

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 14, 2018

Non-accelerated

Filer9/30/20182018Q3FALSEFALSEFALSE--12-310001087294——100,000,000100,000,00015,555,86515,723,07515,555,8

**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, 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
Incorporation or
Organization) (I.R.S. Employer
Identification
No.)

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

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(Address of
Principal
Executive
Offices) (Zip Code)

(615) 255-0068

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files.) Yes 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 Accelerated filer
Non-accelerated filer 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

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 9, 2018
Common stock, no par value	15,527,623

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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, 2018		December 31, 2017
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 38,259,233	\$	45,412,868
Marketable securities	9,533,703		4,672,476
Accounts receivable, net	7,055,138		8,395,112
Inventories, net	6,426,429		6,737,848
Other current assets	2,351,708		3,466,541
Total current assets	63,626,211		68,684,845
Property and equipment, net	539,019		528,882
Intangible assets, net	20,370,330		21,444,545
Deferred tax assets, net	87,210		87,210
Other assets	2,809,306		2,486,830
Total assets	\$ 87,432,076	\$	93,232,312
LIABILITIES AND EQUITY			
Current liabilities:			
Accounts payable	\$ 8,447,429	\$	8,979,929
Other current liabilities	7,070,860		8,714,814
Total current liabilities	15,518,289		17,694,743
Revolving line of credit	12,000,000		9,800,000
Other long-term liabilities	1,969,174		1,815,968
Total liabilities	29,487,463		29,310,711
Commitments and			

contingencies

Equity:

Shareholders'
equity:Common
stock—no par
value;
100,000,000
shares

authorized;

15,555,865 and
15,723,075

51,235,612

52,410,941

shares issued

and outstanding

as of September

30, 2018 and

December 31,

2017,

respectively

Retained
earnings

6,966,252

11,709,222

Total

shareholders'

58,201,864

64,120,163

equity

Noncontrolling
interests

(257,251)

(198,562)

Total equity

57,944,613

63,921,601

Total liabilities
and equity

\$ 87,432,076

\$ 93,232,312

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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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,	
	2018	2017	2018	2017	
Net revenues	\$ 8,492,530	\$ 11,196,961	\$ 27,243,859	\$ 29,500,843	
Costs and expenses:					
Cost of products sold	1,460,463	2,166,353	4,511,743	5,216,776	
Selling and marketing	4,803,112	6,226,438	14,549,873	16,174,391	
Research and development	1,306,055	943,162	4,631,384	2,921,951	
General and administrative	2,067,981	2,090,785	6,732,485	6,554,158	
Amortization	661,802	609,572	1,946,457	1,811,589	
Total costs and expenses	10,299,413	12,036,310	32,371,942	32,678,865	
Operating income (loss)	(1,806,883)	(839,349)	(5,128,083)	(3,178,022)	
Interest income	166,220	94,833	398,420	216,849	
Interest expense	(19,199)	(8,902)	(59,520)	(70,646)	
Income (loss) before income taxes	(1,659,862)	(753,418)	(4,789,183)	(3,031,819)	
Income tax (expense) benefit	(4,159)	(3,822)	(12,477)	(4,196,192)	
Net income (loss)	(1,664,021)	(757,240)	(4,801,660)	(7,228,011)	
Net loss at subsidiary attributable to noncontrolling interests	20,977	14,209	58,689	49,923	
Net income (loss) attributable to common shareholders	\$ (1,643,044)	\$ (743,031)	\$ (4,742,971)	\$ (7,178,088)	

Earnings (loss) per share attributable to common shareholders					
- basic	\$ (0.11)	\$ (0.05)	\$ (0.30)	\$ (0.45)	
- diluted	\$ (0.11)	\$ (0.05)	\$ (0.30)	\$ (0.45)	
Weighted-average shares outstanding					
- basic	15,573,108	15,867,159	15,645,230	15,973,737	
- diluted	15,573,108	15,867,159	15,645,230	15,973,737	
Comprehensive income (loss) attributable to common shareholders	(1,643,044)	(743,031)	(4,742,971)	(7,178,088)	
Net loss at subsidiary attributable to noncontrolling interests	20,977	14,209	58,689	49,923	
Total comprehensive income (loss)	\$ (1,664,021)	\$ (757,240)	\$ (4,801,660)	\$ (7,228,011)	

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Nine months ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	\$ (4,801,660)	\$ (7,228,011)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	2,108,051	1,974,194
Deferred tax expense	—	4,293,963
Share-based compensation	1,005,239	849,198
Excess tax (benefit) expense derived from exercise of stock options	—	(91,109)
Noncash interest expense	44,117	60,708
Noncash investment gains	(131,652)	(48,084)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	1,339,974	124,748
Inventories	311,419	(485,739)
	966,817	(428,176)

