

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**  
**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2015

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 ☐

Accelerated filer ☐

Non-accelerated filer ☒ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

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

Class
Common stock, no par value

Outstanding at November 2, 2015
16,452,665

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## Item 1. Financial Statements (Unaudited)

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

	September 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 38,316,291	\$ 39,866,037
Marketable securities	14,438,830	14,841,418
Accounts receivable, net of allowances	5,798,393	5,504,728
Inventories	4,206,039	5,600,319
Other current assets	4,962,835	5,002,469
Total current assets	67,722,388	70,814,971
Property and equipment, net	541,771	651,030
Intangible assets, net	21,222,380	21,568,541
Other assets	2,572,698	2,370,572
Total assets	\$ 92,059,237	\$ 95,405,114
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,126,687	\$ 3,242,713
Other current liabilities	7,747,800	10,506,769
Total current liabilities	11,874,487	13,749,482
Revolving line of credit	1,700,000	—
Other long-term liabilities	940,719	902,841
Total liabilities	14,515,206	14,652,323
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,496,217 and 17,118,993 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	58,191,138	61,942,410
Retained earnings	19,398,555	18,818,263
Total shareholders' equity	77,589,693	80,760,673
Noncontrolling interests	(45,662)	(7,882)
Total equity	77,544,031	80,752,791
Total liabilities and equity	\$ 92,059,237	\$ 95,405,114

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net revenues	\$ 7,885,048	\$ 9,729,047	\$ 25,481,563	\$ 27,572,459
Costs and expenses:				
Cost of products sold	980,176	1,339,723	3,379,018	3,692,256
Selling and marketing	3,608,828	3,821,953	10,645,229	11,365,966
Research and development	757,442	934,783	3,444,524	2,622,310
General and administrative	1,794,279	2,158,057	5,591,982	6,195,523
Amortization	473,439	485,493	1,471,879	1,083,706
Total costs and expenses	7,614,164	8,740,009	24,532,632	24,959,761
Operating income	270,884	989,038	948,931	2,612,698
Interest income	64,072	108,005	178,320	204,892
Interest expense	(19,815)	(26,877)	(53,854)	(51,358)
Income before income taxes	315,141	1,070,166	1,073,397	2,766,232
Income tax expense	(193,439)	(340,982)	(530,885)	(1,052,330)
Net income	121,702	729,184	542,512	1,713,902
Net loss at subsidiary attributable to noncontrolling interests	4,911	16,736	37,780	40,908
Net income attributable to common shareholders	\$ 126,613	\$ 745,920	\$ 580,292	\$ 1,754,810
Earnings per share attributable to common shareholders				
- basic	\$ 0.01	\$ 0.04	\$ 0.03	\$ 0.10
- diluted	\$ 0.01	\$ 0.04	\$ 0.03	\$ 0.10
Weighted-average shares outstanding				
- basic	16,604,682	17,544,905	16,811,360	17,730,715
- diluted	16,996,376	17,848,110	17,193,854	17,990,561
Comprehensive income attributable to common shareholders	126,613	745,920	580,292	1,754,810
Net loss at subsidiary attributable to noncontrolling interests	4,911	16,736	37,780	40,908
Total comprehensive income	\$ 121,702	\$ 729,184	\$ 542,512	\$ 1,713,902

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net income	\$ 542,512	\$ 1,713,902
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	1,677,906	1,383,611
Deferred tax benefit (expense)	43,991	(36,255)
Share-based compensation	426,651	542,118
Excess tax benefit derived from exercise of stock options	(470,584)	(1,077,099)
Noncash interest expense	33,001	12,038
Noncash investment (gains) losses	(80,321)	138,627
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:		
Accounts receivable	(293,665)	(765,689)
Inventory	1,394,280	1,002,160
Other current assets and other assets	(239,484)	(1,354,793)
Accounts payable and other current liabilities	1,457,656	2,293,818
Other long-term liabilities	61,553	105,416
Net cash provided by operating activities	4,553,496	3,957,854
Cash flows from investing activities:		
Additions to property and equipment	(96,768)	(150,387)
Purchases of marketable securities	(5,201,240)	(3,754,903)
Proceeds from sale of marketable securities	5,684,149	3,001,735
Cash paid for acquisitions	—	(2,000,000)
Additions to intangible assets	(2,392,477)	(1,617,874)
Net cash used in investing activities	(2,006,336)	(4,521,429)
Cash flows from financing activities:		
Net borrowings on line of credit	1,700,000	—
Exercise of stock options	21,366	—
Excess tax benefit derived from exercise of stock options	470,584	1,077,099
Cash settlement of contingent consideration	(1,618,983)	—
Sale of subsidiary shares to noncontrolling interest	—	1,000,005
Repurchase of common shares	(4,669,873)	(2,738,905)
Net cash used in financing activities	(4,096,906)	(661,801)
Net decrease in cash and cash equivalents	(1,549,746)	(1,225,376)
Cash and cash equivalents at beginning of period	39,866,037	40,869,457
Cash and cash equivalents at end of period	\$ 38,316,291	\$ 39,644,081
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Net change in unpaid additions to intangibles, property and equipment	\$ 1,266,759	\$ 974,809

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, 2014	17,118,993	\$ 61,942,410	\$ 18,818,263	\$ (7,882)	\$ 80,752,791
Share-based compensation	86,102	426,651	—	—	426,651
Exercise of options and related tax benefit	3,256	491,950	—	—	491,950
Repurchase of common shares	(712,134)	(4,669,873)	—	—	(4,669,873)
Net income	—	—	580,292	(37,780)	542,512
Balance, September 30, 2015	16,496,217	\$ 58,191,138	\$ 19,398,555	\$ (45,662)	\$ 77,544,031

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, 2014 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, 2014. The results of operations for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income was comprised solely of net income for the three and nine months ended September 30, 2015 and 2014.

