#### CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

May 09, 2018

Non-accelerated

#### **UNITED STATES**

### SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

## **FORM 10-Q**

(Mark One)

**QUARTERLY** 

**REPORT** 

**PURSUANT** 

TO SECTION

ý 13 OR 15(d) OF

THE

**SECURITIES** 

**EXCHANGE** 

**ACT OF 1934** 

For the quarterly period ended March 31, 2018

OR

**TRANSITION** 

**REPORT** 

**PURSUANT** 

TO SECTION

" 13 OR 15(d) OF

THE

**SECURITIES** 

**EXCHANGE** 

**ACT OF 1934** 

For the transition period from to

Commission file number: 001-33637

### **Cumberland Pharmaceuticals Inc.**

(Exact Name of Registrant as Specified In Its Charter)

Tennessee 62-1765329

(State or Other

Jurisdiction of (I.R.S. Employer Incorporation or Identification No.)

Organization)

**2525 West** 

End

Avenue,

37203

**Suite 950,** 

Nashville,

**Tennessee** 

(Zip Code)

(Address of Principal Executive Offices)

#### (615) 255-0068

#### (Registrant's Telephone Number, Including Area Code)

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

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

Large accelerated filer

y´ (Do not check if a smaller reporting company reporting company)

Smaller reporting company ...

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No ý Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Outstanding Class at May 4,

2018

Common

stock, no 15,710,953

par value

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# PART I – FINANCIAL INFORMATION Item 1. Financial Statements (Unaudited) CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets (Unaudited)

(	March 31,	2018	December 31, 2017		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	35,262,976	\$	45,412,868	
Marketable securities	15,610,105		4,672,476		
Accounts receivable, net of allowances	6,301,162		8,395,112		
Inventories, net	6,661,525		6,737,848		
Other current assets	2,987,404		3,466,541		
Total current assets	66,823,172		68,684,845		
Property and equipment, net	566,907		528,882		
Intangible assets, net	21,052,197		21,444,545		
Deferred tax assets, net	87,210		87,210		
Other assets	2,565,354		2,486,830		
Total assets	\$	91,094,840	\$	93,232,312	
LIABILITIES AND EQUITY					
Current liabilities:					
Accounts payable	\$	8,518,879	\$	8,979,929	
Other current liabilities	7,770,977		8,714,814		
Total current liabilities	16,289,856		17,694,743		
Revolving line of credit	12,000,000		9,800,000		
Other long-term liabilities	1,930,679		1,815,968		
Total liabilities	30,220,535		29,310,711		

Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q Commitments and contingencies Equity: Shareholders' equity: Common stock-no par value; 100,000,000 shares authorized; 15,727,250 and 15,723,075 51,755,834 52,410,941 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively Retained 9,329,983 11,709,222 earnings Total shareholders' 61,085,817 64,120,163 equity Noncontrolling (211,512)(198,562)interests Total equity 60,874,305 63,921,601

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

\$

93,232,312

91,094,840

1

Total liabilities

and equity

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

(Chauditeu)					
	Three months ended March 31,				
	2018		2017		
Net revenues	\$	8,587,605	\$	9,636,755	
Costs and expenses:					
Cost of products sold	1,527	,961	1,381,497		
Selling and marketing	4,670	,511	5,293,020		
Research and development	1,874	,939	898,363		
General and administrative	2,330	,281	2,110,233		
Amortization	636,1	35	611,444		
Total costs and expenses	11,03	9,827	10,294,557		
Operating income (loss)	(2,452	2,222)	(657,802)		
Interest income	82,494		52,535		
Interest expense	(18,30	02)	(31,715)		
Income (loss) before income taxes	(2,388,030)		(636,982)		
Income tax (expense) benefit	(4,159	9)	(656,587)		
Net income (loss)	(2,392	2,189)	(1,293,569)		
Net loss at subsidiary attributable to noncontrolling interests	12,950		19,123		
Net income (loss) attributable to common shareholders	\$	(2,379,239)	\$	(1,274,446)	
Earnings (loss) per share attributable to common shareholders					
- basic	\$	(0.15)	\$	(0.08)	
- diluted	\$	(0.15)	\$	(0.08)	

Weighted-average shares outstanding		
- basic	15,689,240	16,042,219
- diluted	15,689,240	16,042,219
Comprehensive income (loss) attributable to common shareholders	(2,379,239)	(1,274,446)
Net loss at subsidiary attributable to noncontrolling interests	12,950	19,123

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

(2,392,189)

\$

(1,293,569)

\$

2

Total

comprehensive

income (loss)

# **CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Statements of Cash Flows**

#### (Unaudited)

(0111111111111)			
	Three months ended March 2018	31, 2017	
Cash flows from operating activities:			
Net income (loss)	\$ (2,392,189)	\$	(1,293,569)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization expense	692,991	661,485	
Deferred tax expense	_	758,112	
Share-based compensation	339,209	254,585	
Excess tax (benefit) expense derived from exercise of stock options	_	(92,741)	
Noncash interest expense	18,303	26,778	
Noncash investment gains	(43,338)	(4,807)	
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	2,093,950	2,395,348	
Inventories	76,323	(275,175)	
Other current assets and other assets	600,884	132,819	

Accounts payable and other current liabilities	(1,254,535)	(1,216,345)
Other long-term liabilities	103,991	92,881
Net cash provided by operating activities	235,589	1,439,371
Cash flows from investing activities:		
Additions to property and equipment	(94,881)	(123,945)
Purchases of marketable securities	(15,151,948)	(792,716)
Proceeds from sale of marketable securities	4,257,657	941,087
Additions to intangible assets	(532,954)	(453,961)
Net cash used in investing activities	(11,522,126)	(429,535)
Cash flows from financing activities:		
Borrowings on line of credit	12,000,000	_
Repayments on line of credit	(9,800,000)	_
Sales of shares of common stock, net of offering costs	200,909	_
Payments of deferred offering costs	(248,108)	_
Repurchase of common shares	(1,016,156)	(545,924)
	1,136,645	(545,924)

