

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 03, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____.

Commission file number: 001-33637

Cumberland Pharmaceuticals Inc.

(Exact Name of Registrant as Specified In Its Charter)

Tennessee 62-1765329

(State or Other Jurisdiction of (I.R.S. Employer

Incorporation or Organization) Identification No.)

2525 West End Avenue, Suite 950, 37203
Nashville, Tennessee

(Address of Principal Executive Offices) (Zip Code)

(615) 255-0068

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer Accelerated filer

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

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

Class Outstanding at November 1, 2016

Common stock, no par value 16,180,604

CUMBERLAND PHARMACEUTICALS INC.
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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$35,546,244	\$38,203,059
Marketable securities	14,600,404	14,564,115
Accounts receivable, net of allowances	6,672,300	6,077,120
Inventories	4,983,227	4,270,143
Other current assets	5,160,817	3,997,637
Total current assets	66,962,992	67,112,074
Property and equipment, net	482,591	536,450
Intangible assets, net	21,172,570	21,168,596
Other assets	2,456,118	3,101,839
Total assets	\$91,074,271	\$91,918,959
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$6,658,196	\$2,877,479
Other current liabilities	5,027,735	9,534,268
Total current liabilities	11,685,931	12,411,747
Revolving line of credit	3,700,000	1,700,000
Other long-term liabilities	1,265,725	987,429
Total liabilities	16,651,656	15,099,176
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 16,195,631 and 16,379,501 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	55,175,133	57,338,294
Retained earnings	19,354,625	19,549,614
Total shareholders' equity	74,529,758	76,887,908
Noncontrolling interests	(107,143)	(68,125)
Total equity	74,422,615	76,819,783
Total liabilities and equity	\$91,074,271	\$91,918,959

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Income (loss)

(Unaudited)

	Three months ended		Nine months ended	
	September 30, 2016	2015	September 30, 2016	2015
Net revenues	\$8,791,753	\$7,885,048	\$23,944,120	\$25,481,563
Costs and expenses:				
Cost of products sold	1,973,948	980,176	4,353,148	3,379,018
Selling and marketing	3,614,714	3,608,828	10,585,955	10,645,229
Research and development	644,662	757,442	2,029,914	3,444,524
General and administrative	1,865,575	1,794,279	5,817,943	5,591,982
Amortization	562,722	473,439	1,632,920	1,471,879
Total costs and expenses	8,661,621	7,614,164	24,419,880	24,532,632
Operating income (loss)	130,132	270,884	(475,760)) 948,931
Interest income	51,636	64,072	160,248	178,320
Interest expense	(29,088)) (19,815)) (77,777)) (53,854)
Income (loss) before income taxes	152,680	315,141	(393,289)) 1,073,397
Income tax (expense) benefit	(57,192)) (193,439)) 159,282) (530,885)
Net income (loss)	95,488	121,702	(234,007)) 542,512
Net loss at subsidiary attributable to noncontrolling interests	10,678	4,911	39,018	37,780
Net income (loss) attributable to common shareholders	\$106,166	\$126,613	\$(194,989)) \$580,292
Earnings (loss) per share attributable to common shareholders				
- basic	\$0.01	\$0.01	\$(0.01)) \$0.03
- diluted	\$0.01	\$0.01	\$(0.01)) \$0.03
Weighted-average shares outstanding				
- basic	16,217,442	16,604,682	16,268,579	16,811,360
- diluted	16,504,568	16,996,376	16,268,579	17,193,854
Comprehensive income (loss) attributable to common shareholders	106,166	126,613	(194,989)) 580,292
Net loss at subsidiary attributable to noncontrolling interests	10,678	4,911	39,018	37,780
Total comprehensive income (loss)	\$95,488	\$121,702	\$(234,007)) \$542,512