***Recent Accounting Guidance***

***Recently Adopted Accounting Guidance***

In April 2014, the Financial Accounting Standards Board (the "FASB") issued amended guidance in the form of a FASB Accounting Standards Update ("ASU") "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity". The new guidance restricts the presentation of discontinued operations to business circumstances when the disposal of business operations represents a strategic shift that has or will have a major effect on an entity's operations and financial results. The guidance became effective on January 1, 2015 and did not have an impact on our financial disclosures.

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

In May 2014, the FASB issued amended guidance in the form of a FASB 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 April 2015, the FASB issued amended guidance in a FASB ASU, "Interest-Imputation of Interest", which simplifies the balance sheet presentation of debt issuance costs. Under the new guidance, debt issuance costs related to a recognized debt liability will be presented on the balance sheet as a direct deduction from the liability. This treatment is consistent with the presentation of debt discounts. The new guidance is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted, and the new guidance should be applied retrospectively. In August 2015, The FASB issued additional related guidance in the form of another ASU "Interest-Imputation of Interest" that

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

specifically addressed "Line -of-Credit Arrangements". The new guidance allows the presentation of deferred debt issuance costs as an asset and subsequently amortizing these costs over the term of the line-of-credit arrangement. This guidance applies whether or not there are any borrowings on the line-of-credit. The Company does not anticipate adoption of either ASU to have a material effect on our condensed consolidated financial statements and disclosures.

In July 2015, the FASB issued amended guidance in the form of a FASB ASU on, "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.

***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. Treasury notes and bonds, U.S. Government Agency notes and bonds, and bank-guaranteed, variable rate demand notes ("VRDN"). At the time of purchase, the Company classifies marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of September 30, 2015 and December 31, 2014, 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.
- 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.



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

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:

	September 30, 2015			December 31, 2014		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$ —	\$ —	\$ —	\$ 1,338,010	\$ —	\$ 1,338,010
U.S. Agency issued mortgage-backed securities – variable rate	—	4,691,254	4,691,254	—	4,003,375	4,003,375
U.S. Agency notes and bonds – fixed rate	—	3,257,977	3,257,977	—	3,251,336	3,251,336
SBA loan pools – variable rate	—	1,754,599	1,754,599	—	1,413,697	1,413,697
Municipal bonds – VRDN	4,735,000	—	4,735,000	4,835,000	—	4,835,000
Total fair value of marketable securities	<u>\$ 4,735,000</u>	<u>\$ 9,703,830</u>	<u>\$ 14,438,830</u>	<u>\$ 6,173,010</u>	<u>\$ 8,668,408</u>	<u>\$ 14,841,418</u>

**(3) EARNINGS PER SHARE**

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three and nine months ended September 30, 2015 and 2014:

	Three months ended September 30,	
	2015	2014
Numerator:		
Net income attributable to common shareholders	\$ 126,613	\$ 745,920
Denominator:		
Weighted-average shares outstanding – basic	16,604,682	17,544,905
Dilutive effect of other securities	391,694	303,205
Weighted-average shares outstanding – diluted	<u>16,996,376</u>	<u>17,848,110</u>
	Nine months ended September 30,	
	2015	2014
Numerator:		
Net income attributable to common shareholders	\$ 580,292	\$ 1,754,810
Denominator:		
Weighted-average shares outstanding – basic	16,811,360	17,730,715
Dilutive effect of other securities	382,494	259,846
Weighted-average shares outstanding – diluted	<u>17,193,854</u>	<u>17,990,561</u>

As of September 30, 2015 and 2014, restricted stock awards and options to purchase 54,798 and 187,248 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.

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

**(4) REVENUES**

*Product Revenues*

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2015 and 2014:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Products:</b>				
Acetadote	\$ 2,065,081	\$ 3,242,014	\$ 6,386,767	\$ 9,026,919
Omeclamox-Pak	691,120	996,974	2,393,495	3,481,264
Kristalose	3,939,294	3,967,885	12,160,037	10,903,255
Vaprisol	670,621	653,070	2,199,645	2,022,835
Caldolor	352,343	821,024	2,007,076	1,950,106
Other	166,589	48,080	334,543	188,080
Total net revenues	<u>\$ 7,885,048</u>	<u>\$ 9,729,047</u>	<u>\$ 25,481,563</u>	<u>\$ 27,572,459</u>

As discussed in Note 10, Cumberland entered into an agreement on February 28, 2014 with Astellas Pharma US, Inc. ("Astellas") to acquire Vaprisol® including certain product rights, intellectual property and related assets. The Company began selling Vaprisol in March 2014 and launched promotional efforts for the brand in May 2014.

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 \$1.1 million and \$1.4 million for the third quarter of 2015 and 2014, respectively, and \$3.3 million and \$4.6 million on a year-to-date basis as of September 30, 2015 and 2014, 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 will recognize 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. The international agreements provide for \$1.4 million in non-refundable up-front payments and milestone payments of up to \$1.7 million related to regulatory approvals and up to \$4.0 million in payments related to product sales. As of September 30, 2015, the Company has recognized a cumulative \$1.4 million in upfront payments as other revenue and has not yet recorded any revenue related to the 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.

Caldolor inventory on hand at September 30, 2015 and December 31, 2014 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.

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

At September 30, 2015 and December 31, 2014, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately \$2.8 million and \$3.2 million, respectively.

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 September 30, 2015 and December 31, 2014.

As of September 30, 2015 and December 31, 2014, inventory was comprised of the following:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Raw materials	\$ 2,282,366	\$ 2,571,465
Finished goods	1,923,673	3,028,854
Total	<u>\$ 4,206,039</u>	<u>\$ 5,600,319</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 and January 2015, 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 nine months ended September 30, 2015 and the nine months ended September 30, 2014, the Company repurchased 712,134 shares and 576,978 shares of common stock for approximately \$4.7 million and \$2.7 million, respectively.

