

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

August 07, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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)

(615) 255-0068

(Registrant's Telephone Number, Including Area Code)

37203

(Zip 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 August 3, 2015

16,628,171

CUMBERLAND PHARMACEUTICALS INC.  
INDEX

<u>PART I – FINANCIAL INFORMATION</u>	<u>1</u>
<u>Item 1. Financial Statements (Unaudited)</u>	<u>1</u>
<u>Condensed Consolidated Balance Sheets</u>	<u>1</u>
<u>Condensed Consolidated Statements of Income and Comprehensive Income</u>	<u>2</u>
<u>Condensed Consolidated Statements of Cash Flows</u>	<u>3</u>
<u>Condensed Consolidated Statement of Equity</u>	<u>4</u>
<u>Notes to the Unaudited Condensed Consolidated Financial Statements</u>	<u>5</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>12</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>22</u>
<u>Item 4. Controls and Procedures</u>	<u>22</u>
<u>PART II – OTHER INFORMATION</u>	<u>23</u>
<u>Item 1. Legal Proceedings</u>	<u>23</u>
<u>Item 1A. Risk Factors</u>	<u>23</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>25</u>
<u>Item 6. Exhibits</u>	<u>26</u>
<u>SIGNATURES</u>	<u>27</u>

---

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements (Unaudited)

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$38,940,681	\$39,866,037
Marketable securities	14,136,925	14,841,418
Accounts receivable, net of allowances	5,808,014	5,504,728
Inventories	4,795,543	5,600,319
Other current assets	4,519,796	5,002,469
Total current assets	68,200,959	70,814,971
Property and equipment, net	568,759	651,030
Intangible assets, net	21,760,085	21,568,541
Other assets	2,386,924	2,370,572
Total assets	\$92,916,727	\$95,405,114
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$4,110,082	\$3,242,713
Other current liabilities	7,437,924	10,506,769
Total current liabilities	11,548,006	13,749,482
Revolving line of credit	1,700,000	—
Other long-term liabilities	966,829	902,841
Total liabilities	14,214,835	14,652,323
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,703,493 and 17,118,993 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	59,470,701	61,942,410
Retained earnings	19,270,542	18,818,263
Total shareholders' equity	78,741,243	80,760,673
Noncontrolling interests	(39,351)	(7,882)
Total equity	78,701,892	80,752,791
Total liabilities and equity	\$92,916,727	\$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 June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Net revenues	\$8,909,741	\$9,750,168	\$17,596,515	\$17,843,412
Costs and expenses:				
Cost of products sold	1,237,001	1,298,816	2,398,842	2,352,533
Selling and marketing	3,505,486	3,930,082	7,036,401	7,544,013
Research and development	828,070	861,154	2,687,082	1,687,527
General and administrative	2,153,562	2,140,249	3,797,703	4,037,466
Amortization	511,691	304,258	998,440	598,213
Total costs and expenses	8,235,810	8,534,559	16,918,468	16,219,752
Operating income	673,931	1,215,609	678,047	1,623,660
Interest income	57,846	29,544	114,248	96,887
Interest expense	(18,489)	) (12,278)	) (34,039)	) (24,481)
Income before income taxes	713,288	1,232,875	758,256	1,696,066
Income tax expense	(318,990)	) (523,339)	) (337,446)	) (711,348)
Net income	394,298	709,536	420,810	984,718
Net loss at subsidiary attributable to noncontrolling interests	11,700	13,034	31,469	24,172
Net income attributable to common shareholders	\$405,998	\$722,570	\$452,279	\$1,008,890
Earnings per share attributable to common shareholders				
- basic	\$0.02	\$0.04	\$0.03	\$0.06
- diluted	\$0.02	\$0.04	\$0.03	\$0.06
Weighted-average shares outstanding				
- basic	16,820,725	17,743,395	16,916,193	17,825,174
- diluted	17,184,345	18,025,913	17,294,087	18,093,391
Comprehensive income attributable to common shareholders	405,998	722,570	452,279	1,008,890
Net loss at subsidiary attributable to noncontrolling interests	11,700	13,034	31,469	24,172
Total comprehensive income	\$394,298	\$709,536	\$420,810	\$984,718