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$(234,007) \$542,512
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	1,785,057	1,677,906
Deferred tax benefit	662,689	43,991
Share-based compensation	623,504	426,651
Excess tax expense (benefit) derived from exercise of stock options	907,270	(470,584)
Noncash interest expense	61,224	33,001
Noncash investment gains	(69,140)	(80,321)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	(595,180)	(293,665)
Inventory	(713,084)	1,394,280
Other current assets and other assets	(1,241,372)	(239,484)
Accounts payable and other current liabilities	(1,705,007)	1,457,656
Other long-term liabilities	267,730	61,553
Net cash (used in) provided by operating activities	(250,316)	4,553,496
Cash flows from investing activities:		
Additions to property and equipment	(98,275)	(96,768)
Purchases of marketable securities	(3,643,894)	(5,201,240)
Proceeds from sale of marketable securities	3,676,745	5,684,149
Additions to intangible assets	(1,554,410)	(2,392,477)
Net cash used in investing activities	(1,619,834)	(2,006,336)
Cash flows from financing activities:		
Net borrowings on line of credit	2,000,000	1,700,000
Exercise of stock options	—	21,366
Excess tax (expense) benefit derived from exercise of stock options	(907,270)	470,584
Cash settlement of contingent consideration	—	(1,618,983)
Repurchase of common shares	(1,879,395)	(4,669,873)
Net cash used in financing activities	(786,665)	(4,096,906)
Net decrease in cash and cash equivalents	(2,656,815)	(1,549,746)
Cash and cash equivalents at beginning of period	38,203,059	39,866,037
Cash and cash equivalents at end of period	\$35,546,244	\$38,316,291
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Net change in unpaid additions to intangibles, property and equipment	\$(82,487) \$1,266,759
See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.		

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Condensed Consolidated Statement of Equity

(Unaudited)

	Common stock		Retained earnings	Noncontrolling interests	Total equity
	Shares	Amount			
Balance, December 31, 2015	16,379,501	\$57,338,294	\$19,549,614	\$ (68,125)	\$76,819,783
Share-based compensation	223,587	623,504	—	—	623,504
Exercise of options and related tax benefit	—	(907,270)	—	—	(907,270)
Repurchase of common shares	(407,457)	(1,879,395)	—	—	(1,879,395)
Net loss	—	—	(194,989)	(39,018)	(234,007)
Balance, September 30, 2016	16,195,631	\$55,175,133	\$19,354,625	\$ (107,143)	\$74,422,615

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

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

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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a basis consistent with the December 31, 2015 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly present the information set forth herein. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements have been prepared in accordance with the regulations of the Securities and Exchange Commission, or the SEC, and omit certain information and footnote disclosure necessary to present the statements in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income (loss) was comprised solely of net income (loss) for the three and nine months ended September 30, 2016 and 2015.

Recent Accounting Guidance

Recently Issued Accounting Guidance Not Yet Adopted

In August 2016, the Financial Accounting Standards Board ("FASB") issued amended guidance in the form of a FASB Accounting Standards Update ("ASU"), "Classification of Certain Cash Receipts and Cash Payments". The core principle of the new guidance is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments in this update are effective for fiscal years beginning after December 15, 2017. The accounting guidance should be applied retrospectively and early adoption is permitted. The Company is evaluating the potential impact of this adoption on our condensed consolidated financial statements and disclosures.

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

In July 2015, the FASB issued amended guidance in the form of a FASB ASU, "Inventory: Simplifying the Measurement of Inventory." The amended guidance requires entities to measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably

predictable costs of completion, disposal, and transportation. The requirement would replace the current lower of cost or market evaluation. Accounting guidance is unchanged for inventory measured using last-in, first-out (“LIFO”) or the retail method. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance should

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

be applied prospectively and early adoption is permitted. The Company is evaluating the potential impact of this adoption on our condensed consolidated financial statements and disclosures.

In November 2015, the FASB amended guidance in the form of a FASB ASU, "Balance Sheet Classification of Deferred Taxes", which requires that all deferred tax assets and liabilities be classified as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The FASB determined that this simplification could reduce cost and complexity without decreasing the usefulness of information provided to financial statement users. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance may be applied prospectively or retrospectively and early adoption is permitted. The Company does not anticipate adoption of this balance sheet classification ASU to have a material effect on its consolidated financial statements and disclosures.

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

In March 2016, the FASB released in the form of a FASB ASU, "Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting". The ASU includes multiple provisions intended to simplify various aspects of the accounting for share-based payments. While aimed at reducing the cost and complexity of the accounting for share-based payments, the amendments are expected to significantly impact net income, earnings per share ("EPS"), and the statement of cash flows. Implementation and administration may present challenges for companies with significant share-based payment activities. The ASU is effective for public companies in annual periods beginning after December 15, 2016, and interim periods within those years. The Company is currently evaluating the impact of adoption on the consolidated financial statements including the unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$44.0 million and the future vesting of shares of restricted stock issued to employees and directors.