### *Restricted Share Grants*

During the nine months ended September 30, 2015, the Company issued approximately 202,786 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 \$1.7 million in borrowings under the Loan Agreement at September 30, 2015. The agreement has a three year term expiring on June 26, 2017 and 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 1.2% at September 30, 2015). 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. The Company was in compliance with all covenants at September 30, 2015.

## **(7) INCOME TAXES**

At September 30, 2015, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$43.6 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

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

taxes paid in each of the years 2009 through 2014. The Company expects to pay minimal income taxes in 2015 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 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. The award notes that as the prevailing party, the Company is entitled to reimbursement of our 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 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.

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, 2014, which is incorporated by reference herein.

## **(10) PRODUCTS ADDED DURING 2014 AND 2013**

### *Vaprisol*

On February 28, 2014, the Company acquired certain product rights, intellectual property and related assets of Vaprisol from Astellas Pharma US, Inc. ("Astellas"). Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvoletic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia. Cumberland's acquisition of Vaprisol is accounted for as a business combination and the products sales are included in the results of operations subsequent to the acquisition date.

The Company provided an upfront payment of \$2.0 million to Astellas at closing. The business combination provided for an additional milestone payment of up to \$2.0 million, dependent upon Cumberland achieving certain first year sales levels for the product. The Company paid Astellas \$1.6 million to fulfill the contingent consideration during April 2015. On a year-to-date basis the Company recognized a \$0.3 million gain on the contingent consideration as the result of the reduction in the cost of the Vaprisol acquisition. Vaprisol contributed \$0.7 million and \$0.7 million in net revenues during the three months ended

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
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**(Unaudited)**

September 30, 2015 and 2014, respectively. On a year-to-date basis, Vaprisol contributed net revenues of \$2.2 million for 2015 and \$2.0 million for 2014.

*Omeclamox-Pak*

On October 28, 2013, the Company entered into an agreement with Pernix Therapeutics ("Pernix") to distribute and promote Omeclamox-Pak. Omeclamox-Pak is a branded prescription product that combines omeprazole, amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection and duodenal ulcer disease. Under the terms of the agreement, the Company promotes the product to gastroenterologists across the United States and Pernix has been responsible for promoting the product through its specialty sales force focusing on select primary care physicians. The Company paid an upfront payment of \$4.0 million to Pernix on October 29, 2013. The agreement calls for additional milestones at the first and second anniversary dates of the execution of the agreement totaling \$4.0 million in the aggregate. Cumberland was not required to make either milestone payment to Pernix as all the criteria for these payments were not met, including Pernix's co-promotion obligations. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits are paid by Cumberland to Pernix. The Company also makes royalty payments to Pernix to reflect their ongoing sales promotional efforts.

The \$4.0 million upfront payment that the Company paid to Pernix on October 29, 2013 is included in product and license rights and is amortized over the remaining expected useful life of the acquired asset, currently the life of the agreement, which ends in June 2032. Omeclamox-Pak contributed \$0.7 million and \$1.0 million in net revenues during the three months ended September 30, 2015 and 2014, respectively. On a year-to-date basis, Omeclamox-Pak contributed net revenues of \$2.4 million for 2015 and \$3.5 million for 2014.

## 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 21 through 36, and “Special Note Regarding Forward-Looking Statements” on pages 36 and 37 of our Annual Report on Form 10-K for the year ended December 31, 2014. We do not undertake to publicly update or revise any of our forward-looking statements, even in the event that experience or future changes indicate that the anticipated results will not be realized. The following presentation of management’s discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Form 10-Q.

### OVERVIEW

#### Our Business

Cumberland Pharmaceuticals Inc. (“Cumberland,” the “Company,” or as used in the context of “we,” “us,” or “our”), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology. These 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;
- **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;
- **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; and
- **Boxaban™** (*ifetroban*) oral capsules, a Phase II candidate for the treatment of patients with Aspirin-Exacerbated Respiratory Disease.

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. In addition, we may explore further clinical work that could be used to support our sales and marketing activities and maximize their efforts to further penetrate existing markets. 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. The addition of Omeclamox-Pak and Vaprisol reflects our strategy and commitment to selectively expanding our product portfolio as both brands met our acquisition criteria. We will also continue to explore opportunities for label expansion to bring our products to new patient populations.
- **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.
- **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

### Clinigen Strategic Alliance

In September 2015, we announced our strategic alliance with Clinigen Group plc (AIM: CLIN) ("Clinigen"), the global pharmaceutical and services company. Clinigen is a specialty pharmaceutical and services company focused on delivering the right drug to the right patient at the right time by providing medicines to patients with high unmet needs through clinical trials, licensed and ethically unlicensed supply.

The alliance will combine the respective strengths, expertise and geographical footprints of Cumberland and Clinigen with respect to potential future products. Under the agreement, we will have the opportunity to support Clinigen products through distribution, marketing and promotion within the United States. Clinigen will be responsible for the marketing, promotion, distribution and sale of our pharmaceutical products in select markets outside of the United States, allowing us to use Clinigen's international reach to enter new markets for our products.

## **Cumberland Emerging Technologies**

### *Cumberland Emerging Technologies Strategic Alliance with Piramal*

In October 2015, we executed a Strategic Alliance Agreement with Piramal Enterprises Limited ("Piramal") for the manufacture and supply of Active Pharmaceutical Ingredients ("API"). Under the terms of this agreement, we will collaborate with Piramal on the manufacture and supply of API for New Chemical Entities ("NCE"). Piramal will provide both development and commercial supplies of API for select product candidates. Piramal is a diversified conglomerate with operations in over thirty countries and five API manufacturing plants.

