CUMBERLAND® PHARMACEUTICALS

2018
Annual Report

We are developing new medicines for the future.

Cumberland Pharmaceuticals

is a special pharmaceutical company with quality products that deliver real patient solutions every day. Our primary mission is to improve upon patient care with products that offer clear advantages over existing treatments, and we strive to provide innovative products that address poorly met medical needs.

OUR FAMILY OF PRODUCTS

Acetadote®

(acetylcysteine) Injection, for the treatment of acetaminophen poisoning

Caldolor®

(ibuprofen) Injection, for the treatment of pain and fever

Kristalose®

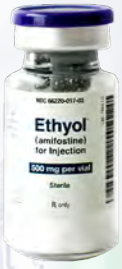
(lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation

Omeclamox®-Pak

(omeprazole, clarithromycin, amoxicillin) for the treatment of Helicobacter pylori (H. pylori) infection and related duodenal ulcer disease

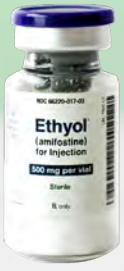
Vaprisol®

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



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



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).

Vibativ®

(telavancin) Injection, for the treatment of certain serious bacterial infections and complicated skin and skin structure infections.

> We are developing new medicines for the future.

A.J. Kazimi
Chief Executive Officer
Cumberland Pharmaceuticals

To Our Shareholders, Employees & Partners:

Cumberland Pharmaceuticals is a specialty pharmaceutical company focused on the acquisition, development, and commercialization of branded prescription products. With a focus on underserved niche markets and a commitment to innovation, we are working hard to develop medicines for the future that improve the quality of care for patients and deliver sustained growth and profitability for our shareholders.

Over the past several years, we have transformed Cumberland through a series of successful business development initiatives. In 2018, our strategy for accomplishing our goals was multi-faceted; we added new brands, launched new marketing campaigns and increased the sales support for our products. Those efforts have strengthened our market presence and diversified our business.

We are investing in near-term initiatives to support and build our in- line branded prescription products. We believe that pursuing opportunities to expand the potential for our existing products represents our lowest risk growth strategy.

But we also we seek select additions to our product portfolio through the acquisition of commercial stage brands. As a result of those efforts, in 2018, we added our newest FDA approved product - Vibativ®.

We acquired Viabtiv from Theravance Biopharma. It's a patented, anti-infective injectable product, designed to treat certain serious bacterial infections - including hospital-acquired pneumonia and complicated skin infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant such as MRSA. Wide-spread use of generic anti-infective products has led to a sharp increase in the number of patients experience resistance to certain products, resulting in a shift in the clinical standard of care for anti-biotic treatments. Given its dual mechanism of action, we believe that Vibativ is a product uniquely positioned to address such concerns and an excellent match for our hospital product infrastructure.

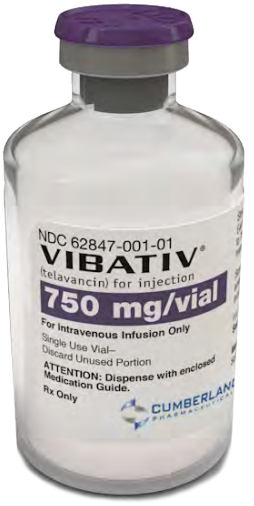
We also continually evaluate opportunities to further develop and expand the labeling of our already approved products. In early 2018, we completed and filed an application for the approval of our Next Generation Caldolor product - featuring an improved package and new formulation patents continuing until 2032. We also continued our study evaluating Caldolor in the youngest of patients - ranging from newborn to six months of age.

Additionally, we announced two new publications for Caldor based on favorable results from investigator-initiated studies – adding to the growing body of literature in support of the brand. One study, found that the use of Caldolor significantly lowered postoperative pain scores and opioid consumption in patients undergoing arthroscopic knee surgeries.

Another clinical trial concluded that preemptive anesthesia with Caldolor, our IV ibuprofen is superior when compared to IV acetaminophen in reducing post-surgical pain and opioid use in patients undergoing the surgical removal of impacted wisdom teeth.

Prudent and careful management of pain is among the most important responsibilities of every healthcare provider. Such favorable study results can help guide clinicians on the use of our injectable non-opioid alternative to reduce, or even avoid, opioids – mitigating the addiction and abuse risks when those products are prescribed.

In order to develop new medicines for the future, we are advancing a robust clinical pipeline that includes several potential orphan drug candidates. If one or more of these candidates are approved, they have the potential to deliver a very significant impact on the value of our company.



In November, we added an 8th product to our portfolio.

Wide-spread use of generic anti-infective products has led to a sharp increase in the number of patients experience resistance to certain products, resulting in a shift to the clinical standard of care for antibiotic treatments. We entered into a definitive agreement to acquire Vibativ® from Theravance Biopharma. Vibativ (telavancin) is a patented, FDA approved anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia and complicated skin & skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Although the market is currently driven by the wide use of generic products, Vibativ can provide a follow-on therapy should the infection fail to respond to the use of generics. We believe that Vibativ is a product that is uniquely positioned to address such concerns and an excellent match for our hospital infrastructure.

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");

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;

RediTrex™ (methotrexate) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

During the year, we completed study enrollment for Portaban - our Portal Hypertension clinical program. An initial review of the data shows ifetroban was well tolerated with no unexpected safety findings. We also continued to advance our Vasculan and Boxaban programs, with patient enrollment progressing in each of those Phase II studies. We now await results from these additional Phase II studies before deciding on the best path for approval of ifetroban - our first new chemical entity.

During 2018, we also completed and submitted to the FDA the New Drug Application for the approval of our RediTrex product line.

We made several key new appointments during year. We added a new Board member, Joe Galante, a music industry leader with a successful entrepreneurial and business track record.




Key Appointments in 2018

In 2018, Cumberland announced several key new appointments to the organization. (left to right):

Joe Galante / Cumberland Board Member & Independent Director
Chris Bitterman / Director, Hospital Sales
Kenny Acevado / Director, Field Sales
Adam Haeberle / Senior Director Clinical & Regulatory Affairs


“Our people are our most valuable asset.”

