

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 06, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2013

OR

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

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

Commission file number: 001-33637

Cumberland Pharmaceuticals Inc.

(Exact Name of Registrant as Specified In Its Charter)

Tennessee

62-1765329

(State or Other Jurisdiction of

(I.R.S. Employer

Incorporation or Organization)

Identification No.)

2525 West End Avenue, Suite 950,

37203

Nashville, Tennessee

(Address of Principal Executive Offices)

(Zip Code)

(615) 255-0068

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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.

Class

Outstanding at October 29, 2013

Common stock, no par value

18,105,750

CUMBERLAND PHARMACEUTICALS INC.  
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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements (Unaudited)

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$46,011,203	\$54,349,381
Marketable securities	19,163,442	16,686,136
Accounts receivable, net of allowances	4,194,415	6,017,201
Inventories	5,435,613	6,218,355
Other current assets	3,465,791	3,961,169
Total current assets	78,270,464	87,232,242
Property and equipment, net	975,016	1,188,914
Intangible assets, net	11,235,866	9,476,798
Other assets	1,429,951	695,777
Total assets	\$91,911,297	\$98,593,731
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$2,272,018	\$2,790,554
Other current liabilities	3,139,884	5,264,806
Total current liabilities	5,411,902	8,055,360
Revolving line of credit	4,859,951	4,359,951
Other long-term liabilities	707,062	611,933
Total liabilities	10,978,915	13,027,244
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 18,157,957 and 18,937,107 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	63,203,085	67,197,167
Retained earnings	17,894,903	18,499,154
Total shareholders' equity	81,097,988	85,696,321
Noncontrolling interests	(165,606)	) (129,834 )
Total equity	80,932,382	85,566,487
Total liabilities and equity	\$91,911,297	\$98,593,731
See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.		

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Net revenues	\$6,528,575	\$12,531,719	\$23,867,795	\$35,154,871
Costs and expenses:				
Cost of products sold	1,030,943	921,862	3,294,411	2,873,417
Selling and marketing	3,410,205	4,914,551	10,626,193	15,387,068
Research and development	1,440,584	1,696,592	4,276,206	4,653,957
General and administrative	1,958,629	1,890,849	6,389,569	6,303,392
Amortization	202,982	128,702	610,677	371,928
Total costs and expenses	8,043,343	9,552,556	25,197,056	29,589,762
Operating (loss) income	(1,514,768)	) 2,979,163	(1,329,261)	) 5,565,109
Interest income	20,350	107,719	161,709	256,074
Interest expense	(24,286)	) (17,222)	) (62,721)	) (56,369)
(Loss) income before income taxes	(1,518,704)	) 3,069,660	(1,230,273)	) 5,764,814
Income tax benefit (expense)	686,209	(1,207,504)	) 590,250	(1,752,563)
Net (loss) income	(832,495)	) 1,862,156	(640,023)	) 4,012,251
Net loss at subsidiary attributable to noncontrolling interests	12,553	7,338	35,772	24,741
Net (loss) income attributable to common shareholders	\$(819,942)	) \$1,869,494	\$(604,251)	) \$4,036,992
Earnings (loss) per share attributable to common shareholders				
- basic	\$(0.04)	) \$0.10	\$(0.03)	) \$0.20
- diluted	\$(0.04)	) \$0.10	\$(0.03)	) \$0.20
Weighted-average shares outstanding				
- basic	18,233,407	19,432,715	18,420,465	19,737,216
- diluted	18,233,407	19,670,741	18,420,465	19,969,051
Comprehensive (loss) income	\$(832,495)	) \$1,862,156	\$(640,023)	) \$4,012,251

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended 2013	September 30, 2012	
Cash flows from operating activities:			
Net (loss) income	\$(640,023	) \$4,012,251	
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization expense	917,012	664,369	
Deferred tax benefit	(76,332	) —	
Share-based compensation	480,806	556,704	
Excess tax expense (benefit) derived from exercise of stock options	511,908	(2,176,222	)
Noncash interest expense	12,038	16,050	
Noncash investment losses (gains)	135,296	(99,286	)
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	1,822,786	1,615,435	
Inventory	782,742	(1,736,947	)
Other current assets and other assets	(177,754	) (1,228,382	)
Accounts payable and other current liabilities	(2,942,455	) 4,178,708	
Other long-term liabilities	112,737	(655,201	)
Net cash provided by operating activities	938,761	5,147,479	
Cash flows from investing activities:			
Additions to property and equipment	(92,435	) (293,693	)
Purchases of marketable securities	(4,371,508	) (18,849,492	)
Proceeds from sale of marketable securities	1,758,906	389,302	
Additions to intangible assets	(2,600,266	) (1,621,100	)
Net cash used in investment activities	(5,305,303	) (20,374,983	)
Cash flows from financing activities:			
Net borrowings (repayments) on line of credit	500,000	(500,000	)
Exercise of stock options	(41,292	) 580,101	
Excess tax (expense) benefit derived from exercise of stock options	(511,908	) 2,176,222	
Repurchase of common shares	(3,918,436	) (6,826,394	)
Net cash used in financing activities	(3,971,636	) (4,570,071	)
Net decrease in cash and cash equivalents	(8,338,178	) (19,797,575	)
Cash and cash equivalents at beginning of period	54,349,381	70,599,146	
Cash and cash equivalents at end of period	\$46,011,203	\$50,801,571	
Supplemental disclosure of cash flow information:			
Non-cash investing and financing activities:			
Net change in unpaid additions to intangibles, property and equipment	\$230,522	\$95,272	
See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.			