Other current assets and other assets		
Accounts payable and other current liabilities	(1,595,243)	640,453
Other long-term liabilities	142,486	239,703
Net cash provided by (used in) operating activities	(610,452)	(98,152)
Cash flows from investing activities:		
Additions to property and equipment	(171,731)	(172,899)
Purchases of marketable securities	(20,851,951)	(2,029,414)
Proceeds from sale of marketable securities	16,122,376	9,644,592
Additions to intangible assets	(1,411,710)	(841,647)
Net cash (used in) provided by investing activities	(6,313,016)	6,600,632
Cash flows from financing activities:		
Borrowings on line of credit	36,000,000	14,700,000
Repayments on line of credit	(33,800,000)	(10,800,000)
Proceeds from sales of common stock, net of offering costs	200,909	—
	(248,108)	—

Payments of deferred offering costs		
Repurchase of common shares	(2,382,968)	(2,893,857)
Net cash provided by (used in) financing activities	(230,167)	1,006,143
Net increase (decrease) in cash and cash equivalents	(7,153,635)	7,508,623
Cash and cash equivalents at beginning of period	\$ 45,412,868	34,510,330
Cash and cash equivalents at end of period	\$ 38,259,233	\$ 42,018,953

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
	Shares	Amount		earnings	interests	equity
Balance, December 31, 2017	15,723,075	52,410,941 \$	11,709,222 \$	(198,562) \$		63,921,601
Proceeds from sales of common stock, net of offering costs	30,700	200,909	—	—		200,909
Share-based compensation	167,700	1,005,239	—	—		1,005,239
Repurchase of common shares	(365,488)	(2,381,477)	—	—		(2,381,477)
Net loss	—	\$ —	(4,742,971) \$	(58,689) \$		(4,801,660)
Balance, September 30, 2018	15,555,865	51,235,612 \$	6,966,251 \$	(257,251) \$		57,944,612

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. (“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 and nine months ended September 30, 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 and nine months ended September 30, 2018 and 2017.

Adoption of Revenue Recognition 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
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wholesaler, sales revenues are reduced and accrued liabilities are increased by the Company's estimate of the rebate that may be claimed.

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 factor 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.

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. 2016-02, "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 its current lease agreements for the impact of its pending adoption of the new standard on its consolidated financial statements

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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 wet laboratory and office space in Nashville, Tennessee by Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary, where it operates the CET Life Sciences Center. This lease currently expires in April 2023. The adoption of the new lease standard will result in the Company recording ROU assets and lease liabilities for these leases.

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 September 30, 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 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

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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:

	September 30, 2018			December 31, 2017		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	\$ 5,005,631	—	\$ 5,005,631	—	—	\$ —
U.S. Agency issued mortgage-backed securities – variable rate	—	—	—	—	3,539,102	3,539,102
U.S. Agency notes and bonds – fixed rate	—	—	—	—	198,293	198,293
Corporate bonds	—	2,506,006	2,506,006	—	—	—
SBA loan pools – variable rate	—	—	—	—	935,081	935,081
Short-term cash investments	—	2,022,066	2,022,066	—	—	—
Total fair value of marketable securities	\$ 5,005,631	4,528,072	9,533,703	—	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 and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,	
	2018	2017
Numerator:		
Net income (loss) attributable to	\$ (1,643,044)	\$ (743,031)

common
shareholders

Denominator:

Weighted-average shares outstanding	-15,573,108	15,867,159
basic		

Dilutive effect of other securities	—	—
--	---	---

Weighted-average shares outstanding	-15,573,108	15,867,159
diluted		

Nine months ended September 30,
2018 **2017**

Numerator:

Net income (loss) attributable to common shareholders	\$ (4,742,971)	\$ (7,178,088)
--	----------------	----------------

Denominator:

Weighted-average shares outstanding	-15,645,230	15,973,737
basic		

Dilutive effect of other securities	—	—
--	---	---

Weighted-average shares outstanding	-15,645,230	15,973,737
diluted		

As of September 30, 2018 and 2017, restricted stock awards and options to purchase 18,325 and 14,175 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.

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,		Nine months ended	
	2018	2017	2018	September 30,
				2017
Products:				
Acetadote	\$ 1,122,544	\$ 1,342,457	\$ 3,238,284	\$ 4,331,675
Omeclamox-Pak	278,017	190,835	509,358	1,213,635
Kristalose	3,017,803	2,749,966	9,490,901	8,037,994
Vaprisol	(67,436)	385,541	1,712,353	1,346,793
Caldolor	1,318,109	896,640	3,458,881	2,762,790
Ethyol	2,593,830	2,566,611	7,659,594	8,325,254
Totect	45,249	2,916,425	727,211	2,916,425
Other	184,414	148,486	447,277	566,277
Total net revenues	\$ 8,492,530	\$ 11,196,961	\$ 27,243,859	\$ 29,500,843

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 September 30, 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 September 30, 2018 and December 31, 2017.