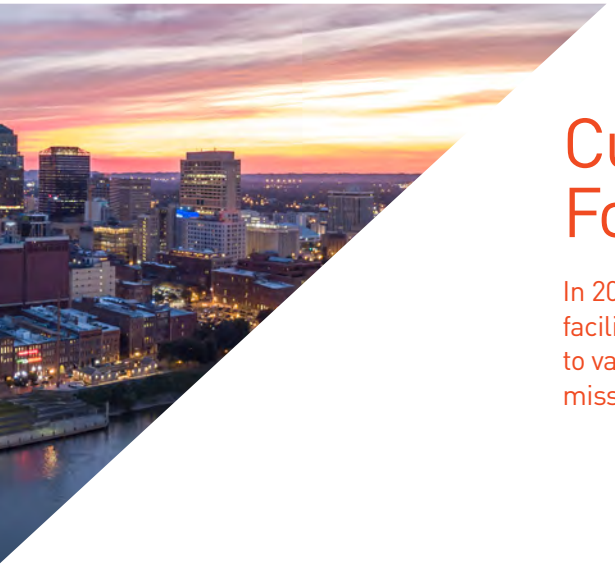
250+

We are headquartered in Nashville – the nation's health care capital.

Nashville is home to more than 250 healthcare companies as well as the Vanderbilt University Medical Center - recently named one of the best hospitals in the country - Nashville is fast becoming a health care mecca. The local health care industry spans hundreds of companies, hundreds of thousands of employees, and generates billions in revenue each year.

Biopharma industry veteran, Adam Haeberle, also joined us as Senior Director of Clinical and Regulatory Affairs. Additionally, we added Chris Bitterman to lead our hospital sales division and promoted Kenny Acevado to lead our field sales force. Chris brings over 25 years of industry experience and a successful track record in leading hospital sales teams and building hospital brands. Kenny brings over 30 years of industry experience with previous sales management responsibilities.

Nashville is known historically as "Music City." However, with over 250 health care companies headquartered in Nashville – 17 of which are publicly traded - modern Nashville is actually a health care city. Health care is now Nashville's largest industry and impacts the health care landscape not only locally, but nationally as well.



Cumberland Pharma Foundation Launched

In 2018, we launched the Cumberland Pharma Foundation to organize and facilitate its ongoing philanthropic endeavors. The Foundation provides support to various non-for-profit organizations whose activities align with Cumberland's mission and are primarily located in the middle Tennessee area.

We are fortunate to be part of such an expansive and diverse collection of companies and are honored to have emerged as the leading biopharmaceutical company based in Tennessee.

In 2018, we entered into a new phase in our company's history as we moved from a growing business to a more significant participant in the local community. We launched the Cumberland Pharma Foundation to organize and facilitate our ongoing philanthropic endeavors and provide support to various non-for-profit organizations whose activities align with our mission of improving patient care and addressing unmet needs.

The foundation provides support to various nonprofit organizations primarily located in the middle Tennessee area, and our Nashville base enables us to participate in the significant health care community here, collaborate with leading research teams at Vanderbilt University, and build upon the strong history of entrepreneurial success associated with this city.

Meanwhile, in order to foster a successful product line over the long-term, we believe it is important to have a conduit of innovative new product opportunities. We formed Cumberland Emerging Technologies (CET) for that purpose. The mission of CET is to bring innovative biomedical technologies and products to the marketplace.

> We expanded our CET university collaborations in 2018 in order to grow our pipeline of promising new products.

CET was founded as a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University and the state of Tennessee's LaunchTN. Through CET, we collaborate with a select group of like-minded academic research institutions. CET currently has collaboration agreements with Universities to co-develop promising biomedical technologies and translate research discoveries into commercial products.

CET entered into an agreement with Louisiana State University and the Medical College of South Carolina. These new arrangements add to CET's roster of academic collaborations which also include: 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.

Furthermore, in late 2018, the U.S. National Cancer Institute awarded $2 million in support of a joint research program involving Cumberland, CET, and Vanderbilt University. The objective of the research program is to further develop a novel small molecule radiosensitizing agent designed to enhance the treatment of certain lung cancers.

I'd like to thank everyone at Cumberland for their hard work and fine efforts in 2018. We will continue to focus on sustained growth and profitability through new product introductions, marketing and product enhancements and the efficient use of our financial resources. We are confident that we have put the key pieces in place to help us to deliver on our goal to improve patient care through the delivery of high-quality pharmaceutical products.

With best wishes,

AJ Kazimi
Chairman and Chief Executive Officer

OUR UNIVERSITY AFFILIATIONS

THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Includes the Colleges of Health Professions, Dentistry, Graduate Health Sciences, Medicine, Nursing and Pharmacy. Since 1911, the University of Tennessee Health Science Center has educated nearly 57,000 health care professionals.

VANDERBILT UNIVERSITY

Vanderbilt is comprised of 10 schools and colleges covering disciplines from the humanities to music to engineering. Vanderbilt is well known for its undergraduate Blair School of Music, and the Vanderbilt University Medical Center is ranked one of the best in the nation.

THE UNIVERSITY of MISSISSIPPI

The mission of the University of Mississippi Medical Center is to improve the health and well-being of patients and the community through excellent training for health care professionals, engagement in innovative research, and the delivery of state-of-the-art health care.

THE UNIVERSITY OF TENNESSEE

The University of Tennessee at Knoxville is the flagship campus of the statewide University of Tennessee system. With ten undergraduate colleges and eleven graduate colleges, it hosts almost 28,000 students from all 50 states and more than 100 foreign countries.

LSU Health NEW ORLEANS

The Louisiana State University Health Sciences Center New Orleans is a public university focused on the health sciences. It is the home of six schools, 12 Centers of Excellence, and 2 patient care clinics.

MUSC MEDICAL UNIVERSITY of SOUTH CAROLINA

The Medical University of South Carolina operates a 700-bed medical center, which includes a nationally recognized children's hospital, the NCI-designated Hollings Cancer Center, a Level I trauma center, Institute of Psychiatry, more than 100 outreach locations, and South Carolina's only transplant center.