Accounting Policies:

Use of Estimates

In preparing the condensed consolidated financial statements in conformity with U.S. GAAP, management must make decisions that impact the reported amounts and the related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgments based on its understanding and analysis of the relevant circumstances, historical experience, and other available information. Actual results could differ from those estimates under different assumptions and conditions. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns, (2) the allowances for obsolescent or unmarketable inventory and (3) the projection of future taxable income for the realization of deferred tax assets.

Operating Segments

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

Substantially all of the Company's assets are located in the United States and total revenues are primarily attributable to U.S. customers.

(2) MARKETABLE SECURITIES

The Company invests in marketable debt securities in order to maximize its return on cash. Marketable securities consist of U.S. Government Agency notes and bonds, and bank-guaranteed, variable rate demand notes ("VRDN"). At the time of purchase, the Company classifies marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of September 30, 2016 and December 31, 2015, the marketable securities are comprised solely of trading securities. Trading securities are carried at fair value with unrealized gains and losses recognized as a component of interest income in the condensed consolidated statements of operations and comprehensive income.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

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.

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

	September 30, 2016			December 31, 2015		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Agency issued mortgage-backed securities – variable rate	\$—	\$6,722,556	\$6,722,556	\$—	\$5,700,335	\$5,700,335
U.S. Agency notes and bonds – fixed rate	—	1,802,779	1,802,779	—	2,447,066	2,447,066
SBA loan pools – variable rate	—	1,440,069	1,440,069	—	1,681,714	1,681,714
Municipal bonds – VRDN	4,635,000	—	4,635,000	4,735,000	—	4,735,000
Total fair value of marketable securities	\$4,635,000	\$9,965,404	\$14,600,404	\$4,735,000	\$9,829,115	\$14,564,115

(3) EARNINGS (LOSS) PER SHARE

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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

	Three months ended September 30,	
	2016	2015
Numerator:		
Net income attributable to common shareholders	\$ 106,166	\$ 126,613
Denominator:		
Weighted-average shares outstanding – basic	16,217,442	16,604,682
Dilutive effect of other securities	287,126	391,694
Weighted-average shares outstanding – diluted	16,504,568	16,996,376

	Nine months ended September 30,	
	2016	2015
Numerator:		
Net income (loss) attributable to common shareholders	\$(194,989)	\$ 580,292
Denominator:		
Weighted-average shares outstanding – basic	16,268,579	16,811,360
Dilutive effect of other securities	—	382,494
Weighted-average shares outstanding – diluted	16,268,579	17,193,854

As of September 30, 2016 and 2015, restricted stock awards and options to purchase 21,950 and 54,798 shares of common stock, respectively, were outstanding but were not included in the computation of diluted earnings per share because the effect would be antidilutive.

(4) REVENUES

Product Revenues

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Products:				
Acetadote	\$ 1,807,495	\$ 2,065,081	\$ 5,532,893	\$ 6,386,767
Omeclamox-Pak	752,808	691,120	2,154,596	2,393,495
Kristalose	3,671,397	3,939,294	10,915,276	12,160,037
Vaprisol	496,279	670,621	1,286,126	2,199,645
Caldolor	1,357,289	352,343	3,060,441	2,007,076
Ethyol	519,400	—	519,400	—
Other	187,085	166,589	475,388	334,543
Total net revenues	\$ 8,791,753	\$ 7,885,048	\$ 23,944,120	\$ 25,481,563

Cumberland supplies Perrigo Company ("Perrigo") with an Authorized Generic version of the Company's Acetadote product. The Company's revenue generated by sales of its Authorized Generic distributed by Perrigo is included in the Acetadote product revenue presented above. The Company's share of Authorized Generic revenue was \$1.2 million and \$1.1 million for the third quarter of 2016 and 2015 and \$3.5 million and \$3.3 million on a year-to-date basis as of September 30, 2016 and 2015, respectively.

Other Revenues

The Company has entered into agreements, beginning in 2012, with international partners for commercialization of the Company's products. The international agreements provide that each of the partners are responsible for seeking

regulatory approvals for the products, and following approvals, each partner will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulations. Under the international agreements, the Company is entitled to receive non-refundable, up-front payments at the time the agreements are entered into and milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company recognizes revenue for these substantive milestones using the milestone method. The Company is also entitled to

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

receive royalties on future sales of the products under the agreements. During the nine months ended September 30, 2016, the Company recognized \$200,000 in milestone payments associated with these international agreements.

