

CUMBERLAND PHARMACEUTICALS INC  
Form 10-Q  
May 04, 2012

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 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)

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**Tennessee**  
(State or other jurisdiction)  
**62-1765329**  
(I.R.S. Employer)  
**of incorporation or organization**  
**2525 West End Avenue, Suite 950, Nashville, Tennessee**  
(Address of principal executive offices)  
**37203**  
(Zipcode)  
**(615) 255-0068**  
(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes  No

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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

<u>Class</u>	<u>Outstanding at April 27, 2012</u>
Common stock, no par value	19,767,137

**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)

	March 31, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 55,643,561	\$ 70,599,146
Marketable securities	16,001,622	
Accounts receivable, net of allowances	4,463,367	7,082,890
Inventories	6,005,478	5,774,694
Other current assets	4,169,221	3,851,337
Total current assets	86,283,249	87,308,067
Property and equipment, net	1,054,771	1,119,339
Intangible assets, net	7,166,652	7,023,064
Other assets	63,472	67,846
Total assets	\$ 94,568,144	\$ 95,518,316
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,304,317	\$ 1,513,548
Other current liabilities	3,855,648	5,086,400
Total current liabilities	6,159,965	6,599,948
Revolving line of credit	5,109,951	4,859,951
Other long-term obligations	1,450,004	1,223,148
Total liabilities	12,719,920	12,683,047
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock - no par value; 100,000,000 shares authorized; 19,870,637 and 20,020,535 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	68,871,269	70,272,155
Retained earnings	13,079,870	12,656,662
Total shareholders' equity	81,951,139	82,928,817
Noncontrolling interests	(102,915)	(93,548)
Total equity	81,848,224	82,835,269
Total liabilities and equity	\$ 94,568,144	\$ 95,518,316

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See accompanying notes to unaudited condensed consolidated financial statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Net and Comprehensive Income

(Unaudited)

	Three Months Ended March 31,	
	2012	2011
Net revenues	\$ 10,256,212	\$ 10,666,927
Costs and expenses:		
Cost of products sold	848,550	786,938
Selling and marketing	4,980,553	5,288,584
Research and development	1,404,022	1,009,673
General and administrative	2,265,025	2,002,004
Amortization of product license right	112,047	171,727
Total costs and expenses	9,610,197	9,258,926
Operating income	646,015	1,408,001
Interest income	72,281	42,909
Interest expense	(22,427)	(216,043)
Income before income tax expense	695,869	1,234,867
Income tax expense	(282,028)	(523,584)
Net and comprehensive income	413,841	711,283
Net loss attributable to noncontrolling interests	9,367	9,877
Net income attributable to common shareholders	\$ 423,208	\$ 721,160
Earnings per share attributable to common shareholders		
- Basic	\$ 0.02	\$ 0.04
- Diluted	\$ 0.02	\$ 0.03
Weighted-average shares outstanding		
- Basic	20,007,998	20,445,921
- Diluted	20,234,438	20,777,666

See accompanying notes to unaudited condensed consolidated financial statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net income	\$ 413,841	\$ 711,283
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	217,263	262,306
Stock-based compensation - nonemployees	70,871	19,856
Stock-based compensation - employees	143,510	147,207
Excess tax benefit derived from exercise of stock options	(191,081)	(141,080)
Noncash interest expense	6,019	24,010
Net unrealized investment gains	(8,800)	
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,619,523	(96)
Inventory	(230,784)	(139,030)
Other current assets and other assets	(324,954)	126,084
Accounts payable and other accrued liabilities	(282,862)	(23,990)
Other long-term liabilities	178,120	(2,570)
Net cash provided by operating activities	2,610,666	983,980
Cash flows from investing activities:		
Additions to property and equipment	(32,800)	(34,260)
Purchases of marketable securities	(15,992,822)	
Additions to intangibles	(180,787)	(20,289)
Net cash used in investment activities	(16,206,409)	(54,549)
Cash flows from financing activities:		
Principal payments on note payable		(666,667)
Net borrowings on line of credit	250,000	
Proceeds from exercise of stock options	545,601	433,055
Excess tax benefit derived from exercise of stock options	191,081	141,080
Payments made in connection with repurchase of common shares	(2,346,524)	(772,025)
Net cash used in financing activities	(1,359,842)	(864,557)
Net (decrease) increase in cash and cash equivalents	(14,955,585)	64,874
Cash and cash equivalents at beginning of period	70,599,146	65,893,970
Cash and cash equivalents at end of period	\$ 55,643,561	\$ 65,958,844
Non-cash investing and financing activities:		
Change in unpaid fixed asset additions		26,689
Change in unpaid intangible additions	82,696	
See accompanying notes to unaudited condensed consolidated financial statements.		

