

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 07, 2014

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, 2014

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

Outstanding at November 3, 2014

Common stock, no par value

17,358,071

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,<br>2014 | December 31,<br>2013 |
|--|-----------------------|----------------------|
| <b>ASSETS</b>  |                       |                      |
| Current assets:  |                       |                      |
| Cash and cash equivalents  | \$39,644,081          | \$40,869,457         |
| Marketable securities  | 14,634,302            | 14,019,761           |
| Accounts receivable, net of allowances   | 5,296,114             | 4,530,424            |
| Inventories  | 6,130,722             | 5,722,882            |
| Other current assets   | 4,444,753             | 3,537,191            |
| Total current assets   | 70,149,972            | 68,679,715           |
| Property and equipment, net  | 731,129               | 880,647              |
| Intangible assets, net   | 19,997,795            | 15,498,819           |
| Other assets   | 3,025,236             | 2,554,557            |
| Total assets   | \$93,904,132          | \$87,613,738         |
| <b>LIABILITIES AND EQUITY</b>  |                       |                      |
| Current liabilities:   |                       |                      |
| Accounts payable   | \$3,205,233           | \$2,035,853          |
| Other current liabilities  | 8,950,250             | 5,509,917            |
| Total current liabilities  | 12,155,483            | 7,545,770            |
| Revolving line of credit   | —                     | —                    |
| Other long-term liabilities  | 863,356               | 776,125              |
| Total liabilities  | 13,018,839            | 8,321,895            |
| Commitments and contingencies  |                       |                      |
| Equity:  |                       |                      |
| Shareholders' equity:  |                       |                      |
| Common stock—no par value; 100,000,000 shares authorized; 17,423,825 and 17,985,503 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively | 62,953,489            | 63,073,941           |
| Retained earnings  | 18,149,350            | 16,394,540           |
| Total shareholders' equity   | 81,102,839            | 79,468,481           |
| Noncontrolling interests   | (217,546)             | (176,638)            |
| Total equity   | 80,885,293            | 79,291,843           |
| Total liabilities and equity   | \$93,904,132          | \$87,613,738         |

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

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

(Unaudited)

|   | Three months ended September 30, |             | Nine months ended September 30, |              |
|---|----------------------------------|-------------|---------------------------------|--------------|
|   | 2014                             | 2013        | 2014                            | 2013         |
| Net revenues  | \$9,729,047                      | \$6,528,575 | \$27,572,459                    | \$23,867,795 |
| Costs and expenses:   |                                  |             |                                 |              |
| Cost of products sold   | 1,339,723                        | 1,030,943   | 3,692,256                       | 3,294,411    |
| Selling and marketing   | 3,821,953                        | 3,410,205   | 11,365,966                      | 10,626,193   |
| Research and development  | 934,783                          | 1,440,584   | 2,622,310                       | 4,276,206    |
| General and administrative                                      | 2,158,057                        | 1,958,629   | 6,195,523                       | 6,389,569    |
| Amortization  | 485,493                          | 202,982     | 1,083,706                       | 610,677      |
| Total costs and expenses  | 8,740,009                        | 8,043,343   | 24,959,761                      | 25,197,056   |
| Operating income (loss)   | 989,038                          | (1,514,768) | 2,612,698                       | (1,329,261)  |
| Interest income   | 108,005                          | 20,350      | 204,892                         | 161,709      |
| Interest expense  | (26,877)                         | (24,286)    | (51,358)                        | (62,721)     |
| Income (loss) before income taxes                               | 1,070,166                        | (1,518,704) | 2,766,232                       | (1,230,273)  |
| Income tax (expense) benefit                                    | (340,982)                        | 686,209     | (1,052,330)                     | 590,250      |
| Net income (loss)   | 729,184                          | (832,495)   | 1,713,902                       | (640,023)    |
| Net loss at subsidiary attributable to noncontrolling interests | 16,736                           | 12,553      | 40,908                          | 35,772       |
| Net income (loss) attributable to common shareholders           | \$745,920                        | \$(819,942) | \$1,754,810                     | \$(604,251)  |
| Earnings (loss) per share attributable to common shareholders   |                                  |             |                                 |              |
| - basic   | \$0.04                           | \$(0.04)    | \$0.10                          | \$(0.03)     |
| - diluted   | \$0.04                           | \$(0.04)    | \$0.10                          | \$(0.03)     |
| Weighted-average shares outstanding                             |                                  |             |                                 |              |
| - basic   | 17,544,905                       | 18,233,407  | 17,730,715                      | 18,420,465   |
| - diluted   | 17,848,110                       | 18,233,407  | 17,990,561                      | 18,420,465   |
| Comprehensive income (loss) attributable to common shareholders | 745,920                          | (819,942)   | 1,754,810                       | (604,251)    |
| Net loss at subsidiary attributable to noncontrolling interests | 16,736                           | 12,553      | 40,908                          | 35,772       |
| Total comprehensive income (loss)                               | \$729,184                        | \$(832,495) | \$1,713,902                     | \$(640,023)  |

