

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 02, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2012

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)

Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

<p><b>Tennessee</b>                  (State or other jurisdiction of                  incorporation or organization)</p>	<p><b>62-1765329</b>                  (I.R.S. Employer                  Identification No.)</p>
<p><b>2525 West End Avenue, Suite 950,</b></p>	
<p><b>Nashville, Tennessee</b>                  (Address of principal executive offices)</p>	<p><b>37203</b>                  (Zipcode)</p>
<p><b>(615) 255-0068</b></p>	
<p><b>(Registrant's telephone number, including area code)</b></p>	

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 27, 2012
Common stock, no par value	19,110,546

**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC.**

**INDEX**

<b><u>PART I FINANCIAL INFORMATION</u></b>	1
<u>Item 1: Financial Statements (Unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Net and Comprehensive Income</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Condensed Consolidated Statement of Equity</u>	4
<u>Notes to the Condensed Consolidated Financial Statements</u>	5
<u>Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 3: Quantitative and Qualitative Disclosure about Market Risk</u>	16
<u>Item 4: Controls and Procedures</u>	16
<b><u>PART II OTHER FINANCIAL INFORMATION</u></b>	17
<u>Item 1: Legal Proceedings</u>	17
<u>Item 1a: Risk Factors</u>	17
<u>Item 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
<u>Item 6: Exhibits</u>	19
<b><u>SIGNATURES</u></b>	20

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1: Financial Statements****CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****(Unaudited)**

	September 30, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 50,801,571	\$ 70,599,146
Marketable securities	18,559,476	
Accounts receivable, net of allowances	5,467,455	7,082,890
Inventories	7,511,641	5,774,694
Other current assets	4,451,786	3,851,337
Total current assets	86,791,929	87,308,067
Property and equipment, net	1,120,591	1,119,339
Intangible assets, net	8,367,508	7,023,064
Other assets	653,768	67,846
Total assets	\$ 96,933,796	\$ 95,518,316
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,228,230	\$ 1,513,548
Other current liabilities	4,429,904	5,086,400
Total current liabilities	8,658,134	6,599,948
Revolving line of credit	4,359,951	4,859,951
Other long-term liabilities	583,790	1,223,148
Total liabilities	13,601,875	12,683,047
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock - no par value; 100,000,000 shares authorized; 19,173,846 and 20,020,535 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	66,756,556	70,272,155
Retained earnings	16,693,654	12,656,662
Total shareholders' equity	83,450,210	82,928,817
Noncontrolling interests	(118,289)	(93,548)
Total equity	83,331,921	82,835,269

Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

Total liabilities and equity	\$ 96,933,796	\$ 95,518,316
------------------------------	---------------	---------------

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net revenues	\$ 12,531,719	\$ 13,054,278	\$ 35,154,871	\$ 38,110,946
Costs and expenses:				
Cost of products sold	921,862	1,341,256	2,873,417	3,411,354
Selling and marketing	4,914,551	5,060,546	15,387,068	16,253,574
Research and development	1,696,592	1,233,025	4,653,957	3,269,746
General and administrative	1,901,986	2,149,364	6,331,109	6,522,874
Amortization of product license right	117,565	171,727	344,211	515,180
Total costs and expenses	9,552,556	9,955,918	29,589,762	29,972,728
Operating income	2,979,163	3,098,360	5,565,109	8,138,218
Interest income	107,719	52,459	256,074	147,628
Interest expense	(17,222)	(33,390)	(56,369)	(329,037)
Income before income taxes	3,069,660	3,117,429	5,764,814	7,956,809
Income tax expense	(1,207,504)	(1,278,472)	(1,752,563)	(3,238,421)
Net income	1,862,156	1,838,957	4,012,251	4,718,388
Net loss at subsidiary attributable to noncontrolling interests	7,338	8,455	24,741	27,803
Net income attributable to common shareholders	\$ 1,869,494	\$ 1,847,412	\$ 4,036,992	\$ 4,746,191
Earnings per share attributable to common shareholders				
- basic	\$ 0.10	\$ 0.09	\$ 0.20	\$ 0.23
- diluted	\$ 0.10	\$ 0.09	\$ 0.20	\$ 0.23
Weighted-average shares outstanding				
- basic	19,432,715	20,327,537	19,737,216	20,414,593
- diluted	19,670,741	20,534,647	19,969,051	20,657,567