1 CANADA—

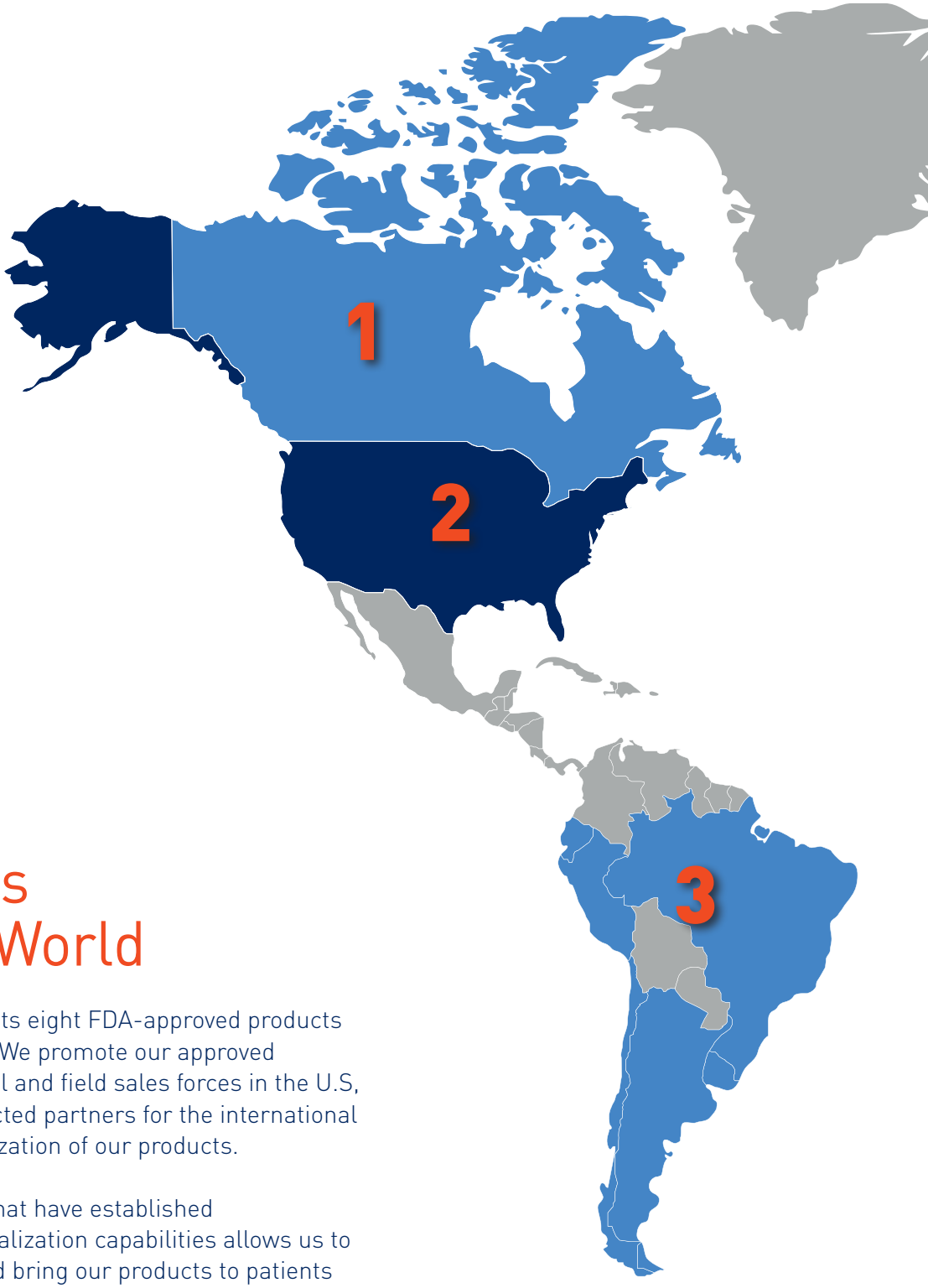
Teligent Inc. *is our commercial partner for Caldolor® and* **Pendopharm** *is our commercial partner for Vibativ®*

2 TENNESSEE—

Cardinal Health Inc. *provides warehousing, shipping and other distribution support for our products in the U.S.*

3 LATIN AMERICA—

Grifols International, S.A. *is our commercial partner for Caldolor®*



Partnerships Around the World

Cumberland currently markets eight FDA-approved products for sale in the United States. We promote our approved products through our hospital and field sales forces in the U.S, and we rely on carefully selected partners for the international distribution and commercialization of our products.

Partnering with companies that have established infrastructure and commercialization capabilities allows us to expand our global impact and bring our products to patients throughout the world.

4 SPAIN & PORTUGAL—

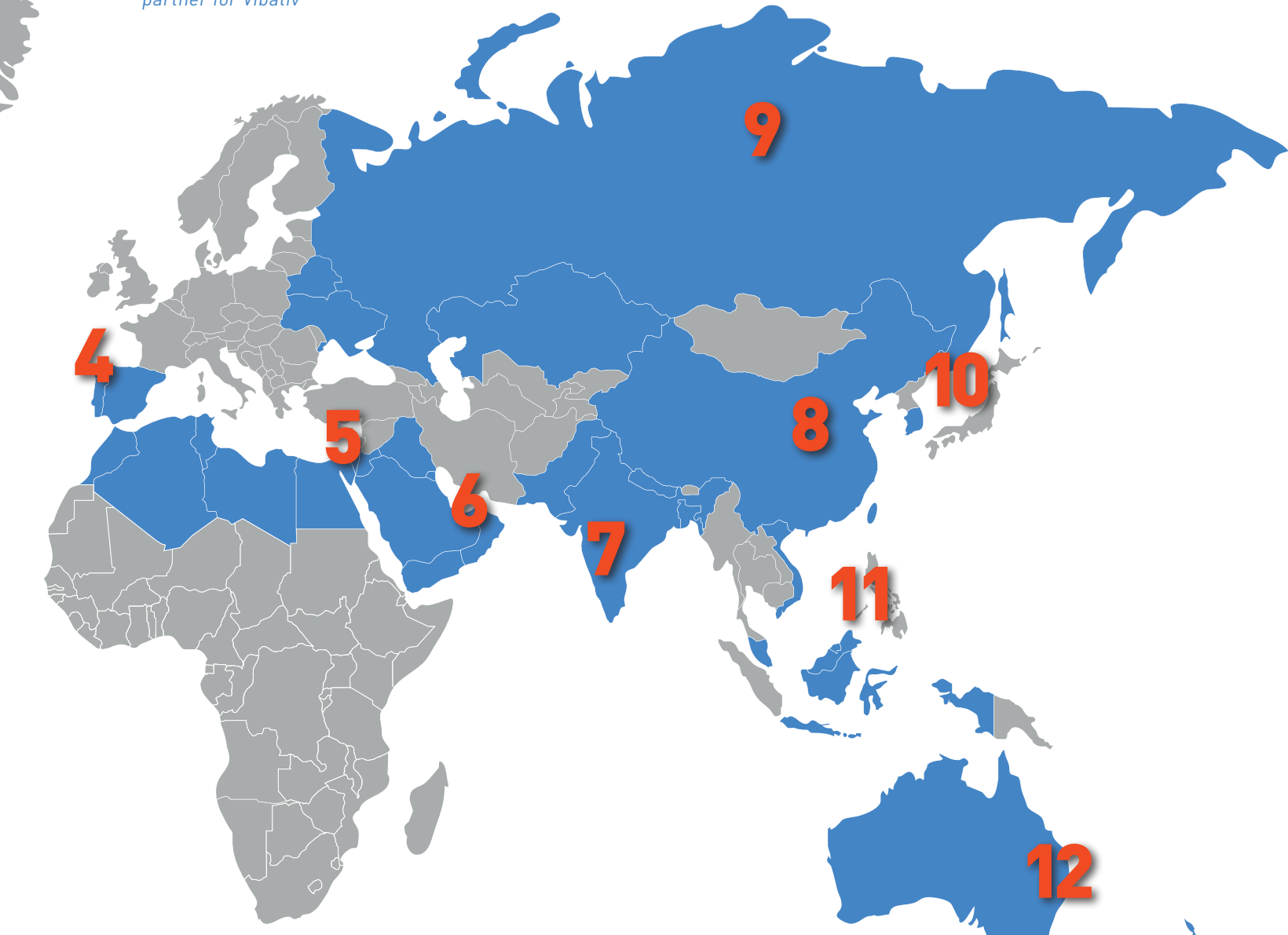
Grifols *is our commercial partner for Caldolor®*