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

|  | Nine months ended<br>2014 | September 30,<br>2013 |   |
|--|---------------------------|-----------------------|---|
| Cash flows from operating activities:  |                           |                       |   |
| Net income (loss)  | \$ 1,713,902              | \$(640,023            | ) |
| Adjustments to reconcile net income to net cash provided by operating activities:                            |                           |                       |   |
| Depreciation and amortization expense  | 1,383,611                 | 917,012               |   |
| Deferred tax benefit   | (36,255                   | ) (76,332             | ) |
| Share-based compensation   | 542,118                   | 480,806               |   |
| Excess tax (benefit) expense derived from exercise of stock options  | (1,077,099                | ) 511,908             |   |
| Noncash interest expense   | 12,038                    | 12,038                |   |
| Noncash investment losses  | 138,627                   | 135,296               |   |
| Net changes in assets and liabilities affecting operating activities, net of effect of business combination: |                           |                       |   |
| Accounts receivable  | (765,689                  | ) 1,822,786           |   |
| Inventory  | 1,002,160                 | 782,742               |   |
| Other current assets and other assets  | (1,354,793                | ) (177,754            | ) |
| Accounts payable and other current liabilities   | 2,293,818                 | (2,942,455            | ) |
| Other long-term liabilities  | 105,416                   | 112,737               |   |
| Net cash provided by operating activities  | 3,957,854                 | 938,761               |   |
| Cash flows from investing activities:  |                           |                       |   |
| Additions to property and equipment  | (150,387                  | ) (92,435             | ) |
| Purchases of marketable securities   | (3,754,903                | ) (4,371,508          | ) |
| Proceeds from sale of marketable securities  | 3,001,735                 | 1,758,906             |   |
| Cash paid for acquisitions   | (2,000,000                | ) —                   |   |
| Additions to intangible assets   | (1,617,874                | ) (2,600,266          | ) |
| Net cash used in investment activities   | (4,521,429                | ) (5,305,303          | ) |
| Cash flows from financing activities:  |                           |                       |   |
| Net borrowings on line of credit   | —                         | 500,000               |   |
| Exercise of stock options  | —                         | (41,292               | ) |
| Excess tax benefit (expense) derived from exercise of stock options  | 1,077,099                 | (511,908              | ) |
| Sale of subsidiary shares to noncontrolling interest   | 1,000,005                 | —                     |   |
| Repurchase of common shares  | (2,738,905                | ) (3,918,436          | ) |
| Net cash used in financing activities  | (661,801                  | ) (3,971,636          | ) |
| Net decrease in cash and cash equivalents  | (1,225,376                | ) (8,338,178          | ) |
| Cash and cash equivalents at beginning of period   | 40,869,457                | 54,349,381            |   |
| Cash and cash equivalents at end of period   | \$39,644,081              | \$46,011,203          |   |
| Supplemental disclosure of cash flow information:  |                           |                       |   |
| Non-cash investing and financing activities:   |                           |                       |   |
| Net change in unpaid additions to intangibles, property and equipment  | \$974,809                 | \$230,522             |   |

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, 2013                           | 17,985,503   | \$63,073,941 | \$16,394,540 | \$ (176,638 )  | \$79,291,843 |
| Share-based compensation                             | 15,300       | 541,349      | —            | —              | 541,349      |
| Exercise of options and related tax benefit          | —            | 1,077,099    | —            | —              | 1,077,099    |
| Sale of subsidiary shares to noncontrolling interest | —            | 1,000,005    | —            | —              | 1,000,005    |
| Repurchase of common shares                          | (576,978 )   | (2,738,905 ) | —            | —              | (2,738,905 ) |
| Net income (loss)                                    | —            | —            | 1,754,810    | (40,908 )      | 1,713,902    |
| Balance, September 30, 2014                          | 17,423,825   | \$62,953,489 | \$18,149,350 | \$ (217,546 )  | \$80,885,293 |

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, 2013 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, 2013. The results of operations for the three and nine months ended September 30, 2014 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, 2014 and 2013.

#### 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 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 becomes effective on January 1, 2015. Adoption is on a prospective basis.

In May 2014, the FASB issued amended guidance in the form of a FASB Accounting Standards Update 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. Early adoption 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 we will adopt the standard in 2017.

#### 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.



## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

## Operating Segments

The Company operates in one segment, specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Substantially all of the Company's assets are located in the United States, and total revenues are primarily attributable to U.S. customers.

## (2) MARKETABLE SECURITIES

The Company invests in marketable debt securities in order to maximize its return on cash. Marketable securities consist of U.S. Treasury notes and bonds, U.S. Government Agency notes and bonds, and bank-guaranteed, variable rate demand notes ("VRDN"). At the time of purchase, the Company classifies marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of September 30, 2014 and December 31, 2013, 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.

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, 2014 |           |              | December 31, 2013 |           |              |
|---|--------------------|-----------|--------------|-------------------|-----------|--------------|
|   | Level 1            | Level 2   | Total        | Level 1           | Level 2   | Total        |
| U.S. Treasury notes and bonds                                 | \$ 1,355,823       | \$—       | \$ 1,355,823 | \$ 2,829,809      | \$—       | \$ 2,829,809 |
| U.S. Agency issued mortgage-backed securities – variable rate | —                  | 3,755,206 | 3,755,206    | —                 | 3,049,754 | 3,049,754    |
| U.S. Agency notes and bonds – fixed rate                      | —                  | 3,239,513 | 3,239,513    | —                 | 1,496,700 | 1,496,700    |

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|   |             |             |              |             |             |              |
|---|-------------|-------------|--------------|-------------|-------------|--------------|
| SBA loan pools – variable rate            | —           | 1,448,760   | 1,448,760    | —           | 1,748,498   | 1,748,498    |
| Municipal bonds – VRDN                    | 4,835,000   | —           | 4,835,000    | 4,895,000   | —           | 4,895,000    |
| Total fair value of marketable securities | \$6,190,823 | \$8,443,479 | \$14,634,302 | \$7,724,809 | \$6,294,952 | \$14,019,761 |

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## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

## (3) EARNINGS (LOSS) PER SHARE

The following table reconciles the numerator and denominator used to calculate diluted earnings per share for the three and nine months ended September 30, 2014 and 2013:

|   | Three months ended September 30, |             |
|---|----------------------------------|-------------|
|   | 2014                             | 2013        |
| Numerator:  |                                  |             |
| Net income (loss) attributable to common shareholders | \$745,920                        | \$(819,942) |
| Denominator:  |                                  |             |
| Weighted-average shares outstanding – basic           | 17,544,905                       | 18,233,407  |
| Dilutive effect of other securities                   | 303,205                          | —           |
| Weighted-average shares outstanding – diluted         | 17,848,110                       | 18,233,407  |
|   | Nine months ended September 30,  |             |
|   | 2014                             | 2013        |
| Numerator:  |                                  |             |
| Net income (loss) attributable to common shareholders | \$1,754,810                      | \$(604,251) |
| Denominator:  |                                  |             |
| Weighted-average shares outstanding – basic           | 17,730,715                       | 18,420,465  |
| Dilutive effect of other securities                   | 259,846                          | —           |
| Weighted-average shares outstanding – diluted         | 17,990,561                       | 18,420,465  |

As of September 30, 2014 and 2013, restricted stock awards and options to purchase 187,248 and 554,279 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