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 4,012,251	\$ 4,718,388
<b>Adjustments to reconcile net income to net cash flows from operating activities:</b>		
Depreciation and amortization expense	664,369	801,483
Stock-based compensation nonemployees	101,038	119,313
Stock-based compensation employees	455,666	467,850
Excess tax benefit derived from exercise of stock options	(2,176,222)	(2,657,259)
Noncash interest expense	16,050	131,469
Net unrealized investment gains	(99,286)	
<b>Net changes in assets and liabilities affecting operating activities:</b>		
Accounts receivable	1,615,435	640,083
Inventory	(1,736,947)	809,243
Other current assets and other assets	(1,228,382)	(1,240,700)
Accounts payable and other accrued liabilities	4,178,708	3,911,450
Other long-term liabilities	(655,201)	(9,262)
<b>Net cash provided by operating activities</b>	<b>5,147,479</b>	<b>7,692,058</b>
<b>Cash flows from investing activities:</b>		
Additions to property and equipment	(293,693)	(241,885)
Purchases of marketable securities	(18,849,492)	
Proceeds from marketable securities	389,302	
Additions to intangibles	(1,621,100)	(140,356)
<b>Net cash used in investment activities</b>	<b>(20,374,983)</b>	<b>(382,241)</b>
<b>Cash flows from financing activities:</b>		
Principal payments on note payable		(5,333,333)
Net (repayments) borrowings on line of credit	(500,000)	2,750,000
Proceeds from exercise of stock options	580,101	681,634
Excess tax benefit derived from exercise of stock options	2,176,222	2,657,259
Repurchase of common shares	(6,826,394)	(2,884,540)
<b>Net cash used in financing activities</b>	<b>(4,570,071)</b>	<b>(2,128,980)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(19,797,575)</b>	<b>5,180,837</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>70,599,146</b>	<b>65,893,970</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 50,801,571</b>	<b>\$ 71,074,807</b>
<b>Supplemental disclosure of cash flow information:</b>		
<b>Non-cash investing and financing activities:</b>		
<b>Net change in unpaid additions to intangibles, property and equipment</b>	<b>\$ 95,272</b>	<b>\$</b>
See accompanying notes to unaudited condensed consolidated financial statements.		





**Table of Contents****CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Statement of Equity****(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, 2011	20,020,535	\$ 70,272,155	\$ 12,656,662	\$ (93,548)	\$ 82,835,269
Stock-based compensation nonemployees	20,199	98,806			98,806
Exercise of options and related tax benefit	162,526	2,756,323			2,756,323
Stock-based compensation employees		455,666			455,666
Repurchase of shares	(1,029,414)	(6,826,394)			(6,826,394)
Net and comprehensive income			4,036,992	(24,741)	4,012,251
Balance, September 30, 2012	19,173,846	\$ 66,756,556	\$ 16,693,654	\$ (118,289)	\$ 83,331,921

See accompanying notes to unaudited condensed consolidated financial statements.

---

**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

**Notes to condensed consolidated financial statements**

**(unaudited)**

**(1) BASIS OF PRESENTATION**

In the opinion of management, the accompanying unaudited condensed consolidated financial statements of Cumberland Pharmaceuticals Inc. and its subsidiaries, or the Company or Cumberland, have been prepared on a basis consistent with the December 31, 2011 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, 2011. The results of operations for the first nine months of 2012 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, 2012 and 2011.

***Accounting Policies:***

***Use of Estimates***

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.

***Operating Segments***

We operate in one segment, specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Substantially all of our assets are located in the United States.

***Subsequent Events***

Management has evaluated events occurring subsequent to September 30, 2012 for accounting and disclosure implications.

**(2) MARKETABLE SECURITIES**

Marketable securities consist of U.S. Treasury notes and bonds, U.S. Government Agency notes and bonds and bank-guaranteed, variable rate demand notes (VRDN). At the time of purchase, we classify our marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of September 30, 2012, the marketable securities were comprised solely of trading securities. Trading securities are carried at fair value with unrealized gains and losses recognized as a component of interest income in the condensed consolidated statements of income. The fair values of marketable securities at September 30, 2012 were determined based on valuations provided by a third-party pricing service, as derived from such services' pricing models, and are considered Level 1 and Level 2 measurements, depending on the nature of the investment. Level 1 valuations are based on quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities. Level 2 valuations are based on observable market-based inputs other than quoted prices in active markets for identical assets. The level of management judgment required in establishing fair value for Level 1 investments is minimal. Similarly, there is little subjectivity or judgment required for Level 2 investments that are valued using valuation models that are standard across the industry and where all parameter inputs are quoted in active markets. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events.