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six months ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net income	\$420,810	\$984,718
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	1,143,002	800,231
Deferred tax benefit	23,593	—
Share-based compensation	549,603	325,344
Excess tax benefit derived from exercise of stock options	(313,955)	(711,348)
Noncash interest expense	19,782	12,038
Noncash investment (gains) losses	(44,870)	181,950
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:		
Accounts receivable	(303,286)	(1,484,052)
Inventory	804,776	136,039
Other current assets and other assets	422,946	(701,604)
Accounts payable and other current liabilities	1,265,725	2,165,828
Other long-term liabilities	79,742	109,244
Net cash provided by operating activities	4,067,868	1,818,388
Cash flows from investing activities:		
Additions to property and equipment	(62,291)	(48,239)
Purchases of marketable securities	(4,046,142)	(3,254,903)
Proceeds from sale of marketable securities	4,795,505	2,267,082
Cash paid for acquisitions	—	(2,000,000)
Additions to intangible assets	(2,740,001)	(732,072)
Net cash used in investing activities	(2,052,929)	(3,768,132)
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	313,955	711,348
Cash settlement of contingent consideration	(1,618,983)	—
Sale of subsidiary shares to noncontrolling interest	—	1,000,005
Repurchase of common shares	(3,356,633)	(1,580,225)
Net cash (used in) provided by financing activities	(2,940,295)	131,128
Net decrease in cash and cash equivalents	(925,356)	(1,818,616)
Cash and cash equivalents at beginning of period	39,866,037	40,869,457
Cash and cash equivalents at end of period	\$38,940,681	\$39,050,841
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Net change in unpaid additions to intangibles, property and equipment	\$1,550,017	\$450,781
See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.		

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statement of Equity

(Unaudited)

	Common stock		Retained	Noncontrolling	Total equity
	Shares	Amount	earnings	interests	
Balance, December 31, 2014	17,118,993	\$61,942,410	\$18,818,263	\$ (7,882 )	\$80,752,791
Share-based compensation	86,102	549,603	—	—	549,603
Exercise of options and related tax benefit	2,000	335,321	—	—	335,321
Repurchase of common shares	(503,602 )	(3,356,633 )	—	—	(3,356,633 )
Net income	—	—	452,279	(31,469 )	420,810
Balance, June 30, 2015	16,703,493	\$59,470,701	\$19,270,542	\$ (39,351 )	\$78,701,892

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 six months ended June 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 six months ended June 30, 2015 and 2014.

#### Recent 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") on "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.

In May 2014, the FASB issued amended guidance in the form of a FASB ASU on, "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 on January 1, 2017. In April 2015, the FASB proposed for comment, a potential one year deferral of the adoption date, which may extend the effective date to January 1, 2018. Adoption prior to January 1, 2017 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 on, "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. The Company is currently assessing the potential financial reporting impact of the new standard.

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



CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

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 June 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.

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.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

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

	June 30, 2015			December 31, 2014		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$ 461,626	\$—	\$ 461,626	\$ 1,338,010	\$—	\$ 1,338,010
U.S. Agency issued mortgage-backed securities – variable rate	—	4,849,357	4,849,357	—	4,003,375	4,003,375
U.S. Agency notes and bonds – fixed rate	—	2,751,473	2,751,473	—	3,251,336	3,251,336
SBA loan pools – variable rate	—	1,339,469	1,339,469	—	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	\$ 5,196,626	\$ 8,940,299	\$ 14,136,925	\$ 6,173,010	\$ 8,668,408	\$ 14,841,418