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As of September 30, 2018 and December 31, 2017, net inventory consisted of the following:

	September 30, 2018	December 31, 2017
Raw materials and work in process	\$ 2,510,870	\$ 3,156,002
Consigned inventory	423,987	249,964
Finished goods	3,491,572	3,331,882
Total	\$ 6,426,429	\$ 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 nine months ended September 30, 2018 and September 30, 2017, the Company repurchased 365,648 shares and 438,715 shares, respectively, of common stock for approximately \$2.4 million and \$2.9 million, respectively.

Share Sale

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 nine months ended September 30, 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 nine months ended September 30, 2018, and September 30, 2017, the Company issued 233,330 shares and 233,525 shares of restricted stock to employees and directors, respectively. 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 October 17, 2018, the Company entered into a second amendment ("Second Amendment") to the Revolving Credit Loan Agreement, dated July 28, 2017, with Pinnacle Bank ("Pinnacle Agreement"). The Second Amendment increases the maximum aggregate principal available for borrowing under the Pinnacle Agreement to \$20 million. Cumberland increased the maximum aggregate principal available for borrowing to support potential future acquisitions and general corporate purposes. The initial revolving line of credit under the Pinnacle Agreement was for up to an aggregate principal amount of \$12 million with the ability to increase the principal amount available for borrowing up to \$20 million, upon the satisfaction of certain conditions. The Second Amendment does not affect the term of the Pinnacle Agreement, which has a three year term expiring on July 31, 2020. 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 the Pinnacle Agreement at September 30, 2018 and \$9.8 million at December 31, 2018.

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% (resulting in an interest rate of 4.0% at September 30, 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 was initially 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. On August 14, 2018 the Company amended the Pinnacle Agreement ("First Amendment") to replace the single financial covenant with the maintenance of either the Funded Debt Ratio or a Tangible Capital Ratio, as defined in the First Amendment. The Company was in compliance with the Tangible Capital Ratio covenant as of September 30, 2018.

(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, providing guidance on applying 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 reflects the income tax effects 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 a reasonable estimate is available, it must record the estimate in the financial statements. If a company cannot determine an estimate, it should continue to apply ASC 740 on the basis of the tax laws that were in effect immediately prior to 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 as of September 30, 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. The Company does not expect to record further amounts related to the Tax Act, but will continue to evaluate additional Internal Revenue Service guidance as it is released. 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 research institutions to identify and pursue promising 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 primarily provided through Federal Small Business Administration (SBIR/STTR) and other grant awards. Expenses incurred under these collaborative agreements are included in research and development expenses and funding received from grants are recorded as net revenues in the condensed consolidated statements of operations and comprehensive income (loss).

(9) EVENT SUBSEQUENT TO THE BALANCE SHEET DATE

On November 6, 2018, Cumberland announced the acquisition of VIBATIV® (telavancin injection) from Theravance Biopharma U.S., Inc and Theravance Biopharma Ireland Limited (collectively, “Theravance Biopharma”). The financial terms include a \$20 million payment to Theravance Biopharma upon closing, a \$5 million additional payment in early 2019 and tiered royalties up to 20% on future U.S. net product sales. The acquisition closed on November 12, 2018.

Cumberland has a Revolving Credit Loan with Pinnacle Bank that had an initial availability of up to \$12 million with the ability to increase the principal amount available for borrowing up to \$20 million. On October 17, 2018, Cumberland and Pinnacle Bank increased the maximum principal available for borrowing to \$20 million. The \$12 million outstanding under the Revolving Credit loan was repaid during October 2018 and the Revolving Credit Loan was then used to fund the \$20 million payment for the VIBATIV acquisition.

The supplemental pro forma financial information that reflects revenue and earnings for VIBATIV is not yet being provided as the initial accounting for the business combination is not yet available to the Company as of the issuance of these financial statements. The Company will provide the supplemental pro forma financial information as it becomes available.