## (4) REVENUES

## Product Revenues

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2014 and 2013:

|                    | Three months ended September 30, |             | Nine months ended September 30, |              |
|--------------------|----------------------------------|-------------|---------------------------------|--------------|
|                    | 2014                             | 2013        | 2014                            | 2013         |
| Products:          |                                  |             |                                 |              |
| Acetadote          | \$3,242,014                      | \$3,770,302 | \$9,026,919                     | \$15,169,270 |
| Omeclamox-Pak      | 996,974                          | —           | 3,481,264                       |              |
| Kristalose         | 3,967,885                        | 2,207,586   | 10,903,255                      | 6,365,879    |
| Vaprisol           | 653,070                          | —           | 2,022,835                       |              |
| Caldolor           | 821,024                          | 484,651     | 1,950,106                       | 1,510,622    |
| Other              | 48,080                           | 66,036      | 188,080                         | 822,024      |
| Total net revenues | \$9,729,047                      | \$6,528,575 | \$27,572,459                    | \$23,867,795 |

As discussed in Note 10, the Company acquired rights to two new products, Omeclamox-Pak and Vaprisol, and both contributed to Cumberland's net revenue during 2014. On October 28, 2013, Cumberland entered into an agreement with Pernix Therapeutics ("Pernix") to distribute and promote Omeclamox-Pak. Under the terms of the agreement, effective October 1, 2013, the Company began to record the revenue of this product and effective January 2014 Cumberland began distributing Omeclamox-Pak and promoting it to gastroenterologists across the United States. On February 28, 2014, Cumberland entered into an agreement 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.

In November 2012, the Company entered into a settlement agreement with Paddock Laboratories, LLC ("Paddock") and Perrigo Company ("Perrigo") involving an Acetadote patent. As part of the agreement, Cumberland supplies 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 \$1.4 million and \$1.9 million for the third quarter of 2014 and 2013, respectively, and \$4.6 million and \$7.0 million for the nine months ended September 30, 2014 and 2013, respectively.

## Other Revenues

During the first half of 2013, the Company entered into five new agreements with international partners for commercialization of certain of the Company's products into additional international territories and amended its agreement with Harbin Gloria Pharmaceuticals Co., Ltd ("Harbin Gloria"), a Chinese pharmaceutical company, to extend its territory. As a result of the new and amended agreements, the Company recognized approximately \$0.6 million of non-refundable up-front payments as other revenue in the condensed consolidated statements of operations and comprehensive income during the six months ended June 30, 2013. The Company did not recognize any non-refundable up-front payments in the third quarter of 2013.

During the full year of 2013, the Company entered into a total of six new agreements and amended one agreement with international partners. The agreements entered into during 2013 provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulation. Under the licensing agreements, Cumberland is entitled to receive additional milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company will recognize revenue for these substantive milestones using the milestone method. The 2013 agreements provide for up to \$0.6 million in milestone payments related to regulatory approvals and up to \$4.0 million in milestone payments related to total and annual product sales. As of September 30, 2014, Cumberland has not recognized any revenues related to

milestones associated with the new agreements. The Company is also entitled to receive royalties on future sales of the products under the agreements.

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## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

## (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 September 30, 2014 and December 31, 2013 had varying original expiration dates that began in the second quarter of 2014 and extend through January 2016. During 2013, the Company provided stability data to the Food and Drug Administration ("FDA") supporting the extension of Caldolor product expiration dates by one year. In January 2014, the FDA notified the Company that it had approved its request to extend the original shelf life of the Caldolor 800mg vials from five to six years.

At September 30, 2014 and December 31, 2013, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately \$3.4 million and \$3.5 million, respectively.

In connection with the acquisition of certain product rights related to the Kristalose brand, the Company is responsible for the purchase of the active pharmaceutical ingredient for Kristalose and maintains the inventory at the third-party manufacturer. As the ingredients are consumed in production, the value of the ingredients is transferred from raw materials to finished goods.

As of September 30, 2014 and December 31, 2013, inventory was comprised of the following:

|                | September 30, 2014 | December 31, 2013 |
|----------------|--------------------|-------------------|
| Raw materials  | \$2,654,786        | \$2,025,020       |
| Finished goods | 3,475,936          | 3,697,862         |
| Total          | \$6,130,722        | \$5,722,882       |

## (6) SHAREHOLDERS' EQUITY AND DEBT

## Share Repurchases

On May 13, 2010, the Company announced a share repurchase program to purchase up to \$10.0 million of its common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012 and January 2013, the Company's Board of Directors replaced the prior authorizations with new \$10.0 million authorizations for repurchases of the Company's outstanding common stock. During the nine months ended September 30, 2014 and the nine months ended September 30, 2013, the Company repurchased 576,978 shares and 828,551 shares of common stock for approximately \$2.7 million and \$3.9 million, respectively.

## Restricted Share Grants

During the first nine months of 2014, the Company issued approximately 193,000 shares of restricted stock to employees and directors. Restricted stock issued to employees generally cliff-vests on the fourth anniversary of the date of grant. Restricted stock issued to directors vests on the one year anniversary of the date of grant. Stock compensation expense is presented as a component of general and administrative expense in the condensed consolidated statements of operations and comprehensive income.

## Cumberland Emerging Technologies

In April 2014, the Company received approximately \$1.0 million from Gloria for its participation in Cumberland Emerging Technologies ("CET"). As a result, Gloria received shares in CET and will have the first right to negotiate a license to CET developed products for the Chinese market. Prior to April 2014, Cumberland owned 85% of CET, with the balance of the enterprise being owned by Vanderbilt University and the Tennessee Technology Development Corporation. In connection with Gloria's investment in CET, the Company also provided an additional investment in CET. Cumberland contributed \$1.0 million in cash and provided \$2.4 million in loan forgiveness to CET in exchange

for newly issued shares. Upon completion of the additional investment by Gloria and Cumberland in April 2014, the Company's ownership in CET is 80%. As a consolidated subsidiary, the Company reports the operating results of CET and allocates the noncontrolling interests to the non-majority partners.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

New Debt Agreement

On June 26, 2014, Cumberland entered into a Revolving Credit Loan Agreement ("Loan Agreement") with SunTrust Bank. The new agreement replaced the August 2011 Fifth Amended and Restated Loan Agreement (the "Agreement") with its previous lender which was to expire on December 31, 2014. There are no borrowings under the Loan Agreement at September 30, 2014, and it has a three year term expiring on June 26, 2017. The Loan Agreement provides for an aggregate principal amount up to \$20 million. The initial revolving line of credit is up to \$12 million, an increase from the \$10 million under the previous Agreement. Similar to the previous Agreement, Cumberland has 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%. 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 is in compliance with all covenants at September 30, 2014.