## (3) EARNINGS PER SHARE

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

	Three months ended June 30,	
	2015	2014
Numerator:		
Net income attributable to common shareholders	\$ 405,998	\$ 722,570
Denominator:		
Weighted-average shares outstanding – basic	16,820,725	17,743,395
Dilutive effect of other securities	363,620	282,518
Weighted-average shares outstanding – diluted	17,184,345	18,025,913
Six months ended June 30,		
2015		
2014		
Numerator:		
Net income attributable to common shareholders	\$ 452,279	\$ 1,008,890
Denominator:		
Weighted-average shares outstanding – basic	16,916,193	17,825,174
Dilutive effect of other securities	377,894	268,217
Weighted-average shares outstanding – diluted	17,294,087	18,093,391

As of June 30, 2015 and 2014, restricted stock awards and options to purchase 53,968 and 188,814 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 six months ended June 30, 2015 and 2014:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Products:				
Acetadote	\$2,778,677	\$3,063,819	\$4,321,686	\$5,784,905
Omeclamox-Pak	944,185	1,344,869	1,702,376	2,484,290
Kristalose	4,121,966	3,559,313	8,220,744	6,935,370
Vaprisol	480,034	1,071,433	1,504,008	1,369,765
Caldolor	460,052	626,684	1,654,733	1,129,082
Other	124,827	84,050	192,968	140,000
Total net revenues	\$8,909,741	\$9,750,168	\$17,596,515	\$17,843,412

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 \$1.8 million for both the second quarter of 2015 and 2014 and \$2.3 million and \$3.2 million on a year-to-date basis as of June 30, 2015 and 2014, respectively.

## Other Revenues

The Company has entered into agreements with a group of 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 related to product sales. As of June 30, 2015, the Company has recognized a cumulative \$1.4 million in other revenue for the upfront payments and no revenues related to milestones under 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 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 June 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.

At June 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 \$2.9 million and \$3.2 million, respectively.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

In connection with the acquisition of certain product rights related to the Kristalose brand, the Company is responsible for the purchase of the active pharmaceutical ingredient ("API") for Kristalose and maintains the inventory at the third-party manufacturer. As the API is consumed in production, the value of the API is transferred from raw materials to finished goods. API for the Company's Vaprisol brand is also included in the raw materials inventory total at June 30, 2015 and December 31, 2014.

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

	June 30, 2015	December 31, 2014
Raw materials	\$2,744,170	\$2,571,465
Finished goods	2,051,373	3,028,854
Total	\$4,795,543	\$5,600,319

## (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 six months ended June 30, 2015 and the six months ended June 30, 2014, the Company repurchased 503,602 shares and 340,436 shares of common stock for approximately \$3.4 million and \$1.6 million, respectively.

## Restricted Share Grants

During the six months ended June 30, 2015, the Company issued approximately 201,000 shares of restricted stock to employees and directors. Restricted stock issued to employees generally cliff-vests on the fourth anniversary of the date of grant. Restricted stock issued to directors vests on the one year anniversary of the date of grant. Stock compensation expense is presented as a component of general and administrative expense in the condensed consolidated statements of 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 June 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 1.184% at June 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 June 30, 2015.

## (7) INCOME TAXES

At June 30, 2015, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$43.9 million. These benefits occurred as a result of the actual tax benefit realized upon an employee's exercise exceeding the cumulative book compensation charge associated with the awards and will be recognized in the year in which they are able to reduce current income taxes payable. Accordingly, deferred tax assets are not recognized for these net operating loss carryforwards or credit carryforwards resulting from

the exercise of nonqualified options. The Company's utilization of these net operating loss carryforwards and a net operating loss in 2013 resulted in minimal income taxes paid in 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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

(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 received notices during 2012, 2013, 2014 and 2015 that its Acetadote patents are being challenged on the basis of invalidity or non-infringement by others. The Company is continuing to seek additional claims to protect its intellectual property associated with Acetadote and have additional pending patent applications relating to Acetadote. The Company continues to consider its legal options and intends to continue to defend and protect its Acetadote product and related intellectual property rights. Also see the discussion of 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.