Net cash provided by (used in) financing activities Net increase (decrease) in (10,149,892) 463,912 cash and cash equivalents Cash and cash equivalents at 45,412,868 34,510,330 beginning of period

Cash and cash

equivalents at \$ 35,262,976 \$ 34,974,242

end of period

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Common stock Share&mount		Retained earnings		Noncontrolling interests		Total equity	
Balance, December 31, 2017	15,7\$3,075	52,410,941	\$	11,709,222	\$	(198,562)	\$	63,921,601
Proceeds from the sale of common stock, net of offering costs	30,7 <b>20</b> 40,909		_		_		200,909	
Share-based compensation	145, <b>339</b> ,209		_		_		339,209	
Repurchase of common shares	(17 <b>2,0,79)</b> 5,223	5)	_		_		(1,195,225	5)
Net loss			(2,379,239	9)	(12,950)		(2,392,189	9)
Balance, March 31, 2018	15,7\$7,250	51,755,834	\$	9,329,983	\$	(211,512)	\$	60,874,305

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

#### (1) ORGANIZATION AND BASIS OF PRESENTATION

Cumberland Pharmaceuticals Inc. ("Cumberland," the "Company," or as used in the context of "we," "us," or "our") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets are hospital acute care, gastroenterology, and oncology supportive care. 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 focuses its resources on maximizing the commercial potential of its products, as well as developing new product candidates, and has both internal development and commercial capabilities. The Company's products are manufactured by third parties, which are overseen by Cumberland's quality control and manufacturing professionals. The Company works closely with its third-party distribution partners to make its products available in the United States.

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, 2017 audited consolidated financial statements, with the exception of the impacts of adopting accounting pronouncements during 2018, 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 (the "SEC"), and certain information and disclosures have been condensed or omitted as permitted by the SEC for interim period presentation. 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, 2017 (the "2017 Annual Report on Form 10-K"). The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income (loss) consisted solely of net income (loss) for the three months ended March 31, 2018 and 2017.

#### Adoption of Revenue Accounting Standard

Effective January 1, 2018, the Company adopted the Financial Accounting Standards Board's ("FASB") amended guidance in the form of Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers," (ASC 606). Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts were not adjusted and are reported in accordance with ASC 605.

#### Net Product Revenue

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which occurs upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction. Payment terms typically range from 30 to 45 days from date of shipment. The Company's net product revenue reflects the reduction from gross product revenue for estimated allowances for chargebacks, discounts and damaged goods, and reflects sales related accruals for rebates, coupons, product returns, and certain administrative and service fees. Significant judgments must be made in determining the transaction price for our sales of products related to these adjustments.

Sales Rebates and Discounts

The allowances against accounts receivable for chargebacks, discounts, expired and damaged goods are determined on a product-by-product basis, and established by management as the Company's best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such allowances. These allowances are established based on the contractual terms with direct and indirect customers and analyses of historical levels of chargebacks, discounts and credits claimed for damaged and expired product.

Other organizations, such as managed care providers, pharmacy benefit management companies and government agencies, may receive rebates from the Company based on either negotiated contracts to carry the Company's products or reimbursements for filled prescriptions. These entities are considered indirect customers of the Company. In conjunction with recognizing a sale to a wholesaler, sales revenues are reduced and accrued liabilities are increased by the Company's estimate of the rebate that may be claimed.

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

Sales Returns

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. The Company's estimate of the provision for returns is based upon historical experience, expiration date by product as well as any other tactor expected to impact future returns. Any changes in the assumptions used to estimate the provision for returns are recognized in the period those assumptions are changed.

#### Recent Accounting Guidance

Recent Adopted Accounting Pronouncements

In May 2014, the FASB issued amended guidance in the form of ASU No. 2014-09, "Revenue from Contracts with Customers." ("ASC 606") 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 replaced most of the existing revenue recognition standards in U.S. GAAP when it became effective. In July 2015, the FASB issued a one-year deferral of the adoption date, which extended the effective date for us to January 1, 2018, at which point Cumberland adopted the standard.

The Company evaluated its revenues and the new guidance had immaterial impacts to recognition practices upon adoption on January 1, 2018. As part of the adoption, the Company elected to apply the new guidance on a modified retrospective basis. The Company did not record a cumulative effect adjustment to historical retained earnings for initially applying the new guidance as no revenue recognition differences were identified in the timing or amount of revenue. The Company is currently applying the standard in its current practices.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows: Restricted Cash." This revised standard is an effort by the FASB to reduce existing diversity in practice by providing specific guidance on the presentation of restricted cash or restricted cash equivalents in the statement of cash flows. The updated guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash and restricted cash equivalents. As such, amounts generally described as restricted cash and restricted cash equivalents should be included in the "beginning-of-period" and "end-of-period" total amounts shown on the statement of cash flows. The Company adopted the new accounting pronouncement on January 1, 2018, and the adoption did not have a material impact to its statement of cash flows.

In August 2016, the FASB issued amended guidance in the form of a FASB ASU No. 2016-15, "Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments." The core principle of the new guidance is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The Company adopted the new accounting pronouncement on January 1, 2018, and the adoption did not have a material impact to its statement of cash flows.

