CUMBERLAND PHARMACEUTICALS INC
Form 10-Q
August 08, 2011

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

(Mark One)

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

For the quarterly period ended June 30, 2011

or

o **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	**62-1765329**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2525 West End Avenue, Suite 950, Nashville, Tennessee	**37203**
(Address of principal executive offices)	(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 þ No o

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 o No o

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 o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(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 o No þ

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 July 29, 2011
Common stock, no par value	20,381,813

CUMBERLAND PHARMACEUTICALS INC.
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PART I FINANCIAL INFORMATION

Item 1: Financial Statements

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

	June 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,832,030	$ 65,893,970
Accounts receivable, net of allowances	4,819,734	5,145,494
Inventories	7,453,251	7,683,842
Other current assets	2,238,864	2,315,536
Total current assets	84,343,879	81,038,842
Property and equipment, net	1,195,924	1,220,010
Intangible assets, net	7,116,260	7,427,223
Other assets	1,924,992	2,367,979
Total assets	$ 94,581,055	$ 92,054,054
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 3,999,999	$ 2,666,668
Accounts payable	2,302,058	2,124,654
Other current liabilities	4,425,873	4,436,298
Total current liabilities	10,727,930	9,227,620
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion		2,666,665
Other long-term obligations, excluding current portion	602,099	618,343
Total liabilities	13,155,980	14,338,579
Commitments and contingencies		
Equity:		
Shareholders equity:		

Common stock no par value; 100,000,000 shares authorized; 20,400,085 and 20,338,461 shares issued and outstanding as of June 30, 2011 and December 31, 2010, respectively	71,609,043	70,778,874
Retained earnings	9,897,585	6,998,806
Total shareholders equity	81,506,628	77,777,680
Noncontrolling interests	(81,553)	(62,205)
Total equity	81,425,075	77,715,475
Total liabilities and equity	$ 94,581,055	$ 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 June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net revenues	$ 14,389,741	$ 10,739,935	$ 25,056,668	$ 20,870,587
Costs and expenses:				
Cost of products sold	1,283,160	863,725	2,070,098	1,723,013
Selling and marketing	5,904,444	5,848,123	11,193,028	11,455,635
Research and development	1,027,048	1,034,800	2,036,721	1,808,668
General and administrative	2,344,064	1,782,834	4,324,455	3,664,037
Amortization of product license right	171,726	171,726	343,453	343,452
Other	27,442	28,867	49,055	55,414
Total costs and expenses	10,757,884	9,730,075	20,016,810	19,050,219
Operating income	3,631,857	1,009,860	5,039,858	1,820,368
Interest income	52,260	50,334	95,169	111,013
Interest expense	(79,604)	(405,956)	(295,647)	(751,908)
Net income before income taxes	3,604,513	654,238	4,839,380	1,179,473
Income tax expense	(1,436,365)	(374,461)	(1,959,949)	(586,198)
Net income	2,168,148	279,777	2,879,431	593,275
Net loss at subsidiary attributable to noncontrolling interests	9,471	7,527	19,348	17,607
Net income attributable to common shareholders	$ 2,177,619	$ 287,304	$ 2,898,779	$ 610,882
Earnings per share attributable to common shareholders				
- basic	$ 0.11	$ 0.01	$ 0.14	$ 0.03
- diluted	$ 0.11	$ 0.01	$ 0.14	$ 0.03
Weighted-average shares outstanding				
- basic	20,471,621	20,445,560	20,458,842	20,340,000
- diluted	20,661,719	21,207,645	20,719,714	21,302,119

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)

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities:		
Net income	$ 2,879,431	$ 593,275
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	527,301	463,676
Non-employee equity compensation	44,574	45,554
Stock-based compensation employee stock options	315,513	318,139
Excess tax benefit derived from exercise of stock options	(1,516,569)	(462,814)
Non-cash interest expense	123,654	132,866
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	325,760	2,216,456
Inventory	230,591	(3,144,216)
Other current assets and other assets	704	349,777
Accounts payable and other accrued liabilities	2,009,529	337,995
Other long-term obligations	(5,141)	(95,541)
Net cash provided by operating activities	4,935,347	755,167
Cash flows from investing activities:		
Additions to property and equipment	(105,838)	(126,315)
Additions to patents	(46,344)	(80,734)
Net cash used in investing activities	(152,182)	(207,049)
Cash flows from financing activities:		
Principal payments on note payable	(1,333,334)	(6,061,973)
Costs of financing for long-term debt and credit facility		(55,000)
Proceeds from exercise of stock options	523,507	979,292
Excess tax benefit derived from exercise of stock options	1,516,569	462,814
Payments made in connection with repurchase of common shares	(1,551,847)	(3,079,628)
Net cash used in financing activities	(845,105)	(7,754,495)
Net increase (decrease) in cash and cash equivalents	3,938,060	(7,206,377)
Cash and cash equivalents at beginning of period	65,893,970	78,701,682
Cash and cash equivalents at end of period	$ 69,832,030	$ 71,495,305