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Condensed Consolidated Statement of Equity

(Unaudited)

	Common stock		Retained	Noncontrolling	Total equity
	Shares	Amount	earnings	interests	
Balance, December 31, 2012	18,937,107	\$67,197,167	\$18,499,154	\$ (129,834 )	\$85,566,487
Share-based compensation	12,643	477,554	—	—	477,554
Exercise of options and related tax benefit	36,758	(553,200 )	—	—	(553,200 )
Repurchase of common shares	(828,551 )	(3,918,436 )	—	—	(3,918,436 )
Net loss	—	—	(604,251 )	(35,772 )	(640,023 )
Balance, September 30, 2013	18,157,957	\$63,203,085	\$17,894,903	\$ (165,606 )	\$80,932,382

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

### Notes to Condensed Consolidated Financial Statements

(unaudited)

#### (1) ORGANIZATION AND BASIS OF PRESENTATION

Cumberland Pharmaceuticals Inc. and its subsidiaries (the Company or Cumberland) is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets are hospital acute care and gastroenterology. These markets are characterized by relatively concentrated prescriber bases that the Company believes can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address poorly met medical needs.

Cumberland focuses its resources on maximizing the commercial potential of its products, as well as developing new product candidates, and has both internal development and commercial capabilities. The Company's products are manufactured by third parties, which are overseen by Cumberland's quality control and manufacturing professionals. The Company works closely with its third-party distribution partner to make its products available in the United States.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements of the Company, have been prepared on a basis consistent with the December 31, 2012 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 unaudited 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 unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report on Form 10-K for the year ended December 31, 2012. The results of operations for the three and nine months ended September 30, 2013 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income (loss) was comprised solely of net income (loss) for the three and nine months ended September 30, 2013 and 2012.

#### 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. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns and (2) the allowances for obsolescent or unmarketable inventory.

##### Operating Segments

The Company operates in one segment, specialty pharmaceutical products. Substantially all of the Company's assets are located in the United States.

##### Reclassifications

Beginning in 2013, the Company reflects all amortization expense of intangible assets in Amortization in the condensed consolidated statements of operations and comprehensive income (loss). A portion of these amounts were previously included as a component of General and Administrative. The 2012 unaudited condensed consolidated financial statements have been reclassified to conform to the presentation in 2013.

#### (2) MARKETABLE SECURITIES

The Company invests in marketable debt securities in order to maximize its return on cash. 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, the Company classifies marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of September 30, 2013 and December 31, 2012, the marketable securities are comprised solely of trading securities. Trading securities are carried at fair value with unrealized gains and losses



## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements - continued

(unaudited)

recognized as a component of interest income in the condensed consolidated statements of operations and comprehensive income (loss).

The Company uses the fair value hierarchy that prioritizes the information used to develop the measurements. It applies whenever other guidance requires (or permits) assets or liabilities to be measured at fair value and gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

A summary of the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels is described below:

Level 1 - Quoted prices for identical instruments in active markets.

Level 2 - Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 - Significant inputs to the valuation model are unobservable.

The Company's fair values of marketable securities are determined based on valuations provided by a third-party pricing service, as derived from such services' pricing models, and are considered either Level 1 or Level 2 measurements, depending on the nature of the investment. The Company has no marketable securities in which the fair value is determined based on Level 3. The level of management judgment required in evaluating fair value for Level 1 investments is minimal. Similarly, there is little subjectivity or judgment required for Level 2 investments valued using valuation models that are standard across the industry and whose 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. Based on the information available, the Company believes that the valuations provided by the third-party pricing service, as derived from such services' pricing models, are representative of prices that would be received to sell the assets at the measurement date (exit prices).

The following table summarizes the fair value of these marketable securities, by level within the fair value hierarchy, as of each period end:

	September 30, 2013			December 31, 2012		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$2,838,754	\$—	\$2,838,754	\$2,473,596	\$—	\$2,473,596
U.S. Agency issued mortgage-backed securities – variable rate	—	3,136,389	3,136,389	—	3,708,920	3,708,920
U.S. Agency notes and bonds – fixed rate	—	1,494,792	1,494,792	—	1,505,177	1,505,177
SBA loan pools – variable rate	—	1,818,507	1,818,507	—	1,988,443	1,988,443
Municipal bonds – VRDN	9,875,000	—	9,875,000	7,010,000	—	7,010,000
Total fair value of marketable securities	\$12,713,754	\$6,449,688	\$19,163,442	\$9,483,596	\$7,202,540	\$16,686,136

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements - continued

(unaudited)

## (3) EARNINGS (LOSS) PER SHARE

The following table reconciles the numerator and denominator used to calculate diluted earnings (loss) per share for the three and nine months ended September 30, 2013 and 2012:

	Three months ended September 30,	
	2013	2012
Numerator:		
Net (loss) income attributable to common shareholders	\$(819,942	) \$1,869,494
Denominator:		
Weighted-average shares outstanding – basic	18,233,407	19,432,715
Dilutive effect of other securities	—	238,026
Weighted-average shares outstanding – diluted	18,233,407	19,670,741
	Nine months ended September 30,	
	2013	2012
Numerator:		
Net (loss) income attributable to common shareholders	\$(604,251	) \$4,036,992
Denominator:		
Weighted-average shares outstanding – basic	18,420,465	19,737,216
Dilutive effect of other securities	—	231,835
Weighted-average shares outstanding – diluted	18,420,465	19,969,051

As of September 30, 2013 and 2012, restricted stock awards and options to purchase 554,029 and 271,256 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

## Product Revenues

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2013 and 2012:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Products:				
Acetadote	\$3,770,302	\$9,802,744	\$15,169,270	\$26,923,996
Kristalose	2,207,586	2,376,231	6,365,879	6,773,287
Caldolor	484,651	295,011	1,510,622	604,414
Other	66,036	57,733	822,024	853,174
Total net revenues	\$6,528,575	\$12,531,719	\$23,867,795	\$35,154,871

As part of the November 12, 2012, Settlement Agreement with Paddock Laboratories, LLC and Perrigo Company ("Perrigo"), the Company supplies Perrigo with an authorized generic version of the Company's Acetadote product. Acetadote product revenue includes the Company's share of revenue from sales of the authorized generic distributed by Perrigo, with those revenues totaling \$1.9 million and \$7.0 million for the three and nine months ended September 30, 2013.



CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(unaudited)

Other Revenues

During 2013, the Company entered into five new agreements with international partners for commercialization of certain of the Company's products into additional international territories and amended its agreement with Harbin Gloria Pharmaceuticals Co., Ltd ("Harbin Gloria"), a Chinese pharmaceutical company, to extend its territory. As a result of the new and amended agreements, the Company recognized approximately \$0.6 million of non-refundable up-front payments as other revenue in the condensed consolidated statement of income during the first half of 2013.

The agreements entered into during 2013 provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulations. Under the licensing agreements, the Company is entitled to receive additional milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company will recognize revenue for these substantive milestones using the milestone method. The agreements provide for up to \$0.5 million in milestone payments related to regulatory approvals and up to \$3.7 million in milestone payments related to total and annual product sales. As of September 30, 2013, the Company has not recognized any revenues related to milestones associated with the new agreements. The Company is also entitled to receive royalties on future sales of the products under the agreements.

In 2012, the Company entered into an exclusive licensing agreement for Acetadote and Caldolor with Harbin Gloria. In connection with the agreement, the Company has certain protective rights, including the right to review and approve all documents submitted to the Chinese State Drug Administration. During 2012, the Company received nonrefundable, up-front payments totaling approximately \$0.7 million in exchange for the transfer of certain intellectual property, including its product dossiers, and recognized these payments as other revenue during the first six months of 2012 when the intellectual property was provided to the licensee. The licensing agreement provides for the Company 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, the Company will receive milestone payments of \$1.1 million upon receiving regulatory approval for each of Acetadote and Caldolor in China. The Company will recognize revenue for these substantive milestones using the milestone method. As of September 30, 2013, the Company has not recognized any revenue related to milestones associated with Harbin Gloria.

(5) INVENTORIES

The Company works closely with third parties to manufacture and package finished goods for sale and it takes title to the finished goods at the time of shipment from the manufacturer and maintains 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.

The Company continually evaluates 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.

Caldolor inventory represented the majority of net inventory on hand at September 30, 2013 and December 31, 2012, and has varying expiration dates that begin in the second quarter of 2014 and extend through January 2015. The Company has provided stability data to the Food and Drug Administration ("FDA") supporting that the Caldolor product expiration dates may be extended by up to a year. The Company expects a decision from the FDA by the end of January 2014. Through September 30, 2013 and December 31, 2012, the Company has recognized charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately \$2.5 million. If actual Caldolor sales in future periods are less than projected sales, or the Company is not successful in extending the Caldolor expiration dates, the Company will incur additional obsolescence losses.

In connection with the purchase of certain Kristalose assets in 2011, the Company is responsible for the purchase of the active pharmaceutical ingredient for Kristalose and maintains 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.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements - continued

(unaudited)

As of September 30, 2013 and December 31, 2012, inventory was comprised of the following:

	September 30, 2013	December 31, 2012
Raw materials	\$1,116,625	\$1,310,670
Finished goods	4,318,988	4,907,685
Total	\$5,435,613	\$6,218,355

**(6) SHAREHOLDERS' EQUITY AND DEBT****Share Repurchases**

On May 13, 2010, the Company announced a share repurchase program to purchase up to \$10.0 million of its common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012 and January 2013, the Company's Board of Directors replaced the prior authorizations with new \$10.0 million authorizations for repurchases of the Company's outstanding common stock. During the first nine months of 2013 and 2012, the Company repurchased 828,551 shares and 1,029,414 shares of common stock for approximately \$3.9 million and \$6.8 million, respectively.