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

The following table summarizes the fair value of our marketable securities, by type, as of September 30, 2012 based on the categories described above:

	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$ 2,473,272	\$	\$ 2,473,272
U.S. Agency issued mortgage-backed securities variable rate		3,856,944	3,856,944
U.S. Agency notes and bonds fixed rate		1,502,920	1,502,920
SBA loan pools variable rate		2,031,340	2,031,340
Municipal bonds VRDN	8,695,000		8,695,000
	\$ 11,168,272	\$ 7,391,204	\$ 18,559,476

**(3) EARNINGS PER SHARE**

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,	
	2012	2011
<b>Numerator:</b>		
Net income attributable to common shareholders	\$ 1,869,494	\$ 1,847,412
<b>Denominator:</b>		
Weighted-average shares outstanding basic	19,432,715	20,327,537
Dilutive effect of other securities	238,026	207,110
Weighted-average shares outstanding diluted	19,670,741	20,534,647
	Nine Months Ended September 30,	
	2012	2011
<b>Numerator:</b>		
Net income attributable to common shareholders	\$ 4,036,992	\$ 4,746,191
<b>Denominator:</b>		
Weighted-average shares outstanding basic	19,737,216	20,414,593
Dilutive effect of other securities	231,835	242,974
Weighted-average shares outstanding diluted	19,969,051	20,657,567

## Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

As of September 30, 2012 and 2011, restricted stock awards and options to purchase 250,284 and 1,082,309 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

**Table of Contents****CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Notes to condensed consolidated financial statements - continued****(unaudited)****(4) REVENUES**

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Products:				
Acetadote	\$ 9,802,744	\$ 10,882,342	\$ 26,923,996	\$ 31,594,237
Kristalose	2,376,231	2,077,310	6,773,287	6,249,662
Caldolor	295,011	47,966	604,414	145,947
Other	57,733	46,660	853,174	121,100
Total net revenues	\$ 12,531,719	\$ 13,054,278	\$ 35,154,871	\$ 38,110,946

In the first quarter of 2012, we entered into an exclusive licensing agreement for Acetadote and Caldolor with Harbin Gloria Pharmaceuticals Co., Ltd., a Chinese pharmaceutical company that has expertise in developing, registering, manufacturing and commercializing products in the China market. In connection with the agreement, we received a nonrefundable, up-front payment of \$0.7 million in exchange for the transfer of certain intellectual property, including our product dossiers. We also have certain protective rights, including the right to review and approve all documents submitted to the Chinese State Drug Administration. We determined the agreement contains two units of accounting- the transfer of certain rights, including the product dossier, for Acetadote and Caldolor, separately. As of March 31, 2012, we had delivered these items for Caldolor to the licensee, and recognized revenue of approximately \$0.5 million as other revenue. The remaining up-front payment of \$0.2 million related to Acetadote was recognized during the second quarter of 2012, when the intellectual property, including the dossier, was provided to the licensee.

The licensing agreement provides for us to receive additional milestone payments of \$0.7 million when the licensee receives notice from the regulatory authority granting approval to conduct clinical trials, or stating that no clinical trials are necessary. In addition, we will receive milestone payments of \$1.1 million upon receiving regulatory approval for each of Acetadote and Caldolor in China. We will recognize revenue for these substantive milestones using the milestone method. We use the milestone method of recognizing revenue for substantive milestones if (1) it is commensurate with either the performance to achieve the milestone or the enhancement of the value of the delivered item, (2) it relates solely to past performance and (3) it is reasonable relative to the other milestones. As of September 30, 2012, we have not recognized any revenue related to milestones associated with Harbin Gloria.

In addition to the revenue recognized for the up-front payments from our international partners, we had product sales of less than \$0.1 million to non-U.S. customers for each of the three and nine months ended September 30, 2012 and 2011.