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

(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 \$0.5 million and \$1.1 million in net revenues during the three months ended June 30, 2015 and 2014, respectively. On a year-to-date basis, Vaprisol contributed net revenues of \$1.5 million for 2015 and \$1.4 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 promotes the product through its specialty sales force focusing on select primary care physicians. The companies cooperate in the marketing and other activities needed to support the commercialization of the brand. 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 the first milestone payment of \$1.0 million to Pernix as all the criteria for that payment were not met. 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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

The \$4.0 million upfront payment that the Company paid to Pernix on October 29, 2013 is included in product and license rights and will be 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 \$0.9 million and \$1.3 million in net revenues during the three months ended June 30, 2015 and 2014, respectively. On a year-to-date basis, Omeclamox-Pak contributed net revenues of \$1.7 million for 2015 and \$2.5 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

Caldolor®

Caldolor Patent 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 second quarter of 2015, we obtained an additional patent for Caldolor. On April 21, 2015, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent number 9,012,508 (the "508 Caldolor Patent") which is assigned to us. The claims of the 508 Caldolor Patent encompass methods of treating pain using intravenous

13

---

ibuprofen in surgical settings. Following its issuance, the 508 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2030.

#### 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, Hospira, Inc., 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 FDA request.

#### 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 have an ongoing sixty four patient study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need.

The study is designed to evaluate escalating dose levels of Hepatoren in Type II patients. Progression to higher dose levels is reviewed and approved by an independent safety committee. The study is 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. Enrollment of the remaining Type I patients is underway and is expected to finish by the end of 2015.

#### Boxaban™

##### New Phase II Program

During 2015, Cumberland announced an expansion of its pipeline with a new Phase II development program. The Company has begun the clinical development of 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 has completed manufacturing of Boxaban oral capsules and has initiated a Phase II clinical study to evaluate Boxaban in patients suffering AERD. The study is designed to gather initial safety and tolerability data on ifetroban in AERD patients. It is a multicenter study of sixteen patients with enrollment well underway at several U.S.

medical centers including the Scripps Clinic. Cumberland expects to announce findings from this study later this year.  
Cumberland Emerging Technologies  
Cumberland Emerging Technologies University Collaborations



Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary currently has collaboration agreements with Universities to co-develop innovative pharmaceutical product candidates. Programs are currently underway with: Vanderbilt University, the University of Virginia, the University of Tennessee and the University of Mississippi. During the second quarter of 2015 CET renewed the collaboration agreements with the University of Tennessee and the University of Mississippi, and expanded the program activities with Vanderbilt University.

#### Cumberland Emerging Technologies Life Sciences Center

In May 2015, we announced that Cumberland Emerging Technologies Life Sciences Center welcomed a new tenant. The Center houses our formulation laboratories and also provides laboratory and office space, equipment and infrastructure to early-stage biomedical ventures. InvisionHeart, which is developing a hand-held ECG device, now occupies nearly 4,400 square feet of office and manufacturing space at the Center. The Life Sciences Center has a growing number of successful tenants and graduates.

#### Acetadote®

##### Acetadote Manufacturer

During the second quarter of 2015, we completed the transfer of the Acetadote manufacturing process to a U.S. based manufacturer. In July 2015, we filed the documentation with the FDA for clearance to use this manufacturer to supply our Acetadote product.

##### Acetadote Generic Competition

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"). In July 2015, Akorn, Inc. announced its launch of a generic injectable acetylcysteine product based on the old formulation that does contain EDTA which represents the second generic acetylcysteine available with the old formulation.

##### 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. Since 2012, the USPTO has issued the following patents to us associated with Acetadote:

Date issued	U.S. Patent number	Expiration	Patent claims
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 are continuing 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. 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.