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 the 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®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolo®** (*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 and 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
- **Totec®** (*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 patient's tissues).
- **Vibativ®** • (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

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®** (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin exacerbated respiratory disease ("AERD");
- **Vascular®** (*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**[™] (*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, maintains product approvals and manages our medical call center. The Company's quality and manufacturing professionals oversee the manufacture, packaging, 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 eight FDA approved brands 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 their potential markets. 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 product candidates that address poorly met medical needs. We will continue to target product acquisition candidates that are competitively differentiated, with attractive financial profiles, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. Our acquisitions of the product rights to Ethylol and RediTrex for 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 which emerged from CET 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. Cumberland has the opportunity to negotiate rights to further develop and commercialize these candidates 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 with the goal of delivering positive cash flow from operations. We remain in a favorable 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

New Product Acquisition

On November 6, 2018, the Company announced the acquisition of Vibativ® (telavancin) from Theravance Biopharma. Vibativ is a patented, FDA approved injectable anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia and complicated skin and skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Under the terms of the agreement, which closed on November 12, 2018, Cumberland assumed full responsibility for the product including its marketing, distribution, manufacturing, and regulatory activities. Cumberland will support Vibativ in the U.S. through its established hospital sales organization. The Company expects to selectively expand its sales force, medical science liaison and corporate teams to ensure the needed support of Vibativ as well as its oncology and acute care brands.

The financial terms include a \$20 million payment to Theravance Biopharma upon closing, a \$5 million additional payment in early 2019, and tiered royalties of up to 20% on future U.S. net product sales. Cumberland has a Revolving Credit Loan with Pinnacle Bank that had an initial availability of up to \$12 million with the ability to increase the principal amount available for borrowing up to \$20 million. On October 17, 2018, Cumberland and Pinnacle Bank increased the maximum principal available for borrowing to \$20 million which was used to fund the initial payment for the Vibativ acquisition.

Caldolor

In February 2018, we completed and filed the application for FDA approval of our Next Generation Caldolor product featuring an improved package and formulation. In April 2018, the FDA determined that the application was complete and notified us of their acceptance for review. On August 2, 2018, we received a complete response from the FDA outlining the additional information needed for the application's approval. The requests were for additional quality and nonclinical data. We held a teleconference with the FDA to discuss their additional requirements. On September 26, 2018, the Company submitted an amendment to our application containing additional quality and nonclinical data. We now await the FDA's response and approval decision and prepare for the manufacture and launch of this new Caldolor product.

RediTrex Approval Submission

During November 2018, we completed the submission and filed with the FDA an application for the approval of our methotrexate product line which is designed for treating patients with arthritis and psoriasis. This filing follows two meetings held with the FDA to discuss the approval pathway and requirements for the submission. We now await FDA's determination of acceptance of the submission for their review. We remitted a payment of \$1.3 million to the FDA for the PDUFA Application Fee associated with the methotrexate product line application.

New Clinical Data Published

In September 2018 the Company and Clinigen, announced a new publication in *Lung Cancer: Targets and Therapy* of a contemporary retrospective series showing that subcutaneous amifostine administered before radiotherapy postponed the onset of acute esophagitis in stage 3 small cell lung cancer patients treated with concomitant doublet chemotherapy and

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hyperfractionated radiotherapy. Cumberland markets branded amifostine in the U.S territory under the name Ethyol on behalf of Clinigen who is the market authorization holder and owner of global rights.

Cumberland also recently announced two favorable Caldolor study publications, adding to the growing library of literature supporting the brand. A study at The Ohio State Wexner Medical Center, published in the journal *Frontiers in Surgery*, reveals more effective pain control and opioid-sparing activity with Caldolor when compared to ketorolac in patients undergoing arthroscopic knee surgery.

Additionally, a clinical trial conducted at Tufts University School of Dental Medicine and published online in the *Journal of Oral and Maxillofacial Surgery*, concluded that preemptive analgesia with Caldolor (IV ibuprofen) is more effective than Ofirmev® (IV acetaminophen) in reducing post-surgical pain and opioid use.

Ifetroban Phase II Studies

During the third quarter, we completed study enrollment for Portaban - the Company's Portal Hypertension clinical program. Thirty patients were enrolled in a randomized, double-blind, placebo-controlled pilot study to assess ifetroban for the treatment of portal hypertension in cirrhotic patients.

This study was primarily designed to evaluate the safety of ifetroban treatment in this population and was not powered for any efficacy measurement. An initial review of the data from the study shows ifetroban was safe and well tolerated with no unexpected safety findings. We also measured hepatic venous pressure. Patients enrolled had a greater degree of variability than expected in their hepatic venous pressure gradient, therefore no definitive conclusions could be made on the impact of ifetroban on modulating that gradient. A full analysis of the data to include biomarkers and exploratory endpoints is ongoing. We will now await results from our other Phase II ifetroban studies before deciding on the best path for approval of our first new chemical entity.

We also continued to advance our Vasculan and Boxaban clinical pipeline programs, with patient enrollment progressing in each of those Phase II studies.