Recent Accounting Pronouncements - Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments-Credit Losses," which changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other instruments, companies will be required to use a new forward-looking

"expected loss" model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, companies will measure credit losses in a manner similar to what they do today, except that the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. Companies will have to disclose significantly more information, including information they use to track credit quality by year of origination for most financing receivables. Companies will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. This standard is effective for the Company on January 1, 2020 with early adoption permitted. The Company is in the initial stage of evaluating the impact of this new standard on its trade and other receivables.

In February 2016, the FASB issued guidance in the form of a FASB ASU No. 2016-12, "Leases." The new standard establishes a right-of-use ("ROU") model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than twelve months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain optional practical expedients available. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating

# **CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to Condensed Consolidated Financial Statements - continued**

(Unaudited)

its current lease agreements for the impact of its pending adoption of the new standard on its consolidated financial statements and disclosures. The Company's significant operating leases include the lease of approximately 25,500 square feet of office space in Nashville, Tennessee for its corporate headquarters. This lease currently expires in October 2022. The operating leases also include the lease of approximately 14,200 square feet of office and wet laboratory space in Nashville, Tennessee by Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary, in which it operates the CET Life Sciences Center. This lease currently expires in April 2023.

#### **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 and (2) the allowances for obsolescent or unmarketable inventory.

#### **Operating Segments**

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

#### (2) MARKETABLE SECURITIES

The Company invests in marketable debt securities in order to maximize its return on cash. Marketable securities consist of short-term cash investments, U.S. Treasury notes and bonds, U.S. government agency issued mortgage-backed securities, U.S. government agency notes and bonds, Small Business Administration ("SBA") loan pools, and corporate bonds. 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 March 31, 2018 and December 31, 2017, 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 (loss).

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 service's 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

#### **CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

# **Notes to Condensed Consolidated Financial Statements - continued** (Unaudited)

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 service's 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:

	March 31, 2018				December 31, 2017					
	Level 1	Level 2		Total		Level 1	Level 2		Total	
U.S. Treasury notes and bonds	\$ 6,486,345	\$	_	\$	6,486,345	\$ —	\$	_	\$	_
U.S. Agency issued mortgage-back securities – variable rate	xe\$1 —	\$	1,569,884	\$	1,569,884	\$ —	\$	3,539,102	\$	3,539,102
U.S. Agency notes and bonds – fixed rate	_	_		_		_	198,29	3	198,29	3
Corporate bonds	_	2,502,97	77	2,502,97	77		_		_	
SBA loan pools – variabl rate	le—	548,641		548,641			935,08	1	935,08	1
Short-term cash investments	_	4,502,25	58	4,502,25	58		_		_	
Total fair value of marketable securities	\$ 6,486,345	\$	9,123,760	\$	15,610,105	\$ —	\$	4,672,476	\$	4,672,476

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

The following table reconciles the numerator and denominator used to calculate diluted earnings (loss) per share for the three months ended March 31, 2018 and 2017:

Three months ended March	31,
2018	2017

Numerator:

\$ (2,379,239) \$ (1,274,446)

Net income (loss)	
attributable to	
common	
shareholders	
Denominator:	
Weighted-average	
shares outstanding -15,689,240	16,042,219
basic	
Dilutive effect of	
other securities	
Weighted-average	
shares outstanding –15,689,240	16,042,219
diluted	

As of March 31, 2018 and 2017, restricted stock awards and options to purchase 247,530 and 237,875 shares of common stock, respectively, were outstanding but were not included in the computation of diluted earnings per share because the effect would be antidilutive.

#### (4) REVENUES

#### **Product Revenues**

The Company accounts for revenues from contracts with customers under ASC 606, which became effective January 1, 2018. As part of the adoption of ASC 606, the Company applied the new standard on a modified retrospective basis analyzing open contracts as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts were not adjusted and are reported in accordance with ASC 605. However, no cumulative effect adjustment to historical retained earnings was necessary as no revenue recognition differences were identified when comparing the revenue recognition criteria under ASC 606 to previous requirements. See further discussion in Note 1.

# **CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to Condensed Consolidated Financial Statements - continued**

Notes to Condensed Consolidated Financial Statements - continued (Unaudited)

The Company's net revenues consisted of the following for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,				
	2018	2018			
Products:					
Acetadote	\$	1,273,764	\$	1,265,440	
Omeclamox-Pak	141	,392	645,325		
Kristalose	3,269,901		2,386,591		
Vaprisol	93,890		684,548		
Caldolor	1,039,747		813,027		
Ethyol	2,256,073		3,666,808		
Totect	412,774		_		
Other	100	100,064			
Total net	\$	8,587,605	\$	9.636.755	
revenues	Ψ	0,507,005	Ψ	7,030,733	

Cumberland supplies Perrigo Company ("Perrigo") with an Authorized Generic version of the Company's Acetadote product. The Company's revenue generated by sales of its Authorized Generic distributed by Perrigo is included in the Acetadote product revenue presented above. The Company's share of Authorized Generic revenue was \$0.8 million and \$0.9 million for first quarter of 2018 and 2017, respectively.

#### Other Revenues

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

#### (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 net realizable value with cost determined using the first-in, first-out method.

The Company continually evaluates inventory for potential losses due to excess, obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates that the carrying value may not be recoverable, a charge is taken to reduce the inventory to its current net realizable value. At March 31, 2018 and December 31, 2017, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses of approximately \$0.1 million and \$0.2 million, respectively. In connection with the acquisition of certain product rights related to the Kristalose brand, the Company is responsible for the purchase of the active pharmaceutical ingredient ("API") for Kristalose and maintains the inventory at the third-party manufacturer. As the API is consumed in production, the value of the API is transferred from raw

materials to finished goods. API for the Company's Vaprisol brand is also included in the raw materials inventory total at March 31, 2018 and December 31, 2017.