(5) INVENTORIES

The Company works closely with third parties to manufacture and package finished goods for sale. Based on the relationship with the manufacturer or packager, the Company will either take title to the finished goods at the time of shipment or at the time of arrival from the manufacturer. The Company then warehouses such goods until distribution and sale. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method. The Company continually evaluates inventory for potential losses due to excess, obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates that the carrying value may not be recoverable, a charge is taken to reduce the inventory to its current net realizable value. At September 30, 2016 and December 31, 2015, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately \$0.7 million and \$2.7 million, respectively. During the third quarter of 2016, the Company began to destroy obsolete Caldolor inventory. This reduced both the inventory and the cumulative charges for obsolete inventory.

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

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

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

	September 30, 2016	December 31, 2015
Raw materials	\$2,618,737	\$2,576,621
Consigned inventory	336,504	235,636
Finished goods	2,027,986	1,457,886
Total	\$4,983,227	\$4,270,143

(6) SHAREHOLDERS' EQUITY AND DEBT

Share Repurchases

On May 13, 2010, the Company announced a share repurchase program to purchase up to \$10.0 million of its common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012, January 2013, January 2015 and January 2016, the Company's Board of Directors replaced the prior authorizations with new \$10.0 million authorizations for repurchases of the Company's outstanding common stock. During the nine months ended September 30, 2016 and the nine months ended September 30, 2015, the Company repurchased 407,457 shares and 712,134 shares of common stock for approximately \$1.9 million and \$4.7 million, respectively.

Restricted Share Grants

During the nine months ended September 30, 2016, the Company issued approximately 226,425 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

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

On June 26, 2014, Cumberland entered into a Revolving Credit Loan Agreement (“Loan Agreement”) with SunTrust Bank, which replaced the agreement with a previous lender. The Company had \$3.7 million and \$1.7 million in borrowings under the Loan Agreement at September 30, 2016 and 2015. On July 29, 2016, Cumberland amended the agreement to extend the original three-year term by an additional year. The agreement provides for an aggregate principal amount up to \$20 million. The initial revolving line of credit is up to \$12 million, with the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions.

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

Under the Loan Agreement, Cumberland is subject to certain financial covenants, including, but not limited to, maintaining a Funded Debt Ratio, as such term is defined in the Loan Agreement and determined on a quarterly basis. On July 29, 2016, Cumberland obtained a compliance waiver for a financial covenant as of June 30, 2016. On October 28, 2016, the Company obtained a compliance waiver and amended the agreement to modify a financial covenant, replacing the EBIT to interest ratio covenant with a minimum liquidity requirement. As a result of the covenant waiver and modification in the October 28, 2016 amendment, the Company achieved compliance with all covenants as of September 30, 2016.

(7) INCOME TAXES

At September 30, 2016, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$44.0 million. These benefits occurred as a result of the actual tax benefit realized upon an employee's exercise exceeding the cumulative book compensation charge associated with the awards and will be recognized in the year in which they are able to reduce current income taxes payable. Accordingly, deferred tax assets are not recognized for these net operating loss carryforwards or credit carryforwards resulting from the exercise of nonqualified options. The Company's utilization of these net operating loss carryforwards and a net operating loss in 2013 resulted in minimal income taxes paid in each of the years 2009 through 2015. The Company expects to achieve taxable income through its operations and pay minimal income taxes in 2016 through utilization of these net operating loss carryforwards.

(8) COLLABORATIVE AGREEMENTS

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

(9) COMMITMENTS AND CONTINGENCIES

Legal Matters

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

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

During the third quarter of 2015, the United States District Court for the Northern District of Illinois, Eastern Division ruled in the Company's favor in its lawsuit against Mylan for infringement of its U.S. Patent number 8,399,445 (the "445 Acetadote Patent"). The opinion upheld the Company's 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The court ruled that Mylan is liable to Cumberland for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

New Drug Application in which Mylan sought to market a generic version of Acetadote. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

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

(10) PRODUCT ADDED DURING 2016

Ethyol

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

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

The following discussion contains certain forward-looking statements which reflect management's current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We caution you that our actual results may differ significantly from the results we discuss in these forward looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; and management of our growth and integration of our acquisitions. Other important factors that may cause actual results to differ materially from forward-looking statements are discussed in "Risk Factors" on pages 22 through 37, and "Special Note Regarding Forward-Looking Statements" on pages 37 and 38 of our Annual Report on Form 10-K for the year ended December 31, 2015. We do not undertake to publicly update or revise any of our forward-looking statements, even in the event that experience or future changes indicate that the anticipated results will not be realized. The following presentation of management's discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Form 10-Q.