**(5) 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 continually evaluate inventory for potential losses due to excess, obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates the carrying value may not be recoverable, a charge is taken to reduce the inventory to the net realizable value.



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

During 2009 and 2010, we built inventory to support the Caldolor product launch. Caldolor inventory represented the majority of net inventory on hand at September 30, 2012 and December 31, 2011, and has varying expiration dates through January 2015. At September 30, 2012 and December 31, 2011, we have recognized a reserve for potential obsolescence and discontinuance primarily for Caldolor of approximately \$2.0 million and \$2.1 million, respectively. If actual sales in future periods are less than projected sales, we could incur additional obsolescence losses.

In connection with the purchase of certain Kristalose assets in 2011, we are responsible for the purchase of the active pharmaceutical ingredient for Kristalose, and maintain the inventory at the third-party manufacturer. As the ingredients are consumed in production, the value of the ingredients is transferred from raw materials to finished goods inventory.

As of September 30, 2012 and December 31, 2011, inventory was comprised of the following:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Raw materials	\$ 1,844,829	\$ 774,637
Finished goods	5,666,812	5,000,057
<b>Total</b>	<b>\$ 7,511,641</b>	<b>\$ 5,774,694</b>

**(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 Exchange Act of 1934. In April 2012, our Board of Directors modified this plan to provide for additional repurchases up to \$10.0 million of our outstanding common shares, in addition to the amounts previously repurchased in 2010 and 2011. In the first nine months of 2012, we repurchased approximately 1.0 million shares for approximately \$6.8 million.

In the second quarter of 2012, we implemented an Option Exchange Program (the Exchange Program) whereby certain outstanding stock options could be exchanged for shares of restricted stock. The Exchange Program expired on May 21, 2012, at which time 424,475 outstanding options were exchanged for 147,828 shares of restricted stock. The restriction period on the restricted stock lapse from one to four years after issuance. The Exchange Program was designed to provide a value-for-value exchange of equity instruments. The fair value of each exchanged option was determined on the date the Exchange Program commenced using the Black-Scholes methodology, and the following assumptions:

	<b>Range of Assumptions</b>	
Dividend yield		
Expected term (years)	1.3	7.3
Expected volatility	37%	78%
Risk-free interest rate	0.23%	1.50%

The Exchange Program did not result in any incremental compensation expense during 2012. The remaining unrecognized compensation costs for the exchanged options on the date of the exchange was approximately \$0.3 million, and will be recognized over the restriction period.

**(7) INCOME TAXES**



## Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

At September 30, 2012, we have unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$55.8 million. These benefits will be recognized in the year in which they are able to reduce current income taxes payable. We expect to pay minimal income taxes in future periods due to the usage of these net operating losses.

As a result of the Exchange Program, we recognized a deferred tax asset of approximately \$0.5 million at September 30, 2012, and a related income tax benefit for the nine months ended September 30, 2012. The deferred tax asset represents the expected tax benefit of previously recognized compensation expense for incentive stock options that were exchanged as part of the Exchange Program. In prior years, we did not receive a tax benefit associated with incentive stock options. We will receive a tax benefit when the restrictions lapse on the restricted stock.

**Table of Contents**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

**Notes to condensed consolidated financial statements - continued**

**(unaudited)**

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 examination was completed during the second quarter of 2012, with no significant findings or adjustments.

**(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 Administration (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) COMMITMENTS AND CONTINGENCIES**

During 2012, we received notices that our Acetadote patent was being challenged on the basis of invalidity or non-infringement by others. We intend to vigorously defend and protect our Acetadote product and related intellectual property rights and have filed lawsuits to contest the infringement of the Acetadote patent. At this point, it is too early to evaluate the outcome of the lawsuits. If we are unable to successfully defend our Acetadote patent, our financial condition and results of operations may be materially adversely affected.

## **Table of Contents**

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

The following discussion contains certain forward-looking statements which reflect management's current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We caution you that our actual results may differ significantly from the results we discuss in these forward looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; 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 17 through 31, and Special Note Regarding Forward-Looking Statements on page 31 of our Annual Report on Form 10-K for the year ended December 31, 2011, as well as Part II, Item 1A, Risk Factors, of this Form 10-Q. 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 growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary specialty 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, for the treatment for pain and fever, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. In early 2011, we acquired the rights to a late-stage Phase II product candidate that we intend to develop under the brand name Hepatoren® (*ifetroban*) Injection for the treatment of hepatorenal syndrome. We promote our approved products through our hospital and field sales forces in the United States, which together comprised approximately 100 sales representatives and managers as of September 30, 2012.

