primarily due to cash generated from our operating activities. Net income for the period was \$4.7 million. In addition, our accounts payable and other current liabilities, net of the excess tax benefit generated by the exercise of nonqualified options in 2011, increased by \$1.3 million from December 31, 2010, which had a favorable impact on our operating cash flows. In addition, our receivables decreased \$0.6 million due to the timing of cash receipts from customers. Contributing to our increase in cash was the cash proceeds received from (1) the exercise of stock options during 2011 and (2) additional funding from our line of credit for working capital needs. As previously noted, we paid in full our outstanding term debt balance during 2011. The scheduled principal payments and the early payoff totaled \$5.3 million for the nine months ended September 30, 2011. In addition, we purchased \$2.9 million of common stock as part of our share repurchase program discussed in Part II, Item 2 of this Form 10-Q.

The net decrease in cash and cash equivalents of \$13.2 million for the nine months ended September 30, 2010 was primarily due to cash used in financing activities, which included (1) principal payments on our term debt of \$12.0 million, (2) the repurchase of common stock of approximately \$4.1 million. These expenditures were offset by proceeds from the exercise of stock options of approximately \$1.2 million and the excess tax benefit derived from the exercise of nonqualified options of approximately \$1.3 million. Cash provided by operating activities for the nine months ended September 30, 2010 was primarily due to net income for the period and the collection of the receivables associated with these sales.

**OFF-BALANCE SHEET ARRANGEMENTS**

During the nine months ended September 30, 2011 and 2010, the Company did not engage in any off-balance sheet arrangements.

**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. 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.

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The interest rate related to borrowings under our revolving credit facility is a variable rate of LIBOR plus an Applicable Margin, as defined in the debt agreement (2.24% at September 30, 2011). As of September 30, 2011, we had outstanding borrowings of approximately \$4.6 million under our revolving credit facility. If interest rates increased by 1.0%, our annual interest expense on our borrowings would increase by less than \$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 September 30, 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 nine months ended September 30, 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 principal financial officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 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.

**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.

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Purchases of Equity Securities**

The following table summarizes the purchase of equity securities by the Company during the three months ended September 30, 2011:

<b>Period</b>	<b>Total Number of Shares (or Units) Purchased</b>	<b>Average Price Paid per Share (or Unit)</b>	<b>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plan or Programs</b>
July 1 July 31	43,272	\$ 6.31	43,272	\$ 8,934,128
August 1 August 31	98,708	6.04	98,708	8,338,044
September 1 September 30	81,339	5.70	81,339	7,874,268
Total	223,319			

**Item 6: Exhibits**

<b>No.</b>	<b>Description</b>
31.1	Certification of Chief Executive 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.
31.2	Certification of Chief 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	Certification of Chief Executive and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**SIGNATURES**

Pursuant to the requirements of the Securities 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: November 7, 2011

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

By: */s/ Rick S. Greene*  
Rick S. Greene  
Chief Financial Officer