New CET Small Business Grant Award

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 towards the market. CET contributes product design, development, and other support services to help our collaborators bridge the gap between discovery and clinical investigation.

In September 2018, CET announced that the U.S. National Cancer Institute awarded \$2 million in support of a joint research program involving Cumberland Pharmaceuticals Inc., CET and researchers at Vanderbilt University. This Phase II grant is awarded under the Small Business Innovation Research funding mechanism and follows successful completion of an initial Phase I award.

The objective of the collaborative research program is to further develop a novel small molecule radiosensitizing agent for the treatment of certain lung cancers. By enhancing the cancer's sensitivity to radiation therapy, this technology addresses a significant medical need of improving clinical outcomes for these oncology patients.

New Board Member

Effective September 19, 2018, the Company appointed Joseph C. Galante, American music industry executive, as its newest member of its Board of Directors. Mr. Galante is the former Chairman of Sony Music in Nashville and the

Former President of RCA Records in New York City. Mr. Galante joins as the Company's seventh "independent director" as defined under applicable SEC and NASDAQ rules and he serves on the Company's Audit and Compensation Committees.

GEL Omeclamox-Pak Agreement

In March 2018, we reached an 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. Under the terms of the agreement, we will no longer be obligated to provide GEL with royalties or fees for overseeing the product's

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manufacturing. As part of this transaction, we will become responsible for maintaining the FDA approval and for overseeing the product's packaging. The closing of this agreement is pending.

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 has been initiated.

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 "Business - Competition" in our 2017 Annual Report on Form 10-K which is incorporated by reference and has been updated as follows:

Totect[®]

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 the product which includes patent number 6,727,253 which is FDA Orange Book listed and has a term until March 13, 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 appear to 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.

RESULTS OF OPERATIONS**Three months ended September 30, 2018 compared to the three months ended September 30, 2017**

The following table presents the unaudited interim statements of operations for the three months ended September 30, 2018 and 2017:

	Three months ended September 30,		
	2018	2017	Change
Net revenues	\$ 8,492,530	\$ 11,196,961	\$ (2,704,431)
Costs and expenses:			
Cost of products sold	1,460,463	2,166,353	(705,890)
Selling and marketing	4,803,112	6,226,438	(1,423,326)
Research and development	1,306,055	943,162	362,893
General and administrative	2,067,981	2,090,785	(22,804)
Amortization	661,802	609,572	52,230
Total costs and expenses	10,299,413	12,036,310	(1,736,897)
Operating income (loss)	(1,806,883)	(839,349)	(967,534)
Interest income	166,220	94,833	71,387
Interest expense	(19,199)	(8,902)	(10,297)
Income (loss) before income taxes	(1,659,862)	(753,418)	(906,444)
Income tax (expense) benefit	(4,159)	(3,822)	(337)
Net income (loss)	\$ (1,664,021)	\$ (757,240)	\$ (906,781)

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

	Three months ended September 30,		
	2018	2017	Change
Products:			
Acetadote	\$ 1,122,544	\$ 1,342,457	\$ (219,913)
Omeclamox-Pak	278,017	190,835	87,182
Kristalose	3,017,803	2,749,966	267,837
Vaprisol	(67,436)	385,541	(452,977)
Caldolor	1,318,109	896,640	421,469
Ethyol	2,593,830	2,566,611	27,219

Totect	45,249	2,916,425	(2,871,176)
Other	184,414	148,486	35,928
Total net revenues	\$ 8,492,530	\$ 11,196,961	\$ (2,704,431)

Net revenues. Net revenues for the three months ended September 30, 2018 were \$8.5 million compared to \$11.2 million for the three months ended September 30, 2017, representing a decrease of \$2.7 million, or 24%. The decrease is due primarily to a decrease in Totect product sales volume compared to the prior year period. We began shipments of Totect during 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. As detailed in the table above, four of our seven marketed products experienced increases in net revenue during the quarter: Omeclamox-Pak, Kristalose, Caldolor, and Ethyol.

Vaprisol revenue experienced a decrease of \$0.5 million during the third quarter of 2018 when compared to the prior year period due to lower sales volumes and higher returns of expired product. Sales of the product surged during the second quarter of 2018 due to shipments of newly arrived inventory following a period of time when there were limited supplies of the

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product. The negative net sales during the third quarter of 2018 resulted from higher than usual expired product returns in the period.

Ethyol revenue remained consistent at \$2.6 million for the three months ended September 30, 2018 and September 30, 2017.

Kristalose revenue increased by \$0.3 million or 9.7% during the third quarter of 2018 when compared to the prior year period. The product's net revenue was positively impacted by increased sales volumes and lower managed care and Medicaid rebates, resulting in improved net pricing for the product.