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		203,802
Additions to property and equipment not paid as of the end of the period	40,070	

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)

	Common stock		Retained	Non-controlling	Total
	Shares	Amount	earnings	interests	equity
Balance, December 31, 2010	20,338,461	$ 70,778,874	$ 6,998,806	$ (62,205)	$ 77,715,475
Stock-based compensation - nonemployees		28,660			28,660
Exercise of options and related tax benefit	346,850	2,040,076			2,040,076
Stock-based compensation - employees		313,280			313,280
Repurchase of shares	(285,226)	(1,551,847)			(1,551,847)
Net and comprehensive income			2,898,779	(19,348)	2,879,431
Balance, June 30, 2011	20,400,085	$ 71,609,043	$ 9,897,585	$ (81,553)	$ 81,425,075

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 six 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 six months ended June 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 June 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 six months ended June 30, 2011 and 2010:

		Three Months Ended June 30, 2011	2010
Numerator:			
Net income attributable to common shareholders		$ 2,177,619	$ 287,304
Denominator:			
Weighted-average shares outstanding	basic	20,471,621	20,445,560
Dilutive effect of other securities		190,098	762,085
Weighted-average shares outstanding	diluted	20,661,719	21,207,645

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

	Six Months Ended June 30,	
	2011	2010
Numerator:		
Net income attributable to common shareholders	$ 2,898,779	$ 610,882
Denominator:		
Weighted-average shares outstanding basic	20,458,842	20,340,000
Dilutive effect of other securities	260,872	962,119
Weighted-average shares outstanding diluted	20,719,714	21,302,119

As of June 30, 2011 and 2010, restricted stock awards and options to purchase 1,149,374 and 657,532 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 did not have any sales to non-U.S. customers during the three months ended June 30, 2011 and 2010, respectively. We had sales of less than $0.1 million to non-U.S. customers during the six months ended June 30, 2011 and 2010, respectively.

The Company s net revenues consisted of the following for the three and six months ended June 30, 2011 and 2010:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Products:				
Acetadote	$ 12,167,302	$ 8,308,560	$ 20,711,895	$ 16,031,833
Kristalose	2,101,971	2,271,418	4,172,352	4,581,401
Caldolor	86,027	45,776	97,981	65,081
Other	34,441	114,181	74,440	192,272
Total net revenues	$ 14,389,741	$ 10,739,935	$ 25,056,668	$ 20,870,587

(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.

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 June 30, 2011 and December 31, 2010, inventory was comprised of the following:

	June 30, 2011	December 31, 2010
Raw materials	$ 588,637	$ 356,676
Finished goods	6,864,614	7,327,166

Total	$ 7,453,251	$ 7,683,842

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

(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 six months of 2011, we repurchased 285,226 shares for $1.6 million.

During 2011, options to purchase 407,544 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 six months ended June 30, 2011, with a corresponding increase in common stock. As of June 30, 2011, we had approximately $60.3 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.

(6) 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. The 2009 federal tax return is the only return open for audit. We expect the examination to be completed in the fourth quarter of 2011.

(7) 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.

(8) SUBSEQUENT EVENTS

Pursuant to the share repurchase plan, as modified by the Board of Directors in January 2011, we repurchased an additional 43,272 shares for approximately $0.3 million for the period from July 1, 2011 to July 29, 2011.

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 August 2011, we amended our revolving credit facility with Bank of America to provide for up to $10 million of credit with the option to increase the line to $20 million. The interest rate is LIBOR plus an Applicable Margin, as defined in the agreement. The credit facility will expire on December 31, 2014. We did not incur any fees associated with the amendment.