# **CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to Condensed Consolidated Financial Statements - continued**

(Unaudited)

As of March 31, 2018 and December 31, 2017, net inventory consisted of the following:

	March 31,	2018	<b>December 31, 2017</b>		
Raw materials and work in process	\$	2,642,543	\$	3,156,002	
Consigned inventory	418,829		249,964		
Finished goods	3,600,153		3,331,882		
Total	\$	6,661,525	\$	6,737,848	

#### (6) SHAREHOLDERS' EQUITY AND DEBT

#### Share Repurchases

The Company currently has a share repurchase program to repurchase up to \$10 million of its common stock pursuant to Rule 10b-18 of the Securities Exchange Act of 1934. In January 2016, the Company's Board of Directors established the current \$10 million repurchase program to replace the prior authorizations. During the three months ended March 31, 2018 and March 31, 2017, the Company repurchased 172,079 shares and 155,150 shares, respectively, of common stock for approximately \$1.2 million and \$1.0 million, respectively. *Share Sales* 

In November 2017, the Company filed a Shelf Registration on Form S-3 with the SEC associated with the sale of up to \$100 million in corporate securities. The Shelf Registration was declared effective in January 2018. During the three months ended March 31, 2018, the Company issued 30,704 shares of common stock for gross proceeds of \$0.2 million as part of its At-The-Market ("ATM") sales agreement with B. Riley FBR.

#### Restricted Share Grants

During the three months ended March 31, 2018, the Company issued 229,205 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 and for directors 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 (loss).

#### Debt Agreement

On July 31, 2017, the Company entered into a Revolving Credit Loan Agreement with Pinnacle Bank ("Pinnacle Agreement"). The Pinnacle Agreement replaced the June 2014 Revolving Credit Loan Agreement with SunTrust Bank, which was to expire on June 30, 2018. The Company had \$12.0 million in borrowings under that agreement at March 31, 2018. The Pinnacle Agreement provides for an aggregate principal amount of up to \$20 million and has a three-year term expiring on July 31, 2020. The initial revolving line of credit is up to \$12 million with the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions.

The interest rate on the Pinnacle 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 1.75% to 2.75% (representing an interest rate of 3.3% at March 31, 2018). 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 Pinnacle Agreement, Cumberland is subject to one financial covenant, the maintenance of a Funded Debt Ratio, as such term is defined in the agreement and determined on a quarterly basis. The Company achieved compliance with the Funded Debt Ratio covenant as of March 31, 2018 through the utilization of the covenant cure section of the agreement.

#### (7) INCOME TAXES

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act ("the Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, (1) reducing the U.S. federal corporate tax rate to 21% (2) eliminating the corporate alternative minimum tax ("AMT") and changing how AMT credits can be realized; (3) capital expensing; and (4) creating new limitations on deductible interest expense and executive compensation.

The SEC staff issued Staff Accounting Bulletin ("SAB") 118 which provides guidance for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those

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

aspects of the Tax Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Act.

In connection with our analysis of the impact of the Tax Act, we have a net tax benefit of \$0.1 million of March 31, 2018. This net tax benefit consists entirely of the release of the valuation allowance against AMT credits that will be realizable under the Tax Act in future periods. While the Company does not expect to record further amounts related to the Tax Act, we will continue to evaluate additional guidance as it is released by the Internal Revenue Service and will record additional amounts if needed.

The Company expects it will continue to pay minimal taxes in future periods through the continued utilization of net operating loss carryforwards, as it is able to achieve taxable income through its operations.

#### (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 ASC Topic 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 (loss).

#### (9) COMMITMENTS AND CONTINGENCIES

Legal Matters

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

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

During the third quarter of 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in the Company's favor in its lawsuit against Mylan for infringement of its U.S. Patent number 8,399,445 (the "445 Acetadote Patent"). The opinion upheld our 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to us for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On November 17, 2015, the District Court entered an order enjoining Mylan and its affiliates from selling or using its

generic version of Acetadote until August 2025, the date of expiration of the 445 Acetadote Patent. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the "Appeals Court").

On January 26, 2017, the Appeals Court affirmed the District Court ruling in the Company's favor in its lawsuit against Mylan for infringement of the 445 Acetadote Patent. The Appeals Court opinion affirmed the District Court's ruling upholding Cumberland's 445 Acetadote Patent and expressly rejected Mylan's validity challenge. Additional information on these developments is included in Part 1, Item 3, Legal Proceedings in our Annual Report on Form 10-K for the year ended December 31, 2017.

#### 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 the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" of our Annual Report on Form 10-K for the year ended December 31, 2017 ("2017 Annual Report on Form 10-K"). 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 report on Form 10-Q.

#### **OVERVIEW**

#### **Our Business**

Cumberland Pharmaceuticals Inc. ("Cumberland," the "Company," or as used in the context of "we," "us," or "our"), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care, gastroenterology, and oncology supportive care. 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 promote 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 portfolio of FDA approved brands includes:

- Acetadote<sup>®</sup> (acetylcysteine) Injection, for the treatment of acetaminophen poisoning;
- Caldolor® (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose**<sup>®</sup> (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- Omeclamox®-Pak, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol**® (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- Ethyol® (amifostine) Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer, and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer; and
- **Totect**® (*dexrazoxane hydrochloride*) Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).

Our pipeline of product candidates includes:

- **Hepatoren**® (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- **Boxaban**<sup>®</sup> (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- **Vasculan**® (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of patients with the systemic sclerosis ("SSc") form of autoimmune disease;
- **Portaban**® (*ifetroban*) Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease; and
- **RediTrex**<sup>TM</sup> (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psoriasis.