**Restricted Share Grants**

During 2013, the Company issued approximately 196,000 shares of restricted stock to employees and directors. Restricted stock issued to employees generally cliff-vests on the fourth anniversary of the date of grant. Restricted stock issued to directors vests on the one year anniversary of the date of grant. Stock compensation expense is presented as a component of general and administrative expense in the condensed consolidated statements of operations and comprehensive income (loss).

**Debt Agreement**

In August 2011, the Company entered into a Fifth Amended and Restated Loan Agreement with its primary lender (the "Agreement") to provide for an increase in the line of credit to \$10 million. The credit facility may be increased up to \$20 million upon the satisfaction of certain conditions. Borrowings under the line of credit are collateralized by substantially all of the Company's assets.

As of September 30, 2013, the Company had outstanding borrowings of approximately 4.9 million under its revolving credit facility. Given the amounts outstanding and the maximum loan amount, the balance available for borrowing under the revolving credit facility was \$5.1 million as of September 30, 2013. The interest rate related to borrowings under the Company's revolving credit facility is a variable rate of LIBOR plus an Applicable Margin, as defined in the debt agreement (2.2% at September 30, 2013).

Under the Agreement, the Company is subject to certain financial covenants including, but not limited to, maintaining a Leverage Ratio and Interest Coverage Ratio, as those terms are defined in the Agreement, that are determined on a quarterly basis. As of September 30, 2013, the Company is in compliance with all covenants.

In March 2013, the Company and its primary lender amended certain provisions of the Agreement related to the repurchase of the Company's common stock. Previously, the Agreement allowed the Company to expend \$10 million for share repurchases over the term of the Agreement. The amendment allows the Company \$10 million for share repurchases from March 1, 2013, through the remaining term of the Agreement.

**(7) INCOME TAXES**

At September 30, 2013, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$49.2 million. These benefits will be recognized in the year in which they are able to reduce current income taxes payable. The usage of these net operating loss carryforwards resulted in the Company paying minimal income taxes in 2009 through 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 that 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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(unaudited)

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 operations and comprehensive income (loss).

(9) COMMITMENTS AND CONTINGENCIES

Legal Matters

The Company received notices during 2012 and 2013, that its Acetadote patents are being challenged on the basis of invalidity or non-infringement by others. The Company intends to vigorously defend and protect its Acetadote product and related intellectual property rights, has filed lawsuits to contest the infringement of the Acetadote patents and continues to evaluate the potential outcomes of the lawsuits.

If the Company is unable to successfully defend the Acetadote patents and related intellectual property rights associated with its Acetadote product, its financial condition and results of operations could be adversely affected in the event of a loss of patent rights and lower sales volumes due to competition.

(10) SUBSEQUENT EVENTS

Pernix Therapeutics agreement

On October 28, 2013 the Company and Pernix Therapeutics, LLC ("Pernix") announced an agreement for the promotion of Omeclamox-Pak® covering the United States. Omeclamox-Pak is a branded prescription product that combines omeprazole, amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. It is the first FDA approved triple combination medication to contain omeprazole as the proton pump inhibitor and is prescribed over a shortened treatment period of ten days.

Under the terms of the agreement, the Company will promote the product to gastroenterologists across the United States through its field sales force which also promotes its Kristalose brand. Pernix will promote the product through its specialty sales force focusing on select primary care physicians. The companies will cooperate in the marketing and other activities needed to support the commercialization of the brand.



## 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 32, and "Special Note Regarding Forward-Looking Statements" on page 32 of our Annual Report on Form 10-K for the year ended December 31, 2012. 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 included in this Form 10-Q.

### OVERVIEW

#### Our Business

Cumberland Pharmaceuticals Inc. ("Cumberland," the "Company," or as used in the context of "we," "us," or "our"), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology. These markets are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address poorly met medical needs.

Our product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, for the treatment for pain and fever, Kristalose® (lactulose) for Oral Solution, a prescription laxative, and Hepatoren® (ifetroban) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome (HRS). We market and sell our approved products through our hospital and field sales forces in the United States, which together comprised more than 60 sales representatives and managers as of September 30, 2013.

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, manufacturing, sales, marketing, 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 quality and manufacturing professionals oversee the manufacture of our products. 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.

Since 2004, we have been profitable on an annual basis generating sufficient cash flows to fund our development and marketing programs. In 2009, we completed an initial public offering of our common stock to help facilitate our further growth.

#### 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:

• Continue to build a high-performance sales organization to address our target markets. We believe our commercial infrastructure can help to maximize prescription volume and product sales. We currently utilize a distinct sales team to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the

gastroenterology market.

Expand our product portfolio by acquiring rights to additional products and late stage product candidates. In addition to our product development activities, we are also seeking to acquire products or late-stage development product candidates to continue to build a portfolio of complementary products. We focus on under-promoted, FDA-

approved drugs ("FDA" or "Food and Drug Administration") as well as late-stage development products that address poorly met medical needs, which we believe helps mitigate our exposure to the risk, cost and time associated with drug discovery and research. We plan to continue to target products that are competitively differentiated, have valuable trademarks or other intellectual property, and allow us to leverage our existing infrastructure. We also plan to explore opportunities to seek approval for new uses of existing pharmaceutical products.