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 third-party distribution partner to ensure availability and delivery of our products to our customers.

We have been profitable since 2004, with annual revenues funding our development and marketing programs and generating positive cash flow. In 2009, we completed an initial public offering of our common stock, and listed on the NASDAQ exchange.

## **Table of Contents**

### **Growth Strategy**

Our growth strategy involves maximizing the potential of our existing products while 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 comprehensive marketing and promotional campaigns 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 have since expanded into Canada, Korea and China.

We seek 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 strategies 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 made available to the public by the SEC at [www.sec.gov](http://www.sec.gov).

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

#### **Caldolor®**

In September 2012, we announced the top-line results from a pediatric pain study evaluating the safety and analgesic efficacy of Caldolor® (*ibuprofen*) Injection in treating pain in tonsillectomy patients ranging from 6 to 16 years old.

When administered prior to surgery, Caldolor use was associated with a statistically significant reduction in the number of post-operative narcotic doses required in patients in the efficacy evaluable population. There were also consistent trends toward reduction in pain scores and the incidence of nausea and vomiting in patients receiving Caldolor. Importantly, no safety concerns were observed during this study.

We expect the results from this study, in combination with the ongoing work to evaluate the treatment of fever in children, will be used to pursue a pediatric indication for Caldolor.

#### **Acetadote Patent Challenge Update**

A new formulation of Acetadote (acetylcysteine) Injection was developed by us as part of a Phase IV commitment we made in response to a request by the Food and Drug Administration (FDA) to evaluate the reduction of ethylene diamine tetraacetic acid (EDTA) from the product's formulation. The new Acetadote formulation does not contain EDTA or any other chelating or stabilization agent and is free of preservatives. The new formulation was listed in the FDA Orange Book following its FDA approval in January 2011. In April 2012, the United States Patent and Trademark Office (the USPTO) issued U.S. Patent number 8,148,356 (the Acetadote Patent) which is assigned to us. The claims of the

## Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the Acetadote Patent was listed in the FDA Orange Book. The Acetadote Patent is scheduled to expire in May 2026 which time period includes a 270-day patent term adjustment granted by the USPTO. We also have additional patent applications relating to the uses of Acetadote which are pending with the USPTO.

## **Table of Contents**

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, we responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. in the United States District Court for the Northern District of Illinois, Eastern Division. The second lawsuit was filed against InnoPharma, Inc. in the United States District Court for the District of Delaware. The third lawsuit was also filed in the United States District Court for the District of Delaware against Paddock Laboratories, LLC and Perrigo Company. On May 20, 2012, we received a fourth Paragraph IV certification notice from Sagent Agila LLC challenging the Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo Company. On August 9, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Perrigo Company in the United States District Court for the Northern District of Illinois, Eastern Division. We intend to vigorously defend and protect our Acetadote product and related intellectual property rights.

By statute, where the Paragraph IV certification is to a patent timely listed before an Abbreviated New Drug Application ( ANDA ) is filed, a company has 45 days to institute a patent infringement lawsuit during which period the FDA may not approve another application. In addition, such a lawsuit for patent infringement filed within such 45-day period may stay, or bar, the FDA from approving another product application for two and a half years or until a district court decision that is adverse to the asserted patents, whichever is earlier. On May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us with respect to the lawsuits.

On May 18, 2012, we also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that we evaluate the reduction or removal of EDTA from our original Acetadote formulation.

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

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 35 through 38 in Management's Discussion and Analysis of our Annual Report on Form 10-K for the year ended December 31, 2011.

### **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 cannot be 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, inventories, fair value of marketable securities, provision for income taxes, stock-based compensation, research and development expenses and intangible assets.

### **Fair Value of Marketable Securities**

We invest in variable rate demand notes and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate, mortgage-backed securities), in order to maximize our return on cash. We classify these investments as trading securities, and mark the investments to fair value at the end of each reporting period, with the adjustment being recognized in the statement of income as a component of interest income. These investments are generally valued using observable market prices by third-party pricing services, or are derived from such services' pricing models. The level of management judgment required in establishing fair value of financial instruments for which there is a quoted price in an active market is minimal. Similarly there is little subjectivity or judgment required for instruments valued using valuation models that are standard across the industry and where all parameter inputs are quoted in active markets. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security.