## 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 June 30, 2015 compared to the three months ended June 30, 2014

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

	Three months ended June 30,		Change	
	2015	2014		
Net revenues	\$8,909,741	\$9,750,168	\$(840,427)	)
Costs and expenses:				
Cost of products sold	1,237,001	1,298,816	(61,815)	)
Selling and marketing	3,505,486	3,930,082	(424,596)	)
Research and development	828,070	861,154	(33,084)	)
General and administrative	2,153,562	2,140,249	13,313	
Amortization	511,691	304,258	207,433	
Total costs and expenses	8,235,810	8,534,559	(298,749)	)
Operating income	673,931	1,215,609	(541,678)	)
Interest income	57,846	29,544	28,302	
Interest expense	(18,489)	(12,278)	(6,211)	)
Income before income taxes	713,288	1,232,875	(519,587)	)
Income tax expense	(318,990)	(523,339)	204,349	)
Net income	\$394,298	\$709,536	\$(315,238)	)

Net revenues. Net revenues for the three months ended June 30, 2015 were approximately \$8.9 million compared to \$9.8 million for the three months ended June 30, 2014, representing a decrease of \$0.8 million, or 8.6%.

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

Products:	Three months ended June 30,		Change	
	2015	2014		
Acetadote	\$2,778,677	\$3,063,819	\$(285,142)	)
Omeclamox-Pak	944,185	1,344,869	(400,684)	)
Kristalose	4,121,966	3,559,313	562,653	
Vaprisol	480,034	1,071,433	(591,399)	)
Caldolor	460,052	626,684	(166,632)	)
Other	124,827	84,050	40,777	
Total net revenues	\$8,909,741	\$9,750,168	\$(840,427)	)

The revenue decrease compared to the prior year period was driven primarily by a reduction in our two most recently added branded prescription products: Vaprisol with a decrease in revenue of \$0.6 million and Omeclamox-Pak with a decrease in revenue of \$0.4 million. Caldolor revenue also decreased \$0.2 million, and Acetadote product revenue decreased \$0.3 million. The revenue reductions were partially offset by an increase in our Kristalose revenue of \$0.6 million.

Kristalose revenue increased 15.8% over the prior year period primarily due to new positioning for the product. The revenue increase during the three months ended June 30, 2015 were due to both increased sales volume and improved net revenue per unit 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. The net revenue per unit improvements resulted from a lower level of net revenue deductions from managed care contracts. Vaprisol revenue decreased during the three months ended June 30, 2015 compared to the prior year period primarily as a result of lower sales volume as we transitioned our marketable inventory from the Astellas labeled product to our Cumberland labeled product.



The Caldolor product revenue decrease of \$0.2 million was a 26.6% decline during the three months ended June 30, 2015 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 impacted this product's revenue in the second quarter of 2015. 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.

Acetadote net revenue for both the second quarter of 2015 and 2014 included \$1.8 million in revenue from sales of our Authorized Generic distributed by Perrigo. Net revenue of our Authorized Generic in the second quarter of 2015 benefited from the successful resolution of a temporary packaging delay and resulting shortage of marketable product that had impacted revenue during a portion of the first quarter of 2015. Our branded Acetadote net revenue accounted for the \$0.3 million decline in total Acetadote revenue and was primarily due to a reduction in sales volume during the three months ended June 30, 2015 as a result of generic competition. 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.

Cost of products sold. Overall cost of products sold for the second quarter of 2015 was consistent with the prior year. As a percentage of net revenues, cost of products sold experienced a slight increase to 13.9% during the three months ended June 30, 2015 compared to 13.3% during the three months ended June 30, 2014. This increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix.

Selling and marketing. Selling and marketing expense for the three months ended June 30, 2015 totaled approximately \$3.5 million, which was a decrease of \$0.4 million compared to the prior year's expense of \$3.9 million. The decrease was the result of a \$0.2 million reduction in Omeclamox product royalties and a decrease in sales force salaries, travel expenses, print materials and product samples. 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 second quarter of 2015 were \$0.8 million, compared to \$0.9 million for the same period last year, representing a decrease of approximately 3.8%. We continue to fund clinical studies for both our Boxaban and Hepatoren product candidates.