The Company incurred no early termination penalties upon termination of the previous Agreement and incurred approximately \$0.1 million in deferred financing costs related to the new Loan Agreement, which will be amortized to interest expense using the effective interest method over the term of the Loan Agreement.

(7) INCOME TAXES

At September 30, 2014, the Company has unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately \$47.4 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 it paying minimal income taxes in each of the years 2009 through 2013. The Company expects to pay minimal income taxes in 2014 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 received notices during 2012 and 2013, that its Acetadote patents are being challenged on the basis of invalidity or non-infringement by others. The Company 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 vigorously 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, 2013, 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 in the event of a loss of patent rights and lower sales volumes due to competition.

## CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements - continued

(Unaudited)

## (10) NEW PRODUCTS

## Omeclamox-Pak

On October 28, 2013, the Company entered into an agreement with 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. There are additional milestones at the first and second anniversary dates of the execution of the agreement totaling \$4.0 million in the aggregate. Cumberland does not expect it will be required to make the first milestone payment to Pernix as all the criteria for that payment are not expected to be 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.

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 \$1.0 million and \$3.5 million in net revenues during the three and nine months ended September 30, 2014, respectively.

## Vaprisol

On February 28, 2014, the Company acquired certain product rights, intellectual property and related assets of Vaprisol from Astellas. Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic 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. The Company provided an upfront payment of \$2.0 million to Astellas at closing. There is an additional milestone payment due forty-five days after the first anniversary date of the closing of the transaction of up to \$2.0 million, dependent upon Cumberland achieving certain first year sales levels for the product. 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 following table summarizes the preliminary allocation of the fair values of the assets acquired and liabilities assumed as of the acquisition date for Vaprisol:

|   |              |   |
|---|--------------|---|
| Intellectual property intangible assets | \$ 2,990,000 |   |
| Inventories                             | 1,410,000    |   |
| Acquired contingent liabilities         | (400,000     | ) |
| Contingent consideration obligation     | (2,000,000   | ) |
| Total net assets acquired               | \$ 2,000,000 |   |

The contingent consideration obligation represents the additional milestone payment discussed above. Cumberland prepared the valuations of the contingent consideration obligation and the intangible assets utilizing significant unobservable inputs. As a result, the valuations are classified as Level 3 fair value measurements. The Company continues to evaluate the assets acquired and liabilities assumed during the measurement period. Vaprisol contributed \$0.7 million and \$2.0 million in net revenues during the three and nine months ended September 30, 2014, respectively. The pro-forma effects of the acquisition on the condensed consolidated financial statements were not deemed material for disclosure purposes.

## 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 19 through 34, and "Special Note Regarding Forward-Looking Statements" on page 34 of our Annual Report on Form 10-K for the year ended December 31, 2013. 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," "we," "our," or the "Company"), 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 duodenal ulcer disease,

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

• **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").

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 products while continuing to build a portfolio of new, differentiated products. Specifically, we expect to grow by executing the following plans:

•

Continue to internally develop a line of late stage product candidates that address unmet medical needs. Our development team that has successfully registered our Acetadote and Caldolor products is working to identify and develop new late stage product candidates. Those efforts have led to the advancement of Hepatoren into a multicenter Phase II study. We will also continue to explore opportunities for label expansion to bring our marketed products to new patient populations.

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Expand our product portfolio by acquiring rights to additional marketed 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.

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. 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 Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland has the opportunity to negotiate rights to further develop and commercialize them in the U.S and other markets.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. In 2009, we completed an initial public offering of our common stock and listing of our shares 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, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments, as well as other documents following their filing with the SEC. These filings are also made available to the public by the SEC at [www.sec.gov](http://www.sec.gov).

#### Recent Developments and Highlights

##### Omeclamox®-Pak

###### Launch of Omeclamox-Pak

We launched our promotion and distribution efforts to support Omeclamox-Pak in early 2014. Our field sales force promotes Omeclamox-Pak to the gastroenterologist segment, which accounts for the largest component of the prescriber base for this product. Omeclamox-Pak is a branded prescription product used for the treatment of *Helicobacter pylori* (*H. pylori*) infection and duodenal ulcer disease. This innovative product combines three well-known and widely prescribed medications: omeprazole, clarithromycin, and amoxicillin. Omeclamox-Pak is the first FDA approved triple therapy combination medication to contain omeprazole as the proton pump inhibitor, which works to decrease the amount of acid the stomach produces. Clarithromycin and amoxicillin are both antibiotic agents which hinder the growth of *H. pylori*. Interaction of these agents allows the stomach lining to heal effectively. The medications are packaged together on convenient daily dosing cards, making it simple to follow the twice a day dosing before meals.

While there are competing products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the competing branded products, Omeclamox-Pak combines the lowest pill burden, fewest days of therapy and the lowest cost. Our involvement with Omeclamox-Pak was effective October 2013, through an agreement with Pernix Therapeutics ("Pernix"). Pernix continues to promote the product through its specialty sales force focusing on select primary care physicians. We are responsible for the marketing, sale and distribution of the product.

##### Vaprisol®

###### Launch of Vaprisol

In February 2014, we entered into an agreement with Astellas Pharma US, Inc. ("Astellas") to acquire Vaprisol including certain product rights, intellectual property and related assets. 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, and the first and only intravenously administered branded treatment.

Hyponatremia, an imbalance of serum sodium to body water, is the most common electrolyte disorder among hospitalized patients. These electrolyte disturbances occur when the sodium ion concentration in the plasma is lower than normal and are often associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia. Vaprisol raises serum sodium to appropriate levels and promotes free water secretion.