OVERVIEW

Our Business

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

Our product portfolio includes:

• **Acetadote®** (acetylcysteine) Injection, for the treatment of acetaminophen poisoning;

• **Caldolor®** (ibuprofen) Injection, for the treatment of pain and fever; recently approved for use in pediatric patients;

• **Kristalose®** (lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;

• **Omeclamox®-Pak**, (omeprazole, clarithromycin, amoxicillin) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;

• **Vaprisol®** (conivaptan) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia, and

• **Ethylol®** (amifostine) Injection for the reduction of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer.

Our pipeline of product candidates includes:

• **Hepatoren®** (ifetroban) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");

• Boxaban™ (ifetroban) oral capsules, a Phase II candidate for the treatment of patients with aspirin-exacerbated respiratory disease (AERD);

• Vasculan™ (ifetroban) oral capsules, a Phase II candidate for the treatment of patients with systemic sclerosis (SSc);
and

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Portaban™ (ifetroban) oral formulation, a Phase II candidate for the treatment of patients with portal hypertension associated with liver 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 six products approved for sale in the United States. Through our international partners, we are working to bring our products to patients in countries outside the U.S. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to identify and develop promising, early-stage product candidates, which Cumberland has the opportunity to further develop and commercialize. Specifically, we expect to grow by executing the following plans:

Continue to build a high-performance sales organization to address our target markets. We believe that our commercial infrastructure can help drive prescription volume and product sales. We currently utilize two distinct sales teams to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the gastroenterology market. We believe that active promotion of our products, supported by non-personal promotional activities developed and implemented by our marketing team, can maximize the opportunity for our brands.

Further develop our existing products and develop new late stage product candidates. We continue to evaluate our products following FDA approval to determine if further clinical work could expand the potential market opportunities for our products and help new patient populations. We will also continue to explore opportunities for label expansion to bring our products to new patient populations. The Caldolor pediatric approval reflects our successful implementation of this strategy. Our clinical team is also working to develop late stage product candidates that could further expand our product portfolio if approved by the FDA.

Expand our product portfolio by acquiring rights to additional products and late-stage product candidates. In addition to our product development activities, we are also seeking to acquire products or late-stage development product candidates to continue to build a portfolio of complementary brands. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that address poorly met medical needs. We plan to continue to target product acquisition candidates that are competitively differentiated, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. Our acquisition of rights to Ethyol in the U.S. represents a recent example of our implementation of this strategy.

Expand our global presence through select international partnerships. We have established our own commercial capabilities, including a sales organization to cover the U.S. market for our products. We are building a network of select international partners to register our products and make them available to patients in their countries. We will continue to expand our network of international partners and continue to support our partners' registration and commercialization efforts in their respective territories. The launch of Caldolor in Australia by CSL's Seqirus is an example of our international partnerships.

Develop a pipeline of early-stage products through Cumberland Emerging Technologies ("CET"). In order to build our product pipeline, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities at CET. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland has the opportunity to negotiate rights to further develop and commercialize them in the U.S and other markets.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. During 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange. Our website address is www.cumberlandpharma.com. 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.

Recent Developments and Highlights

Board of Directors Appointment

Caroline Young's appointment to Cumberland's Board of Directors was effective September 13, 2016. She is the prior President of the Nashville Health Care Council and founding Executive Director of the Tennessee Biotechnology Association.

Ethylol® Agreement

During August 2016, we began distribution of Ethylol for injection to wholesalers within the United States and in September 2016, we launched the national promotional support for the brand. Ethylol is Cumberland's first oncology product and complements our current hospital product line. We entered into an exclusive agreement earlier this year with Clinigen Group plc whereby Cumberland is responsible for all distribution, promotion, and medical support of Ethylol in the United States.