**Table of Contents**

**RESULTS OF OPERATIONS**

**Three months ended September 30, 2012 compared to the three months ended September 30, 2011**

*Net revenues.* Net revenues for the three months ended September 30, 2012 totaled approximately \$12.5 million compared to \$13.1 million over the same period in 2011. Net revenue for Acetadote decreased approximately \$1.1 million due primarily to a decrease in sales volume, partially offset by an increase in the average selling price. The decrease in Acetadote volume was driven by increased sales volume in 2011 caused by a shortage of the oral form of competitive products. Caldolor net revenue increased \$0.2 million due to an increase in sales volume as we continued to gain acceptance in our target market. Kristalose net revenue increased approximately \$0.3 million due primarily to an increase in the average selling price offset by a decrease in volume.

*Cost of products sold.* As a percentage of net revenues, cost of products sold decreased from 10.3% for the three months ended September 30, 2011 to 7.4% for the same period in 2012. The decrease was primarily due to the recognition in 2011 of \$0.5 million of inventory reserves for potential obsolescence. Excluding this adjustment, cost of products sold as a percentage of net revenues for the three months ended September 30, 2011 was 6.3%. On an adjusted basis, the increase in 2012 over 2011 was due to a change in the sales mix.

*Selling and marketing.* Selling and marketing expense for the three months ended September 30, 2012 totaled approximately \$4.9 million, representing a decrease of approximately \$0.1 million, or 3%, over the same period in 2011. The decrease was primarily due to (1) lower royalty expense due to our acquisition of the Kristalose brand during late 2011 and (2) lower hiring and consulting expenses due to the implementation of our new commercial strategy in 2012.

*Research and development.* Research and development expense for the three months ended September 30, 2012 totaled approximately \$1.7 million, representing an increase of approximately \$0.5 million, or 38%, over the same period in 2011. The increase was primarily due to (1) increased expenses associated with continuing clinical studies for our current products and product candidates, (2) increased costs related to the expansion of our medical science liaison team and (3) increased expense related to our annual FDA fees.

*General and administrative.* General and administrative expense for the three months ended September 30, 2012 totaled approximately \$1.9 million, representing a decrease of approximately \$0.2 million, or 12%, over the same period in 2011. The decrease was primarily due to inventory donations made in 2011 for humanitarian needs.

**Nine months ended September 30, 2012 compared to the nine months ended September 30, 2011**

*Net revenues.* Net revenues for the nine months ended September 30, 2012 totaled approximately \$35.2 million, representing a decrease of approximately \$3.0 million, or 8%, over the same period in 2011. The decrease in net revenues was primarily due to decreased Acetadote revenue of \$4.7 million partially offset by increases of \$0.5 million in revenue for each of Kristalose and Caldolor. The decrease in Acetadote revenue was primarily due to a decrease in volume partially offset by an increase in the average selling price. The decrease in Acetadote volume was driven by increased sales volume in 2011 caused by a shortage of the oral form of competitive products. The increase in Kristalose revenue was primarily due to an increase in the average selling price. The increase in Caldolor revenue was due to an increase in wholesaler reorders as we continue to gain acceptance in our target market.

## **Table of Contents**

Other revenues increased approximately \$0.7 million due to the recognition of approximately \$0.7 million in revenue related to an out-licensing agreement with Harbin Gloria Pharmaceuticals Co. in the first quarter of 2012.

*Cost of products sold.* Cost of products sold as a percentage of net revenues decreased from 9.0% for the nine months ended September 30, 2011 to 8.2% for the same period in 2012. We recognized approximately \$0.9 million of inventory reserves for potential obsolescence during the nine months ended September 30, 2011. Excluding this reserve, the increase in 2012 as compared to the adjusted percentage in 2011 was primarily due to a change in the sales mix between the periods.

*Selling and marketing.* Selling and marketing expense for the nine months ended September 30, 2012 totaled approximately \$15.4 million, representing a decrease of approximately \$0.9 million, or 5%, over the same period in 2011. The decrease was primarily due to (1) a decrease in royalty expense due to the Acetadote royalty agreement expiring in January 2011, (2) decreased marketing and advertising expense related to the implementation of our new commercial strategy in 2012 and (3) decreased freight expense for outgoing shipments due to improved pricing and lower sales volume.