We re-launched active promotion of the brand in early May 2014 utilizing our hospital sales force, which also features our Caldolor and Acetadote products.

#### Cumberland Emerging Technologies

In April 2014, we received approximately \$1.0 million from Harbin Gloria Pharmaceuticals Co., Ltd. ("Gloria") for their participation in CET. As a result, Gloria received shares in CET and joined the CET ownership group. As part of this transaction, Gloria will have the first right to negotiate a license to CET developed products for the Chinese market. The funds from this new investment are being used to support and accelerate the development of CET product candidates. CET's lead product candidate is ifetroban which is being developed by Cumberland under the brand name Hepatoren. During the second quarter of 2014 we also filed and cleared an amendment to the existing IND with the FDA to begin to evaluate an oral formulation of ifetroban.

Prior to April 2014, we owned 85% of CET, with the balance of the enterprise being owned by Vanderbilt University and the Tennessee Technology Development Corporation. In connection with Gloria's investment in CET, we also provided an additional investment in CET through \$1.0 million in cash and \$2.4 million in loan forgiveness. Upon completion of the additional investment by Gloria and Cumberland in April 2014, our ownership in CET is 80%. During the third quarter of 2014 Cumberland Pharmaceuticals received a grant from the National Institutes of Health through its Small Business Technology Transfer ("STTR") grant program. The STTR program provides federal funding for innovative research and development by expanding partnerships between businesses and nonprofit research institutions. The STTR program provides for formal collaboration between a research institution and a business to ensure that the related science and technology results in the successful commercialization of the scientific innovations. The STTR grant is for approximately \$0.2 million and is in conjunction with Vanderbilt University School of Medicine.

#### Caldolor®

##### Caldolor Patents

On May 27, 2014, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,735,452 (the "452 Caldolor Patent") which is assigned to us. The claims of the 452 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 452 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

On October 28, 2014, the USPTO issued U.S. Patent number 8,871,810 (the "810 Caldolor Patent") which is assigned to us. The claims of the 810 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 810 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029. We also have additional patent applications related to Caldolor which are pending with the USPTO.

##### Caldolor Pediatric Presentation

Data from our Caldolor pediatric fever studies that reflect treatment with intravenous ibuprofen was superior in reducing temperatures in hospitalized, febrile pediatric patients when compared to treatment with oral or suppository acetaminophen was presented as part of the American Academy of Pediatrics National Conference & Exhibition in San Diego, California in October 2014. An abstract presentation entitled "A Multi-Center, Open-Label, Parallel, Active-Comparator Trial to Determine the Efficacy and Safety of Intravenous Ibuprofen in Pediatric Patients" was presented by Dr. Corrie Chumpitazi of Texas Children's Hospital, Houston, Texas. The abstract was presented in the section of Emergency Medicine and again in the section on Pharmacy and Therapeutics.

The studies were designed to evaluate the safety and efficacy in IV ibuprofen when compared to oral or suppository acetaminophen in the treatment of hospitalized, febrile pediatric patients. The studies showed that when given intravenous ibuprofen hospitalized children experienced significant reduction in temperature compared to those receiving acetaminophen (oral or suppository). Both single and multiple doses of IV ibuprofen were well tolerated and no significant adverse events were noted.

A poster presentation entitled "A Multi-Center, Randomized, Open-label, Parallel, Active-Comparator Trial to Determine the Efficacy and Safety of Intravenous Ibuprofen in Pediatric children" was also presented twice at this National Conference. The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults.

##### Caldolor Laparoscopic Cholecystectomy Presentation

Data from the Caldolor study reflects that treatment with preoperative intravenous ibuprofen improved overall quality of recovery in patients undergoing laparoscopic cholecystectomy surgery. These results were presented as a poster presentation entitled "The Effect of Preoperative Administration of IV Ibuprofen on Stress Response in Patients Undergoing Laparoscopic Cholecystectomy" in October 2014 at the American Anesthesiology 2014 Annual Meeting in New Orleans, Louisiana.



The investigator study was completed at the University of Medicine and Dentistry of New Jersey/Rutgers University and New York Methodist with Alex Bekker, MD, PhD, as the primary investigator. The study concluded that preoperative intravenous ibuprofen improved the overall quality of recovery including comfort, emotion and pain and reduced fatigue in the early postoperative period. Further, the study results indicated that preoperative administration of intravenous ibuprofen decreased the stress hormones catecholamines and cortisol postoperatively after laparoscopic cholecystectomy.

Acetadote®

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 |

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 vigorously defend and protect our Acetadote product and related intellectual property rights. Information and discussion regarding our Acetadote patent defense is contained in Part 1, Item 1, Business -Trademarks and Patents, of our Form 10-K for the year ended December 31, 2013, which is incorporated by reference herein. We have no recent developments that would impact those disclosures.

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

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 40 through 43 in “Management’s Discussion and Analysis” of our Annual Report on Form 10-K for the year ended December 31, 2013.

#### 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, 2014 compared to the three months ended September 30, 2013

The following table presents the unaudited interim statements of operations for the three months ended September 30, 2014 and 2013:

|                                   | Three months ended September 30, |              |              |
|-----------------------------------|----------------------------------|--------------|--------------|
|                                   | 2014                             | 2013         | Change       |
| Net revenues                      | \$9,729,047                      | \$6,528,575  | \$3,200,472  |
| Costs and expenses:               |                                  |              |              |
| Cost of products sold             | 1,339,723                        | 1,030,943    | 308,780      |
| Selling and marketing             | 3,821,953                        | 3,410,205    | 411,748      |
| Research and development          | 934,783                          | 1,440,584    | (505,801 )   |
| General and administrative        | 2,158,057                        | 1,958,629    | 199,428      |
| Amortization                      | 485,493                          | 202,982      | 282,511      |
| Total costs and expenses          | 8,740,009                        | 8,043,343    | 696,666      |
| Operating income (loss)           | 989,038                          | (1,514,768 ) | 2,503,806    |
| Interest income                   | 108,005                          | 20,350       | 87,655       |
| Interest expense                  | (26,877 )                        | (24,286 )    | (2,591 )     |
| Income (loss) before income taxes | 1,070,166                        | (1,518,704 ) | 2,588,870    |
| Income tax (expense) benefit      | (340,982 )                       | 686,209      | (1,027,191 ) |
| Net income (loss)                 | \$729,184                        | \$(832,495 ) | \$1,561,679  |

Net revenues. Net revenues for the three months ended September 30, 2014 were approximately \$9.7 million compared to \$6.5 million for the three months ended September 30, 2013, representing an increase of \$3.2 million, or 49.0%.