## **Caldolor®**

### *Caldolor Patents Issued*

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty obligations related to Caldolor. During the third quarter of 2015, we obtained three additional patents for Caldolor. On July 7, 2015, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent number's 9,072,710 (the "710 Caldolor Patent") and 9,072,661 (the "661 Caldolor Patent") which are assigned to us. The claims of the 710 Caldolor Patent and the 661 Caldolor Patent include composition and methods of treating pain, inflammation and fever using intravenous ibuprofen. These Caldolor Patents are scheduled to expire in March 2032.

On August 25, 2015, the USPTO issued U.S. Patent number 9,114,068 (the "068 Caldolor Patent") which is assigned to us. The claims of the 068 Caldolor Patent include methods of treating pain and inflammation using intravenous ibuprofen. Following its issuance, the 068 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

### *Caldolor Competition*

Information and discussion of Caldolor's competing products are included in *Part 1, Item 1, Business - Competition*, of our Form 10-K for the year ended December 31, 2014. As noted, Caldolor is marketed for the treatment of pain and fever, primarily in a hospital setting. A variety of other products address the acute pain market including Dyloject, an injectable diclofenac product approved by the FDA during 2014. We anticipate this new competing product will be launched by its manufacturer during 2015.

### *Caldolor Pediatric Information*

Cumberland has completed a series of Phase IV studies for Caldolor in more than 1,000 patients in over 30 leading medical centers across the U.S. These studies included evaluation of the product in both children and adults. Following the completion of these Phase IV studies, we submitted a supplemental new drug application (sNDA) to the FDA for the product during the first quarter of 2015. This submission requested changes to the package insert to include pediatric data from Cumberland's post-marketing pediatric development program and we expect a response to this request during the fourth quarter of 2015.

### *Caldolor Label Safety Update*

In July 2015, the FDA decided to strengthen the existing cardiovascular warning for nonsteroidal anti-inflammatory drugs (NSAIDs). This is a class label change for all NSAIDs including over-the-counter and prescription products. It was previously thought that all NSAIDs may have similar cardiovascular risks. While newer information makes it less clear that the cardiovascular risks are similar for all NSAIDs, this information is not sufficient for the FDA to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID. While we have not seen a cardiovascular side effect in our extensive Caldolor safety database, we will update our Caldolor label for this requested information once it becomes finalized by the FDA.

## **Hepatoren®**

### *Top Line 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 initiated 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.

We completed the enrollment of Type II patients at the end of 2014. Top line results from these patients indicate that Hepatoren was overall well tolerated with no safety concerns noted. Furthermore, the 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. Based on these results, we will proceed with clinical development of this product candidate.

We subsequently completed enrollment of the Type I patients during the third quarter of 2015 and the analysis of those patient results is underway.

### **Boxaban™**

#### *New Phase II Program*

During 2015, Cumberland announced an expansion of its pipeline with another Phase II development program. The Company is developing Boxaban for the treatment of Aspirin-Exacerbated Respiratory Disease ("AERD"). AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin. It 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.

Cumberland completed manufacturing of Boxaban oral capsules and initiated 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. The enrollment in this study was recently completed and top line results indicate that no adverse events were experienced by patients receiving Boxaban when compared to those receiving placebo. Further analysis of the full data set obtained from the study is underway.

#### *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, 2014. 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 September 30, 2015, 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 September 30, 2015, 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. 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

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, 2014, which is incorporated by reference herein.

### **Corporate Update**

During the third quarter of 2015, we extended our lease agreement on the approximate 25,550 square feet of office space in Nashville, Tennessee for our corporate headquarters. The extended lease is now set to expire in October 2022 and we believe these facilities are adequate to meet our current and expected needs for office space.

On October 2, 2015, we announced that Rick S. Greene, who had been serving as the Company's Vice President and Chief Financial Officer, transitioned out of that role effective October 14, 2015, as he pursues interests outside of the Company. A.J. Kazimi, Chief Executive Officer of the Company, serves as the Company's Principal Financial Officer in addition to his duties as Principal Executive Officer.

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

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 43 through 46 in “Management’s Discussion and Analysis” of our Annual Report on Form 10-K for the year ended December 31, 2014.

### **Accounting Estimates and Judgments**

The preparation of condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. We base our estimates on past experience and on other factors we deem reasonable given the circumstances. Past results help form the basis of our judgments about the carrying value of assets and liabilities that cannot be determined from other sources. Actual results could differ from these estimates. These estimates, judgments and assumptions are most critical with respect to our accounting for revenue recognition, fair value of marketable securities, inventories, provision for income taxes, share-based compensation, research and development expenses and intangible assets.

## RESULTS OF OPERATIONS

### Three months ended September 30, 2015 compared to the three months ended September 30, 2014

The following table presents the unaudited interim statements of operations for the three months ended September 30, 2015 and 2014:

	Three months ended September 30,		
	2015	2014	Change
Net revenues	\$ 7,885,048	\$ 9,729,047	\$ (1,843,999)
Costs and expenses:			
Cost of products sold	980,176	1,339,723	(359,547)
Selling and marketing	3,608,828	3,821,953	(213,125)
Research and development	757,442	934,783	(177,341)
General and administrative	1,794,279	2,158,057	(363,778)
Amortization	473,439	485,493	(12,054)
Total costs and expenses	7,614,164	8,740,009	(1,125,845)
Operating income	270,884	989,038	(718,154)
Interest income	64,072	108,005	(43,933)
Interest expense	(19,815)	(26,877)	7,062
Income before income taxes	315,141	1,070,166	(755,025)
Income tax expense	(193,439)	(340,982)	147,543
Net income	\$ 121,702	\$ 729,184	\$ (607,482)

*Net revenues.* Net revenues for the three months ended September 30, 2015 were approximately \$7.9 million compared to \$9.7 million for the three months ended September 30, 2014, representing a decrease of \$1.8 million, or 19.0%.