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statement of Equity

(Unaudited)

	Common stock		Retained earnings	Non-controlling interests	Total equity
	Shares	Amount			
Balance, December 31, 2011	20,020,535	\$ 70,272,155	\$ 12,656,662	\$ (93,548)	\$ 82,835,269
Stock-based compensation - nonemployees	17,199	65,446			65,446
Exercise of options and related tax benefit	152,626	736,682			736,682
Stock-based compensation - employees		143,510			143,510
Repurchase of shares	(319,723)	(2,346,524)			(2,346,524)
Net and comprehensive income			423,208	(9,367)	413,841
Balance, March 31, 2012	19,870,637	\$ 68,871,269	\$ 13,079,870	\$ (102,915)	\$ 81,848,224

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, 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 three 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 months ended March 31, 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.

***Subsequent Events***

Management has evaluated events occurring subsequent to March 31, 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 March 31, 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 March 31, 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 measure 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.

## 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 March 31, 2012 based on the categories described above:

	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$ 1,995,383	\$	\$ 1,995,383
Mortgage-backed securities variable rate	1,560,266	1,659,451	3,219,717
Agency notes and bonds fixed rate	995,659		995,659
SBA loan pools variable rate		1,095,863	1,095,863
Municipal bonds VRDN	8,695,000		8,695,000
	\$ 13,246,308	\$ 2,755,314	\$ 16,001,622

**(3) EARNINGS PER SHARE**

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three months ended March 31, 2012 and 2011:

	Three Months Ended March 31,	
	2012	2011
<b>Numerator:</b>		
Net income attributable to common shareholders	\$ 423,208	\$ 721,160
<b>Denominator:</b>		
Weighted-average shares outstanding basic	20,007,998	20,445,921
Dilutive effect of other securities	226,440	331,745
Weighted-average shares outstanding diluted	20,234,438	20,777,666

As of March 31, 2012 and 2011, restricted stock awards and options to purchase 666,733 and 1,300,895 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

**(4) REVENUES**

We operate in one segment, specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. All of our assets are located in the United States. We had no sales to non-U.S. customers for the three months ended March 31, 2012, and sales of \$0.1 million for the three months ended March 31, 2011.

The Company's net revenues consisted of the following for the three months ended March 31, 2012 and 2011:

	Three Months Ended March 31,	
	2012	2011
Products:		

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Acetadote	\$ 7,351,084	\$ 8,544,593
Kristalose	2,256,273	2,070,381
Caldolor	99,079	11,954
Other	549,776	39,999
Total net revenues	\$ 10,256,212	\$ 10,666,927

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 have delivered these items for Caldolor to the licensee, and have recognized revenue of approximately \$0.5 million as other revenue. The remaining up-front payment of \$0.2 million related to Acetadote is deferred and will be recognized when the intellectual property, including the dossier, is provided to the licensee. The deferred revenue balance is included in other long-term obligations in the condensed consolidated balance sheet at March 31, 2012.

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

The licensing agreement provides for us to receive 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 both 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 March 31, 2012 and 2011, we have not recognized any revenue related to milestones.

**(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.

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

In the fourth quarter of 2010, we purchased certain packaging materials related to the manufacture of Caldolor. As these materials are consumed as part of the manufacturing process, the costs associated with these materials will be used to offset the finished goods price from the manufacturer.

In connection with the purchase of certain Kristalose assets in 2011, we purchase 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.