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

|                    | Three months ended September 30, |             |              |
|--------------------|----------------------------------|-------------|--------------|
|                    | 2014                             | 2013        | Change       |
| Products:          |                                  |             |              |
| Acetadote          | \$3,242,014                      | \$3,770,302 | \$(528,288 ) |
| Omeclamox-Pak      | 996,974                          | —           | 996,974      |
| Kristalose         | 3,967,885                        | 2,207,586   | 1,760,299    |
| Vaprisol           | 653,070                          | —           | 653,070      |
| Caldolor           | 821,024                          | 484,651     | 336,373      |
| Other              | 48,080                           | 66,036      | (17,956 )    |
| Total net revenues | \$9,729,047                      | \$6,528,575 | \$3,200,472  |

The significant revenue increase compared to the prior year period was driven primarily by growth in four of our five branded prescription products. Our revenue gains were led by increases in Kristalose revenue of \$1.8 million, Omeclamox-Pak revenue of \$1.0 million and Vaprisol revenue of \$0.7 million. Caldolor experienced a \$0.3 million revenue increase while a decrease in Acetadote product revenue of \$0.5 million partially offset the overall revenue increase.

Kristalose revenue increased 79.7% over the prior year 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.

Acetadote net revenue for the third quarter of 2014 included \$1.4 million in revenue from sales of our Authorized Generic distributed by Perrigo, compared to \$1.9 million for the same period last year. This \$0.5 million decrease in sales of the generic product accounted for the decline in total Acetadote revenue, while revenue from the branded Acetadote product was relatively consistent with the prior year despite generic competition.



While our recently added Omeclamox-Pak brand contributed revenue of \$1.0 million during the three months ended September 30, 2014, the brand's sales were negatively impacted by a temporary shortage of marketable product during a portion of the period. This temporary product shortage was resolved at the end of October 2014.

Cost of products sold. As a percentage of net revenues, cost of products sold decreased to 13.8% during the three months ended September 30, 2014 compared to 15.8% during the three months ended September 30, 2013. The decrease in costs of sales as a percentage of revenue was attributable to a change in the product sales mix and increased pricing.

Selling and marketing. Selling and marketing expense for the three months ended September 30, 2014 totaled approximately \$3.8 million, which was an increase of \$0.4 million compared to the prior year's expense of \$3.4 million. The increase was the result of increased sales, primarily due to increases in Omeclamox-Pak product royalties and increased distribution costs of products and product samples. We continue to evaluate our selling and marketing costs and efforts under our commercial strategy, including the incremental costs of promoting our recently added products.

Research and development. Research and development costs for the third quarter of 2014 were \$0.9 million, compared to \$1.4 million for the same period last year, representing a decrease of approximately \$0.5 million, or 35.1%. This change was the result of decreased product development and clinical study costs during 2014 compared to 2013 following the conclusion of clinical studies related to Caldolor.

General and administrative. General and administrative expense was \$2.2 million for the three months ended September 30, 2014, compared to \$2.0 million during the three months ended September 30, 2013. The \$0.2 million increase was driven by increases in salary, wages and benefits costs during the quarter. We continue to realign the organization to support the current mix of brands.

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, 2014 totaled approximately \$0.5 million, which was an increase of \$0.3 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) benefit. Income tax expense for the three months ended September 30, 2014 totaled approximately \$0.3 million, compared to an income tax benefit of \$0.7 million in third quarter of 2013, representing an increase in expense of approximately \$1.0 million. The increase was the result of pretax income in the third quarter of 2014 compared to pretax loss in the same period last year. As a percentage of income before income taxes, income tax expense was 31.9% for the three months ended September 30, 2014 compared to 45.2% for the three months ended September 30, 2013. The tax expense for the three months ended September 30, 2014 was positively impacted by a reduction in our state tax expense during 2014.

As of September 30, 2014, we have approximately \$47.4 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, 2014 Compared to the Nine months ended September 30, 2013

The following table presents the unaudited interim statements of operations for the nine months ended September 30, 2014 and 2013:

|                                   | Nine months ended September 30, |              | Change        |
|-----------------------------------|---------------------------------|--------------|---------------|
|                                   | 2014                            | 2013         |               |
| Net revenues                      | \$27,572,459                    | \$23,867,795 | \$3,704,664   |
| Costs and expenses:               |                                 |              |               |
| Cost of products sold             | 3,692,256                       | 3,294,411    | 397,845       |
| Selling and marketing             | 11,365,966                      | 10,626,193   | 739,773       |
| Research and development          | 2,622,310                       | 4,276,206    | (1,653,896 )  |
| General and administrative        | 6,195,523                       | 6,389,569    | (194,046 )    |
| Amortization                      | 1,083,706                       | 610,677      | 473,029       |
| Total costs and expenses          | 24,959,761                      | 25,197,056   | (237,295 )    |
| Operating income (loss)           | 2,612,698                       | (1,329,261   | ) 3,941,959   |
| Interest income                   | 204,892                         | 161,709      | 43,183        |
| Interest expense                  | (51,358                         | ) (62,721    | ) 11,363      |
| Income (loss) before income taxes | 2,766,232                       | (1,230,273   | ) 3,996,505   |
| Income tax (expense) benefit      | (1,052,330                      | ) 590,250    | (1,642,580 )  |
| Net income (loss)                 | \$1,713,902                     | \$(640,023   | ) \$2,353,925 |

Net revenues. Net revenues for the nine months ended September 30, 2014 were approximately \$27.6 million compared to \$23.9 million for the nine months ended September 30, 2013, representing an increase of \$3.7 million or 15.5%.