Expand our global presence through select international partnerships. We have established our own commercial capabilities, including a sales organization to cover the U.S. market for our products. We are also building a network of select international partners to register our products and make them available to patients in their countries.

Develop a pipeline of early-stage products through Cumberland Emerging Technologies, or CET. In order to build our product pipeline, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities of CET, our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland has the opportunity to negotiate rights to further develop and commercialize them.

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).

#### Recent Developments and Highlights

##### Caldolor®

##### Caldolor Pediatric Fever Study

In August 2013, we announced top-line results from a clinical pediatric fever study evaluating the safety and efficacy of Caldolor (ibuprofen) Injection compared to acetaminophen in treating fever (greater than or equal to 101.0°F) in hospitalized patients ranging from birth to 16 years old. One hundred and three patients were enrolled in this multi-center, randomized, open-label active comparator study. The pediatric patients received either 10 mg/kg intravenous ibuprofen (not to exceed 400 mg per dose) or 10 mg/kg acetaminophen (not to exceed 650 mg per dose). The primary endpoint of the study was to assess the area under the change in temperature versus time curve from baseline to two hours after the start of the initial dose of the study drug. In the two hours following dosing, pediatric patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen,  $p=0.012$ ; therefore meeting the primary endpoint of the study.

After a single dose, significantly more patients receiving intravenous ibuprofen (93%) were no longer considered to be febrile (temperature less than 100.4°F) compared to patients receiving acetaminophen (78%),  $p=0.036$ .

Patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen upon all temperature assessments during the four hours after dosing with reductions reaching statistical significance by ninety minutes post-dose.

No safety concerns were identified in the study, as the incidence of adverse events was similar across treatment groups.

##### Caldolor Follow-Up Knee Arthroscopy Study

In February 2013, we announced favorable top-line results from a pilot clinical study evaluating the safety and analgesic efficacy of Caldolor (ibuprofen) Injection compared to ketorolac injection in treating pain following knee arthroscopy procedures in adult patients. A follow-up, larger, multi-center study has been initiated to further study the safety and analgesic efficacy of Caldolor (ibuprofen) Injection compared to ketorolac injection in treating pain following knee arthroscopy procedures in adult patients. One hundred patients are to be enrolled across three U.S. medical centers.

##### Caldolor Poster Presentations

Posters with data from three Caldolor studies were presented at the Annual Meeting of the American Society of Anesthesiologists in San Francisco in October 2013. The poster presentations were presented by Dr. Alberto Uribe, Post-Doctoral Researcher, Department of Anesthesiology, Wexner Medical Center at the Ohio State University.



A poster entitled "Multicenter, Open-label Surveillance Trials to Evaluate the Safety and Efficacy of a Shortened Infusion Time of Intravenous Ibuprofen" was presented. Two registry studies made up this presentation. In the first registry study eligible patients were enrolled to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from 13 clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The second registry study was a phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg of intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from 21 clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

Another poster presentation was entitled "A Pilot Study to Determine the Efficacy of Intravenous Ibuprofen for Pain Control Following Arthroscopic Knee Surgery." This study was conducted at the Ohio State University Medical Center. The study enrolled fifty-one patients and the results indicate, compared to patients receiving ketorolac, patients receiving intravenous ibuprofen experienced less postoperative pain prior to discharge. Patients receiving Caldolor also needed fewer narcotics and were less likely to require narcotics prior to discharge. This data supports the benefits of using Caldolor in a pre-emptive model of multimodal analgesia.

Acetadote®

#### Acetadote Patent Challenge Update

We developed a new formulation of Acetadote (acetylcysteine) Injection as part of a Phase IV commitment in response to a request by the FDA. In April 2012, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,148,356 (the "356 Acetadote Patent") which is assigned to us. The claims of the 356 Acetadote Patent encompasses the Acetadote formulation and includes composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

Following the issuance of the 356 Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc. ("InnoPharma"), Paddock Laboratories, LLC, Mylan Institutional LLC, Sagent Agila LLC ("Sagent") and Perrigo Company ("Perrigo") challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity. We responded by filing five separate infringement lawsuits to contest each of the challenges. On November 12, 2012, we entered into a settlement agreement with Paddock Laboratories, LLC and Perrigo to resolve the challenges and the pending litigation with those two companies. The remaining infringement suits are currently pending.

On November 13, 2012, we brought suit against the FDA contesting the FDA's decision to approve the InnoPharma generic.

On March 19, 2013, the USPTO issued U.S. Patent number 8,399,445 (the "445 Acetadote Patent") which is also assigned to us. The claims of the 445 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. On April 8, 2013, the 445 Acetadote Patent was listed in the FDA Orange Book. The 445 Acetadote Patent is scheduled to expire in August 2025. Following the issuance of the 445 Acetadote Patent we received separate Paragraph IV certification notices from Perrigo, Sagent Pharmaceuticals, Inc., and Mylan Institutional LLC challenging the 445 Acetadote Patent on the basis of non-infringement, unenforceability and/or invalidity.