Omeclamox-Pak revenue increased \$0.1 million primarily due to higher sales volumes as well as lower managed care and Medicaid rebates during the period.

Acetadote revenue includes net sales of our Acetadote brand and our share of net sales from our Authorized Generic. During the quarter, there was a \$0.2 million decrease in revenue from our Acetadote brand when compared to the prior year period as a result of increased competition.

Caldolor revenue increased \$0.4 million for the three months ended September 30, 2018 primarily due to increased domestic and international sales revenue in the third quarter of 2018 compared to the third quarter of 2017. Domestic revenue of the brand grew due to improvement in deductions associated with shipment of the product.

Cost of products sold. Cost of products sold for the third quarter of 2018 decreased \$0.7 million compared to the prior year period as a result of lower sales. Cost of products sold, as a percentage of net revenues, improved to 17.2% during the three months ended September 30, 2018 compared to 19.3% during the three months ended September 30, 2017. This improvement in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix, including the decrease in Totect sales, during the quarter compared to the prior year period.

Selling and marketing. Selling and marketing expense for the third quarter of 2018 decreased \$1.4 million compared to the prior year period. This decrease is attributable to less royalties related to product sales during the third quarter of 2018.

Research and development. Research and development costs for the third quarter of 2018 were \$1.3 million, compared to \$0.9 million for the same period last year. A portion of our research and development costs is variable based on the number of trials, study sites and patients involved in the development of our new product candidates. The \$0.4 million increase was the result of additional investments in our ongoing clinical and manufacturing initiatives associated with our pipeline products as well as increases in our FDA fees.

General and administrative. General and administrative expense for both the third quarter of 2018 and third quarter of 2017 remained consistent at \$2.1 million.

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, 2018 and the three months ended September 30, 2017 totaled approximately \$0.7 million and \$0.6 million, respectively.

Income taxes. Income tax expense for the three months ended September 30, 2018 was \$4,159. As a percentage of income (loss) before income taxes, income tax expense was 0.3% for the three months ended September 30, 2018 compared to 0.5% for the three months ended September 30, 2017.

As of September 30, 2018, we have approximately \$44 million of net operating loss carryforwards resulting from the exercise of nonqualified stock options in 2009 that have historically been used to significantly offset future income tax obligations. Since they were generated during 2009, we have utilized these net operating loss carryforwards to pay minimal income taxes. We will continue to pay minimal income taxes during 2018 and beyond, through the continued utilization of these net operating loss carryforwards, as we are able to achieve taxable income through our operations.

Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017

The following table presents the unaudited interim statements of operations for the nine months ended September 30, 2018 and 2017:

	Nine months ended September 30,		
	2018	2017	Change
Net revenues	\$ 27,243,859	\$ 29,500,843	\$ (2,256,984)
Costs and expenses:			
Cost of products sold	4,511,743	5,216,776	(705,033)
Selling and marketing	14,549,873	16,174,391	(1,624,518)
Research and development	4,631,384	2,921,951	1,709,433
General and administrative	6,732,485	6,554,158	178,327
Amortization	1,946,457	1,811,589	134,868
Total costs and expenses	32,371,942	32,678,865	(306,923)
Operating income (loss)	(5,128,083)	(3,178,022)	(1,950,061)
Interest income	398,420	216,849	181,571
Interest expense	(59,520)	(70,646)	11,126
Income (loss) before income taxes	(4,789,183)	(3,031,819)	(1,757,364)
Income tax (expense) benefit	(12,477)	(4,196,192)	4,183,715
Net income (loss)	\$ (4,801,660)	\$ (7,228,011)	\$ 2,426,351

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

	Nine months ended September 30,		
	2018	2017	Change
Products:			
Acetadote	\$ 3,238,284	\$ 4,331,675	\$ (1,093,391)
Omeclamox-Pak	509,358	1,213,635	(704,277)
Kristalose	9,490,901	8,037,994	1,452,907
Vaprisol	1,712,353	1,346,793	365,560
Caldolor	3,458,881	2,762,790	696,091
Ethyol	7,659,594	8,325,254	(665,660)
Totect	727,211	2,916,425	(2,189,214)

Other	447,277	566,277	(119,000)
Total net revenues	\$ 27,243,859	\$ 29,500,843	\$ (2,256,984)

Net revenues. Net revenues for the nine months ended September 30, 2018 were \$27.2 million compared to \$29.5 million for the nine months ended September 30, 2017, representing a decrease of \$2.3 million, or 8%. The decrease is due primarily to a decrease in Totect product sales volume compared to the prior year period. We began shipments of Totect during 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. As detailed in the table above, three of our seven marketed products experienced increases in net revenue during the period: Kristalose, Vaprisol and Caldolor.