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

| Products:          | Nine months ended September 30, |              | Change         |
|--------------------|---------------------------------|--------------|----------------|
|                    | 2014                            | 2013         |                |
| Acetadote          | \$9,026,919                     | \$15,169,270 | \$(6,142,351 ) |
| Omeclamox-Pak      | 3,481,264                       | —            | 3,481,264      |
| Kristalose         | 10,903,255                      | 6,365,879    | 4,537,376      |
| Vaprisol           | 2,022,835                       | —            | 2,022,835      |
| Caldolor           | 1,950,106                       | 1,510,622    | 439,484        |
| Other              | 188,080                         | 822,024      | (633,944 )     |
| Total net revenues | \$27,572,459                    | \$23,867,795 | \$3,704,664    |

The revenue increase in the first nine months of 2014 was driven primarily by increases in Kristalose product revenue of \$4.5 million, Omeclamox-Pak revenue of \$3.5 million and Vaprisol revenue of \$2.0 million. A decrease in Acetadote product revenue of \$6.1 million partially offset this overall revenue increase.

Kristalose revenue increased 71.3% over the prior year 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.

The year over year decrease in Acetadote net revenue was primarily due to decreased sales volume of the branded Acetadote product largely as a result of generic competition. In addition, Acetadote product revenue for the first nine months of 2014 included \$4.6 million in sales of the Authorized Generic product compared to prior year sales of \$7.0 million.

We recognized \$0.6 million of other revenue in the first nine months of 2013 as the result of upfront payments we received in connection with out-licensing agreements with international commercial partners.



Cost of products sold. As a percentage of net revenues, cost of products sold decreased to 13.4% during the nine months ended September 30, 2014, compared to 13.8% in the prior year. The decrease in costs of sales as a percentage of revenue was attributable to a change in the product sales mix and increased pricing.

Selling and marketing. Selling and marketing expense for the nine months ended September 30, 2014 was \$11.4 million, compared to \$10.6 million for the nine months ended September 30, 2013, representing an increase of \$0.7 million. The increase was the result of increased sales, including a \$0.6 million increase in Omeclamox-Pak product royalties and increased distribution costs of products and product samples. We continue to evaluate our selling and marketing costs and efforts under our commercial strategy, including the incremental costs of promoting our recently added products.

Research and development. Research and development costs for the nine months ended September 30, 2014 were \$2.6 million, compared to \$4.3 million for the same period last year, representing a decrease of approximately \$1.7 million, or 38.7%. This change was a result of decreased product development and clinical study costs during 2014 compared to 2013 following the conclusion of clinical studies related to Caldolor.

General and administrative. General and administrative expense for the nine months ended September 30, 2014 totaled approximately \$6.2 million, compared to \$6.4 million in the same period last year. The decrease was attributable to decreases in travel costs, legal expenses and consulting fees, partially offset by increased salary, wages and benefits costs during the period. We continue to realign the organization to support the current mix of brands.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization expense for the first nine months of 2014 was \$1.1 million compared to \$0.6 million in the same period last year, representing an increase of \$0.5 million. The increase in amortization was attributable to additional product and license rights, capitalized patents and patent defense costs.

Income tax (expense) benefit. Income tax expense for the nine months ended September 30, 2014 totaled approximately \$1.1 million, representing an increase in expense over the income tax benefit in the prior year of \$0.6 million. The primary reason for the increase was the result of pretax income for the nine months ended September 30, 2014 compared to pretax loss in the same period last year. As a percentage of income before income taxes, income tax expense was 38.0% for the first nine months of 2014 compared to a benefit percentage of 48.0% for the same period last year. The tax benefit for the nine months ended September 30, 2013 was positively impacted by the reinstatement of the U.S. research and development tax credit during 2013.

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

Our primary sources of liquidity are cash flows provided by our operations, the availability under our line of credit and the cash proceeds from our initial public offering of common stock that was completed in August 2009. For the nine months ended September 30, 2014 and 2013, we generated \$4.0 million and \$0.9 million in cash flow from operations, respectively. We believe that our internally generated cash flows and amounts available under our line of credit will be adequate to service existing debt, finance internal growth and fund capital expenditures.

We invest a portion of our cash reserves in variable rate demand notes ("VRDNs") and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate, mortgage-backed securities). The VRDNs are generally issued by municipal governments and are backed by a financial institution letter of credit. We hold a put right on the VRDNs, which allows us to liquidate the investments relatively quickly (less than one week). The government-backed securities have an active secondary market that generally provides for liquidity in less than one week. At September 30, 2014 and December 31, 2013, we had approximately \$14.6 million and \$14.0 million invested in marketable securities, respectively.

The following table summarizes our liquidity and working capital as of September 30, 2014 and December 31, 2013:

|   | September 30,<br>2014 | December 31,<br>2013 |
|---|-----------------------|----------------------|
| Cash and cash equivalents   | \$39,644,081          | \$40,869,457         |
| Marketable securities   | 14,634,302            | 14,019,761           |
| Total cash, cash equivalents and marketable securities            | \$54,278,383          | \$54,889,218         |
| Working capital (current assets less current liabilities)         | \$57,994,489          | \$61,133,945         |
| Current ratio (multiple of current assets to current liabilities) | 5.8                   | 9.1                  |
| Revolving line of credit availability                             | \$12,000,000          | \$10,000,000         |

The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2014 and September 30, 2013:

|   | Nine months ended September 30, |               |
|---|---------------------------------|---------------|
|   | 2014                            | 2013          |
| Net cash provided by (used in):           |                                 |               |
| Operating activities                      | \$3,957,854                     | \$938,761     |
| Investing activities                      | (4,521,429)                     | (5,305,303)   |
| Financing activities                      | (661,801)                       | (3,971,636)   |
| Net decrease in cash and cash equivalents | \$(1,225,376)                   | \$(8,338,178) |

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

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

As of September 30, 2014, we have approximately \$47.4 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. The new agreement replaced the August 2011 Fifth Amended and Restated Loan Agreement with a previous lender which was to expire on December 31, 2014. There are no borrowings under the Loan Agreement at September 30, 2014. The Loan Agreement provides for an aggregate principal amount of up to \$20 million, and it has a three year term expiring on June 26, 2017. The initial revolving line of credit is up to \$12 million, an increase from the \$10 million under the previous agreement. We have the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions. Our interest rate 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%. 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 our 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, determined on a quarterly basis. We are in compliance with all covenants at September 30, 2014.