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

Portaban™ Program

In September 2016, we announced the addition of Portaban to our pipeline. Cumberland has initiated the clinical development of Portaban (ifetroban) oral formulation for the treatment of portal hypertension associated with liver disease. The U.S. Food and Drug Administration (FDA) has cleared our investigational new drug application (IND) for a Phase II clinical program for Portaban. Preclinical studies have shown ifetroban can reduce portal pressure, necrosis, inflammation, and fibrosis in multiple models of liver injury.

Caldolor®

Caldolor® Pediatric Launch

We launched the promotion of Caldolor for the treatment of pain and fever in children in March 2016. Caldolor has been approved for use in adults for the management of pain, as well as the reduction of fever, since 2009. We received approval and three-year exclusivity from the FDA in November 2015 for the use of Caldolor in children six months of age and older. Cumberland seeks to maximize the potential of its FDA approved product line and expand the use of its products into new patient populations. The pediatric approval and launch of Caldolor for use in children is an example of the successful execution of that strategy.

Hepatoren®

Phase II Study Results

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

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

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

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

Boxaban™

Phase II Study Results

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

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

New Hospital Product Candidate

Cumberland was responsible for the formulation, development and FDA approval of both Acetadote and Caldolor. Our Medical Advisory Board has helped us identify additional opportunities that address unmet or poorly met medical needs. As a result, we have targeted a cholesterol reducing agent for use in the hospital setting. Cumberland has successfully designed, formulated and completed the preclinical studies for such a product candidate. In late October, the FDA cleared the related IND and we are now initiating a Phase I study in healthy volunteers to determine the pharmacokinetic and safety profile for this new product candidate.

Acetadote®

Acetadote Litigation and Arbitration updates

Information and discussion of Acetadote's competing products are included in Part 1, Item 1, Business - Competition, of our Form 10-K for the year ended December 31, 2015. As noted, Acetadote is our injectable formulation of N-Acetylcysteine ("NAC") for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC as well as injectable products. Our branded Acetadote and Authorized Generic Acetadote products contain the new formulation that does not include ethylene diamine tetra acetic acid ("EDTA"). As included in Part 2, Item 1, Legal Proceedings in our Form 10-Q for the quarter ended March 31, 2016, on September 14, 2015, the arbitrator issued a final award in our favor, enjoining Mylan Pharma Group Limited and Mylan Teoranta, together with all their affiliates, from selling, delivering, or giving away any acetylcysteine injectable drug product to another entity or person until April 30, 2018. The award notes that as the prevailing party, we are entitled to reimbursement of our attorney's fees and related costs associated with the arbitration.

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

Acetadote Patents

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

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
May 2016	9,327,028	July 2031	Administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection

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

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

Accounting Estimates and Judgments

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

RESULTS OF OPERATIONS

Three months ended September 30, 2016 compared to the three months ended September 30, 2015

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

	Three months ended September 30,		
	2016	2015	Change
Net revenues	\$8,791,753	\$7,885,048	\$906,705
Costs and expenses:			
Cost of products sold	1,973,948	980,176	993,772
Selling and marketing	3,614,714	3,608,828	5,886
Research and development	644,662	757,442	(112,780)
General and administrative	1,865,575	1,794,279	71,296
Amortization	562,722	473,439	89,283
Total costs and expenses	8,661,621	7,614,164	1,047,457
Operating income	130,132	270,884	(140,752)
Interest income	51,636	64,072	(12,436)
Interest expense	(29,088)	(19,815)	(9,273)
Income before income taxes	152,680	315,141	(162,461)
Income tax expense	(57,192)	(193,439)	136,247
Net income	\$95,488	\$121,702	\$(26,214)

Net revenues. Net revenues for the three months ended September 30, 2016 were approximately \$8.8 million compared to \$7.9 million for the three months ended September 30, 2015, representing an increase of \$0.9 million, or 11.5%.