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

	Three months ended September 30,		
	2015	2014	Change
Products:			
Acetadote	\$ 2,065,081	\$ 3,242,014	\$ (1,176,933)
Omeclamox-Pak	691,120	996,974	(305,854)
Kristalose	3,939,294	3,967,885	(28,591)
Vaprisol	670,621	653,070	17,551
Caldolor	352,343	821,024	(468,681)
Other	166,589	48,080	118,509
Total net revenues	\$ 7,885,048	\$ 9,729,047	\$ (1,843,999)

The change in revenue from the prior year period was driven primarily by a \$1.2 million reduction in Acetadote revenue and decreases in Caldolor revenue of \$0.5 million and Omeclamox-Pak revenue of \$0.3 million, while Vaprisol net revenue improved compared to the third quarter of 2014.

Our branded Acetadote net revenue accounted for \$0.8 million of the decline in total Acetadote revenue. This decrease was primarily due to a reduction in sales volume during the three months ended September 30, 2015 as a result of generic competition. Total Acetadote net revenue for the third quarter of 2015 and 2014 included \$1.1 million and \$1.4 million in revenue, respectively, from sales of our Authorized Generic distributed by Perrigo. It is likely that there will be further reductions in our revenue generated by Acetadote and our Authorized Generic as a result of generic competition.

The Caldolor product revenue decrease of \$0.5 million for the three months ended September 30, 2015 was a 57.1% decline compared to the same period last year. The revenue decline was primarily due to the resumption in the supply of competing products following shortages earlier in the year. During the first quarter of 2015, we experienced the highest quarterly net revenue for Caldolor since the product was launched, which has impacted this product's revenue and sales volume in the following two quarters. While we expect 2015 Caldolor annual product revenue to continue to grow compared to 2014, we

anticipate quarterly fluctuations due to wholesaler and hospital buying patterns and other factors. During the third quarter of 2014 we also experienced higher than average net revenue for our Caldolor brand. Caldolor revenue in the third quarter of 2015 was also impacted by the lack of international sales while awaiting new supplies of the product. International Caldolor sales are expected to resume in the fourth quarter of 2015.

During the third quarter of 2015, Omeclamox-Pak revenue decreased \$0.3 million compared to the same period last year. The decrease was the result of lower sales volume partially offset by improved pricing. The sales volume decrease was impacted by the lack of sales calls supporting the product by our co-promotion partner for this period.

Kristalose revenue remained relatively consistent during the third quarter of 2015 when compared to the prior year period. The product's net revenue was negatively impacted by reduced sales volume. It was positively impacted from improved pricing and improvements in product net revenue per unit as we incurred a lower level of net revenue deductions from managed care contracts.

Vaprisol's revenue increase over the prior year was attributable to improved pricing with relatively consistent sales volume.

*Cost of products sold.* Cost of products sold for the third quarter of 2015 decreased \$0.4 million compared to the prior year. As a percentage of net revenues, cost of products sold experienced a decrease to 12.4% during the three months ended September 30, 2015 compared to 13.8% during the three months ended September 30, 2014. This decrease in costs of products sold as a percentage of revenue was attributable to a change in product mix during the quarter compared to the prior year.

*Selling and marketing.* Selling and marketing expense for the three months ended September 30, 2015 totaled approximately \$3.6 million, which was a decrease of \$0.2 million compared to the prior year's expense of \$3.8 million. The decrease was the result of a \$0.1 million reduction in Omeclamox product royalties and a decrease in sales force and promotional expenses. We continue to actively manage our selling and marketing efforts and expenses to efficiently support our five commercial brands.

*Research and development.* Research and development costs for the third quarter of 2015 were \$0.8 million, compared to \$0.9 million for the same period last year, representing a decrease of approximately 19.0%. We continued to fund clinical studies for both our Boxaban and Hepatoren product candidates during the third quarter of 2015. 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 16.9% to \$1.8 million for the three months ended September 30, 2015 compared to \$2.2 million for the prior year. The \$0.4 million decrease was primarily driven by a decrease 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 September 30, 2015 and the three months ended September 30, 2014 totaled approximately \$0.5 million.

*Income tax expense.* Income tax expense for the three months ended September 30, 2015 totaled \$0.2 million, compared to income tax expense of \$0.3 million in the third quarter of 2014. The change was the result of the reduction in pretax income in the third quarter of 2015 compared to the same period last year. As a percentage of income before income taxes, income tax expense was 61.4% for the three months ended September 30, 2015 compared to 31.9% for the three months ended September 30, 2014. The income tax rate for the three months ended September 30, 2015 was primarily a result of the lower pretax income impacted by adjustments to our valuation allowance and increases in our state income tax expense, including changes from legislation. The income tax rate for the three months ended September 30, 2014 was positively impacted by a reduction in our state tax expense during 2014.

As of September 30, 2015, we have approximately \$43.6 million of unrecognized net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that will be used to significantly offset future income tax obligations. These benefits will be recognized in the year in which they are able to reduce current income taxes payable.

#### **Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014**

The following table presents the unaudited interim statements of operations for the nine months ended September 30, 2015 and 2014:

	Nine months ended September 30,		
	2015	2014	Change
Net revenues	\$ 25,481,563	\$ 27,572,459	\$ (2,090,896)
Costs and expenses:			
Cost of products sold	3,379,018	3,692,256	(313,238)
Selling and marketing	10,645,229	11,365,966	(720,737)
Research and development	3,444,524	2,622,310	822,214
General and administrative	5,591,982	6,195,523	(603,541)
Amortization	1,471,879	1,083,706	388,173
Total costs and expenses	24,532,632	24,959,761	(427,129)
Operating income	948,931	2,612,698	(1,663,767)
Interest income	178,320	204,892	(26,572)
Interest expense	(53,854)	(51,358)	(2,496)
Income before income taxes	1,073,397	2,766,232	(1,692,835)
Income tax expense	(530,885)	(1,052,330)	521,445
Net income	\$ 542,512	\$ 1,713,902	\$ (1,171,390)

*Net revenues.* Net revenues for the nine months ended September 30, 2015 were approximately \$25.5 million compared to \$27.6 million for the nine months ended September 30, 2014, representing a decrease of \$2.1 million, or 7.6%.