We have both product development and commercial capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Cumberland's 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, licensing and co-promotion opportunities. Cumberland's product development team creates proprietary product formulations, manages our clinical studies, prepares all regulatory submissions and manages our medical call center. The Company's quality and manufacturing professionals oversee the manufacture, release, and shipment of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our distribution partners to ensure availability and delivery of our products.

#### **Growth Strategy**

Our growth strategy involves maximizing the potential of our existing brands while continuing to build a portfolio of differentiated products. We currently market seven FDA approved products for sale in the United States. Through our international partners, we are working to bring our products to patients in their countries. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Our clinical team is developing a pipeline of new product candidates to address unmet medical needs. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. Specifically, we are seeking long term sustainable growth by executing the following plans:

- Support and expand the use of our marketed products. We continue to evaluate our products following their FDA approval to determine if further clinical work could expand the potential market opportunities. We will continue to explore opportunities for label expansion to bring our products to new patient populations. The Caldolor pediatric approval reflects our successful implementation of this strategy.
- Selectively add complementary brands. 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 will continue to target product acquisition candidates that are competitively differentiated, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. Our acquisitions of the product rights to Ethyol and Totect in the U.S. represent recent examples of our execution of this strategy.
- Progress clinical pipeline and incubate future product opportunities at CET. We believe it is important to build a pipeline of innovative new product opportunities. Our ifetroban Phase II development programs represent the implementation of this strategy. At CET, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities. 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.

- Leverage our infrastructure through co-promotion partnerships. We believe that our commercial infrastructure can help drive prescription volume and product sales. We look for strategic partners that can accentuate our operational effectiveness and maximize the opportunity for our brands. Our recent co-promotion partnership with Poly Pharmaceuticals, Inc. allows us to expand current promotional support for Kristalose across the United States.
- Continue to build the international contribution to our business. We have established our own commercial capabilities, including two sales divisions to cover the U.S. market for our products. We are also 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.
- Continue to manage our operations with financial discipline. We continually work to manage our expenses in line with our revenues in order to deliver positive cash flow from operations. We remain in a strong financial position, with high margins, and a strong balance sheet.

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

#### RECENT DEVELOPMENTS

#### **Shelf Registration**

In November 2017, the Company filed a Shelf Registration on Form S-3 with the SEC associated with the sale of up to \$100 million in corporate securities. The Shelf Registration was declared effective in January 2018. It also included an At-The-Market ("ATM") feature enabling the Company to sell common shares at market prices, along with an agreement with B. Riley FBR to support such a placement of shares.

#### **GEL Agreement**

In March 2018, we reached agreement with Gastro-Entero-Logic LLC ("GEL"), to acquire the assets associated with Omeclamox-Pak including the product's FDA approved New Drug Application, trademarks and other assets. As a result of this acquisition we will no longer be obligated to provide GEL with royalty or fees for overseeing the product's manufacturing. As part of this transaction, we will become responsible for maintaining the FDA approval and for overseeing the product's packaging.

#### **New CET Collaboration Agreements**

At CET, we are working with a select group of academic research institutions located in the mid-south region of the U.S. These relationships enable CET to identify therapeutic compounds addressing poorly met medical needs and partner with university-based researchers to advance their scientific discoveries through pre-clinical development. CET contributes product design and development support services to help our collaborators bridge the gap between discovery and clinical investigation.

In February 2018, CET and Louisiana State University entered into an agreement, adding to CET's roster of academic collaborations which also includes Vanderbilt University, the University of Mississippi, and the University of Tennessee Research Foundation. These partnerships combine the strengths and capabilities of each organization by working together to identify, formulate, and develop attractive new biomedical products.

#### **Ethyol Study Publication**

In January 2018, the Company announced a new publication in Leukemia & Lymphoma, with study results showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma. Cumberland markets branded amifostine in the U.S. under the name Ethyol.

#### **Omeclamox-Pak Study Publication**

In March 2018, the Company announced a publication of an open access article in Infection and Drug Resistance, with results demonstrating an 85% eradication rate of Helicobacter pylori (H. pylori) infection using clarithromycin-based triple therapy. Cumberland markets a branded clarithromycin-based triple therapy in the U.S. under the name Omeclamox-Pak.

#### Caldolor

During the first quarter, the Company completed and filed the application for FDA approval of its Next Generation Caldolor product featuring an improved package and formulation. Cumberland continued to advance its study of Caldolor in patients ranging from newborn to six months of age. The Company also learned that Caldolor was approved for sale in India during the first quarter. Cumberland is preparing for the launch of the brand with its partner for that market.

#### **RediTrex Approval Submission**

We also held a meeting with the FDA during 2017 to discuss the approval pathway for our injectable methotrexate products in the United States. As a result, we are now gathering the relevant information and preparing the submission for that approval during 2018.

#### **Ifetroban Phase II Studies**

In early 2017, the FDA cleared Cumberland's investigational new drug ("IND") application for Boxaban - the Company's AERD clinical program. Following this clearance, we initiated a follow-on multicenter Phase II efficacy study to evaluate the efficacy of Boxaban in seventy-six patients with symptomatic AERD. Enrollment in this multi-center, placebo controlled study is now underway at a growing number of allergy and asthma centers across the United States. We also continued to advance our Vasculan and Portaban clinical pipeline programs, with patient enrollment progressing in each of those Phase II studies.

#### **New Hospital Product Candidate**

Cumberland was responsible for the formulation, development and FDA approval of both Acetadote and Caldolor. Our Medical Advisory Board has helped us identify additional opportunities that address unmet or poorly met medical needs. As a result, Cumberland has successfully designed, formulated and completed the preclinical studies for a cholesterol reducing agent for use in the hospital setting. During 2017, we completed a Phase I study which defined the pharmacokinetic properties and provided a favorable safety profile for this new product candidate. The study results and a proposed clinical development plan were discussed with the FDA and, as a result, a Phase II study is being designed.