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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; 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 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 steady product supply.

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.

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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 effort, and we are working to bring our products to select international markets with our first international launch occurring in 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. 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.

Quarter Highlights and Recent Developments

Acetadote®

New Formulation

In January 2011, the U.S. Food and Drug Administration (FDA) approved our supplemental new drug application (sNDA) for our 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. 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 response from the medical community has been favorable. During the second quarter, we also amended our supply agreement for Acetadote with Bioniche, which was recently acquired by Mylan.

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 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 (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 IND 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.

International Markets

In the second quarter of 2011 we executed agreements with partners for commercialization of Caldolor and Acetadote in two new Asian markets, Malaysia and Taiwan. In Malaysia, we are partnering with Insanbakti and in Taiwan with Harvest & Health Co., Ltd. These agreements are part of a larger initiative to secure widespread distribution of our products in appropriate Asian markets, and follow our recent agreement with DB Pharm Korea for Caldolor in South Korea.

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

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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.

RESULTS OF OPERATIONS

Three months ended June 30, 2011 compared to the three months ended June 30, 2010

Net revenues. Net revenues for the three months ended June 30, 2011 totaled approximately $14.4 million, representing an increase of approximately $3.7 million, or 34%, over the same period in 2010. The increase was primarily due to increased revenue associated with Acetadote, partially offset by slightly lower revenue for Kristalose. The increase in Acetadote revenue was driven by (1) acceptance of the new formulation of Acetadote and (2) increased sales volume that was caused by a shortage of the oral form of acetylcysteine during 2011. The decrease in Kristalose revenue was primarily due to increased generic competition.

Cost of products sold. Cost of products sold as a percentage of net revenues increased slightly from 8.0% for the three months ended June 30, 2010 to 8.9% for the same period in 2011. The increase in cost of products sold as a percentage of net revenues was driven by the change in our sales mix during the periods, with Acetadote comprising more of our net revenues during the three months ended June 30, 2011 as compared to the same period in 2010 offset by the recognition in 2011 of product inventory reserves of approximately $0.4 million.

General and administrative. General and administrative expense for the three months ended June 30, 2011 totaled approximately $2.3 million, representing an increase of approximately $0.6 million, or 31%, 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 three months ended June 30, 2011 totaled approximately $0.1 million, representing a decrease of approximately $0.3 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.

During the second quarter of 2011, we notified Bank of America of our intent to repay the outstanding balance of our term debt ($4.0 million at June 30, 2011) in early July 2011. As a result, we accelerated the recognition of unamortized deferred financing costs associated with the term debt. In addition, we reversed the accrual made in the first quarter of 2011 associated with the additional loan fees based on certain financial metrics determined as of September 30, 2011. These costs substantially offset each other.

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Income tax expense. Income tax expense for the three months ended June 30, 2011 totaled approximately $1.4 million, representing an increase of $1.1 million over the same period in 2010. As a percentage of net income before income taxes, income tax expense decreased from 57.2% for the three months ended June 30, 2010 to 39.8% for the three months ended June 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 June 2011, significant stock options were exercised that resulted in an excess tax benefit to us. As of June 30, 2011, we have approximately $60.3 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 June 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.

Six months ended June 30, 2011 compared to the six months ended June 30, 2010

Net revenues. Net revenues for the six months ended June 30, 2011 totaled approximately $25.1 million, representing an increase of approximately $4.2 million, or 20%, over the same period in 2010. The increase in net revenues is primarily due to increased Acetadote revenue partially offset by a decrease in Kristalose revenue. The increase in Acetadote revenue was driven by (1) acceptance of the new formulation of Acetadote and (2) increased sales volume that was caused by a shortage of the oral form of acetylcysteine during 2011. The decrease in Kristalose revenue was primarily due increased generic competition.

Cost of products sold. Cost of products sold as a percentage of net revenues remained consistent at 8.3% for the six months ended June 30, 2011 and 2010. 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 during 2011 that offset the impact of the change in the sales mix.

Selling and marketing. Selling and marketing expense for the six months ended June 30, 2011 totaled approximately $11.2 million, representing a decrease of approximately $0.3 million, or 2%, 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, (2) decreased sales force and related expenses as a result of converting our hospital sales force from contract employees to Cumberland employees. These decreases were partially offset by increased marketing and advertising expenses as we rolled out new advertising campaigns in 2011, as well as launching our Speakers Bureau in early 2011. The Speakers Bureau is a Company-sponsored event whereby a well-respected doctor will present and advocate the use of Caldolor in pain management to a targeted audience.