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

	Nine months ended September 30,		
	2015	2014	Change
Products:			
Acetadote	\$ 6,386,767	\$ 9,026,919	\$ (2,640,152)
Omeclamox-Pak	2,393,495	3,481,264	(1,087,769)
Kristalose	12,160,037	10,903,255	1,256,782
Vaprisol	2,199,645	2,022,835	176,810
Caldolor	2,007,076	1,950,106	56,970
Other	334,543	188,080	146,463
Total net revenues	\$ 25,481,563	\$ 27,572,459	\$ (2,090,896)

Revenue increases in three of our five branded prescription products were offset by decreases in Omeclamox-Pak revenue of \$1.1 million and Acetadote product revenue of \$2.6 million. Our products with revenue gains were led by increases in Kristalose revenue of \$1.3 million and Vaprisol revenue of \$0.2 million.

Kristalose revenue increased by \$1.3 million or 11.5% over the prior year period primarily due to new positioning for the product. We increased the price of Kristalose during the first quarter of 2014 to bring Kristalose more in line with the other marketed branded prescription products in its class. Concurrent with the price increase, we increased our patient focused initiatives to enhance patient affordability and increase demand. During the nine months ended September 30, 2015 we also experienced improvements in product net revenue per unit as we incurred a lower level of net revenue deductions from managed care contracts.

Vaprisol revenue increased 8.7% during the nine months ended September 30, 2015 compared to the prior year period primarily due to greater sales volume as a result of owning the product two additional months during 2015 compared to 2014. This increase was partly offset by lower sales volume during a portion of the nine months ended September 30, 2015 as we transitioned our marketable inventory from the Astellas labeled product to our Cumberland labeled product. Vaprisol's revenue increase over the prior year was also attributable to improved pricing.

The Caldolor product revenue also experienced a \$0.1 million improvement which represents an increase of 2.9% during the nine months ended September 30, 2015 compared to the same period last year. Caldolor sales and net revenue were positively impacted by the efforts of our sales force, marketing initiatives and a temporary shortage of a competing product. While we expect 2015 Caldolor annual product revenue to continue to grow compared to 2014, we anticipate quarterly fluctuations due to wholesaler buying patterns and other factors.

Acetadote net revenue for the first nine months of 2015 included \$3.3 million in revenue from sales of our Authorized Generic distributed by Perrigo, compared to \$4.6 million for the same period last year. This decrease in sales of our Authorized Generic product accounted for almost half of the decline in total Acetadote revenue. The Authorized Generic sales were impacted by a temporary packaging delay and resulting shortage of marketable product that impacted revenue during a portion of the year-to-date period. Our branded Acetadote product net revenue decreased \$1.4 million due to a reduction in sales volume as a result of generic competition, along with an increase in revenue deductions related to an increase in expired product during the first quarter of 2015. It is likely that there will be further reductions in our revenue generated by Acetadote and our Authorized Generic as a result of generic competition.

Omeclamox-Pak revenue declined 31.2% during the first nine months of 2015 compared to the prior year. The decrease was the result of lower sales volume partially offset by improved pricing. The sales volume decrease was impacted by the lack of sales calls supporting the product by our co-promotion partner for this period.

*Cost of products sold.* Cost of products sold for the first nine months of 2015 decreased 8.5% as compared to the same period in the prior year. As a percentage of net revenues, cost of products sold was consistent with the prior year at 13.3% and is in line with the decline in net revenues.

*Selling and marketing.* Selling and marketing expense for the nine months ended September 30, 2015 totaled approximately \$10.6 million, which was a decrease of \$0.7 million compared to the prior year's expense of \$11.4 million. The decrease was the result of a \$0.3 million reduction in Omeclamox product royalties as well as decreases in sales force salaries and related costs. These decreases were partially offset by an increase in non-personal promotional spending. We continue to actively manage our selling and marketing efforts and expenses under our strategy to efficiently support our five commercial brands.

*Research and development.* Research and development costs for the first nine months of 2015 were \$3.4 million, compared to \$2.6 million for the same period last year, representing an increase of approximately \$0.8 million, or 31.4%. This change was 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 requested changes to the Caldolor package insert to include pediatric data from Cumberland's post-marketing pediatric development program. We continued to fund clinical studies for both our Boxaban and Hepatoren product candidates during 2015. 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 \$5.6 million for the nine months ended September 30, 2015, compared to \$6.2 million during the same period last year. The \$0.6 million decrease was primarily driven by a \$0.3 million gain on contingent consideration as the result of a reduction in the cost of the Vaprisol acquisition. General and administrative expense was also benefited by a reduction in our travel and legal fees along with a decrease 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 nine months ended September 30, 2015 totaled approximately \$1.5 million, which was an increase of \$0.4 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 expense for the nine months ended September 30, 2015 totaled \$0.5 million, compared to income tax expense of \$1.1 million in the nine months ended September 30, 2014. The change was the result of the reduction in pretax income in the first nine months of 2015 compared to the same period last year. As a percentage of income before income taxes, income tax expense was 49.5% for the nine months ended September 30, 2015 compared to 38.0% for the nine months ended September 30, 2014. The income tax rate for the nine months ended September 30, 2015 was primarily a result of the lower pretax income impacted by adjustments to our valuation allowance and increases in our state income tax expense, including changes from legislation. The income tax rate for the nine months ended September 30, 2014 was positively impacted by a reduction in our state tax expense during 2014.