General and administrative. General and administrative expense increased 0.6% to \$2.2 million for the three months ended June 30, 2015 compared to \$2.1 million for the prior year. The increase was primarily driven by increases in salaries, wages and benefits costs but were partially offset by a reduction in our travel and legal fees 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 three months ended June 30, 2015 totaled approximately \$0.5 million, which was an increase of \$0.2 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 three months ended June 30, 2015 totaled \$0.3 million, compared to income tax expense of \$0.5 million in the second quarter of 2014. The change was the result of the reduction in pretax income in the second quarter of 2015 compared to the same period last year. As a percentage of income before income taxes, income tax expense was 44.7% for the three months ended June 30, 2015 compared to 42.4% for the three months ended June 30, 2014, primarily as a result of legislative changes to certain state income taxes.

As of June 30, 2015, we have approximately \$43.9 million of unrecognized net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that will be used to significantly offset future income tax obligations. These benefits will be recognized in the year in which they are able to reduce current income taxes payable.



Six months ended June 30, 2015 compared to the six months ended June 30, 2014

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

	Six months ended June 30,		Change
	2015	2014	
Net revenues	\$17,596,515	\$17,843,412	\$(246,897 )
Costs and expenses:			
Cost of products sold	2,398,842	2,352,533	46,309
Selling and marketing	7,036,401	7,544,013	(507,612 )
Research and development	2,687,082	1,687,527	999,555
General and administrative	3,797,703	4,037,466	(239,763 )
Amortization	998,440	598,213	400,227
Total costs and expenses	16,918,468	16,219,752	698,716
Operating income	678,047	1,623,660	(945,613 )
Interest income	114,248	96,887	17,361
Interest expense	(34,039 )	(24,481 )	(9,558 )
Income before income taxes	758,256	1,696,066	(937,810 )
Income tax expense	(337,446 )	(711,348 )	373,902
Net income	\$420,810	\$984,718	\$(563,908 )

Net revenues. Net revenues for the six months ended June 30, 2015 were approximately \$17.6 million compared to \$17.8 million for the six months ended June 30, 2014, representing a slight decrease of \$0.2 million, or 1.4%.

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

	Six months ended June 30,		Change
	2015	2014	
Products:			
Acetadote	\$4,321,686	\$5,784,905	\$(1,463,219 )
Omeclamox-Pak	1,702,376	2,484,290	(781,914 )
Kristalose	8,220,744	6,935,370	1,285,374
Vaprisol	1,504,008	1,369,765	134,243
Caldolor	1,654,733	1,129,082	525,651
Other	192,968	140,000	52,968
Total net revenues	\$17,596,515	\$17,843,412	\$(246,897 )

Revenue increases in three of our five branded prescription products were offset by decreases in Omeclamox-Pak revenue of \$0.8 million and Acetadote product revenue of \$1.5 million. Our products with revenue gains were led by increases in Kristalose revenue of \$1.3 million, Caldolor revenue of \$0.5 million and Vaprisol revenue of \$0.1 million.

Kristalose revenue increased 18.5% 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 six months ended June 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 9.8% during the six months ended June 30, 2015 compared to the prior year period primarily 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 six months ended June 30, 2015 as we transitioned our marketable inventory from the Astellas labeled product to our Cumberland labeled product.

The Caldolor product revenue increase of \$0.5 million was a 46.6% improvement during six months ended June 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

19

---

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 six months of 2015 included \$2.3 million in revenue from sales of our Authorized Generic distributed by Perrigo, compared to \$3.2 million for the same period last year. This \$0.9 million decrease in sales of our Authorized Generic product accounted for the majority 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. The \$0.6 million reduction in our branded Acetadote product net revenue was the result of 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.

Cost of products sold. Overall cost of products sold for the first six months of 2015 was consistent with the prior year. As a percentage of net revenues, cost of products sold experienced a slight increase to 13.6% during the six months ended June 30, 2015 compared to 13.2% during the same period last year. This increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix.