5 ISRAEL& PALESTINE—

MegaPharm *is our commercial partner for Vibativ®*

6 ARABIAN GULF —

GerminMed *is our commercial partner for Caldolor® and* **Hikma** *is our commercial partner for Vibativ®*



7 INDIA—

Sandor Medicaids Pvt. Ltd.
is our commercial partner for Caldolor®

8 CHINA—

Harbin Gloria Pharmaceuticals Co. Ltd *is our commercial partner for Caldolor® and Acetadote®, as well as an investor in Cumberland Emerging Technologies.*

9 RUSSIA—

R-Pharm *is our commercial partner for Vibativ®*

10 SOUTH KOREA—

DB Pharm Korea Co. Ltd.
is our commercial partner for Caldolor®

11 INDONESIA—

The **PT. ETHICA Group** *is our commercial partner for Caldolor®*

12 AUSTRALIA & NEW ZEALAND—

Seqirus™, *is a CSL Company, is our commercial partner for Caldolor®* **Phebra Pty Ltd.** *is our commercial partner for Acetadote®*

We remain in a strong financial position at year end with $112.7 million in total assets including $36.2 million in cash and marketable securities. We now have a $20MM line of credit available on attractive terms and remain financially disciplined, managing expenses in line with revenues.

Selected Financial Data

(dollars in thousands except per share data)	2014	2015	2016	2017	2018
Net Revenues	$ 36,902	$ 33,519	$ 33,026	$ 41,150	$ 40,742
Operating Income (Loss)	3,559	1,112	(1,433)	(4,081)	(7,391)
Operating Margin	9.6 %	3.3 %	(4.3) %	(9.9) %	(18.1) %
Net Income (Loss)	2,362	671	(1,004)	(8,050)	(7,039)
Diluted Earnings (Loss) per Share	0.14	0.04	(0.06)	(0.50)	(0.45)
Total Assets	95,405	91,919	93,405	93,232	112,693
Long-Term Obligations	903	2,687	5,491	11,616	29,319
Shareholders' Equity	80,753	76,820	73,248	64,120	55,845
Supplemental Financial Measures (Unaudited) [1]					
Adjusted Earnings (Loss)	$ 6,310	$ 4,477	$ 1,816	$ 54	$ (457)
Adjusted Margin	17.1 %	13.4 %	5.5 %	0.1 %	(1.1) %
Adjusted Diluted Earnings (Loss) per Share	$ 0.35	$ 0.26	$ 0.11	$ 0.00	(0.03) %

Reconciliation of Net Income (Loss) Attributable to Common Shareholders to Adjusted Earnings and Adjusted Diluted Earnings Per Share [1] (Unaudited)

(dollars in thousands except per share data)	2014	2015	2016	2017	2018
Net Income (Loss) Attributable to Common Shareholders	$ 2,424	$ 731	$ (945)	$ 7,979	$ (6,963)
Less: Net Loss at Subsidiary Attributable to Noncontrolling Interests	62	60	59	71	76
Net Income (Loss)	2,362	671	(1,004)	8,050	(7,039)
Adjustments to Net Income (Loss)					
Income Tax Expense (Benefit)	1,381	576	(331)	4,175	16
Depreciation and Amortization Expense	1,990	2,247	2,397	2,648	2,983
Share-Based Compensation Expense	761	623	852	1,115	1,365
Other Adjustments to Net Income [1]	–	495	–	372	2,586
Interest Income	(251)	(209)	(204)	(299)	(564)
Interest Expense	67	74	106	93	196
Adjusted Earnings	$ 6,310	$ 4,477	$ 1,816	$ 54	$ (457)
Adjusted Diluted Earnings per Share	$ 0.35	$ 0.26	$ 0.11	$ 0.00	$ (0.03)
Diluted Weighted-Average Common Shares Outstanding:	17,900	17,095	16,559	16,325	15,614

(1) The supplemental financial measures are Non-GAAP as defined, the reconciliation of these supplemental measures is above.

2018 Financial Review

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

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PART I

Item 1. Business.

THE COMPANY

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 field sales forces in the United States and are establishing a network of international partners to bring our medicines to patients in their countries.

Our portfolio of FDA approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **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;
- **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); and
- **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");
- **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™** (*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. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, regulatory, manufacturing, sales marketing and finance. Our business development team identifies, evaluates and negotiates product acquisition, licensing and co-promotion opportunities. Our product development team creates proprietary product formulations, manages our clinical studies, prepares all regulatory submissions and manages our medical call center. Our 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.

Cumberland's 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 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, through new indications, and through the support of 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. Furthermore, we are supplementing these activities with the earlier stage drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to identify and progress promising, new product candidates, which Cumberland has the opportunity to further develop and commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. During 2009, we completed an initial public offering of our common shares and listing on the Nasdaq stock 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 material press releases, other filings and amendments to those reports as soon as reasonably practicable after their filing with the U.S. Securities and Exchange Commission, (“SEC”). These filings are also available to the public at *www.sec.gov.*

PRODUCTS

Our key products include:

Products	Indication	Status
Acetadote®	Acetaminophen Poisoning	Marketed
Caldolor®	Pain and Fever	Marketed
Kristalose®	Chronic and Acute Constipation	Marketed
Omeclamox®-Pak	H. pylori infection and related Duodenal Ulcer disease	Marketed
Vaprisol®	Euvolemic and Hypervolemic Hyponatremia	Marketed
Ethyol®	Radiation xerostomia and chemotherapy renal toxicity	Marketed
Totect®	Toxic chemotherapy extravasation	Marketed
Vibativ®	Serious bacterial infections	Marketed
Hepatoren®	Hepatorenal Syndrome	Phase II
Boxaban®	Aspirin-Exacerbated Respiratory Disease	Phase II
Vasculan®	Systemic Sclerosis	Phase II
Portaban®	Portal Hypertension associated with liver disease	Phase II
RediTrex™	Arthritis and psoriasis	Pre-approval

