

**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 June 30, 2016

OR

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

For the transition period from            to            .

Commission file number: 001-33637

**Cumberland Pharmaceuticals Inc.**

(Exact Name of Registrant as Specified In Its Charter)

**Tennessee**

(State or Other Jurisdiction of  
Incorporation or Organization)

**62-1765329**

(I.R.S. Employer  
Identification No.)

**2525 West End Avenue, Suite 950,  
Nashville, Tennessee**

(Address of Principal Executive Offices)

**37203**

(Zip Code)

**(615) 255-0068**

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

Class	Outstanding at August 3, 2016
Common stock, no par value	16,225,617

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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements (Unaudited)**

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

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 35,837,240	\$ 38,203,059
Marketable securities	14,565,154	14,564,115
Accounts receivable, net of allowances	4,550,945	6,077,120
Inventories	4,921,681	4,270,143
Other current assets	4,117,059	3,997,637
Total current assets	63,992,079	67,112,074
Property and equipment, net	505,667	536,450
Intangible assets, net	20,881,286	21,168,596
Other assets	2,509,898	3,101,839
Total assets	\$ 87,888,930	\$ 91,918,959
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,667,440	\$ 2,877,479
Other current liabilities	5,227,831	9,534,268
Total current liabilities	8,895,271	12,411,747
Revolving line of credit	3,500,000	1,700,000
Other long-term liabilities	1,119,201	987,429
Total liabilities	13,514,472	15,099,176
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,236,348 and 16,379,501 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	55,222,464	57,338,294
Retained earnings	19,248,459	19,549,614
Total shareholders' equity	74,470,923	76,887,908
Noncontrolling interests	(96,465)	(68,125)
Total equity	74,374,458	76,819,783
Total liabilities and equity	\$ 87,888,930	\$ 91,918,959

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 June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net revenues	\$ 7,414,835	\$ 8,909,741	\$ 15,152,367	\$ 17,596,515
Costs and expenses:				
Cost of products sold	1,155,261	1,237,001	2,379,200	2,398,842
Selling and marketing	3,272,279	3,505,486	6,971,241	7,036,401
Research and development	678,780	828,070	1,385,252	2,687,082
General and administrative	1,874,396	2,153,562	3,952,368	3,797,703
Amortization	539,428	511,691	1,070,198	998,440
Total costs and expenses	7,520,144	8,235,810	15,758,259	16,918,468
Operating income (loss)	(105,309)	673,931	(605,892)	678,047
Interest income	31,483	57,846	108,612	114,248
Interest expense	(28,247)	(18,489)	(48,689)	(34,039)
Income (loss) before income taxes	(102,073)	713,288	(545,969)	758,256
Income tax (expense) benefit	41,135	(318,990)	216,474	(337,446)
Net income (loss)	(60,938)	394,298	(329,495)	420,810
Net loss at subsidiary attributable to noncontrolling interests	12,894	11,700	28,340	31,469
Net income (loss) attributable to common shareholders	<u>\$ (48,044)</u>	<u>\$ 405,998</u>	<u>\$ (301,155)</u>	<u>\$ 452,279</u>
Earnings (loss) per share attributable to common shareholders				
- basic	\$ —	\$ 0.02	\$ (0.02)	\$ 0.03
- diluted	\$ —	\$ 0.02	\$ (0.02)	\$ 0.03
Weighted-average shares outstanding				
- basic	16,247,028	16,820,725	16,293,744	16,916,193
- diluted	16,247,028	17,184,345	16,293,744	17,294,087
Comprehensive income (loss) attributable to common shareholders	(48,044)	405,998	(301,155)	452,279
Net loss at subsidiary attributable to noncontrolling interests	12,894	11,700	28,340	31,469
Total comprehensive income (loss)	<u>\$ (60,938)</u>	<u>\$ 394,298</u>	<u>\$ (329,495)</u>	<u>\$ 420,810</u>

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Six months ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$ (329,495)	\$ 420,810
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	1,171,437	1,143,002
Deferred tax benefit	533,067	23,593
Share-based compensation	408,226	549,603
Excess tax expense (benefit) derived from exercise of stock options	835,016	(313,955)
Noncash interest expense	37,323	19,782
Noncash investment gains	(51,213)	(44,870)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	1,526,175	(303,286)
Inventory	(651,538)	804,776
Other current assets and other assets	(97,871)	422,946
Accounts payable and other current liabilities	(4,061,546)	1,265,725
Other long-term liabilities	136,483	79,742
Net cash (used in) provided by operating activities	(543,936)	4,067,868
Cash flows from investing activities:		
Additions to property and equipment	(70,454)	(62,291)
Purchases of marketable securities	(2,959,285)	(4,046,142)
Proceeds from sale of marketable securities	3,009,459	4,795,505
Additions to intangible assets	(1,077,547)	(2,740,001)
Net cash used in investing activities	(1,097,827)	(2,052,929)
Cash flows from financing activities:		
Net borrowings on line of credit	1,800,000	1,700,000
Exercise of stock options	—	21,366
Excess tax (expense) benefit derived from exercise of stock options	(835,016)	313,955
Cash settlement of contingent consideration	—	(1,618,983)
Repurchase of common shares	(1,689,040)	(3,356,633)
Net cash used in financing activities	(724,056)	(2,940,295)
Net decrease in cash and cash equivalents	(2,365,819)	(925,356)
Cash and cash equivalents at beginning of period	38,203,059	39,866,037
Cash and cash equivalents at end of period	\$ 35,837,240	\$ 38,940,681

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statement of Equity**  
**(Unaudited)**

	Common stock		Retained earnings	Noncontrolling interests	Total equity
	Shares	Amount			
Balance, December 31, 2015	16,379,501	\$ 57,338,294	\$ 19,549,614	\$ (68,125)	\$ 76,819,783
Share-based compensation	223,587	408,226	—	—	408,226
Exercise of options and related tax benefit	—	(835,016)	—	—	(835,016)
Repurchase of common shares	(366,740)	(1,689,040)	—	—	(1,689,040)
Net loss	—	—	(301,155)	(28,340)	(329,495)
Balance, June 30, 2016	16,236,348	\$ 55,222,464	\$ 19,248,459	\$ (96,465)	\$ 74,374,458

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," "Cumberland," or in certain context "our" or "we") 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 medical specialties are characterized by relatively concentrated prescriber bases that the Company believes can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs.

Cumberland has both internal product development and commercial capabilities. The Company is focused on maximizing the commercial potential of its current brands, as well as expanding its product portfolio through select acquisitions and development of new product candidates. Cumberland's products are manufactured by third parties, which are overseen by the Company's quality assurance professionals. The Company works closely with its distribution partners to ensure the delivery and availability of the Company's products.