On June 10, 2013, we became aware of a Paragraph IV certification notice from Akorn, Inc. challenging the 445 Acetadote Patent and the 356 Acetadote Patent on the basis of non-infringement. On July 12, 2013, we filed a lawsuit for infringement of the 356 Acetadote Patent against Akorn, Inc. in the United States District Court for the District of Delaware.

We also have additional patent applications relating to Acetadote which are pending with the USPTO.

On September 30, 2013, the United States District Court for the District of Columbia filed an opinion granting a summary judgment in favor of the FDA regarding Cumberland's November 13, 2012 suit. On November 1, 2013, the United States District Court for the District of Delaware filed opinions granting Sagent's and InnoPharma's motions to

dismiss our May 2012 and June 2012 suits. We are considering our legal options and intend to continue to vigorously defend and protect our Acetadote product and related intellectual property rights.

#### International Licensing Agreements

During the first quarter of 2013, we entered into three separate agreements with international partners for commercialization of certain of our products into additional international territories. One of the three agreements was with an India-based Company that will register and commercialize Caldolor® (ibuprofen) Injection in India and several adjacent countries. Another agreement was with an Indonesia-based Company that will register and commercialize Caldolor throughout Indonesia. A third agreement was with a Qatar-based Company that will register and commercialize Caldolor, Acetadote® (acetylcysteine) Injection and Kristalose® (lactulose) within the greater Arabian Peninsula market.

During the second quarter of 2013, we entered into two additional agreements for the registration and commercialization of Caldolor outside the United States. The first agreement was with a Spanish-based company for a territory that includes Spain, Portugal, Argentina, Chile, Brazil, Ecuador, Peru, and Uruguay. The second agreement was with an Indonesian-based company and includes a territory of Singapore, Thailand, Vietnam, Cambodia, Laos, Brunei and the Philippines.

Also during the second quarter, we amended our agreement with Harbin Gloria Pharmaceuticals (“Gloria”) for the registration and commercialization of Caldolor and Acetadote in China by extending the territory to include Hong Kong and Macau. During the third quarter, we entered into an agreement with Gloria for their participation in Cumberland Emerging Technologies Inc. (“CET”). Gloria will purchase shares in CET in exchange for rights to CET products for the Chinese market.

The commercialization agreements entered into during 2013, provide that each of the partners, are responsible for seeking regulatory approvals for the products, and following approvals, will handle ongoing distribution and sales in the respective international territories. We maintain responsibility for the intellectual property and product formulations. With the exception of one partner, we will maintain responsibility for the development and manufacturing and will provide finished product for sale. Under the licensing agreements, we are entitled to receive upfront and milestone payments upon the achievement of defined regulatory approvals and sales milestones.

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

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 38 through 41 in “Management’s Discussion and Analysis” of our Annual Report on Form 10-K for the year ended December 31, 2012.

#### 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, fair value of marketable securities, inventories, provision for income taxes, share-based compensation, research and development expenses and intangible assets.

## RESULTS OF OPERATIONS

Three months ended September 30, 2013 compared to the three months ended September 30, 2012

Net revenues. Net revenues for the three months ended September 30, 2013 decreased to approximately \$6.5 million compared to \$12.5 million for the three months ended September 30, 2012. The decline was attributable to a decrease in Acetadote product revenue of \$6.0 million. An increase in Caldolor product revenue of \$0.2 million was offset by a decrease in Kristalose product revenue of \$0.2 million.

The increase in Caldolor revenue was primarily due to increased volume associated with continued success in penetrating our target market. We have continued to focus more of our sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product.

The decrease in Acetadote net revenue was due to decreased sales volume of the branded Acetadote product largely as a result of generic competition during 2013. Generic competition may continue to place downward pressure on our branded Acetadote product sales. Our Acetadote product revenue for the three months ended September 30, 2013 also included \$1.9 million in sales of the authorized generic distributed by Perrigo.

Cost of products sold. As a percentage of net revenues, cost of products sold increased to 15.8% during the three months ended September 30, 2013 compared to 7.4% during the three months ended September 30, 2012. The increase in costs of sales as a percentage of revenue was attributable to a change in the sales mix.

Selling and marketing. Selling and marketing expense for the three months ended September 30, 2013 totaled approximately \$3.4 million, compared to \$4.9 million in the three months ended September 30, 2012, representing a decrease of approximately \$1.5 million, or 30.6%. The decrease was driven by \$1.6 million in decreased salaries, benefits and other selling expenses. These reductions were primarily a result of our new commercial strategy and sales force realignment that went into effect during the fourth quarter of 2012.

Research and development. Research and development costs for the three months ended September 30, 2013 totaled approximately \$1.4 million, compared to \$1.7 million in the three months ended September 30, 2012, representing a decrease of approximately \$0.3 million, or 15.1%. The decrease is a result of lower study costs in 2013 compared to 2012.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the three months ended September 30, 2013 totaled approximately \$0.2 million, representing an increase of approximately \$0.1 million over the three months ended September 30, 2012. The increase was primarily due to increased capitalized patents and capitalized patent defense costs.