*Research and development.* Research and development expense for the nine months ended September 30, 2012 totaled approximately \$4.7 million, representing an increase of approximately \$1.4 million, or 42%, over the same period in 2011. The increase was primarily due to (1) increased clinical studies expenses related to our current products and product candidates, (2) increased costs related to the annual FDA product and establishment fees for our products and (3) increased costs related to the expansion of our medical science liaison team.

*General and administrative.* General and administrative expense decreased \$0.2 million, or 3%, for the nine months ended September 30, 2012 as compared to the same period in 2011. The decrease was primarily due to a decrease in charitable donations of inventory for humanitarian needs partially offset by increased legal and printing costs associated with our stock option exchange program during the second quarter of 2012.

*Interest income.* Interest income for the nine months ended September 30, 2012 totaled approximately \$0.3 million as compared to \$0.1 million for the same period in 2011. The increase in 2012 was primarily due to investing a portion of our cash balances in longer duration marketable securities beginning in the first quarter of 2012.

*Interest expense.* Interest expense for the nine months ended September 30, 2012 totaled approximately \$0.05 million as compared to approximately \$0.3 million in 2011. The decrease was primarily due to the early payoff of our term debt in 2011.

*Income tax expense.* Income tax expense for the nine months ended September 30, 2012 totaled approximately \$1.8 million, representing a decrease of approximately \$1.5 million, over the same period in 2011. As a percentage of net income before income taxes, income tax expense decreased from 40.7% for the nine months ended September 30, 2011 to 30.4% for the same period in 2012. The decrease was primarily due to the recognition of a deferred tax benefit associated with the exchange of certain incentive stock options during the second quarter of 2012.

As of September 30, 2012, we have approximately \$55.8 million of unrecognized net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that will be used to significantly offset future income tax obligations. These net operating losses will be recognized in the consolidated financial statements when they reduce income taxes currently payable.



**Table of Contents****LIQUIDITY AND CAPITAL RESOURCES****Working Capital**

Our primary sources of liquidity are cash flows provided by operations, our availability under our line of credit and the cash proceeds from our initial public offering of common stock that was completed in August 2009. For the nine months ended September 30, 2012, we generated \$5.1 million in cash flow from operations compared to \$7.7 million for the same period in 2011. 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.

In 2012, we began investing a portion of our cash reserves in variable rate demand notes and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate, mortgage-backed securities). The variable rate demand notes, or VRDNs, are generally issued by municipal governments and are backed by a financial institution letter of credit. We hold a put right on the VRDNs, which allows us to liquidate the investment relatively quickly (less than one week). The government-backed securities have an active secondary market that generally provides for liquidity in less than one week. At September 30, 2012, we had a total of approximately \$18.6 million invested in marketable securities.

As of September 30, 2012 and December 31, 2011, our cash and cash equivalents, including marketable securities, totaled \$69.4 million and \$70.6 million, respectively.

At September 30, 2012 and December 31, 2011, our working capital (current assets minus current liabilities) was \$78.1 million and \$80.7 million, respectively, and our current ratio (current assets to current liabilities) was 10.0x and 13.2x, respectively. As of September 30, 2012, we had an additional \$5.6 million available to us on our line of credit.

The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2012 and 2011:

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 5,147	\$ 7,692
Investing activities	(20,375)	(382)
Financing activities	(4,570)	(2,129)
<b>Net (decrease) increase cash and cash equivalents <sup>(1)</sup></b>	<b>\$ (19,798)</b>	<b>\$ 5,181</b>

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

The net decrease in cash and cash equivalents for the nine months ended September 30, 2012 was primarily due to the investment of our cash reserves in certain government and government-backed securities, as previously noted. Our cash flow from operating activities was primarily due to the net income for the period supplemented by cash inflows from our receivables. We continue to repurchase shares of our common stock under our Rule 10(b)-5 Plan.

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. We paid in full our outstanding term debt balance during 2011, with scheduled principal payments and the early payoff totaling \$5.3 million for the nine months ended September 30, 2011.