#### **COMPETITION**

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our continued success in developing and commercializing pharmaceutical products will depend, in part, upon our ability to compete against existing and future products in our target markets. For more information see Part 1, Item 1, Business-Competitors in our Annual Report on Form 10-K for the year ended December 31, 2017 which is incorporated by reference and has been updated as follows:

#### Ethyol®

Ethyol is our patented, branded amifostine product indicated to reduce xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer. We launched the product in late 2016, and the authorized generic form of the product was withdrawn by Clinigen who markets branded Ethyol internationally. We have an exclusive license to promote, sell and distribute Ethyol in the United States, under various patents. There are several Ethyol patents associated with the subcutaneous administration of the product that are not yet Orange Book listed. In July 2017, Mylan Laboratories Ltd. ("Mylan") received approval for an Abbreviated New Drug Application for a generic amifostine product. Sun Pharmaceuticals Industries Limited ("Sun") had also previously received approval for a generic amifostine product. Both the Mylan and Sun approvals appear to be only for the ovarian cancer indication but not the xerostomia indication. Therefore, we believe that Ethyol is currently the only amifostine product with FDA approval for both the xerostomia and ovarian cancer indications.

#### Totect<sup>®</sup>

Totect is our patented, branded dexrazoxane injection product indicated for the treatment of the extravasation associated with anthracycline chemotherapy. We have an exclusive license to promote, sell and distribute Totect in the United States, under U.S. Patent number 6,727,253 which has claims directed to methods of preventing or treating local tissue damage in patients receiving topoisomerase II poison. This Totect patent is listed in the FDA Orange Book and is scheduled to expire in March

2020. Pfizer Inc.'s Zinecard® brand is a dexrazoxane product with FDA approval for a different indication - the cardiac complications associated with certain chemotherapeutic agents. Mylan, Gland Pharma Ltd and West-Ward Pharmaceuticals Corp have previously received FDA approval for a generic dexrazoxane with the Zinecard cardiac protection indication. When we launched Totect, the FDA reported a national dexrazoxane shortage with both the Pfizer and Mylan products unavailable.

Following our launch, supplies of dexrazoxane became available from Mylan, Pfizer, and two approved generic suppliers, all with labeling for the cardiac indication. Totect is the only dexrazoxane available in the U.S. FDA approved for the extravasation indication.

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

Please see a discussion of our critical accounting policies and significant judgments and estimates in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2017 Annual Report on Form 10-K.

#### **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.

#### Three months ended March 31, 2018 compared to the three months ended March 31, 2017

The following table presents the unaudited interim statements of operations for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,					
	201	8	2017		Change	
Net revenues	\$	8,587,605	\$	9,636,755	\$	(1,049,150)
Costs and expenses:						
Cost of products sold	1,52	27,961	1,381,497		146,464	
Selling and marketing	4,67	70,511	5,293,020		(622,509)	
Research and development	1,87	74,939	898,363		976,576	
General and administrative	2,33	30,281	2,110,233		220,048	
Amortization	636	,135	611,444		24,691	
Total costs and expenses	11,0	039,827	10,294,557		745,270	
Operating income (loss)	(2,4	52,222)	(657,802)		(1,794,420)	

Interest income	82,	494	52,535		29,959	
Interest expense	(18	,302)	(31,715)		13,413	
Income (loss) before income taxes	(2,3	388,030)	(636,982)		(1,751,048)	)
Income tax (expense) benefit	(4,1	159)	(656,587)		652,428	
Net income (loss)	\$	(2,392,189)	\$	(1,293,569)	\$	(1,098,620)

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

	Three months ended March 31,				
	2018	2017	Change		
Products:					
Acetadote	\$ 1,273,764	\$ 1,265,	440 \$ 8,324		
Omeclamox-Pak	141,392	645,325	(503,933)		
Kristalose	3,269,901	2,386,591	883,310		
Vaprisol	93,890	684,548	(590,658)		
Caldolor	1,039,747	813,027	226,720		
Ethyol	2,256,073	3,666,808	(1,410,735)		
Totect	412,774	_	412,774		
Other	100,064	175,016	(74,952)		
Total net revenues	\$ 8,587,605	\$ 9,636,	755 \$ (1,049,150)		

Net revenues. Net revenues for the three months ended March 31, 2018 were \$8.6 million compared to \$9.6 million for the three months ended March 31, 2017, representing a decrease of \$1.0 million, or 10.9%. As detailed in the table above, four of our seven marketed products experienced increases in net revenue: Acetadote, Kristalose, Caldolor and Totect. These increases partially offset the revenue decreases that were attributed primarily to Ethyol and Vaprisol. Kristalose revenue increased by \$0.9 million primarily as a result of increased sales volume during the three months ended March 31, 2018. The product's 37.0% increase in net revenue was also partially attributable to a modest improvement in net pricing during the period.

The Company began shipments of Totect in July of 2017, resulting in \$0.4 million in sales during the three months ended March 31, 2018. The 2017 launch of Totect was positively impacted by a national shortage of dexrazoxane, resulting in strong initial demand for the product. Following our launch, supplies of dexrazoxane became available from competing suppliers, all with labeling for the cardiac indication. Totect is the only dexrazoxane available in the U.S. FDA approved for the extravasation indication.

Caldolor revenue experienced an increase of \$0.2 million during the three months ended March 31, 2018 compared to the same period last year. This 27.9% increase in revenue in the three months ended March 31, 2018 primarily resulted from an increase in domestic and international shipments and also impacted by a modest increase in pricing.