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

	Three months ended September 30,		
	2016	2015	Change
Products:			
Acetadote	\$1,807,495	\$2,065,081	\$(257,586)
Omeclamox-Pak	752,808	691,120	61,688
Kristalose	3,671,397	3,939,294	(267,897)
Vaprisol	496,279	670,621	(174,342)
Caldolor	1,357,289	352,343	1,004,946
Ethyol	519,400	—	519,400
Other	187,085	166,589	20,496
Total net revenues	\$8,791,753	\$7,885,048	\$906,705

The increase in total net revenues from the prior year period was driven primarily by an increase in Caldolor net revenue of \$1.0 million and net revenue for our newest brand, Ethyol of \$0.5 million. Omeclamox-Pak revenue increased \$0.1 million or 9%. Acetadote revenue decreased by \$0.3 million compared to the third quarter of 2015 and Kristalose revenue decreased by \$0.3 million compared to the third quarter of 2015.

The Caldolor product revenue increase of \$1.0 million for the three months ended September 30, 2016 was a 285.2% improvement compared to the same period last year. Caldolor revenue in the third quarter of 2016 was positively impacted by growth in both international sales and domestic net revenue.

Ethyol revenue for the third quarter of 2016 was \$0.5 million. The Company began generating revenue from the sale of Ethyol during the third quarter of 2016.

Kristalose revenue decreased by \$0.3 million during the third quarter of 2016 when compared to the prior year period. The product's net revenue was impacted by reduced sales volume. It was positively impacted from improved pricing. Our Authorized Generic distributed by Perrigo experienced a \$0.1 million increase in revenue when compared to the prior year period. Authorized Generic sales were consistent on a sequential basis when compared to the second quarter of 2016. We experienced a decrease of \$0.4 million in our branded Acetadote net revenue from the prior year period. Our branded Acetadote revenue was consistent on a sequential basis when compared to the second quarter of 2016. Vaprisol revenue decreased during the third quarter of 2016 when compared to the prior year period due primarily to lower sales volumes.

Omeclamox-Pak revenue increased \$0.1 million or 9% due to improved net pricing and customer mix. This increase was partially offset by slightly lower sales volumes.

Cost of products sold. Cost of products sold for the third quarter of 2016 increased \$1.0 million compared to the prior year. As a percentage of net revenues, cost of products sold experienced an increase to 22.5% during the three months ended September 30, 2016 compared to 12.4% during the three months ended September 30, 2015. This increase in costs of products sold as a percentage of revenue was attributable to the increase in international sales and a change in the product sales mix during the quarter compared to the prior year. The costs of products sold during the three months ended September 30, 2016 included the new Caldolor inventory received and sold during the period. These new Caldolor units had a higher cost than our previous inventory as well as a higher cost than the future shipments we will receive from this supplier. As such, we expect this to be a temporary increase in the costs of products sold for the domestic Caldolor market.

Selling and marketing. Selling and marketing expense for the three months ended September 30, 2016 and September 30, 2015 remained consistent totaling approximately \$3.6 million.

Research and development. Research and development costs for the third quarter of 2016 were \$0.6 million, compared to \$0.8 million for the same period last year, representing a decrease of approximately 14.9%. A portion of our research and development costs are variable based on the number of studies, sites and participants involved in our product development activities.

General and administrative. General and administrative expense increased 4.0% to \$1.9 million for the three months ended September 30, 2016 compared to \$1.8 million for the prior year. The \$0.1 million increase from the prior year was primarily driven by increases in compensation and benefit expense during the period.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the three months ended September 30, 2016 and September 30, 2015 totaled approximately \$0.6 million and \$0.5 million, respectively.

Income taxes. Income taxes for the three months ended September 30, 2016 decreased \$0.1 million, compared to the third quarter of 2015. The change was the result of lower pretax income in the third quarter of 2016 compared to the same period last year. As a percentage of income before income taxes, income taxes were 37.5% for the three months ended September 30, 2016 compared to 61.4% for the three months ended September 30, 2015. The income tax rate for the three months ended September 30, 2015 was impacted by adjustments to our valuation allowance and increases in our state income tax expense, including changes from legislation.

As of September 30, 2016, we have approximately \$44.0 million of unrecognized net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that will be used to significantly offset future income tax obligations. These benefits will be recognized in the year in which they are able to reduce current income taxes payable.

Nine months ended September 30, 2016 compared to the nine months ended September 30, 2015

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

	Nine months ended September 30,		
	2016	2015	Change
Net revenues	\$23,944,120	\$25,481,563	\$(1,537,443)
Costs and expenses:			
Cost of products sold	4,353,148	3,379,018	974,130
Selling and marketing	10,585,955	10,645,229	