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, 2015 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 ("U.S. GAAP"). 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, 2015. The results of operations for the three and six months ended June 30, 2016 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 six months ended June 30, 2016 and 2015.

***Recent Accounting Guidance***

***Recently Issued Accounting Guidance Not Yet Adopted***

In May 2014, the Financial Accounting Standards Board ("FASB") issued amended guidance in the form of a FASB Accounting Standards Update ("ASU"), "Revenue from Contracts with Customers". The core principle of the new guidance is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The new guidance defines a five-step process to achieve this core principle and, in doing so, additional judgments and estimates may be required within the revenue recognition process. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective. In July 2015, the FASB issued a one-year deferral of the adoption date, which extended the effective date for the Company to January 1, 2018. Adoption prior to January 1, 2017, the original effective date, is not permitted. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing the potential impact of the new standard on financial reporting and has not yet selected a transition method by which it will adopt the standard.

In July 2015, the FASB issued amended guidance in the form of a FASB ASU, "Inventory: Simplifying the Measurement of Inventory." The amended guidance requires entities to measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The requirement would replace the current lower of cost or market evaluation. Accounting guidance is unchanged for inventory measured using last-in, first-out ("LIFO") or the retail method. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance should be applied prospectively and early adoption is permitted. The Company is evaluating the potential impact of this adoption on our condensed consolidated financial statements and disclosures.

In November 2015, the FASB amended guidance in the form of a FASB ASU, "Balance Sheet Classification of Deferred Taxes", which requires that all deferred tax assets and liabilities be classified as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The FASB determined that this simplification could reduce cost and complexity without decreasing the usefulness of information provided to financial statement users. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance may be applied prospectively

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements - continued**  
**(Unaudited)**

or retrospectively and early adoption is permitted. The Company does not anticipate adoption of this balance sheet classification ASU to have a material effect on its consolidated financial statements and disclosures.

In February 2016, the FASB issued guidance in the form of a FASB ASU, "Leases". The new standard establishes a right-of-use (ROU) model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain optional practical expedients available. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating the impact of its pending adoption of the new standard on Cumberland's consolidated financial statements and disclosures.

In March 2016, the FASB released in the form of a FASB ASU, "Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting". The ASU includes multiple provisions intended to simplify various aspects of the accounting for share-based payments. While aimed at reducing the cost and complexity of the accounting for share-based payments, the amendments are expected to significantly impact net income, earnings per share ("EPS"), and the statement of cash flows. Implementation and administration may present challenges for companies with significant share-based payment activities. The ASU is effective for public companies in annual periods beginning after December 15, 2016, and interim periods within those years. The Company is currently evaluating the impact of adoption on the consolidated financial statements.

***Accounting Policies:***

***Use of Estimates***

In preparing the condensed consolidated financial statements in conformity with U.S. GAAP, 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 results could differ from those estimates under different assumptions and conditions. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns, (2) the allowances for obsolescent or unmarketable inventory and (3) the projection of future taxable income for the realization of deferred tax assets.

***Operating Segments***

The Company has one operating segment which is specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Operating segments are identified as components of an enterprise about which separate discrete financial information is evaluated by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company, which uses consolidated financial information in determining how to allocate resources and assess performance, evaluated that our specialty pharmaceutical products compete in similar economic markets and similar circumstances. Substantially all of the Company's assets are located in the United States and total revenues are primarily attributable to U.S. customers.

**(2) MARKETABLE SECURITIES**

The Company invests in marketable debt securities in order to maximize its return on cash. Marketable securities consist of 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 June 30, 2016 and December 31, 2015, the marketable securities are 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 operations and comprehensive income.

The Company's fair value measurements follow the appropriate rules as well as 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.



**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements - continued**  
**(Unaudited)**

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 measurements. 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). There were no transfers of assets between levels within the fair value hierarchy.

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

	June 30, 2016			December 31, 2015		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Agency issued mortgage-backed securities – variable rate	\$ —	\$ 6,913,844	\$ 6,913,844	\$ —	\$ 5,700,335	\$ 5,700,335
U.S. Agency notes and bonds – fixed rate	—	1,502,621	1,502,621	—	2,447,066	2,447,066
SBA loan pools – variable rate	—	1,513,689	1,513,689	—	1,681,714	1,681,714
Municipal bonds – VRDN	4,635,000	—	4,635,000	4,735,000	—	4,735,000
Total fair value of marketable securities	<u>\$ 4,635,000</u>	<u>\$ 9,930,154</u>	<u>\$ 14,565,154</u>	<u>\$ 4,735,000</u>	<u>\$ 9,829,115</u>	<u>\$ 14,564,115</u>

### (3) EARNINGS (LOSS) PER SHARE

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,	
	2016	2015
Numerator:		
Net income (loss) attributable to common shareholders	\$ (48,044)	\$ 405,998
Denominator:		
Weighted-average shares outstanding – basic	16,247,028	16,820,725
Dilutive effect of other securities	—	363,620
Weighted-average shares outstanding – diluted	<u>16,247,028</u>	<u>17,184,345</u>
	Six months ended June 30,	
	2016	2015
Numerator:		
Net income (loss) attributable to common shareholders	\$ (301,155)	\$ 452,279
Denominator:		
Weighted-average shares outstanding – basic	16,293,744	16,916,193
Dilutive effect of other securities	—	377,894
Weighted-average shares outstanding – diluted	<u>16,293,744</u>	<u>17,294,087</u>

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements - continued**  
**(Unaudited)**

As of June 30, 2016 and 2015, restricted stock awards and options to purchase 276,652 and 53,968 shares of common stock, respectively, were outstanding but were not included in the computation of diluted earnings per share because the effect would be antidilutive.

**(4) REVENUES**

*Product Revenues*

The Company's net revenues consisted of the following for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Products:				
Acetadote	\$ 1,895,199	\$ 2,778,677	\$ 3,732,661	\$ 4,321,686
Omeclamox-Pak	641,469	944,185	1,401,788	1,702,376
Kristalose	3,626,076	4,121,966	7,243,882	8,220,744
Vaprisol	421,800	480,034	789,848	1,504,008
Caldolor	631,893	460,052	1,703,861	1,654,733
Other	198,398	124,827	280,327	192,968
Total net revenues	<u>\$ 7,414,835</u>	<u>\$ 8,909,741</u>	<u>\$ 15,152,367</u>	<u>\$ 17,596,515</u>

Cumberland supplies Perrigo Company ("Perrigo") with an Authorized Generic version of the Company's Acetadote product. The Company's revenue generated by sales of its Authorized Generic distributed by Perrigo is included in the Acetadote product revenue presented above. The Company's share of Authorized Generic revenue was \$1.2 million and \$1.8 million for the second quarter of 2016 and 2015 and \$2.4 million and \$2.3 million on a year-to-date basis as of June 30, 2016 and 2015, respectively.