Acetadote®

Acetadote is an intravenous formulation of N-acetylcysteine, indicated for the treatment of the liver toxicity associated with acetaminophen poisoning. Acetadote, has been available in the United States since Cumberland's 2004 introduction of the product through our hospital sales force. Acetadote is typically used in hospital emergency departments to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter and prescription pain relieving and fever-reducing products. Acetaminophen continues to be a leading cause of poisonings reported by hospital emergency departments in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

Acetadote received U.S. Food and Drug Administration ("FDA") approval as an orphan drug, which provided seven years of marketing exclusivity from the date of approval. In connection with the FDA's approval of Acetadote, we committed to certain post-marketing activities for the product. Completion of our first Phase IV commitment resulted in the FDA's 2006 approval of expanded labeling for the product for use in pediatric patients. Completion of our second Phase IV commitment resulted in further revised labeling for the product with FDA approval of additional safety data in 2008. Completion of our third and final Phase IV commitment in 2010 culminated in the FDA’s approval of a new formulation for the product. The next generation formulation, contains no ethylene diamine tetracetic acid ("EDTA") or other stabilization agent, chelating agent or preservative. In early 2011, Cumberland introduced this new Acetadote formulation replacing the original form of the product which we no longer manufacture.

In June 2013, the FDA approved updated labeling for Acetadote revising the product's indication and providing new dosing guidance for specific patient populations. As a result, dosing guidance is now included for patients weighing over 100 kg, and new language has been added to alert health care providers that, in certain clinical situations, therapy should be extended for some patients.

Beginning in 2012, the United States Patent and Trademark Office (the "USPTO") issued us a series of patents associated with our Acetadote product. These patents are discussed in Part I, Item I, "*Business - Trademarks and Patents*" of this Form 10-K. On November 8, 2012, we learned that the FDA approved an abbreviated new drug application (ANDA) filed by InnoPharma, Inc. and referencing Acetadote. That product, with the old formulation containing EDTA, was subsequently introduced by APP, a division of Fresenius Kabi USA, at the end of 2012. In early 2013, we entered into an agreement with Perrigo Company resulting in the distribution of our Authorized Generic acetylcysteine injection (our "Authorized Generic") product. Both Acetadote and our Authorized Generic utilize the new, EDTA-free formulation which accounted for continued significant market share during 2018.

In November 2015, an Illinois judge issued a final ruling in favor of Cumberland Pharmaceuticals Inc. in a patent case associated with Acetadote. By ruling in Cumberland's favor, the court upheld the validity of the patent which encompasses our EDTA-Free formulation and has a term until August 2025. The court also granted a permanent injunction preventing challengers from marketing a generic version of our proprietary Acetadote product formulation before the expiration of Cumberland’s patent in August 2025.

On January 26, 2017, an Appeals Court affirmed the District Court ruling in the Company's favor upholding Cumberland's Acetadote patent and expressly rejected the validity challenge.

Caldolor®

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the U.S. for the treatment of both pain and fever. We conducted a series of clinical studies in over nine hundred adult patients to develop the data to support our FDA submission for the product's registration. The FDA approved Caldolor for marketing in the United States in 2009 following a priority review. The product was indicated for use by adults for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics. It was also the first FDA approved intravenous therapy for treating fever.

In late 2009, we launched Caldolor and stocked the product at major wholesalers serving hospitals nationwide. We initially worked to establish a core group of medical facilities approving and purchasing the product and then focused on building more sales volume and treating a broader range of patients within those stocked facilities. We promote Caldolor in the United States through our dedicated hospital sales force.

We completed a series of Phase IV studies to gather additional data to support our Caldolor product. Those clinical trials involved another 1,000 patients, adult and pediatric patients. These studies included data on a shortened infusion time and pre-surgical administration of the product. To address our Phase IV commitment to the FDA, these studies also included evaluation of the product for the reduction of fever in hospitalized children and the treatment of pain in children undergoing tonsillectomy surgeries.

In 2015 we received FDA approval for the use of Caldolor in pediatric patients six months of age and older. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in children. We then initiated a study to collect data on the use of Caldolor in children ranging in age from birth up to six months of age. Enrollment in that study progressed in 2018.

In early 2018, we completed and filed the application for FDA approval of a 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 of the submission for review. There were then a number of communications with questions addressed through multiple amendments that were submitted to the application. On August 2, 2018, we received a complete response from the FDA outlining the additional information needed for the application’s approval. We held a teleconference with the FDA to discuss their additional requirements. In September 2018, the Company submitted an amendment to our application containing additional quality and nonclinical data. As noted in the "Subsequent Events" section of this Item, the application was subsequently approved by the FDA.

Kristalose®

Kristalose is a prescription laxative administered orally for the treatment of acute and chronic constipation. An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient acceptance and compliance. Kristalose is the only prescription laxative available in pre-measured powder packets. Kristalose dissolves easily in four ounces of water, offering patients a virtually taste-free, grit-free and essentially calorie-free alternative to lactulose syrups. We conducted a preference study which indicated that seventy-seven percent of patients surveyed prefer the taste, consistency and portability of Kristalose over similar products in syrup forms.

We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a dedicated field sales force and re-launched it in September 2006 as a Cumberland brand. We direct our sales efforts to physicians who are the most prolific writers of prescription laxatives, including gastroenterologists and internists. We supplement this personal promotion with telemarketing campaigns to expand our reach and support of the product.

In late 2011, through a series of transactions, we entered into an agreement with Mylan Inc. to acquire certain assets associated with the Kristalose brand including the Kristalose trademark and the FDA registration.

Using the preference data as a cornerstone of our marketing efforts, we repositioned the brand in early 2014. The marketing strategy which continued in 2018 included an enhanced patient coupon program and expanded managed care coverage for the product.

We added a co-promotion partner to provide support for the brand in 2017. Poly Pharmaceuticals is promoting Kristalose to physician targets not covered by our field sales forces. In 2018 we added another co-promotion partner, 2R Pharmaceuticals who is repackaging Kristalose and featuring it with additional new physician targets.