## **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. For the nine months ended September 30, 2015 and 2014, we generated \$4.6 million and \$4.0 million in cash flow from operations, respectively, and we borrowed \$1.7 million on our line of credit during 2015. 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 September 30, 2015 and December 31, 2014, we had approximately \$14.4 million and \$14.8 million invested in marketable securities, respectively.

The following table summarizes our liquidity and working capital as of September 30, 2015 and December 31, 2014:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Cash and cash equivalents	\$ 38,316,291	\$ 39,866,037
Marketable securities	14,438,830	14,841,418
Total cash, cash equivalents and marketable securities	<u>\$ 52,755,121</u>	<u>\$ 54,707,455</u>
Working capital (current assets less current liabilities)	\$ 55,847,901	\$ 57,065,489
Current ratio (multiple of current assets to current liabilities)	5.7	5.2
Revolving line of credit availability	<u>\$ 10,300,000</u>	<u>\$ 12,000,000</u>

The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2015 and September 30, 2014:

	<b>Nine months ended September 30, 2015</b>	<b>2014</b>
Net cash provided by (used in):		
Operating activities	\$ 4,553,496	\$ 3,957,854
Investing activities	(2,006,336)	(4,521,429)
Financing activities	(4,096,906)	(661,801)
Net decrease in cash and cash equivalents	<u>\$ (1,549,746)</u>	<u>\$ (1,225,376)</u>

Operating activities provided \$4.6 million in cash during the nine months ended September 30, 2015. The net \$1.5 million decrease in cash and cash equivalents for the nine months ended September 30, 2015 was attributable to cash used in investing and financing activities, which was partly offset by the \$4.6 million in cash generated from operations. Cash used in investing activities included a net cash investment in our intangible assets of \$2.4 million, which was partially offset by net proceeds of \$0.5 million associated with our investing activities in marketable securities. Our financing activities included \$4.7 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 \$2.1 million and included positive changes in our working capital of \$2.4 million.

Operating activities provided \$4.0 million in cash during the nine months ended September 30, 2014. The net decrease in cash and cash equivalents for the nine months ended September 30, 2014 was mainly attributable to our \$2.0 million payment for the acquisition of Vaprisol, which is included in investing activities. We also used cash in investing activities as we increased our net investment in marketable securities by \$0.8 million and our intangible assets by \$1.6 million. Our financing activities included the \$1.0 million investment Gloria Pharmaceuticals Co. Ltd. made in CET and the repurchase of shares of our common stock totaling \$2.7 million during the nine months ended September 30, 2014. Cash provided by operating activities was \$4.0 million and included net income of \$1.7 million.

As of September 30, 2015, we have approximately \$43.6 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 September 30, 2015 we had \$1.7 million in borrowings under the Loan Agreement. The agreement has a three year term expiring on June 26, 2017 and 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 1.2% at September 30, 2015). 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, 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. We were in compliance with all covenants at September 30, 2015.

## **OFF-BALANCE SHEET ARRANGEMENTS**

During the nine months ended September 30, 2015 and 2014, 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 \$14.4 million in marketable securities outstanding at September 30, 2015, 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 September 30, 2015, we had \$1.7 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 nine months ended September 30, 2015 and 2014. Neither a 10% increase nor decrease from current exchange rates would have a significant effect on our operating results or financial condition.

### **Item 4. Controls and Procedures**

Our principal executive and principal financial officers evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2015. 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 three months ended September 30, 2015, 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

On April 14, 2014, we filed with the American Arbitration Association a request for arbitration with Mylan Inc., Mylan Institutional LLC, Mylan Pharma Group Limited, and Mylan Teoranta (collectively, “Mylan”). We are seeking to arbitrate claims against Mylan in connection with our Alliance Agreement dated January 15, 2002, and Manufacturing and Supply Agreement as amended April 25, 2011, which require that Mylan and its affiliates manufacture and supply acetylcysteine drug product, including Acetadote, for us exclusively until April 2016. We have asserted in the request for arbitration claims against Mylan for breach of contract, breach of implied covenant of good faith and fair dealing, and unjust enrichment and seek monetary damages or to enjoin Mylan and its affiliates from selling or supplying acetylcysteine drug product to another entity or person until April 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.

Also 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, 2014, which is incorporated by reference herein.

### Item 1a. Risk Factors

Information regarding risk factors appears on pages 21 through 36 in our Annual Report on Form 10-K for the year ended December 31, 2014 under the section titled “Risk Factors.” The following risk factor was included in our Form 10-K for the year ended December 31, 2014 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 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 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.

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, two others expiring in September 2029 and one other expiring in September 2030.

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

The following table summarizes our purchase of Cumberland equity securities during the three months ended September 30, 2015:

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)
July	69,642	\$ 6.79	69,642	\$ 6,500,014
August	62,303	6.03	62,303	6,124,170
September	76,655 (1)	6.07	76,655	5,659,194
Total	208,600		208,600	

(1) Of this amount, 1,702 shares were repurchased directly through private purchases at the then-current fair market value of common stock.

**Item 6. Exhibits**

No.	Description
10.21.3 ††	Third Amendment to Office Lease Agreement, dated September 29, 2015, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc.
31.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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
††	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Quarterly Report and submitted separately to the Securities and Exchange Commission.

## SIGNATURES

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

Cumberland Pharmaceuticals Inc.

Dated: November 6, 2015

By: /s/ A. J. Kazimi

A. J. Kazimi  
Chief Executive and  
Principal Financial Officer

\*Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment which has been filed separately with the SEC.