*Other Revenues*

The Company has entered into agreements, beginning in 2012, with international partners for commercialization of the Company's products. The international agreements provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, each partner will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulations. Under the international agreements, the Company is entitled to receive non-refundable, up-front payments at the time the agreements are entered into and milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company recognizes revenue for these substantive milestones using the milestone method. The Company is also entitled to receive royalties on future sales of the products under the agreements. During the six months ended June 30, 2016, the Company recognized \$100,000 in milestone payments associated with these international agreements.

**(5) INVENTORIES**

The Company works closely with third parties to manufacture and package finished goods for sale. Based on the relationship with the manufacturer or packager, the Company will either take title to the finished goods at the time of shipment or at the time of arrival from the manufacturer. The Company then warehouses 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 that the carrying value may not be recoverable, a charge is taken to reduce the inventory to its current net realizable value. At June 30, 2016 and December 31, 2015, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately \$2.8 million and \$2.7 million, respectively.

Caldolor inventory on hand at June 30, 2016 and December 31, 2015 had varying original expiration dates ranging from the second quarter of 2014 and extending through January 2016. During 2013 and again in 2014, the Company provided stability data to the Food and Drug Administration ("FDA") supporting the extension of the Caldolor product expiration dates by an additional year. The FDA notified the Company that it had approved both requests to extend the original shelf life of the Caldolor 800mg vials from five to six years in January 2014 and from six to seven years in March 2015. The current Caldolor inventory at June 30, 2016 has FDA extended expiration dates through early 2017. The Company expects to receive new Caldolor 800 mg vials, with seven years of shelf life, for sale in the United States during the third quarter of 2016.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements - continued**  
**(Unaudited)**

In connection with the acquisition of certain product rights related to the Kristalose brand, the Company is responsible for the purchase of the active pharmaceutical ingredient ("API") for Kristalose and maintains the inventory at the third-party manufacturer. As the API is consumed in production, the value of the API is transferred from raw materials to finished goods. API for the Company's Vaprisol brand is also included in the raw materials inventory total at June 30, 2016 and December 31, 2015.

As of June 30, 2016 and December 31, 2015, net inventory was comprised of the following:

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
Raw materials	\$ 3,206,926	\$ 2,576,621
Consigned inventory	307,589	235,636
Finished goods	1,407,166	1,457,886
Total	<u>\$ 4,921,681</u>	<u>\$ 4,270,143</u>

**(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, January 2013, January 2015 and January 2016, 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 six months ended June 30, 2016 and the six months ended June 30, 2015, the Company repurchased 366,740 shares and 503,602 shares of common stock for approximately \$1.7 million and \$3.4 million, respectively.

*Restricted Share Grants*

During the six months ended June 30, 2016, the Company issued approximately 217,775 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 income and comprehensive income.

*Debt Agreement*

On June 26, 2014, Cumberland entered into a Revolving Credit Loan Agreement ("Loan Agreement") with SunTrust Bank, which replaced the agreement with a previous lender. The Company had \$3.5 million and \$1.7 million in borrowings under the Loan Agreement at June 30, 2016 and 2015. On July 29, 2016, Cumberland amended the agreement to extend the original three-year term by an additional year and obtained a compliance waiver for a financial covenant as of June 30, 2016. As a result of the amendment, the Company is in compliance with all covenants and the loan agreement expires on June 30, 2018. The agreement provides for an aggregate principal amount up to \$20 million. The initial revolving line of credit is up to \$12 million, with the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions.

The interest rate on the Loan Agreement is based on LIBOR plus an interest rate spread. There is no LIBOR minimum and the LIBOR pricing provides for an interest rate spread of 1.0% to 2.85% (representing an interest rate of 1.5% at June 30, 2016). In addition, a fee of 0.25% per year is charged on the unused line of credit. Interest and the unused line fee are payable quarterly. Borrowings under the line of credit are collateralized by substantially all of the Company's assets.

Under the Loan Agreement, Cumberland is subject to certain financial covenants, including, but not limited to, maintaining an EBIT to Interest Expense Ratio and a Funded Debt Ratio, as such terms are defined in the Loan Agreement and that are determined on a quarterly basis.

**(7) INCOME TAXES**

At June 30, 2016, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$43.0 million. These benefits occurred as a result of the actual tax benefit realized upon an employee's exercise exceeding the cumulative book compensation charge associated with the awards and will be recognized in the year in which they are able to reduce current income taxes payable. Accordingly, deferred tax assets are not recognized for these net operating loss carryforwards or credit carryforwards resulting from the exercise of nonqualified options. The Company's utilization of these net operating loss carryforwards and a net operating loss in 2013 resulted in minimal income taxes paid in

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements - continued**  
**(Unaudited)**

each of the years 2009 through 2015. The Company expects to achieve taxable income through its operations and pay minimal income taxes in 2016 through utilization of these net operating loss carryforwards.

**(8) COLLABORATIVE AGREEMENTS**

Cumberland is 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 and funding received from private sector investments and grants are recorded as net revenues in the condensed consolidated statements of operations and comprehensive income.

**(9) COMMITMENTS AND CONTINGENCIES**

*Legal Matters*

The Company developed a new formulation of Acetadote (acetylcysteine) Injection as part of the Phase IV commitment in response to a request by the FDA regarding the role of EDTA in the products formulation. The Company has received several patents from the United States Patent and Trademark Office ("USPTO") since 2012 as well as notices that its Acetadote patents are being challenged on the basis of invalidity or non-infringement by others.

During the third quarter of 2015, an arbitrator issued a final award in the Company's favor, enjoining Mylan Pharma Group Limited and Mylan Teoranta, together with all their affiliates ("Mylan"), from selling, delivering, or giving away any acetylcysteine injectable drug product to another entity or person until April 30, 2018. The arbitration request was filed with the American Arbitration Association for claims against Mylan in connection with agreements which require that Mylan manufacture and supply acetylcysteine drug product, including Acetadote, for us exclusively until April 2016. As the prevailing party, the Company received reimbursement of its attorney's fees and related costs associated with the arbitration.