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

	<b>March 31, 2012</b>	<b>December 31, 2011</b>
Raw materials	\$ 1,035,928	\$ 774,637
Finished goods	4,969,550	5,000,057
<b>Total</b>	<b>\$ 6,005,478</b>	<b>\$ 5,774,694</b>

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

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

**(unaudited)**

**(6) SHAREHOLDERS EQUITY**

In May 2010, we announced a share repurchase program to repurchase up to \$10.0 million of our outstanding common shares pursuant to Rule 10b-18 of the Securities Act. In 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 three months of 2012, we repurchased 319,723 shares for approximately \$2.3 million.

**(7) INCOME TAXES**

At March 31, 2012, we have unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$57.8 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.

During the second quarter of 2011, we were notified by the Internal Revenue Service that our 2009 federal tax return was selected for examination. We expect the examination to be completed during 2012.

**(8) COLLABORATIVE AGREEMENTS**

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

## 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 20 through 35, and Special Note Regarding Forward-Looking Statements on page 36 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 more than 100 sales representatives and managers as of March 31, 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.

## 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 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

Acetadote®

A new formulation of Acetadote (acetylcysteine) Injection was developed as part of a Phase IV commitment by us 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 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.

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 (the Paragraph IV Challenges ). We are currently reviewing the Paragraph IV Challenges and analyzing our options and intend to vigorously defend and protect its Acetadote product and related intellectual property rights. As of the date of this report, we have not filed a patent infringement lawsuit against any of the challengers.

## International Markets

In February 2012, we entered into an exclusive agreement with China's Harbin Gloria Pharmaceuticals Co., Ltd. for the commercialization of Acetadote® (*acetylcysteine*) Injection, which is used to treat acetaminophen overdose, and Caldolor® (*ibuprofen*) Injection, which is used to treat pain and fever in the hospital setting. The agreement will provide Harbin Gloria exclusive rights to register and commercialize both drugs in China.

## CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 41 through 44 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 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, inventories, provision for income taxes, stock-based compensation, research and development accounting and intangible assets.

### Fair Value of Marketable Securities

We invest in government and government-agency bonds, including U.S. Treasury notes, in order to maximize our return on cash. We classify these investments as trading securities, and mark the investments to current market value at the end of each reporting period, with the adjustment being recognized in the statement of income. These investments are generally valued using observable market prices or by third-party pricing services, as 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.

## RESULTS OF OPERATIONS

### Three months ended March 31, 2012 compared to the three months ended March 31, 2011

*Net revenues.* Net revenues for the three months ended March 31, 2012 totaled approximately \$10.3 million compared to \$10.7 million over the same period in 2011. Net revenue for Acetadote decreased approximately \$1.2 million due largely to lower sales volume in the first quarter of 2012 as compared to 2011. Kristalose net revenue increased approximately \$0.2 million, primarily due to increased sales volume. Caldolor net revenue increased approximately \$0.1 million due to increased volume as we continued to gain acceptance in our target market.

Other revenues for the three months ending March 31, 2012 were approximately \$0.5 million compared to \$0.04 million for the same period in the prior year. The increase was a result of the Company recognizing approximately \$0.5 million in revenue related to the out-licensing agreement with Harbin Gloria Pharmaceuticals Co., as previously discussed.



*Cost of products sold.* Cost of products sold as a percentage of net revenues increased from 7.4% for the three months ended March 31, 2011 to 8.3% for the same period in 2012, and this difference was primarily due to a change in the product sales mix between the two periods.

*Selling and marketing.* Selling and marketing expense for the three months ended March 31, 2012 totaled approximately \$5.0 million, representing a decrease of approximately \$0.3 million, or 6%, over the same period in 2011. The decrease was primarily due to lower personnel costs related to a reduction in the number of sales representatives, lower hiring costs and lower royalty expense for Acetadote. The royalty arrangement for Acetadote terminated in January 2011.

*Research and development.* Research and development expense for the three months ended March 31, 2012 totaled approximately \$1.4 million, representing an increase of approximately \$0.4 million, or 39%, over the same period in 2011. The increase was primarily due to (1) increased salary and hiring costs as a result of expanding our Medical Science Liaison program and (2) increased expenses associated with continuing clinical studies. We expect research and development expenses to increase throughout 2012 as we continue our clinical study programs.