### THIRD AMENDMENT TO OFFICE LEASE AGREEMENT

THIS THIRD AMENDMENT TO OFFICE LEASE AGREEMENT (this “**Amendment**”) is entered into between **2525 WEST END, LLC**, a Delaware limited liability company (“**Landlord**”), and **CUMBERLAND PHARMACEUTICALS INC.**, a Tennessee corporation (“**Tenant**”), with reference to the following:

A. Nashville Hines Development, LLC (predecessor-in-interest to Landlord) and Tenant entered into that certain Office Lease Agreement dated September 10, 2005; Landlord and Tenant entered into that certain First Amendment to Office Lease Agreement dated April 25, 2008, and that certain Second Amendment to Lease dated March 2, 2010 (as amended, the “**Lease**”) currently covering approximately 25,523 RSF on the ninth (9th) floor (the “**Premises**”) of 2525 West End Avenue, Nashville, Tennessee (the “**Building**”).

B. Landlord and Tenant now desire to further amend the Lease as set forth below. Unless otherwise expressly provided in this Amendment, capitalized terms used in this Amendment shall have the same meanings as in the Lease.

FOR GOOD AND VALUABLE CONSIDERATION, the receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. **Third Extension Period.** The Term of the Lease for the Premises shall be extended for a period of 6 years commencing November 1, 2016 and expiring October 31, 2022 (“**Third Extension Period**”). Tenant acknowledges that it has no further extension or renewal rights or options under the Lease.

2. **Base Rental.** Commencing on November 1, 2016, and continuing through the Third Extension Period, Tenant shall, at the time and place and in the manner provided in the Lease, pay to Landlord as Base Rental for the Premises the amounts set forth in the following rent schedule, plus any applicable tax thereon:

<u>PERIOD</u>	<u>Rate</u>	<u>Monthly Base Rental</u>
November 1, 2016 through October 31, 2017	\$ [***]	\$ [***]
November 1, 2017 through October 31, 2018	\$ [***]	\$ [***]
November 1, 2018 through October 31, 2019	\$ [***]	\$ [***]
November 1, 2019 through October 31, 2020	\$ [***]	\$ [***]
November 1, 2020 through October 31, 2021	\$ [***]	\$ [***]
November 1, 2021 through October 31, 2022	\$ [***]	\$ [***]

3. **Additional Rent.** Commencing on November 1, 2016 and continuing through the Third Extension Period, the Expense Stop for the Premises refers to Landlord absorbing and being responsible for paying Operating Expenses (as defined in the Lease) during any calendar year to the extent such Operating Expenses are less than \$[\*\*\*] per square foot of space in the Building leased to rent paying tenants as such term is used in Section 2.3(c) of the Lease.

4. **Condition of the Premises.** Tenant accepts the Premises in its “as-is” condition. Tenant acknowledges that Landlord has not undertaken to perform any modification, alteration or improvement to the Premises. **BY TAKING POSSESSION OF THE PREMISES, TENANT WAIVES (i) ANY CLAIMS DUE TO DEFECTS IN THE PREMISES; AND (ii) ALL EXPRESS AND IMPLIED WARRANTIES OF SUITABILITY, HABITABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE.** Tenant waives the right to terminate the Lease due to the condition of the Premises.

5. **Consent.** This Amendment is subject to, and conditioned upon, any required consent or approval being unconditionally granted by Landlord’s mortgagee(s). If any such consent shall be denied, or granted subject to an unacceptable condition, this Amendment shall be null and void and the Lease shall remain unchanged and in full force and effect.

6. **No Broker.** Tenant represents and warrants that it has not been represented by any broker or agent in connection with the execution of this Amendment. Tenant shall indemnify and hold harmless Landlord and its designated property management, construction and marketing firms, and their respective partners, members, affiliates and subsidiaries, and all of their respective

officers, directors, shareholders, employees, servants, partners, members, representatives, insurers and agents from and against all claims (including costs of defense and investigation) of any broker or agent or similar party claiming by, through or under Tenant in connection with this Amendment.

**7. Time of the Essence.** Time is of the essence with respect to Tenant's execution and delivery to Landlord of this Amendment. If Tenant fails to execute and deliver a signed copy of this Amendment to Landlord by 5:00 p.m. (in the city in which the Premises is located) on September 1, 2015, this Amendment shall be deemed null and void and shall have no force or effect, unless otherwise agreed in writing by Landlord. Landlord's acceptance, execution and return of this Amendment shall constitute Landlord's agreement to waive Tenant's failure to meet such deadline.

**8. Miscellaneous.** This Amendment shall become effective only upon full execution and delivery of this Amendment by Landlord and Tenant. This Amendment contains the parties' entire agreement regarding the subject matter covered by this Amendment, and supersedes all prior correspondence, negotiations, and agreements, if any, whether oral or written, between the parties concerning such subject matter. There are no contemporaneous oral agreements, and there are no representations or warranties between the parties not contained in this Amendment. Except as modified by this Amendment, the terms and provisions of the Lease shall remain in full force and effect, and the Lease, as modified by this Amendment, shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

[Signatures to follow]



LANDLORD AND TENANT enter into this Amendment as of the Effective Date (below).

**LANDLORD:**

**2525 WEST END, LLC**, a Delaware limited liability company

By: Cash Flow Asset Management, L.P., a Texas limited partnership, its sole manager

By: CFAM GP, L.L.C., a Texas limited liability company, its sole general partner

By: /s/ Aaron P. Russell

Name: Aaron P. Russell

Title: Asset Manager

Effective Date: September 29, 2015

**TENANT:**

**CUMBERLAND PHARMACEUTICALS INC.**, a Tennessee corporation

By: /s/ A.J. Kazimi

Name: A.J. Kazimi

Title: Chief Executive 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.

November 6, 2015

By: /s/ A.J. Kazimi

A.J. Kazimi

Chief Executive and  
Principal 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 September 30, 2015 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 and Principal 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 and  
Principal Financial Officer

November 6, 2015