#### OFF-BALANCE SHEET ARRANGEMENTS



During the nine months ended September 30, 2014 and 2013, we did not engage in any off-balance sheet arrangements.

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### 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.

During 2012, we analyzed our return on our investments and determined investing 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), would yield a higher return with minimal additional risk. 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 \$14.6 million in marketable securities outstanding at September 30, 2014, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income of \$0.1 million

The interest rate related to our revolving credit facility is a variable rate based on LIBOR plus an interest rate spread. As of September 30, 2014, no borrowings were 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. As of September 30, 2014, our outstanding payables denominated in a foreign currency were less than \$0.1 million.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange gains and losses were immaterial for the nine months ended September 30, 2014 and 2013. Neither a 10% increase nor decrease from current exchange rates would have a significant effect on our operating results or financial condition.

#### Item 4. Controls and Procedures

Our principal executive and principal financial officers evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2014. Based on that evaluation, our disclosure controls and procedures are considered effective to ensure that material information relating to us and our consolidated subsidiaries is made known to officers within these entities in order to allow for timely decisions regarding required disclosure.

## PART II – OTHER 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, 2013, which is incorporated by reference herein.

### Item 1a. Risk Factors

Information regarding risk factors appears on pages 19 through 33 in our Annual Report on Form 10-K for the year ended December 31, 2013 under the section titled “Risk Factors.” The following risk factor was included in our Form 10-K for the year ended December 31, 2013 and has been updated for recent developments:

Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited protection from competition.

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product formulation.

Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver.

In April 2012, the United States Patent and Trademark Office (the “USPTO”) issued U.S. Patent number 8,148,356 (the “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO. Following the issuance of the 356 Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC (“Paddock”) and Mylan Institutional LLC challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity.

On May 17, 2012, we responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the 356 Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. (“Mylan”) in the United States District Court for the Northern District of Illinois, Eastern Division. The second lawsuit was filed against InnoPharma, Inc. in the United States District Court for the District of Delaware. The third lawsuit was also filed in the United States District Court for the District of Delaware against Paddock and Perrigo Company (“Perrigo”). On May 20, 2012, we received a Paragraph IV certification notice from Sagent Agila LLC challenging the 356 Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the 356 Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. (“Sagent”) in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo. On August 9, 2012, we filed a lawsuit for infringement of the 356 Acetadote Patent against Perrigo in the United States District Court for the Northern District of Illinois, Eastern Division.

On November 12, 2012, we entered into a Settlement Agreement (the “Settlement Agreement”) with Paddock and Perrigo to resolve the challenges and the pending litigation with each of Paddock and Perrigo involving the 356 Acetadote Patent. Under the Settlement Agreement, Paddock and Perrigo admit that the 356 Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, we entered into a License and

Supply Agreement with Paddock and Perrigo (the “License and Supply Agreement”). Under the terms of the License and Supply Agreement, if a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party has made such generic version available for purchase in commercial quantities in the United States, we will supply Perrigo with an Authorized Generic version of our Acetadote product (the “Authorized Generic”).

By statute, where the Paragraph IV certification is to a patent timely listed before an Abbreviated New Drug Application (“ANDA”) is filed, a company has 45 days to institute a patent infringement lawsuit during which period the FDA may not approve another application. In addition, such a lawsuit for patent infringement filed within such 45-day period may stay, or bar, the FDA from approving another product application for two and a half years or until a district court decision that is adverse to the asserted

patents, whichever is earlier. On May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us with respect to the remaining lawsuits.

On May 18, 2012, we also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that we evaluate the reduction or removal of EDTA from its original Acetadote formulation. On November 7, 2012, the FDA responded to the Citizen Petition denying our request and stating that ANDAs referencing Acetadote that contain EDTA may be accepted and approved provided they meet all applicable requirements. We believe this response contradicts the FDA's request to evaluate the reduction or removal of EDTA. On November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. On November 13, 2012, we brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of our Citizen Petition and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law.

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

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

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

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

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

We intend to continue to vigorously defend and protect our Acetadote product and related intellectual property.

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.

We also have additional patent applications relating to Acetadote which are pending with the USPTO and may or may not be issued. As noted, we intend to continue to vigorously defend and protect our Acetadote product and related intellectual property rights. If we are unsuccessful in protecting our Acetadote intellectual property rights, our competitors may be able to introduce products into the marketplace that reduce the sales and market share of our Acetadote product which may require us to take measures such as reducing prices or increasing our marketing expense, any of which may result in a material adverse effect to our financial condition and results of operations.

We have U.S. Patent number 6,727,286 (the “286 Caldolor Patent”) and related international patents which include composition of matter claims that encompass the Caldolor formulation and claims directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor, ibuprofen, is in the public domain, and a competitor could try to develop, test and seek FDA approval for a sufficiently distinct formulation for another ibuprofen product that competes with Caldolor. The 286 Caldolor U.S. Patent is listed in the FDA Orange Book and expires in November of 2021.

On May 27, 2014, the USPTO issued U.S. Patent number 8,735,452 (the “452 Caldolor Patent”) which is assigned to us. The claims of the 452 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 452 Caldolor Patent was listed in the FDA Orange Book. The 452 Caldolor Patent is scheduled to expire in September 2029.

On October 28, 2014, the USPTO issued U.S. Patent number 8,871,810 (the “810 Caldolor Patent”) which is assigned to us. The claims of the 810 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 810 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029. We also have additional patent applications related to Caldolor which are pending with the USPTO.

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents.

Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

### Purchases of Equity Securities

The following table summarizes our purchase of Cumberland equity securities during the three months ended September 30, 2014:

| Period    | Total Number of Shares (or Units) Purchased | Average Price Paid per Share (or Unit) | Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup> |
|-----------|---|--|---|--|
| July      | 75,018                                      | \$4.60                                 | 75,018  | \$3,676,848  |
| August    | 90,028                                      | 4.99                                   | 90,028  | 3,227,474  |
| September | 71,496                                      | (1) 5.09                               | 71,496  | 2,863,388  |
| Total     | 236,542                                     |  | 236,542   |  |

(1) Of this amount, 16,000 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: November 7, 2014

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

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