During the third quarter of 2015, the United States District Court for the Northern District of Illinois, Eastern Division ruled in the Company's favor in its lawsuit against Mylan for infringement of its U.S. Patent number 8,399,445 (the "445 Acetadote Patent"). The opinion upheld the Company's 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The court ruled that Mylan is liable to Cumberland for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

The Company is continuing to seek additional claims to protect its intellectual property associated with Acetadote and has additional patent applications pending. The Company continues to consider its legal options and intends to continue to defend and protect its Acetadote product and related intellectual property rights. Additional information on these matters is provided in the Company's Acetadote patent defense legal proceedings contained in *Part 1, Item 1, Business -Trademarks and Patents*, of the Company's Form 10-K for the year ended December 31, 2015, which is incorporated by reference herein.

**(10) PRODUCT ADDED DURING 2016**

*Ethyol*

On May 10, 2016, the Company announced an agreement with Clinigen Group Plc ("Clinigen") in which Cumberland acquired the exclusive rights to commercialize Ethyol® (amifostine) in the United States. Ethyol is a FDA approved cytoprotective drug indicated as an adjuvant therapy to reduce the incidence of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer. Under the terms of the agreement, Cumberland will be responsible for all marketing, promotion, and distribution of the product in the United States. There are no upfront payments required under the agreement. Cumberland will pay Clinigen royalty payments based on tiered levels of net sales. The Company is expected to start generating revenue from the sale of Ethyol during the third quarter of 2016.

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

The following discussion contains certain forward-looking statements which reflect management's current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We caution you that our actual results may differ significantly from the results we discuss in these forward looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; and management of our growth and integration of our acquisitions. Other important factors that may cause actual results to differ materially from forward-looking statements are discussed in "Risk Factors" on pages 22 through 37, and "Special Note Regarding Forward-Looking Statements" on pages 37 and 38 of our Annual Report on Form 10-K for the year ended December 31, 2015. 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 markets are hospital acute care and gastroenterology. These medical specialties are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs. We market and sell our approved products through our hospital and gastroenterology sales forces in the United States and are establishing a network of international partners to bring our products to patients in their countries.

Our product portfolio includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever; recently approved for use in pediatric patients;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia, and
- **Ethyol®** (*amifostine*) Injection for the reduction of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer.

Our pipeline of product candidates includes:

- **Hepatoren®** (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- **Boxaban™** (*ifetroban*) oral capsules, a Phase II candidate for the treatment of patients with aspirin-exacerbated respiratory disease (AERD); and
- **Vasculan™** (*ifetroban*) oral capsules, a Phase II candidate for the treatment of patients with systemic sclerosis (SSc).

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, regulatory, manufacturing, sales, marketing 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 and release of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our distribution partners to ensure availability and delivery of our products.

## Growth Strategy

Our growth strategy involves maximizing the potential of our existing brands while continuing to build a portfolio of differentiated products. We currently market five products approved for sale in the United States. Through our international partners, we are working to bring our products to patients in countries outside the U.S. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to identify and develop promising, early-stage product candidates, which Cumberland has the opportunity to further develop and commercialize. 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 that our commercial infrastructure can help drive prescription volume and product sales. We currently utilize two distinct sales teams to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the gastroenterology market. We believe that active promotion of our products, supported by non-personal promotional activities developed and implemented by our marketing team, can maximize the opportunity for our brands.
- **Further develop our existing products and develop new late stage product candidates.** We continue to evaluate our products following FDA approval to determine if further clinical work could expand the potential market opportunities for our products and help new patient populations. We will also continue to explore opportunities for label expansion to bring our products to new patient populations. The Caldolor pediatric approval reflects our successful implementation of this strategy. Our clinical team is also working to develop late stage product candidates that could further expand our product portfolio if approved by the FDA.
- **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 brands. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that address poorly met medical needs. We plan to continue to target product acquisition candidates that are competitively differentiated, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. Our acquisition of rights to Ethylol in the U.S. represents a recent example of our implementation of this strategy.
- **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 building a network of select international partners to register our products and make them available to patients in their countries. We will continue to expand our network of international partners and continue to support our partners' registration and commercialization efforts in their respective territories. The launch of Caldolor in Australia by CSL's Seqirus is an example of our international partnerships.
- **Develop a pipeline of early-stage products through Cumberland Emerging Technologies ("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 at CET. 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 in the U.S and other markets.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. During 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange. Our website address is [www.cumberlandpharma.com](http://www.cumberlandpharma.com). We make available through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all other press releases, filings and amendments to those reports as soon as reasonably practicable after their filing with the SEC. These filings are also available to the public at [www.sec.gov](http://www.sec.gov).

## **Recent Developments and Highlights**

### **Board of Directors Appointment**

On June 10, 2016, we announced the addition of Caroline Young to our Board of Directors. She is the prior President of the Nashville Health Care Council and founding Executive Director of the Tennessee Biotechnology Association. Her appointment to Cumberland's Board will be effective September 13, 2016.

### **Ethylol® Agreement**

In May 2016, we announced an agreement for the commercialization of Ethylol® (amifostine) in the United States. This is the first product to be licensed by Cumberland from the Clinigen Group Plc. under the Strategic Alliance entered into last year. Under the terms of the agreement, we will be responsible for all marketing, promotion, and distribution of the product in the United States.

Ethylol is an FDA approved cytoprotective drug indicated as an adjuvant therapy to reduce the incidence of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer. Ethylol is our first oncology support product and complements our hospital product line.

### **Vasculan™ Program**

In April 2016, we announced the addition of Vasculan to our pipeline. Cumberland has initiated the clinical development of Vasculan (ifetroban) oral capsule for the treatment of systemic sclerosis. The U.S. Food and Drug Administration (FDA) has cleared our investigational new drug application (IND) for a Phase II clinical program for Vasculan in patients with systemic sclerosis.

Systemic sclerosis (SSc), also called scleroderma, is a rare autoimmune disorder that affects the skin and internal organs. It is characterized by vasculopathy, inflammation, and fibrosis. This disease has a high morbidity and the highest case-specific mortality of any rheumatic disorder with 50% of patients dying or developing major internal organ complications within 3 years of diagnosis.

Although several medications are used to treat the skin disease associated with SSc, there is no universally effective treatment to improve the function of affected internal organs such as the lungs, heart, and gastrointestinal tract.

### **Caldolor®**

#### *Caldolor® Pediatric Launch*

We launched the promotion of Caldolor for the treatment of pain and fever in children at our National Sales Meeting in March 2016. Caldolor has been approved for use in adults for the management of pain, as well as the reduction of fever, since 2009. We received pediatric approval and three year exclusivity from the FDA of Caldolor for use in children six months of age and older in November 2015. Cumberland seeks to maximize the potential of its FDA approved product line and expand the use of its products into new patient populations. The pediatric approval and launch of Caldolor for use in children is one more achievement toward supporting those objectives.