Kristalose revenue increased by 18.1% or \$1.5 million during the nine months ended September 30, 2018. The product's net revenue was positively impacted by increased sales volumes and lower managed care and Medicaid rebates, resulting in improved net pricing for the product.

Vaprisol revenue increased 27.1% or \$0.4 million during the nine months ended September 30, 2018 compared to the prior year period primarily due to increased sales volume. Sales of the product surged during the second quarter of 2018 due to shipments

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of newly arrived inventory following a period of time when there were limited supplies of the product. During April 2018, the Vaprisol supply issue was resolved as we received new shipments from our manufacturer.

Caldolor revenue experienced an increase of \$0.7 million during the nine months ended September 30, 2018 compared to the same period last year. This 25% increase in revenue in the nine months ended September 30, 2018 compared to the prior year period resulted from increased international shipments, an increase in international sales volumes and an increase in the products price. The year over year net revenue increase was partially offset by lower expired product sales returns which positively impacted the nine months ended September 30, 2017.

Acetadote revenue included net sales of our branded product and our share of net sales from our Authorized Generic. During the nine months ended September 30, 2018 the Acetadote net revenue decreased \$1.1 million as a result of increased competition.

Ethyol revenue for the nine months ended September 30, 2018 was \$7.7 million, which is a decrease of \$0.7 million from the nine months ended September 30, 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 nine months ended September 30, 2018 are consistent with the shipments experienced during the second half of 2017.

Omeclamox-Pak revenue decreased \$0.7 million during the nine months ended September 30, 2018 compared to the prior year. The decrease was primarily due to lower sales volumes as well as increases in expired product sales returns during the period.

Cost of products sold. Cost of products sold for the nine months ended September 30, 2018 and nine months ended September 30, 2017 were \$4.5 million and \$5.2 million, respectively. Cost of products sold, as a percentage of net revenues were 16.6% compared to 17.7% during the prior year. The decrease 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 nine months ended September 30, 2018 were \$14.5 million, compared to \$16.2 million for the prior year period, representing a decrease of approximately \$1.6 million. This decrease was primarily attributable to less royalties related to product sales as well as lower promotional spending during the nine months ended September 30, 2018. Promotional spending was higher during 2017, primarily related to development of marketing materials.

Research and development. Research and development costs for the nine months ended September 30, 2018 were \$4.6 million, compared to \$2.9 million for the same period last year, representing an increase of approximately \$1.7 million. A portion of our research and development costs is 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 \$6.7 million for the nine months ended September 30, 2018, compared to \$6.6 million during the same period last year. The \$0.2 million increase from the prior year was primarily driven by 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 nine months ended September 30, 2018 totaled approximately \$1.9 million, which was an increase of \$0.1 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 nine months ended September 30, 2018 totaled \$12,477 compared to \$4,196,192 in the nine months ended September 30, 2017. As a percentage of income (loss) before income taxes, income taxes were 0.3% for the nine months ended September 30, 2018 compared to 138.4% for the nine months ended September 30, 2017. The effective tax rate for the nine months ended September 30, 2017 was primarily impacted by a valuation allowance of \$1.0 million for our federal Orphan Drug and Research and Development tax credits as well as recording a full valuation allowance of \$3.5 million for our remaining deferred tax assets. This additional non-cash valuation allowance impacted our effective tax rate during the nine months ended September 30, 2017.

LIQUIDITY AND CAPITAL RESOURCES**Working Capital**

Our primary sources of liquidity are cash flows provided by our operations, the amounts borrowed and available 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, existing working capital and our line of credit, including its recent expansion to \$20 million, will be adequate to finance internal growth, finance business development initiatives, 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 September 30, 2018 and December 31, 2017, we had approximately \$9.5 million and \$4.7 million, respectively, invested in marketable securities.

The following table summarizes our liquidity and working capital as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 38,259,233	\$ 45,412,868
Marketable securities	9,533,703	4,672,476
Total cash, cash equivalents and marketable securities	\$ 47,792,936	\$ 50,085,344
Working capital (current assets less current liabilities)	\$ 48,107,922	\$ 50,990,102
Current ratio (multiple of current assets to current liabilities)	4.1	3.9
Revolving line of credit availability	\$ —	\$ 2,200,000

As discussed below, our Revolving Credit Loan was expanded on October 17, 2018 from \$12 million to \$20 million. The \$12 million outstanding under the Revolving Credit Loan was repaid during October 2018 and the Revolving Credit Loan was then used to fund the \$20 million payment for the VIBATIV acquisition.