Income tax benefit (expense). Income tax benefit for the three months ended September 30, 2013 totaled approximately \$0.7 million, representing a decrease in expense of approximately \$1.9 million, from the same period in 2012. As a percentage of (loss) income before income taxes, the income tax benefit was 45.2% for the three months ended September 30, 2013 compared to an income tax expense of 39.3% for the three months ended September 30, 2012. The tax rate for the three months ended September 30, 2013 was impacted positively by the reinstatement of the U.S. research and development tax credit during 2013.

As of September 30, 2013, we have approximately \$49.2 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 benefits will be recognized in the year in which they are able to reduce current income taxes payable.

Nine months ended September 30, 2013 compared to the nine months ended September 30, 2012

Net revenues. Net revenues for the nine months ended September 30, 2013 decreased approximately \$11.3 million compared to the nine months ended September 30, 2012. The decline in net revenues was attributable to decreases in Acetadote product revenue of \$11.8 million and decreases of Kristalose product revenue of \$0.4 million. These decreases were partially offset by an increase in Caldolor product revenue of \$0.9 million.



The increase in Caldolor revenue was primarily due to increased volume associated with continued success in penetrating our target market. We have continued to focus more of our sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product.

The decrease in Acetadote net revenue was a result of decreased sales volume of the branded Acetadote product largely as a result of generic competition during 2013. Our Acetadote product revenue for the nine months ended September 30, 2013 also included \$7.0 million in sales of the authorized generic distributed by Perrigo.

We recognized \$0.8 million of other revenue in both the nine months ended September 30, 2013 and 2012, primarily as the result of upfront payments we received in connection with out-licensing agreements with international commercial partners.

**Cost of products sold.** As a percentage of net revenues, cost of products sold increased to 13.8% during the nine months ended September 30, 2013 compared to 8.2% during the nine months ended September 30, 2012. The increase in costs of sales as a percentage of revenue was attributable to a change in the sales mix.

**Selling and marketing.** Selling and marketing expense for the nine months ended September 30, 2013 totaled approximately \$10.6 million, compared to \$15.4 million for the nine months ended September 30, 2012. The \$4.8 million decrease was driven by \$5.2 million in decreased salaries, benefits and other selling expenses. These reductions were primarily a result of our new commercial strategy and sales force realignment that went into effect during the fourth quarter of 2012. These cost decreases were partially offset by a \$0.4 million increase in marketing research and direct marketing.

**Research and development.** Research and development costs for the nine months ended September 30, 2013 totaled approximately \$4.3 million, compared to \$4.7 million in the nine months ended September 30, 2012, representing a decrease of approximately \$0.4 million, or 8.1%. The decrease is a result of lower study costs in 2013 compared to 2012.

**Amortization.** Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the nine months ended September 30, 2013 totaled approximately \$0.6 million, representing an increase of approximately \$0.2 million compared to the nine months ended September 30, 2012. The increase was primarily due to increased capitalized patents and capitalized patent defense costs.

**Income tax expense.** Income tax benefit for the nine months ended September 30, 2013 totaled approximately \$0.6 million, representing a decrease in expense of \$2.3 million from the \$1.8 million of income tax expense for the same period of 2012. As a percentage of income before income taxes, the income tax benefit was 48.0% for the nine months ended September 30, 2013 compared to 30.4% for the nine months ended September 30, 2012. The tax rate for the nine months ended September 30, 2013 was positively impacted by the reinstatement of the U.S. research and development tax credit during 2013.

The tax rate percentage in 2012 was primarily due to the recognition of a deferred tax benefit associated with the exchange of certain incentive stock options.

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

Our primary sources of liquidity are cash flows provided by our 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, 2013 and 2012, we generated \$0.9 million and \$5.1 million in cash flow from operations, respectively. We believe that our internally generated cash flows and amounts available under our line of credit will be adequate to service existing debt, finance internal growth and fund capital expenditures.

During 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 investments 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, 2013 and December 31, 2012, we had a total of approximately \$19.2 million and \$16.7 million invested in marketable securities.

The following table summarizes our liquidity and working capital as of September 30, 2013 and December 31, 2012:

	September 30, 2013	December 31, 2012
Cash and cash equivalents	\$46,011,203	\$54,349,381
Marketable securities	19,163,442	16,686,136
Total cash, cash equivalents and marketable securities	\$65,174,645	\$71,035,517
Working capital (current assets less current liabilities)	\$72,858,562	\$79,176,882
Current ratio (multiple of current assets to current liabilities)	14.5	10.8
Revolving line of credit availability	\$5,140,049	\$5,640,049

The following table summarizes our net changes in cash and cash equivalents for the nine months ended

September 30, 2013 and September 30, 2012:

	Nine months ended September 30,	
	2013	2012
Net cash provided by (used in):		
Operating activities	\$938,761	\$5,147,479
Investing activities	(5,305,303)	(20,374,983)
Financing activities	(3,971,636)	(4,570,071)
Net decrease in cash and cash equivalents	\$(8,338,178)	\$(19,797,575)

The net decrease in cash and cash equivalents for the nine months ended September 30, 2013 was partly attributable to the net investment of \$2.6 million of our cash reserves in certain government and government-backed securities, as previously noted. In addition, we continue to repurchase shares of our common stock, totaling \$3.9 million during the period. The year-to-date net loss of \$0.6 million also contributed to the net decrease.