### **Hepatoren®**

#### *Phase II Study Results*

We are developing Hepatoren as a potential treatment for Hepatorenal Syndrome ("HRS") - a life threatening condition, with a high mortality rate and no approved pharmaceutical therapy in this country. We completed a sixty-four patient Phase II study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need.

The study was designed to evaluate escalating dose levels of Hepatoren in HRS patients. Progression to higher dose levels is reviewed and approved by an independent safety committee. The study was stratified into Type I or Type II patients with HRS based upon the progression of their disease.

Top line results from this study indicated that Hepatoren was overall well tolerated in the HRS patients with no safety concerns noted. Furthermore, the Type II patients receiving the higher dose levels of Hepatoren were more likely to experience increases in urine output, a signal of improved kidney function, compared to patients who received placebo.

We are completing the data analysis and reports from this study and are planning the next steps for this development program which are expected to include a Phase IIb efficacy trial.

## **Boxaban™**

### *Phase II Study Results*

We are developing Boxaban for the treatment of Aspirin-Exacerbated Respiratory Disease ("AERD"), a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin. AERD is characterized by sharp increases in inflammatory mediators and platelet activity within the respiratory system. Ifetroban, an active thromboxane receptor antagonist, may interfere with these pathways to modify the disease and provide symptomatic relief.

We completed manufacturing of Boxaban oral capsules and completed a Phase II clinical study to evaluate Boxaban in patients suffering AERD. The study was designed to gather initial safety and tolerability data on ifetroban in AERD patients. It was a multicenter study of sixteen patients with enrollment at several U.S. medical centers including the Scripps Clinic. Results indicate that no adverse events were experienced by patients receiving Boxaban when compared to those receiving placebo. Boxaban was well tolerated and safe for subjects with a history of AERD.

We are completing the data analysis and reports for this study while also planning the next steps for this program.

## **Acetadote®**

### *Acetadote Litigation and Arbitration updates*

Information and discussion of Acetadote's competing products are included in *Part 1, Item 1, Business - Competition*, of our Form 10-K for the year ended December 31, 2015. As noted, Acetadote is our injectable formulation of N-Acetylcysteine ("NAC") for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC as well as injectable products. Our branded Acetadote and Authorized Generic Acetadote products contain the new formulation that does not include ethylene diamine tetra acetic acid ("EDTA").

As included in *Part 2, Item 1, Legal Proceedings* in this Form 10-Q for the quarter ended June 30, 2016, on September 14, 2015, the arbitrator issued a final award in our favor, enjoining Mylan Pharma Group Limited and Mylan Teoranta, together with all their affiliates, from selling, delivering, or giving away any acetylcysteine injectable drug product to another entity or person until April 30, 2018. The award notes that as the prevailing party, we are entitled to reimbursement of our attorney's fees and related costs associated with the arbitration.

As included in *Part 2, Item 1a, Risk Factors*, in this Form 10-Q for the quarter ended June 30, 2016, on September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ruled in our favor in our lawsuit against Mylan for infringement of our U.S. Patent number 8,399,445 (the "445 Acetadote Patent"). The opinion upheld our 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The court ruled that Mylan is liable to us for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

### *Acetadote Patents*

We developed a new formulation of Acetadote (*acetylcysteine*) Injection as part of the Phase IV commitment in response to a request by the FDA regarding the role of EDTA in the products formulation. During the second quarter of 2016, we obtained an additional patent for Acetadote. On May 3, 2016, the USPTO issued U.S. Patent number 9,327,028 (the "028 Acetadote Patent") which is assigned to us. The claims of the 028 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 028 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in July 2031. Since 2012, the USPTO has issued the following patents to us associated with Acetadote:



<b>Date issued</b>	<b>U.S. Patent number</b>	<b>Expiration</b>	<b>Patent claims</b>
April 2012	8,148,356	May 2026	Acetadote formulation and composition of matter
March 2013	8,399,445	August 2025	200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose
February 2014	8,653,061	August 2025	200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose
May 2014	8,722,738	April 2032	Administration method of acetylcysteine injection, without specification of the presence or lack of EDTA in the formulation
February 2015	8,952,065	August 2025	200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose
May 2016	9,327,028	July 2031	Administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection

We continue to seek additional claims to protect our intellectual property associated with Acetadote and have additional patent applications relating to Acetadote which are pending with the USPTO. We intend to defend and protect our Acetadote product and related intellectual property rights. Additional information and discussion regarding our Acetadote patents and defense is contained in *Part 1, Item 1, Business -Trademarks and Patents*, of our Form 10-K for the year ended December 31, 2015, which is incorporated by reference herein.

## CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 44 through 47 in “Management’s Discussion and Analysis” of our Annual Report on Form 10-K for the year ended December 31, 2015.

### 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 June 30, 2016 compared to the three months ended June 30, 2015

The following table presents the unaudited interim statements of operations for the three months ended June 30, 2016 and 2015:

	Three months ended June 30,		
	2016	2015	Change
Net revenues	\$ 7,414,835	\$ 8,909,741	\$ (1,494,906)
Costs and expenses:			
Cost of products sold	1,155,261	1,237,001	(81,740)
Selling and marketing	3,272,279	3,505,486	(233,207)
Research and development	678,780	828,070	(149,290)
General and administrative	1,874,396	2,153,562	(279,166)
Amortization	539,428	511,691	27,737
Total costs and expenses	7,520,144	8,235,810	(715,666)
Operating income (loss)	(105,309)	673,931	(779,240)
Interest income	31,483	57,846	(26,363)
Interest expense	(28,247)	(18,489)	(9,758)
Income (loss) before income taxes	(102,073)	713,288	(815,361)
Income tax (expense) benefit	41,135	(318,990)	360,125
Net income (loss)	\$ (60,938)	\$ 394,298	\$ (455,236)

*Net revenues.* Net revenues for the three months ended June 30, 2016 were approximately \$7.4 million compared to \$8.9 million for the three months ended June 30, 2015, representing a decrease of \$1.5 million, or 16.8%.

The following table summarizes net revenues by product for the periods presented:

	Three months ended June 30,		
	2016	2015	Change
Products:			
Acetadote	\$ 1,895,199	\$ 2,778,677	\$ (883,478)
Omeclamox-Pak	641,469	944,185	(302,716)
Kristalose	3,626,076	4,121,966	(495,890)
Vaprisol	421,800	480,034	(58,234)
Caldolor	631,893	460,052	171,841
Other	198,398	124,827	73,571
Total net revenues	\$ 7,414,835	\$ 8,909,741	\$ (1,494,906)

The change in total net revenues from the prior year period was driven primarily by decreases in Acetadote net revenue of \$0.9 million and a decrease in Kristalose revenue of \$0.5 million. Omeclamox-Pak revenue decreased by \$0.3 million compared to the second quarter of 2015 and Caldolor revenue increased by \$0.2 million compared to the second quarter of 2015.