*General and administrative.* General and administrative expense for the three months ended March 31, 2012 totaled approximately \$2.2 million, representing an increase of approximately \$0.3 million, or 13%, over the same period in 2011. The increase was primarily due to increased salary and benefit costs, and increased professional fees. These increases reflect the continued expansion of our infrastructure to support our growth.

*Interest expense.* Interest expense for the three months ended March 31, 2012 totaled approximately \$0.02 million, representing a decrease of approximately \$0.2 million as compared to the same period in 2011 due primarily to the early payoff of our term debt facility in the third quarter of 2011.

*Income tax expense.* Income tax expense for the three months ended March 31, 2012 totaled approximately \$0.3 million, representing a decrease of approximately \$0.2 million over the same period in 2011. As a percentage of income before income taxes, income tax expense decreased from 42.4% for the three months ended March 31, 2011 to 40.5% for the three months ended March 31, 2012. The decrease in the percentage was primarily due to a reduction in our permanent differences, namely compensation expense for incentive stock options. As of March 31, 2012, we have approximately \$57.8 million of net operating loss carryforward that will be used to significantly offset future income tax obligations.

## **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. For the three months ended March 31, 2012, we generated \$2.6 million in cash flow from operations compared to \$1.0 million for the same period in 2011. This increase was largely due to the management of accounts receivable and related collections. 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.

During the quarter, 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 VRDN, 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. As of March 31, 2012, we had a total of approximately \$16.0 million invested in these securities.

As of March 31, 2012 and December 31, 2011, our cash and cash equivalents, including marketable securities, totaled \$71.6 million and \$70.6 million, respectively.

At March 31, 2012 and December 31, 2011, our working capital (current assets minus current liabilities) was \$80.1 million and \$80.7 million, respectively, and our current ratio (current assets to current liabilities) was 14.0x and 13.2x, respectively. As of March 31, 2012, we had an additional \$4.9 million available to us on our line of credit.

The following table summarizes our net changes in cash and cash equivalents for the three months ended March 31, 2012 and 2011:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 2,611	\$ 984
Investing activities	(16,206)	(55)
Financing activities	(1,360)	(865)
 Net (decrease) increase cash and cash equivalents <sup>(1)</sup>	 \$ (14,956)	 \$ 65

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

The net decrease in cash and cash equivalents for the three months ended March 31, 2012 was primarily due to the investment of our cash reserves in certain government and government-backed securities, as previously noted. The decrease in cash from the purchase of these securities was partially offset by the collection of our accounts receivable during the first quarter of 2012.

The net increase in cash and cash equivalents for the three months ended March 31, 2011 was primarily due to our net income, adjusted for non-cash depreciation and amortization expense, offset by cash used in financing activities. During the first quarter of 2011, our cash flows from financing activities included (1) scheduled principal payments of approximately \$0.7 million on our term debt and (2) payments made in connection with the repurchase of our common shares of approximately \$0.8 million, offset by \$0.6 million of cash provided from the exercise of stock options.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

During the three months ended March 31, 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 (2.24% at March 31, 2012). As of March 31, 2012, we had outstanding borrowings of approximately \$5.1 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 March 31, 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 three months ended March 31, 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 March 31, 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.

## PART II OTHER FINANCIAL INFORMATION

### Item 1a: Risk Factors

Information regarding risk factors appears on pages 20 through 35 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 (the Paragraph IV Challenges). We are currently reviewing the Paragraph IV Challenges. By statute, where the Paragraph IV certification is to a patent timely listed before an ANDA is filed, a company has 45 days to institute a patent infringement lawsuit, during which period 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. The aforementioned bar or stay may or may not be available to us in the event it does file a patent infringement lawsuit. We are currently analyzing our options and intend to vigorously defend and protect our Acetadote product and related intellectual property rights. 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 March 31, 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
January 1 - January 31	52,050	\$ 5.93	52,050	\$ 6,579,746
February 1 - February 29	73,000	7.44	73,000	6,036,380
March 1 - March 31	194,673 <sup>(1)</sup>	7.68	101,000	5,265,000
Total	319,723		226,050	

- (1) Of this amount, 93,673 shares were repurchased directly from certain shareholders at the fair market value as of the close of business on the transaction dates.

**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.

**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: May 4, 2012

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

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