Omeclamox®-Pak

Many ulcers of the gastrointestinal tract are caused by an infection from the Helicobacter pylori (“H. pylori”) bacterium. Omeclamox-Pak is a branded prescription product used for the treatment of these infections and the related duodenal ulcer disease. This innovative product combines three well-known and widely prescribed medications: omeprazole, clarithromycin, and amoxicillin. Omeclamox-Pak was the first FDA approved triple therapy combination medication to contain omeprazole as the proton pump inhibitor, which works to decrease the amount of acid the stomach produces. Clarithromycin and amoxicillin are both antibiotic agents which hinder the growth of the H. pylori bacteria. Interaction of these agents allows the stomach lining to heal effectively. The medications are packaged together on convenient daily dosing cards, making it simple to follow the twice a day dosing before meals.

While there are competing combination products, Omeclamox-Pak is one of the few actively marketed brands for this condition. In addition, compared to the competitors, Omeclamox-Pak involves the lowest pill burden and fewest days of therapy. Our involvement with Omeclamox-Pak began in October 2013, through a co-promotion agreement with Pernix Therapeutics ("Pernix"). In November 2015, Cumberland entered into an exclusive license and supply agreement with Gastro-Entero Logic, LLC (“GEL”), assumed full commercial responsibility for Omeclamox-Pak in the United States, and concluded our agreements with Pernix. Cumberland became responsible for the distribution, national accounts and all sales promotion of Omeclamox-Pak under the GEL agreement.

In December 2018, we closed on an agreement with GEL to acquire all remaining assets associated with Omeclamox-Pak including the Product’s FDA-approved New Drug Application, the domestic and international trademarks. The closing of this transaction ended Cumberland’s payments of royalties and manufacturing fees to GEL, and we assumed responsibility for the maintenance of the Product’s FDA approval and for the oversight of the Product’s manufacturing and packaging.

Our field sales force promotes Omeclamox-Pak to the gastroenterology market segment, which accounts for the largest component of the prescriber base for this product. We supplement this personal promotion through telemarketing campaigns to expand the support and use of the product. We have also established a series of contracts to provide managed care coverage for Omeclamox-Pak.

Vaprisol®

In early 2014, we entered into an agreement with Astellas Pharma US, Inc. ("Astellas") to acquire Vaprisol, including certain product rights, intellectual property and related assets. Vaprisol is a prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the only intravenously administered branded treatment.

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

We re-launched active promotion of the brand during the middle of 2014 utilizing our hospital sales force supported by a series of marketing initiatives. In late 2017, we encountered delays in manufacture and supply of the product which impacted its sales until the second quarter of 2018 when new inventory arrived. We then restocked the distribution channels for Vaprisol and increased our inventory level of the brand.

Ethyol®

In May 2016, the Company announced an agreement with Clinigen Group Plc ("Clinigen") in which Cumberland acquired the exclusive rights to commercialize Ethyol in the United States. Ethyol is an FDA approved cytoprotective drug containing amifostine for injection. It is indicated as an adjuvant therapy to reduce the incidence of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer. Under the terms of the agreement, Cumberland is responsible for all marketing, promotion, and distribution of the product in the United States.

In late 2016, we began distribution of Ethyol for injection to wholesalers within the United States and launched national promotional support for the brand by our hospital sales division.

In early 2018, we announced a publication in *Leukemia and Lymphoma*, with study results showing that amifostine decreases gastro-intestinal toxicity in patients who receive treatment for their multiple myeloma. In September 2018 the Company announced a publication in *Lung Cancer: Targets and Therapy* of a contemporary retrospective study showing that subcutaneous amifostine administered before radiotherapy postponed the onset of acute esophagitis in stage three small cell lung cancer patients treated with concomitant doublet chemotherapy and hyperfractionated radiotherapy.

Totect®

In January 2017, we announced an exclusive agreement with Clinigen to commercialize the oncology support drug, Totect in the United States. It is an FDA approved hospital based emergency oncology intervention drug, indicated to treat the toxic effects of anthracycline chemotherapy. It treats anthracycline extravasation that occurs when the injected medication escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications. Totect can limit such damage without the need for additional surgeries or procedures and enables patients to continue their essential anti-cancer treatment.

In late July 2017, we initiated distribution and sale of Totect (dexrazoxane hydrochloride) in the United States. This followed the FDA approval of the updated labeling and product manufacturer for the product. In late September 2017, we announced the launch of Totect promotion in the United States.

We launched Totect during a national shortage of dexrazoxane in late 2017, resulting in strong initial demand for the product. During 2018 a number of competitive products returned, reducing Totect's share of the market.

Vibativ®

In November 2018, the Company announced an agreement with Theravance Biopharma ("Theravance") to acquire the Vibativ assets from Theravance and assume global responsibility for Vibativ including the marketing, distribution, manufacturing and regulatory activities associated with the brand. 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.

Immediately after the closing, we initiated shipments of Vibativ and assumed responsibility for the supply chain and distribution of the product in the U.S. Vibativ is supported by our hospital sales division.

Hepatoren®

In 2011, we entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. Our acquisition of the rights to the ifetroban program includes an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property. Ifetroban was initially developed by a large pharmaceutical company for significant cardiovascular indications. That company conducted extensive studies for their target indications and eventually donated the entire program to Vanderbilt University. Researchers at Vanderbilt identified ifetroban as a potentially valuable compound in treating patients for several niche indications. Cumberland acquired the rights to the ifetroban program from Vanderbilt through CET with the intention to develop the product for several potential new indications.

We have commenced manufacturing of an intravenous formulation of ifetroban and the FDA has cleared our IND application for this product candidate. We have initiated clinical development under the brand name Hepatoren and are evaluating this candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome ("HRS"). HRS is a life threatening condition involving liver and kidney failure, with a high mortality rate and no approved pharmaceutical therapy in the U.S. We completed a sixty-four patient Phase II study to evaluate the safety, efficacy and pharmacokinetics of escalating doses of Hepatoren in HRS patients. Progression to higher dose levels was reviewed and approved by an independent safety committee. The study was stratified into Type I or Type II patients with HRS based upon the progression of their disease.

Top line results from this study indicated that Hepatoren was overall well tolerated in the HRS patients with no safety concerns noted. We have filed the results from this study with the FDA and began evaluating the design for a follow-on Phase II efficacy study. During 2018 we decided to await results from our other Phase II ifetroban studies before determining the strategy for the best path to approval for ifetroban, our first new chemical entity.