Acetadote revenue included net sales of our branded product and our share of net sales from our Authorized Generic. During the three months ended March 31, 2018 the Acetadote net revenue grew 1% as a result of increased sales volumes.

Ethyol revenue for the three months ended March 31, 2018 was \$2.3 million, which is a decrease of \$1.4 million from the three months ended March 31, 2017. The decrease was primarily the result of lower sales volume when compared to the prior year period, when wholesalers began to increase their inventory to meet hospital demand. The Ethyol shipments for the three months ended March 31, 2018 are consistent with the quarterly shipments experienced during the second half of 2017.

Vaprisol revenue decreased \$0.6 million during the three months ended March 31, 2018 compared to the prior year period primarily due to decreased sales volume. We experienced decreased sales volume during the three months ended March 31, 2018 as the manufacturer was temporarily unable to provide requested supplies of Vaprisol which led to limited inventory and sales of the product. During April 2018, the Vaprisol inventory supply issue was resolved as we received new shipments from our manufacturer.

Omeclamox-Pak revenue decreased \$0.5 million during the three months ended March 31, 2018 compared to the prior year. The decrease was primarily the result of lower sales volume and higher expired product sales returns.

Cost of products sold. Cost of products sold for the three months ended March 31, 2018 were \$1.5 million, compared to \$1.4 million for the same period last year, representing an increase of approximately \$0.1 million, or 10.6%. Cost of products sold, as a percentage of net revenues were 17.8% compared to 14.3% during the prior year. The increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix during the period compared to the prior year.

Selling and marketing. Selling and marketing expenses for the three months ended March 31, 2018 were \$4.7 million, compared to \$5.3 million for the prior year period, representing a decrease of approximately \$0.6 million. This decrease was primarily the result of decreased royalties related to decreased product sales as well as lower promotional spending for the three months ended March 31, 2018.

Research and development. Research and development costs for the three months ended March 31, 2018 were \$1.9 million, compared to \$0.9 million for the same period last year, representing an increase of approximately \$1.0 million. A portion of our research and development costs are variable based on the number of trials, study sites and patients involved in the development of our product candidates. The increase was primarily the result of additional investment in our ongoing clinical initiatives associated with our pipeline products as well as increases in our FDA fees.

General and administrative. General and administrative expenses were \$2.3 million for the three months ended March 31, 2018, compared to \$2.1 million during the same period last year. The \$0.2 million increase from the prior year was primarily driven by increases an increase in compensation and benefits, including non-cash stock based compensation.

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 March 31, 2018 totaled approximately \$0.6 million, which was an increase of \$0.02 million over the prior year. The increase in amortization was attributable to additional product and license rights and capitalized patents.

*Income taxes.* Income tax expense for the three months ended March 31, 2018 totaled \$4,159 compared to \$656,587 in the three months ended March 31, 2017. As a percentage of income (loss) before income taxes, income taxes were 0.2% for the three months ended March 31, 2018 compared to 103.1% for the three months ended March 31, 2017. The effective tax rate for the three months ended March 31, 2017 was primarily impacted by a valuation allowance of \$1.0 million for our federal Orphan Drug and Research and Development tax credits. The additional valuation allowance was the result of our adoption of the FASB guidance on stock based compensation and our continued evaluation of our utilization of net operating loss carryforwards, including updates to our forecasts of future taxable income. These non-cash valuation allowance adjustments impacted our effective tax rate during the three months ended March 31, 2017.

#### LIQUIDITY AND CAPITAL RESOURCES

#### **Working Capital**

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

We invest a portion of our cash reserves in marketable securities including short-term cash investments, U.S. Treasury notes and bonds, U.S. government agency notes and bonds, corporate bonds, and other marketable securities. At March 31, 2018 and December 31, 2017, we had approximately \$15.6 million and \$4.7 million, respectively, invested in marketable securities.

The following table summarizes our liquidity and working capital as of March 31, 2018 and December 31, 2017:

March 31, 2018

**December 31, 2017** 

Cash and cash equivalents	\$	35,262,976	\$	45,412,868
Marketable securities	15,610,105		4,672,476	
Total cash, cash equivalents and marketable securities	\$	50,873,081	\$	50,085,344
Working capital (current assets less current liabilities)	\$	50,533,316	\$	50,990,102
Current ratio (multiple of current assets to current liabilities)	4.1		3.9	
Revolving line of credit availability 18	\$	_	\$	2,200,000

The following table summarizes our net changes in cash and cash equivalents for the three months ended March 31, 2018 and March 31, 2017:

	Three months ended March 31,			
	2018		2017	
Net cash provided by (used in):				
Operating activities	\$	235,589	\$	1,439,371
Investing activities	(11,522,126)		(429,535)	
Financing activities	1,136,645		(545,924)	
Net increase (decrease) in cash and cash equivalents	\$	(10,149,892)	\$	463,912

The net \$10.1 million decrease in cash and cash equivalents for the three months ended March 31, 2018 was attributable to cash used in investing activities partially offset by cash provided by financing and operating activities. Cash provided by operating activities of \$0.2 million was primarily impacted by changes in our working capital which provided net cash of \$1.6 million, including net collections of accounts receivable of \$2.1 million and non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$1.0 million. The generation of operating cash was offset by a net loss for the period of \$2.4 million. Cash used in investing activities included net cash investment in marketable securities of \$10.9 million and additions to intangibles of \$0.5 million. Our financing activities included \$2.2 million in net cash provided by borrowings under our line of credit offset by \$1.0 million in cash used to repurchase shares of our common stock.