Kristalose revenue decreased by \$0.5 million during the second quarter of 2016 when compared to the prior year period. The product's net revenue was impacted by reduced sales volume. It was positively impacted from improved pricing and improvements in product net revenue per unit. The improvement in net revenue per unit was the result of new managed care agreements entered into during 2016 that lower the amount of rebates.

Our Authorized Generic distributed by Perrigo accounted for \$0.6 million of the decrease in total Acetadote revenue. Authorized Generic sales were consistent on a sequential basis when compared to the first quarter of 2016. The comparative decrease in revenue in the second quarter of 2016 was attributable to strong sales during the three months ended June 30, 2015 as a result of the successful resolution of a temporary shortage of marketable product during a portion of the period. We experienced a decrease of \$0.3 million in our branded Acetadote net revenue. While Acetadote experienced an increase on a sequential basis, when compared to the first quarter of 2016, it is possible that our future Acetadote and Authorized Generic revenue will be impacted by generic competition.

Vaprisol and Omeclamox-Pak revenues decreased during the second quarter of 2016 when compared to the prior year period due primarily to lower sales volumes but partially offset by improved pricing.

The Caldolor product revenue increase of \$0.2 million for the three months ended June 30, 2016 was a 37.4% improvement compared to the same period last year. Caldolor revenue in the second quarter of 2016 was positively impacted by international sales and the growth in domestic volumes. During the first quarter of 2015, we experienced the highest quarterly net revenue for Caldolor since the product was launched, which impacted the second quarter of 2015. While we expect Caldolor annual product revenue to continue to grow, we anticipate quarterly fluctuations due to wholesaler and hospital buying patterns and other factors.

*Cost of products sold.* Cost of products sold for the second quarter of 2016 decreased \$0.1 million compared to the prior year. As a percentage of net revenues, cost of products sold experienced an increase to 15.6% during the three months ended June 30, 2016 compared to 13.9% during the three months ended June 30, 2015. This increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix during the quarter compared to the prior year.

*Selling and marketing.* Selling and marketing expense for the three months ended June 30, 2016 totaled approximately \$3.3 million, which was a decrease of \$0.2 million compared to the prior year's expense of \$3.5 million. The decrease was the result of decreased product royalties as well as promotional spending including print materials, direct mailings and product samples. The decreases were offset by incremental expenses as we prepare our Ethyol product launch. We continue to actively align our selling and marketing efforts and expenses to efficiently support our commercial brands.

*Research and development.* Research and development costs for the second quarter of 2016 were \$0.7 million, compared to \$0.8 million for the same period last year, representing a decrease of \$0.1 million, or approximately 18.0%. A portion of our research and development costs are variable based on the number of studies, sites and participants involved in our product development activities.

*General and administrative.* General and administrative expense decreased 13.0% to \$1.9 million for the three months ended June 30, 2016 compared to \$2.2 million for the prior year. The \$0.3 million decrease from the prior year was primarily driven by decreases in compensation and benefit expense during the period.

*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 both the three months ended June 30, 2016 and the three months ended June 30, 2015 totaled approximately \$0.5 million.

*Income taxes.* Income taxes for the three months ended June 30, 2016 decreased \$0.4 million, compared to the second quarter of 2015. The change was the result of the pretax loss in the second quarter of 2016 compared to income in the same period last year. As a percentage of income (loss) before income taxes, income taxes were 40.3% for the three months ended June 30, 2016 compared to 44.7% for the three months ended June 30, 2015.

As of June 30, 2016, we have approximately \$43.0 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.

## Six months ended June 30, 2016 compared to the six months ended June 30, 2015

The following table presents the unaudited interim statements of operations for the six months ended June 30, 2016 and 2015:

	Six months ended June 30,		
	2016	2015	Change
Net revenues	\$ 15,152,367	\$ 17,596,515	\$ (2,444,148)
Costs and expenses:			
Cost of products sold	2,379,200	2,398,842	(19,642)
Selling and marketing	6,971,241	7,036,401	(65,160)
Research and development	1,385,252	2,687,082	(1,301,830)
General and administrative	3,952,368	3,797,703	154,665
Amortization	1,070,198	998,440	71,758
Total costs and expenses	15,758,259	16,918,468	(1,160,209)
Operating income (loss)	(605,892)	678,047	(1,283,939)
Interest income	108,612	114,248	(5,636)
Interest expense	(48,689)	(34,039)	(14,650)
Income (loss) before income taxes	(545,969)	758,256	(1,304,225)
Income tax (expense) benefit	216,474	(337,446)	553,920
Net income (loss)	\$ (329,495)	\$ 420,810	\$ (750,305)

*Net revenues.* Net revenues for the six months ended June 30, 2016 were approximately \$15.2 million compared to \$17.6 million for the six months ended June 30, 2015, representing a decrease of \$2.4 million, or 13.9%.

The following table summarizes net revenues by product for the periods presented:

	Six months ended June 30,		
	2016	2015	Change
Products:			
Acetadote	\$ 3,732,661	\$ 4,321,686	\$ (589,025)
Omeclamox-Pak	1,401,788	1,702,376	(300,588)
Kristalose	7,243,882	8,220,744	(976,862)
Vaprisol	789,848	1,504,008	(714,160)
Caldolor	1,703,861	1,654,733	49,128
Other	280,327	192,968	87,359
Total net revenues	\$ 15,152,367	\$ 17,596,515	\$ (2,444,148)

The change in revenue from the prior year period was driven primarily by decreases in four of our five branded prescription products.

Kristalose revenue decreased by \$1.0 million or 11.9% primarily by reduced sales volume. This reduction was partially offset by improved pricing during the six months ended June 30, 2016. We also experienced improvements in the level of net revenue deductions from managed care as a result of new managed care agreements entered into during 2016 that lower the amount of rebates.

Vaprisol revenue decreased \$0.7 million during the six months ended June 30, 2016 compared to the prior year period primarily due to lower sales volume but partially offset by improved pricing.