Boxaban®

We have completed the manufacturing and initiated clinical development of an oral formulation of ifetroban under the brand name Boxaban. We are evaluating this candidate for patients suffering from Aspirin-Exacerbated Respiratory Disease ("AERD"), also known as Samter’s Triad, a chronic medical condition that consists of three clinical features: asthma, sinus disease with nasal polyposis and sensitivity to aspirin. AERD is characterized by sharp increases in inflammatory mediators and platelet activity within the respiratory system. Approximately one in twenty asthmatic adults in the U.S. suffer from AERD and awareness of the disease is growing within the medical community. There is no U.S. approved pharmaceutical treatment for AERD.

We completed an initial Phase II clinical study to evaluate the safety and tolerability of Boxaban in AERD patients. The multicenter study involved sixteen patients at several U.S. medical centers led by the Scripps Research Institute. Results indicated that Boxaban was well tolerated with no safety concerns noted in patients with a history of AERD.

In early 2017, the FDA cleared Cumberland’s investigational new drug (“IND”) application for 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 progressed in 2018 at a growing number of allergy and asthma centers across the United States.

Vasculan®

In April 2016, we announced the addition of Vasculan to our pipeline. Through Cumberland's ifetroban program, Cumberland has initiated the clinical development of ifetroban oral capsules for the treatment of systemic sclerosis.

Systemic sclerosis (SSc), also called scleroderma, is a debilitating autoimmune disorder characterized by diffuse fibrosis of the skin and internal organs, as well as vascular dysfunction. Preclinical studies have shown that ifetroban prevents and can restore cardiac function in a preclinical model of pulmonary arterial hypertension. This disease has a high morbidity and the highest case-specific mortality of any rheumatic disorder with 50% of patients dying or developing major internal organ complications within 3 years of diagnosis.

Although several medications are used to treat the skin disease associated with SSc, there is no universally effective treatment to improve the function of affected internal organs such as the lungs, heart, and gastrointestinal tract.

The FDA has cleared our IND to evaluate the safety and efficacy of Vasculan in patients with SSc. As a result, we initiated a Phase II multicenter study in thirty-four SSc patients. Enrollment in this randomized, placebo controlled trial progressed at several scleroderma centers of excellence in the United States during 2018.

Portaban®

In September 2016, we announced the addition of Portaban to our pipeline. Cumberland has initiated the clinical development of Portaban for the treatment of portal hypertension ("PH") associated with chronic liver disease. Preclinical studies have shown ifetroban can reduce portal pressure, inflammation, and fibrosis in multiple models of liver injury.

The FDA cleared our IND for a clinical development program evaluating Portaban in thirty patients with PH. Following that clearance, a multicenter Phase II study was initiated. During 2018 enrollment in this randomized, placebo controlled study was completed.

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 for ifetroban, our first new chemical entity.

RediTrex™

In November 2016, we announced that we had entered into an Agreement with Nordic Group B.V. to commercialize their methotrexate product line in the United States which is designed for treating patients with arthritis and psoriasis. Cumberland is responsible for the registration and commercialization of these products while Nordic will handle the product’s supply. Nordic has registered and is selling their methotrexate products in several European countries.

During late 2018, we completed the submission and filed with the FDA a New Drug Application for the approval of our methotrexate product line. This filing follows two meetings held with the FDA to discuss the approval pathway and requirements for the submission. As noted in the "Subsequent Event" section of this Item, the FDA subsequently determined that the application was complete and ready for their review.

OUR 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 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 early stage 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 additional clinical data could expand their market and use. We will continue to explore opportunities for label expansion to bring our products to new patient populations. We have secured pediatric approval, expanding the labeling for both our Acetadote and Caldolor brands.

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 acquisition of Vibativ represents our largest product acquisition.

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, which Cumberland has the opportunity to further develop and commercialize. We expanded our network of University collaborations with the addition of Louisiana State University and the Medical University of South Carolina.

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 complement our capabilities and enhance 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.

Build an 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 develop and expand our network of international partners while supporting our partners' registration and commercialization efforts in their respective territories. The acquisition of Vibativ resulted in several new international partners and market opportunities.

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 favorable gross margins, and a strong balance sheet. We use excess cash flow for our ongoing share repurchase program.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including approximately 50 sales representatives and district managers, direct our national marketing campaigns and maintain key national account relationships.

Hospital market: We promote Caldolor, Vaprisol, Acetadote, Ethyol, Totect and Vibativ through our dedicated hospital sales division. This organization targets key hospitals across the U.S. and is comprised of sales professionals with substantial experience in the hospital market. Independent market data continues to indicate that the majority of pharmaceutical promotional spending is directed toward large, outpatient markets on drugs intended for chronic use rather than short-term, hospital use.

We believe the hospital market is under-served and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity. Our established position in the hospital market provided the rationale for adding Ethyol and Totect as our first oncology products that complement our hospital product line. Our strategy has been to increase the focus of our hospital sales team on targeted, high priority accounts.

Gastroenterology market: We promote Kristalose and Omeclamox-Pak through a dedicated field sales team addressing a targeted group of physicians who are large prescribers of both products. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe it provides product opportunities that can be penetrated with a modest sized sales force.

By investing in our sales and marketing activities we believe that we can increase market share for both products. Our field sales force features both Kristalose and Omeclamox-Pak during most of their physician calls, establishing our presence in the gastroenterology market.

Our marketing executives conduct ongoing analysis to evaluate marketing campaigns and promotional programs. The evaluations include development of product profiles, testing of the profiles against the needs of the market, determining what additional product information or development work is needed to effectively market the products and preparing financial forecasts.

We utilize professional branding and packaging as well as promotional items to support our products, including direct mail, sales brochures, journal advertising, educational and reminder leave-behinds, patient educational pieces, coupons, and product sampling. We also regularly attend select medical meetings and trade shows to expand the awareness of our products.

Our national accounts function is responsible for key large buyers and related marketing programs. National accounts maintains relationships with our wholesaler customers as well as with third-party payors such as group purchasing organizations, pharmacy benefit managers, hospital buying groups, state and federal government purchasers and health insurance companies.