The net \$0.5 million increase in cash and cash equivalents for the three months ended March 31, 2017 was attributable to cash provided by operating activities offset by cash used in investing and financing activities. Cash provided by operating activities of \$1.4 million was primarily impacted by changes in our working capital of \$1.1 million, including a decrease in accounts receivable of \$2.4 million and non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$0.9 million. These were offset by net reductions in accounts payable and accrued liabilities of \$1.2 million. Cash provided by operating activities also includes the net loss for the period of \$1.3 million. Cash used by investing activities included a net cash investment in our intangible assets of \$0.5 million. Our financing activities included \$0.5 million in cash used to repurchase shares of our common stock.

#### **Debt Agreement**

On July 31, 2017, we entered into a Revolving Credit Loan Agreement with Pinnacle Bank (the "Pinnacle Agreement"). The new agreement replaced the June 2014 Revolving Credit Loan Agreement with SunTrust Bank which was to expire on June 30, 2018. The Company had \$12 million in borrowings under that agreement at March 31, 2018. The Pinnacle Agreement provides for an aggregate principal amount of up to \$20 million and has a three-year term expiring on July 31, 2020. The initial revolving line of credit is up to \$12 million with the ability to increase the borrowing amount up to \$20 million, upon the satisfaction of certain conditions.

The interest rate on the Pinnacle 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 1.75% to 2.75% (representing an interest rate of 3.3% at March 31, 2018). 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 Pinnacle Agreement, we are subject to one financial covenant, the maintenance of a Funded Debt Ratio, as such term is defined in the agreement and determined on a quarterly basis. We achieved compliance with the Funded Debt Ratio covenant as of March 31, 2018 through the utilization of the covenant cure section of the agreement. We expect to maintain compliance with this covenant in future periods, including the use of the covenant cure section of the agreement.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

During the three months ended March 31, 2018 and 2017, we did not engage in any off-balance sheet arrangements. Item 3. Quantitative and Qualitative Disclosures about Market Risk Interest Rate Risk

We are exposed to market risk related to changes in interest rates on our cash on deposit in highly-liquid money market accounts and revolving credit facility. We do not utilize derivative financial instruments or other market risk-sensitive instruments to manage exposure to interest rate changes. The main objective of our cash investment activities is to preserve principal while maximizing interest income through low-risk investments.

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. Based on the \$15.6 million in marketable securities outstanding at March 31, 2018, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income (loss) of \$0.2 million.

Based on current interest rates, we do not believe we are exposed to significant downside risk related to change in interest on our investment accounts.

The interest rate risk related to borrowings under our line of credit 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 1.75% to 2.75% (representing an interest rate of 3.3% at March 31, 2018). As of March 31, 2018, we had \$12.0 million in borrowings outstanding under our revolving credit facility.

#### **Exchange Rate Risk**

While we operate primarily in the United States, we are exposed to foreign currency risk. 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 three months ended March 31, 2018 and 2017. Neither a five percent increase nor decrease from current exchange rates would have a material effect on our operating results or financial condition.

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

We maintain disclosure controls and procedures that are designed with the objective of providing reasonable assurance that information required to be disclosed in our reports filed or submitted to the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2018. Based on that evaluation, our CEO and CFO concluded that, 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 in order to allow for timely decisions regarding required disclosure.

During the three months ended March 31, 2018, there has not been any change in our internal control over financial reporting that has materially affected, or is likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### **Item 1. Legal Proceedings**

See the discussion of our Acetadote patent defense legal proceedings contained in Note 7 - Commitments and Contingencies - Legal Matters in the accompanying condensed consolidated financial statements and in the section entitled "Business - Patents, Trademarks and Other Intellectual Proprietary Rights", of our 2017 Annual Report on Form 10-K, which is incorporated by reference herein.

#### **Item 1A. Risk Factors**

Information regarding risk factors appears in the 2017 Annual Report on Form 10-K under the section titled "Risk Factors."

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

We currently have a share repurchase program to purchase up to \$10 million of our common stock pursuant to Rule 10b-18 of the Securities Exchange Act. In January 2016, our Board of Directors established the current \$10 million repurchase program to replace the prior authorizations for repurchases of our outstanding common stock. The following table summarizes the activity, by month, during the three months ended March 31, 2018:

Period	Total Number of Shares (or Units) Purchased (1)		Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs (1)
January	58,023		\$7.08	58,023	\$3,426,680
February	29,487		6.97	29,487	3,221,153
March	84,569	(2)	6.84	84,569	2,642,393
Total	172,079			172,079	

<sup>(1)</sup> Shares repurchased by the Company under the share repurchase program established by our Board of Directors.

<sup>(2)</sup> Of this amount, 60,094 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 Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL INSTANCE DOCUMENT - THE INSTANCE DOCUMENT DOES NOT APPEAR IN THE INTERACTIVE DATA FILE BECAUSE ITS XBRL TAGS ARE EMBEDDED WITHIN THE INLINE XBRL DOCUMENT.
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

XBRL TAXONOMY

**EXTENSION** 

101.CAL\* CALCULATION

LINKBASE DOCUMENT

XBRL TAXONOMY

**EXTENSION** 

101.DEF\* DEFINITION

LINKBASE DOCUMENT

XBRL TAXONOMY

**EXTENSION LABEL** 

101.LAB\* LINKBASE

**DOCUMENT** 

XBRL TAXONOMY

**EXTENSION** 

101.PRE\* PRESENTATION

LINKBASE DOCUMENT

. Filed

herewith.

\*\* Furnished

herewith.

#### **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

By:

Pharmaceuticals Inc.

May 9, 2018

/s/ Michael

Bonner

Michael Bonner Chief Financial Officer