Research and development. Research and development expense for the six months ended June 30, 2011 totaled approximately $2.0 million, representing an increase of approximately $0.2 million, or 13%, 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.

General and administrative. General and administrative expense for the six months ended June 30, 2011 totaled approximately $4.3 million, representing an increase of approximately $0.7 million, or 18%, 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.

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Interest expense. Interest expense for the six months ended June 30, 2011 totaled approximately $0.3 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. Offsetting this decrease was an increase in amortization 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 six months ended June 30, 2011 totaled approximately $2.0 million, representing an increase of approximately $1.4 million, over the same period in 2010. As a percentage of net income before income taxes, income tax expense decreased from 49.7% for the six months ended June 30, 2010 to 40.5% for the six months ended June 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 June 30, 2011 and December 31, 2010, cash and cash equivalents was $69.8 million and $65.9 million, respectively, working capital (current assets minus current liabilities) was $73.6 million and $71.8 million, respectively, and our current ratio (current assets to current liabilities) was 7.9x and 8.8x, respectively. As of June 30, 2011, we had an additional $4.2 million available to us on our line of credit.

In July 2011, we repaid all amounts owed under our term debt agreement with Bank of America.

On August 2, 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. 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 the 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.

The foregoing description of the Agreement is qualified in its entirety by the full text of the Agreement, a copy of which is attached as Exhibit 10.16 and incorporated herein by reference.

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The following table summarizes our net changes in cash and cash equivalents for the six months ended June 30, 2011 and 2010:

	Six Months Ended June 30,	
	2011	2010
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 4,935	$ 755
Investing activities	(152)	(207)
Financing activities	(845)	(7,754)
Net increase (decrease) in cash and cash equivalents [1]	$ 3,938	$ (7,206)

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

The net increase in cash and cash equivalents of $3.9 million for the six months ended June 30, 2011 was primarily due to cash generated from our operating activities. Net income for the period was $2.9 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 $2.0 million from December 31, 2010, which had a favorable impact on our operating cash flows. Contributing to our increase in cash was the cash proceeds received from the exercise of stock options during 2011. These increases in cash and cash equivalents resulting from our operating activities were partially offset by scheduled debt payments of $1.3 million.

The net decrease in cash and cash equivalents of $7.2 million for the six months ended June 30, 2010 was primarily due to cash used in financing activities, which included (1) principal payments on our term debt of approximately $6.1 million, (2) the repurchase of common stock of approximately $3.1 million, (3) proceeds from the exercise of stock options of approximately $1.0 million and (4) the excess tax benefit derived from the exercise of nonqualified options of approximately $0.5 million.

The share repurchase program discussed in Part II, Item 2, is incorporated by reference into this Item.

OFF-BALANCE SHEET ARRANGEMENTS

During the six months ended June 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 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 (4.69% at June 30, 2011). As of June 30, 2011, we had outstanding borrowings of approximately $5.8 million under our revolving credit facility and term debt combined. As previously noted, we repaid all outstanding amounts under our term debt agreement with Bank of America in July 2011. 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 June 30, 2011, our outstanding payables denominated in a foreign currency were less than

$0.1 million.

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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 six months ended June 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 financial officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 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.

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 the Company during the three months ended June 30, 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
April 1 April 30	36,588	$ 5.19	36,588	$ 9,796,912
May 1 May 31	120,311(1)	5.13	59,617	9,494,796
June 1 June 30	57,459	5.01	57,459	9,206,961
Total	214,358			

(1) The purchase of 60,694 shares of common stock was made pursuant to a net-share settlement under which the stock option holder tendered these shares acquired upon exercise for settlement of the exercise price of the options. The purchase price of this transaction was the then-current fair market value of common stock on the date of the transaction.

Item 5: Other Information

On August 2, 2011, we entered into the Fifth Amended and Restated Loan Agreement with Bank of America, N.A. The information included in Part I, Item 2, under Working Capital, pertaining to this agreement is incorporated herein by reference to that section.

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Item 6: Exhibits

No.	Description
10.16	Fifth Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated August 2, 2011
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	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.
	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

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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: August 8, 2011

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