The net decrease in cash and cash equivalents for the nine months ended September 30, 2012 was primarily attributable to the investment of \$18.5 million of our cash reserves in certain government and government-backed securities. We repurchased shares of our common stock totaling \$6.8 million during the period. These decreases were partially offset by \$4.0 million in net income.

As of September 30, 2013, we have approximately \$49.2 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 benefits will be recognized in the year in which they are able to reduce current income taxes payable.

#### OFF-BALANCE SHEET ARRANGEMENTS

During the nine months ended September 30, 2013 and 2012, 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 (2.2% at September 30, 2013). As of September 30, 2013, we had outstanding borrowings of approximately \$4.9 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, 2013, 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, 2013 and 2012. 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 officers evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2013. 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 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 32 in our Annual Report on Form 10-K for the year ended December 31, 2012 under the section titled “Risk Factors.” The following risk factor was included in our Form 10-K for the year ended December 31, 2012 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 “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

Following the issuance of the 356 Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC (“Paddock”) and Mylan Institutional LLC challenging the 356 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 356 Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. (“Mylan”) 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 and Perrigo Company (“Perrigo”). On May 20, 2012, we received a Paragraph IV certification notice from Sagent Agila LLC challenging the 356 Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the 356 Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. (“Sagent”) in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo. On August 9, 2012, we filed a lawsuit for infringement of the 356 Acetadote Patent against Perrigo in the United States District Court for the Northern District of Illinois, Eastern Division.

On November 12, 2012, we entered into a Settlement Agreement (the “Settlement Agreement”) with Paddock and Perrigo to resolve the challenges and the pending litigation with each of Paddock and Perrigo involving the 356 Acetadote Patent. Under the Settlement Agreement, Paddock and Perrigo admit that the 356 Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, we entered into a License and Supply Agreement with Paddock and Perrigo (the “License and Supply Agreement”). Under the terms of the License and Supply Agreement, if a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party has made such generic version available for purchase in commercial quantities in the United States, we will supply Perrigo with an authorized generic version of our Acetadote product (the “Authorized Generic”).

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 remaining 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. On November 7, 2012, the FDA responded to the Citizen Petition denying our request and stating that ANDAs referencing Acetadote that contain EDTA may be accepted and approved provided they meet all applicable requirements. We believe this response contradicts the FDA's request to evaluate the reduction or removal of EDTA. On November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. On November 13, 2012, we brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of our Citizen Petition and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law.

We found during the resulting legal proceedings that the FDA initially concluded that the original Acetadote formulation was withdrawn for safety reasons and no generic versions should be approved. The FDA later reversed its position based on the possibility of drug shortages and the presence of EDTA in other formulations. At the same time, the FDA noted that exclusively marketing a non-EDTA containing product would be preferable because it would eliminate the potential risk of EDTA.

On January 7, 2013, Perrigo announced initial distribution of our authorized generic acetylcysteine injection product. On March 19, 2013, the USPTO issued U.S. Patent number 8,399,445 (the "445 Acetadote Patent") which is also assigned to us. The claims of the 445 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. On April 8, 2013, the 445 Acetadote Patent was listed in the FDA Orange Book. The 445 Acetadote Patent is scheduled to expire in August 2025. Following the issuance of the 445 Acetadote Patent we have received separate Paragraph IV certification notices from Perrigo, Sagent, and Mylan challenging the 445 Acetadote Patent on the basis of non-infringement, unenforceability and/or invalidity.

On June 10, 2013, we became aware of a Paragraph IV certification notice from Akorn, Inc. challenging the 445 Acetadote Patent and the 356 Acetadote Patent on the basis of non-infringement. On July 12, 2013, we filed a lawsuit for infringement of the 356 Acetadote Patent against Akorn, Inc. in the United States District Court for the District of Delaware.

On June 10, 2013, we announced that the FDA approved updated labeling for Acetadote. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations.

On September 30, 2013, the United States District Court for the District of Columbia filed an opinion granting a Summary Judgment in favor of the FDA regarding Cumberland's November 13, 2012 suit. On November 1, 2013, the United States District Court for the District of Delaware filed opinions granting Sagent's and InnoPharma's motions to dismiss our May 2012 and June 2012 suits. We are considering our legal options and intend to continue to vigorously defend and protect our Acetadote product and related intellectual property.

We also have additional patent applications relating to Acetadote which are pending with the USPTO and may or may not be issued. As noted, we intend to continue 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 to 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. As our marketing exclusivity has expired, 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 our purchase of Cumberland equity securities during the three months ended September 30, 2013:

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 Plans or Programs <sup>(1)</sup>
July	49,776	\$5.50	49,776	\$ 6,967,330
August	39,955	4.89	39,955	6,772,130
September	62,269	4.61	62,269	6,484,766
Total	152,000		152,000	

(1) In January 2013, 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.

Item 6. Exhibits

No.	Description
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.
101.INS	XBRL INSTANCE DOCUMENT
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
101.LAB	XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

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 6, 2013

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

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