**Table of Contents**

**OFF-BALANCE SHEET ARRANGEMENTS**

During the nine months ended September 30, 2012 and 2011, we 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.

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 (2.22% at September 30, 2012). As of September 30, 2012, we had outstanding borrowings of approximately \$4.4 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, some of our research and development is performed abroad. As of September 30, 2012, 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 30 days based on invoice terms. Foreign currency exchange gains and losses were not significant for the nine months ended September 30, 2012 and 2011. 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, 2012. 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.

---

**Table of Contents**

**PART II OTHER FINANCIAL INFORMATION**

**Item 1: Legal Proceedings**

See Item 1A, Risk Factors, below for a discussion regarding legal proceedings, which is incorporated by reference herein.

**Item 1a: Risk Factors**

Information regarding risk factors appears on pages 17 through 31 in our Annual Report on Form 10-K for the year ended December 31, 2011 under the section titled Risk Factors. The following risk factor was included in our Form 10-K for the year ended December 31, 2011, and has been updated for recent developments:

**Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited protection from competition.**

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product formulation.

Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. In April 2012, the United States Patent and Trademark Office (the USPTO ) issued U.S. Patent number 8,148,356 (the Acetadote Patent ) which is assigned to us. The claims of the Acetadote Patent encompass the new Acetadote formulation. Following its issuance, the Acetadote Patent was listed in the FDA Orange Book. The Acetadote Patent is scheduled to expire in May 2026 which time period includes a 270-day patent term adjustment granted by the USPTO. We also have additional patent applications relating to the uses of Acetadote which are pending with the USPTO and may or may not be issued.

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, we responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. in the United States District Court for the Northern District of Illinois, Eastern Division. The second lawsuit was filed against InnoPharma, Inc. in the United States District Court for the District of Delaware. The third lawsuit was also filed in the United States District Court for the District of Delaware against Paddock Laboratories, LLC and Perrigo Company. On May 20, 2012, we received a fourth Paragraph IV certification notice from Sagent Agila LLC challenging the Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo Company. On August 9, 2012, the Company filed a lawsuit for infringement of the Acetadote Patent against Perrigo Company in the United States District Court for the Northern District of Illinois, Eastern Division. We intend to vigorously defend and protect our Acetadote product and related intellectual property rights.

By statute, where the Paragraph IV certification is to a patent timely listed before an Abbreviated New Drug Application ( ANDA ) is filed, a company has 45 days to institute a patent infringement lawsuit during which period the FDA may not approve another application. In addition, such a lawsuit for patent infringement filed within such 45-day period may stay, or bar, the FDA from approving another product application for two and a half years or until a district court decision that is adverse to the asserted patents, whichever is earlier. On May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us with respect to the lawsuits.

On May 18, 2012, we also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that we evaluate the reduction or removal of EDTA from its original Acetadote formulation.

**Table of Contents**

If we are unsuccessful in protecting our Acetadote intellectual property rights, our competitors may be able to introduce products into the marketplace that reduce the sales and market share of our Acetadote product which may require us to take measures such as reducing prices or increasing our marketing expense, any of which may result in a material adverse effect our financial condition and results of operations.

We have a U.S. patent for Caldolor, and some related international patents, which are directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor ibuprofen is in the public domain, and if a competitor were to develop a sufficiently distinct formulation, it could develop and seek FDA approval for another ibuprofen product that competes with Caldolor. Upon receipt of FDA approval in June 2009, we received three years of marketing exclusivity for Caldolor. Upon the expiration of our marketing exclusivity, a competitor with a generic form of injectable ibuprofen could enter the market.

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

**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 September 30, 2012:

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plan or Programs <sup>(1)</sup>
July 1 July 31	118,074	\$ 6.20	118,074	\$ 8,051,695
August 1 August 31	358,040 <sup>(2)</sup>	6.00	91,900	7,498,546
September 1 September 30	62,177	6.14	62,177	7,116,971
Total	538,291		272,151	

(1) In April 2012, our Board of Directors modified the repurchase plan for an additional purchase of up to \$10.0 million of our outstanding common stock, in addition to the amounts previously purchased.

(2) Of this amount, 266,140 shares were repurchased directly from a shareholder at the fair market value as of the close of business on the transaction date.

**Table of Contents**

**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.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cumberland Pharmaceuticals Inc.

Dated: November 2, 2012

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

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