Acetadote net revenue for the first six months of 2016 included \$2.4 million in revenue from sales of our Authorized Generic distributed by Perrigo, compared to \$2.3 million for the same period last year. This increase in sales of our Authorized Generic product partially offset the decrease in total Acetadote revenue. Our branded Acetadote product net revenue decreased \$0.7 million due to a reduction in sales volume as a result of generic competition. The reduced sales volume revenue decrease was partially offset by a decrease in revenue deductions related to expired products during the six months ended June 30, 2016. It is possible that our future Acetadote and Authorized Generic revenue will be impacted by generic competition.

Omeclamox-Pak revenue declined \$0.3 million during the six months ended June 30, 2016 compared to the prior year. The decrease was the result of lower sales volume.

The Caldolor product revenue experienced an increase of 3.0% during the six months ended June 30, 2016 compared to the same period last year. While we expect Caldolor annual product revenue to continue to grow, we anticipate quarterly fluctuations due to wholesaler and hospital buying patterns and other factors. Caldolor revenue in the six months ended June 30, 2016 was positively impacted by international sales.

*Cost of products sold.* Cost of products sold for the first six months of 2016 remained consistent at \$2.4 million compared to the same period in the prior year. As a percentage of net revenues, cost of products sold were 15.7% compared to 13.6% during the prior year. This increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix during the quarter compared to the prior year.

*Selling and marketing.* Selling and marketing expense for both the six months ended June 30, 2016 and the six months ended June 30, 2015 totaled approximately \$7.0 million. There were increases in certain promotional spending categories including print materials, direct mailings and product samples, offset by decreases in compensation and benefits expense. During the period we also incurred incremental expenses as we prepare our Ethylol product launch. We continue to actively align our selling and marketing efforts and expenses to efficiently support our commercial brands.

*Research and development.* Research and development costs for the first six months of 2016 were \$1.4 million, compared to \$2.7 million for the same period last year, representing a decrease of approximately \$1.3 million, or 48.4%. This change was primarily the result of a \$1.2 million required fee that accompanied the Caldolor sNDA filed with the FDA during the first quarter of 2015. This submission was successful and the FDA approved Caldolor for a pediatric indication. A portion of our research and development costs are variable based on the number of studies, sites and participants involved in our product development activities.

*General and administrative.* General and administrative expense was \$4.0 million for the six months ended June 30, 2016, compared to \$3.8 million during the same period last year. The \$0.2 million increase from the prior year was primarily driven by a \$0.3 million reduction in contingent consideration during the prior year as the result of a decrease in the cost of the Vaprisol acquisition. We also experienced increases in legal and professional fees during 2016. The general and administrative expense increases were partially offset by decreases in compensation and benefit expense during the period.

*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 six months ended June 30, 2016 totaled approximately \$1.1 million, which was an increase of \$0.1 million over the prior year. The increase in amortization was attributable to additional product and license rights, capitalized patents and patent defense costs.

*Income tax expense.* Income tax benefit for the six months ended June 30, 2016 totaled \$0.2 million, compared to income tax expense of \$0.3 million in the six months ended June 30, 2015. The change was the result of the pretax loss during the six months ended June 30, 2016 compared to the same period last year. As a percentage of income (loss) before income taxes, income tax expense was 39.6% for the six months ended June 30, 2016 compared to 44.5% for the six months ended June 30, 2015.

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Working Capital**

Our primary sources of liquidity are cash flows provided by our operations, the availability under our line of credit and the cash proceeds from our initial public offering of common stock that was completed in August 2009. We believe that our internally generated cash flows and amounts available under our line of credit will be adequate to finance internal growth and fund capital expenditures.

We invest a portion of our cash reserves in variable rate demand notes ("VRDNs") and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate, mortgage-backed securities). The 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 both June 30, 2016 and December 31, 2015, we had approximately \$14.6 million invested in marketable securities.

The following table summarizes our liquidity and working capital as of June 30, 2016 and December 31, 2015:

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
Cash and cash equivalents	\$ 35,837,240	\$ 38,203,059
Marketable securities	14,565,154	14,564,115
Total cash, cash equivalents and marketable securities	<u>\$ 50,402,394</u>	<u>\$ 52,767,174</u>
Working capital (current assets less current liabilities)	\$ 55,096,808	\$ 54,700,327
Current ratio (multiple of current assets to current liabilities)	7.2	5.4
Revolving line of credit availability	<u>\$ 8,500,000</u>	<u>\$ 10,300,000</u>

The following table summarizes our net changes in cash and cash equivalents for the six months ended June 30, 2016 and June 30, 2015:

	<b>Six months ended June 30, 2016</b>	<b>2015</b>
Net cash provided by (used in):		
Operating activities	\$ (543,936)	\$ 4,067,868
Investing activities	(1,097,827)	(2,052,929)
Financing activities	(724,056)	(2,940,295)
Net decrease in cash and cash equivalents	<u>\$ (2,365,819)</u>	<u>\$ (925,356)</u>

The net \$2.4 million decrease in cash and cash equivalents for the six months ended June 30, 2016 was attributable to cash used in operating, investing, and financing activities. Cash used in operating activities of \$0.5 million was primarily impacted by changes in our working capital of \$3.1 million, including net reductions in accounts payable and accrued liabilities of \$4.1 million. Cash used in operating activities also include the net loss for the period of \$0.3 million. These uses of operating cash were offset by non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$1.6 million. Cash used in investing activities included a net cash investment in our intangible assets of \$1.1 million and \$0.1 million associated with our investing activities in marketable securities. Our financing activities included \$1.7 million in cash used to repurchase shares of our common stock and \$1.8 million in cash provided by borrowings under our line of credit.

The \$0.9 million decrease in cash and cash equivalents for the six months ended June 30, 2015 was attributable to cash used in investing and financing activities, which was partly offset by \$4.1 million in cash generated from operations. Cash used in investing activities included a net cash investment in our intangible assets of \$2.7 million, which was partially offset by net proceeds of \$0.7 million associated with our investing activities in marketable securities. Our financing activities included \$3.4 million in cash used to repurchase shares of our common stock, \$1.6 million used to settle the remaining cash consideration for Vaprisol and \$1.7 million in cash provided by borrowings under our line of credit. Cash provided by operating activities benefited from the non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$1.7 million and included positive changes in our working capital of \$2.3 million.

As of June 30, 2016, we have approximately \$43.0 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.

On June 26, 2014, we entered into a Revolving Credit Loan Agreement ("Loan Agreement") with SunTrust Bank, which replaced the agreement with a previous lender. At June 30, 2016, we had \$3.5 million in borrowings under the Loan Agreement. On July 29, 2016, we amended the agreement to extend the original three-year term by an additional year and obtained a compliance waiver for a financial covenant as of June 30, 2016. As a result of the amendment, we are in compliance with all covenants and the loan agreement expires on June 30, 2018. The agreement provides for an aggregate principal amount up to \$20 million. The initial revolving line of credit is up to \$12 million, with the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions.