Selling and marketing. Selling and marketing expense for the six months ended June 30, 2015 totaled approximately \$7.0 million, which was a decrease of \$0.5 million compared to the prior year's expense of \$7.5 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 travel 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 six months of 2015 were \$2.7 million, compared to \$1.7 million for the same period last year, representing an increase of approximately \$1.0 million, or 59.2%. 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 continue to fund clinical studies for both our Boxaban and Hepatoren product candidates.

General and administrative. General and administrative expense was \$3.8 million for the six months ended June 30, 2015, compared to \$4.0 million during the six months ended June 30, 2014. The \$0.2 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 during the period. These reductions in expenses were partially offset by increases in salaries, wages and benefits costs.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the six months ended June 30, 2015 totaled approximately \$1.0 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 six months ended June 30, 2015 totaled \$0.3 million, compared to income tax expense of \$0.7 million in the six months ended June 30, 2014. The change was the result of the reduction in pretax income in the first half of 2015 compared to the same period last year. As a percentage of income before income taxes, income tax expense was 44.5% for the six months ended June 30, 2015 compared to 41.9% for the six months ended June 30, 2014, primarily as a result of legislative changes to certain state income taxes.

## 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 six months ended June 30, 2015 and 2014, we generated \$4.1 million and \$1.8 million in cash flow from operations, respectively, and we borrowed \$1.7 million on our line of credit during the second quarter of 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

20

---

in less than one week. At June 30, 2015 and December 31, 2014, we had approximately \$14.1 million and \$14.8 million invested in marketable securities, respectively.

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

	June 30, 2015	December 31, 2014
Cash and cash equivalents	\$38,940,681	\$39,866,037
Marketable securities	14,136,925	14,841,418
Total cash, cash equivalents and marketable securities	\$53,077,606	\$54,707,455
Working capital (current assets less current liabilities)	\$56,652,953	\$57,065,489
Current ratio (multiple of current assets to current liabilities)	5.9	5.2
Revolving line of credit availability	\$10,300,000	\$12,000,000

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

	Six months ended June 30, 2015	2014
Net cash provided by (used in):		
Operating activities	\$4,067,868	\$1,818,388
Investing activities	(2,052,929	) (3,768,132
Financing activities	(2,940,295	) 131,128
Net decrease in cash and cash equivalents	\$(925,356	) \$(1,818,616

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

The decrease in cash and cash equivalents for the six months ended June 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 \$1.0 million. Our financing activities include the \$1.0 million investment Gloria Pharmaceuticals Co. Ltd. made in CET and the repurchase of shares of our common stock totaling \$1.6 million during the six months ended June 30, 2014. Cash provided by operating activities was \$1.8 million and included net income of \$1.0 million.

As of June 30, 2015, we have approximately \$43.9 million of unrecognized net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that will be used to significantly offset future income tax obligations. These benefits will be recognized in the year in which they are able to reduce current income taxes payable.

On June 26, 2014, we entered into a Revolving Credit Loan Agreement (“Loan Agreement”) with SunTrust Bank, which replaced the agreement with a previous lender. At June 30, 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 1.184% at June 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 June 30, 2015.

#### OFF-BALANCE SHEET ARRANGEMENTS

During the six months ended June 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 risk related to interest rates for these accounts will produce less income than expected if market interest rates fall. Based on the \$14.1 million in marketable securities outstanding at June 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 June 30, 2015, 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 six months ended June 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 June 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 June 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.

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 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 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.

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

24

---

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. 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 June 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 <sup>(1)</sup>
April	76,421	\$6.96	76,421	\$8,086,014
May	74,241	6.78	74,241	7,582,833
June	84,555	(1) 7.21	84,555	6,972,785
Total	235,217		235,217	

(1) Of this amount, 7,670 shares were repurchased directly through private purchases at the then-current fair market value of common stock.

Item 6. Exhibits

No.	Description
31.1	Certification of Chief Executive Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL INSTANCE DOCUMENT
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
101.LAB	XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

SIGNATURES

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

Cumberland Pharmaceuticals Inc.

Dated: August 7, 2015

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

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