The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2018 and September 30, 2017:

	Nine months ended September 30, 2018	2017
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Net cash provided by (used in):		
Operating activities	\$ (610,452)	\$ (98,152)
Investing activities	(6,313,016)	6,600,632
Financing activities	(230,167)	1,006,143
Net increase (decrease) in cash and cash equivalents	\$ (7,153,635)	\$ 7,508,623

The net \$7.2 million decrease in cash and cash equivalents for the nine months ended September 30, 2018 was attributable to cash used in investing, financing and operating activities. Cash used in operating activities of \$0.6 million was primarily impacted by the net loss for the period of \$4.8 million. This use of cash was offset by changes in our working capital which provided net cash of \$1.2 million, including net collections of accounts receivable of \$1.3 million. The use of operating cash was further offset by the add back of non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$3.1 million. Cash used in investing activities included net cash invested in marketable securities of \$4.7 million and additions to intangibles of \$1.4 million. Our financing activities included \$2.2 million in net cash provided by borrowings under our line of credit offset by \$2.4 million in cash used to repurchase shares of our common stock.

The net \$7.5 million increase in cash and cash equivalents for the nine months ended September 30, 2017 was attributable to cash provided by investing and financing activities offset by cash used in operating activities. Cash used by operating activities of \$0.1 million was primarily impacted by a net loss for the period of \$7.2 million. These uses of operating cash were offset by non-cash expenses of depreciation and amortization and share-based compensation expense totaling \$2.8 million. Changes in our working capital used cash of \$0.1 million, including an increase in accounts payable of \$0.6 million offset by a decrease in accounts receivable of \$0.1 million. Cash provided by investing activities included net proceeds from marketable securities of

\$7.6 million offset by additions to intangibles of \$0.8 million. Our financing activities included \$3.9 million in cash provided by borrowings under our line of credit and offset by \$2.9 million in cash used to repurchase shares of our common stock.

Debt Agreement

On October 17, 2018, we entered into a second amendment ("Second Amendment") to amend the Revolving Credit Loan Agreement, dated July 28, 2017, with Pinnacle Bank (the "Pinnacle Agreement"). The Second Amendment increases the maximum aggregate principal available for borrowing under the Pinnacle Agreement to \$20 million. We had \$12 million in borrowings under that agreement at September 30, 2018. For a summary of the material terms of the Pinnacle Agreement, as amended, see Note 6 to the accompanying unaudited condensed consolidated financial statements

Under the Pinnacle Agreement, we were initially 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. On August 14, 2018 we amended the Pinnacle Agreement ("First Amendment") to replace the single financial covenant with the maintenance of either the Funded Debt Ratio or a Tangible Capital Ratio, as defined in the First Amendment. We were in compliance with the Tangible Capital Ratio covenant as of September 30, 2018 and expect to maintain compliance with this covenant in future periods.

OFF-BALANCE SHEET ARRANGEMENTS

During the nine months ended September 30, 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 our 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 \$9.5 million in marketable securities outstanding at September 30, 2018, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income (loss) of \$0.1 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 2% to 3% (representing an interest rate of 4% at September 30, 2018). As of September 30, 2018, we had \$12 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 nine months ended September 30, 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

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 defined in Rules 13a-15(e) and 15-15(e) of the Exchange Act, as of September 30, 2018. Based on that evaluation, our CEO and CFO concluded that, as of September 30, 2018, our disclosure controls and procedures are considered effective to ensure that the

information required to be disclosed by the Company in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the Company's management, including the Company's CEO and CFO, as appropriate, to allow for timely decisions regarding required disclosure.

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During the three months ended September 30, 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.

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PART II – OTHER INFORMATION**Item 1. Legal Proceedings**

None.

Item 1A. Risk Factors

There have been no material changes to the information regarding risk factors that 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 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 September 30, 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)
July	29,850	\$ 6.18	29,850	\$ 1,672,075
August	21,676 (2)	5.92	21,676	1,543,814
September	14,752	5.95	14,752	1,456,058
Total	66,278		66,278	

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

(2) Of this amount, 8,199 shares were repurchased directly through private purchases at the then-current fair market value of common stock.

Item 6. Exhibits

No.	Description
10.1	<p><u>First Amendment to Revolving Credit Note and Second Amendment to Revolving Credit Loan Agreement, dated as of October 17, 2018, by and between Cumberland Pharmaceuticals Inc. and Pinnacle Bank, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on October 19, 2018.</u></p>
31.1*	<p><u>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.</u></p>
31.2*	<p><u>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.</u></p>
32.1**	<p><u>Certification of Chief Executive and Principal Financial</u></p>

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

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

- * 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
Pharmaceuticals Inc.

Date: November
14, 2018

By: /s/ Michael
Bonner
Michael
Bonner
Chief
Financial
Officer