The interest rate on the Loan Agreement is based on LIBOR plus an interest rate spread. There is no LIBOR minimum and the LIBOR pricing provides for an interest rate spread of 1.0% to 2.85% (representing an interest rate of 1.5% at June 30, 2016). In addition, a fee of 0.25% per year is charged on the unused line of credit. Interest and the unused line fee are payable quarterly. Borrowings under the line of credit are collateralized by substantially all of Cumberland's assets.

Under the Loan Agreement, we are subject to certain financial covenants, including, but not limited to, maintaining an EBIT to Interest Expense Ratio and a Funded Debt Ratio, as such terms are defined in the Loan Agreement and that are determined on a quarterly basis.

## **OFF-BALANCE SHEET ARRANGEMENTS**

During the six months ended June 30, 2016 and 2015, we did not engage in any off-balance sheet arrangements.

## **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

### **Interest Rate Risk**

We are exposed to market risk related to changes in interest rates on our cash on deposit in highly-liquid money market accounts and 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. Our investment policy focuses on principal preservation and liquidity.

We believe that our interest rate risk related to our cash and cash equivalents is not material. The risk related to interest rates for these accounts would produce less income than expected if market interest rates fall. Based on current interest rates, we do not believe we are exposed to significant downside risk related to a change in interest on our money market accounts.

We invest in VRDNs and a portfolio of government backed securities (including U.S. Treasuries, government sponsored enterprise debentures and government sponsored adjustable rate mortgage backed securities) to obtain a higher return while preserving our capital. The VRDNs are generally issued by municipal governments and are backed by a financial institution letter of credit. The VRDNs allow us the ability 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. The primary risk related to interest rates for these accounts are that they will produce less income than expected if market interest rates fall. Based on the \$14.6 million in marketable securities outstanding at June 30, 2016, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income of \$0.1 million.

The interest rate related to our revolving credit facility is a variable rate based on LIBOR plus an interest rate spread. As of June 30, 2016, we had \$3.5 million in borrowings outstanding under our revolving credit facility.

### **Exchange Rate Risk**

While we operate primarily in the United States, we are exposed to foreign currency risk. A portion of our research and development is performed abroad.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange gains and losses were immaterial for the six months ended June 30, 2016 and 2015. 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 June 30, 2016. 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. During the six months ended June 30, 2016, there has not been any change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

See the discussion of our Acetadote patent defense legal proceedings contained in *Part 1, Item 1, Business -Trademarks and Patents*, of our Form 10-K for the year ended December 31, 2015, which is incorporated by reference herein.

#### Item 1a. Risk Factors

Information regarding risk factors appears on pages 22 through 37 in our Annual Report on Form 10-K for the year ended December 31, 2015 under the section titled “Risk Factors.” The following risk factor was included in our Form 10-K for the year ended December 31, 2015 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.**

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.

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.

On February 18, 2014, the USPTO issued U.S. Patent number 8,653,061 (the “061 Acetadote Patent”) which is assigned to us. The claims of the 061 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. Following its issuance, the 061 Acetadote Patent was listed in the FDA Orange Book. The 061 Acetadote Patent is scheduled to expire in August 2025.

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the “738 Acetadote Patent”) which is assigned to us. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, we became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

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 February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the “065 Acetadote Patent”) which is assigned to us. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division (“District Court”) ruled in our favor in our lawsuit against Mylan for infringement of the 445 Acetadote Patent. The opinion upheld our 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to us for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On November 17, 2015, the District Court entered an order enjoining Mylan and its affiliates from selling or using its generic version of Acetadote until August 2025, the date of expiration of the 445 Acetadote Patent. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

On May 3, 2016, the USPTO issued U.S. Patent number 9,327,028 (the “028 Acetadote Patent”) which is assigned to us. The claims of the 028 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 028 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in July 2031.

We also have additional patent applications relating to Acetadote which are pending with the USPTO and may or may not be issued. 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 U.S. patents and related international patents which include composition of matter claims that encompass the Caldolor formulation, including methods of treating pain using intravenous ibuprofen and claims 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 a competitor could try to develop, test and seek FDA approval for a sufficiently distinct formulation for another ibuprofen product that competes with Caldolor. The U.S. patents are listed in the FDA Orange Book, with one expiring in November 2021, five others expiring in September 2029 and one other expiring in September 2030. On November 20, 2015, the FDA awarded three years of marketing exclusivity to Caldolor in connection with the approval of the Caldolor supplemental new drug application. Such exclusivity extends through November 20, 2018.

We have numerous U.S. patents and related international patents for Vaprisol. These patents were acquired in our February 2014 acquisition of certain product rights, intellectual property and related assets of Vaprisol from Astellas. The primary patent is U.S. Patent No. 5,723,606 (the “606 Vaprisol Patent”) which includes composition of matter claims that encompass the Vaprisol formulation as well as methods for the intravenous treatment of patients with euvoletic hyponatremia. The 606 Vaprisol Patent is listed in the FDA Orange Book and expires in December 2019.

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

On May 13, 2010, we 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, January 2013, January 2015 and January 2016, our Board of Directors replaced the prior authorizations with new \$10.0 million authorizations for repurchases of our outstanding common stock.

The following table summarizes the activity, by month, during the six months ended June 30, 2016:

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 (1)
April	68,471	\$ 4.67	68,471	\$ 8,763,032
May	67,670 (1)	4.57	67,670	8,453,659
June	17,724	4.55	17,724	8,372,947
Total	153,865		153,865	

(1) Of this amount, 32,312 shares were repurchased directly through private purchases at the then-current fair market value of common stock.

**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 Principal 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.

August 5, 2016

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

By: /s/ Michael Bonner  
Michael Bonner  
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, A.J. Kazimi, certify that:

1. I have reviewed this Form 10-Q of Cumberland Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 5, 2016

By: /s/ A.J. Kazimi

A.J. Kazimi

Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Michael Bonner, certify that:

1. I have reviewed this Form 10-Q of Cumberland Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 5, 2016

By: /s/ Michael Bonner

Michael Bonner

Chief Financial Officer

**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**

In connection with the Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016 of Cumberland Pharmaceuticals Inc. (the “Company”), as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, A.J. Kazimi, Chief Executive Officer and Michael Bonner, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. section 1350), that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ A. J. Kazimi*

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A.J. Kazimi  
Chief Executive Officer  
August 5, 2016

*/s/ Michael Bonner*

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Michael Bonner  
Chief Financial Officer  
August 5, 2016