MATERIAL CUSTOMERS

Our primary customers are wholesale pharmaceutical distributors in the United States. Total revenue by customer for each customer representing 10% or more of consolidated gross revenues are summarized below for the year ended December 31, 2018:

	2018
Customer 1	26%
Customer 2	24%
Customer 3	25%
Customer 4	11%

INTERNATIONAL PARTNERSHIPS

We have established our own capabilities to support the commercialization of our products in the U.S. Our international strategy is to identify and partner with other companies that have the appropriate capabilities to support our products in their respective countries. We have entered into a series of agreements to establish an international network, which is summarized in the table below and includes information on our primary partners:

International Partner	Product(s)	Territory	Status
Phebra Pty Ltd	Acetadote	Australia and New Zealand	Marketed
DB Pharm Korea Co., Ltd.	Caldolor	South Korea	Marketed
Seqirus (a CSL company)	Caldolor	Australia and New Zealand	Marketed
Sandor Medicaids Pvt. Ltd.	Caldolor	India, Pakistan, Bangladesh and Nepal	Registration
GerminMED	Caldolor	Qatar and Arabian Peninsula	Registration
PT. ETHICA Industri Farmasi	Caldolor	Indonesia	Registration
Laboratorios Grifols, S.A.	Caldolor	Spain, Portugal and South America	Development
Gloria Pharmaceuticals Co. Ltd.	Caldolor & Acetadote	China and Hong Kong	Development
R-Pharm JSC	Vibativ	Russia	Marketed
Hikma Pharmaceuticals	Vibativ	Arabian Gulf	Registration
MegaPharma Ltd	Vibativ	Isreal and Palestine	Marketed

Our international commercialization agreements include a license to one or more Cumberland products for a specific territory as noted in the table above. We seek partners who have the local infrastructure to support the registration and commercialization of our products in their territory.

Under the terms of our agreements our partners are responsible for:

- Seeking regulatory approvals for the products;
- Launching the brand;
- Managing the ongoing marketing, sales and product distribution;
- Addressing the ongoing regulatory requirements in the international territories;
- Remitting any upfront, regulatory and sales milestone payments;
- Providing the transfer price for supplies of product; and
- Calculating and paying any royalties, as applicable.

Our responsibilities include:

- Providing a dossier of relevant information to support product registration;
- Maintaining our intellectual property associated with the product;
- Sharing our marketing strategy, experience and materials for the brand; and
- Manufacturing and providing finished product for sale.

During 2018 Caldolor was approved for use in India. We also worked to support our existing international partners and to identify new companies to represent our products in select additional territories. During 2018 we reached an understanding with Teligent Pharmaceuticals Inc to end our license for Caldolor in Canada following Teligent's acquisition of our previous partner for that market. Also, during 2018, we began the transition with Theravance for the Vibativ license arrangements for several international markets.

CLINICAL AND REGULATORY AFFAIRS

We have in-house capabilities for the management of our clinical, professional and regulatory affairs. Our team develops and manages our clinical trials, prepares regulatory submissions, manages ongoing product-related regulatory responsibilities and manages our medical information call center. Team members have been responsible for devising the regulatory and clinical strategies for all our products as well as obtaining FDA approvals for Acetadote and Caldolor.

Clinical development

Our clinical development personnel are responsible for:

- creating clinical development strategies;
- designing, implementing and monitoring our clinical trials; and
- creating case report forms and other study-related documents.

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- preparing and submitting INDs for clearance to begin patient studies;
- preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- maintaining investigational and marketing applications through the submission of appropriate reports;
- submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;
- monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices ("GMPs"), Good Laboratory Practices ("GLPs"), and Good Clinical Practices ("GCPs"), and performing periodic audits of such vendors; and
- maintaining systems for document control, product and process change control, customer complaint handling, product stability studies and annual drug product reviews.

PROFESSIONAL AND MEDICAL AFFAIRS

Our medical team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center and medical science liaisons. In addition to coordinating the call center, our clinical/ regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

CLINICAL DEVELOPMENT AND STUDY RESULTS

Ethyol Study

In January 2018, we announced a new publication in *Leukemia and Lymphoma*, with results from an investigator initiated study showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma.

Omeclamox-Pak Study

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.

New Caldolor Clinical Data

In October 2018, Cumberland announced two favorable Caldolor study publications, adding to the growing library of literature supporting the brand. An investigator initiated study at The Ohio State Wexner Medical Center, published in the journal *Frontiers in Surgery*, revealed more effective pain control and opioid-sparing activity with Caldolor when compared to ketorolac in patients undergoing arthroscopic knee surgery.

Additionally, an investigator initiated 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.

Caldolor Pediatric Study

We previously received FDA approval for the use of Caldolor in pediatric patients six months of age and older. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in children. We then initiated a study to collect data on the use of Caldolor in children ranging in age from birth up to six months of age. Enrollment in that multi-center study progressed in 2018.

Ifetroban Phase II Studies

During 2018, 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 Hospital Product Candidate Study

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, in 2018 a Phase II study was initiated.

BUSINESS DEVELOPMENT

Since inception, we have had an active business development program focused on acquiring rights to marketed products and product candidates that fit our strategy and target markets. We source business development opportunities through our international network of advisory firms and individual pharmaceutical industry and medical advisors. A multi-disciplinary internal management team reviews these opportunities on a regular basis using a list of selection criteria. We have historically focused on product opportunities that are a strategic fit with our commercial organization, development expertise and medical focus, employing a variety of transaction structures. Our additions of Omeclamox-Pak, Vaprisol, Ethyol, Totect and Vibativ reflect our business development process and follow our selection criteria.

We intend to continue to build a portfolio of complementary, niche products largely through product acquisitions and late-stage product development. Our primary targets are under-promoted, FDA approved drugs with existing brand recognition and late-stage development product candidates that address unmet or poorly met medical needs in the hospital acute care and gastroenterology markets. We believe that by focusing mainly on approved or late-stage products, we can minimize the significant risk, cost and time associated with drug development.

Piramal Co-promotion Agreement

In November 2015, we announced a co-promotion agreement with Piramal Critical Care ("Piramal"). Through this agreement, Piramal initiated co-promotion two of Cumberland's branded hospital products, Caldolor and Vaprisol throughout the United States. Piramal has helped expand Cumberland's reach for these products by providing coverage to an additional group of hospitals where Piramal's critical care sales force has existing relationships. The multi-year collaboration provides expanded sales promotion for the two brands, increased communication to medical professionals and enhanced availability of the products to support patient care.

Nordic License Agreement

In November 2016, we announced our agreement to acquire the exclusive U.S. rights to Nordic Group B.V.'s injectable methotrexate product line. The products are designed for the treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, severe psoriatic arthritis, and severe disabling psoriasis. The product line is approved for patient use in various European countries. Cumberland will register and commercialize the methotrexate products in the United States.

Clinigen Strategic Alliance Agreement

We previously entered into a strategic alliance with the Clinigen Group plc ("Clinigen"), an international specialty pharmaceutical and services company, to commercialize select Clinigen products in the U.S. In May 2016, we announced an agreement with Clinigen to acquire an exclusive license and commercialize Ethyol® in the U.S. We then announced in January 2017, our second agreement with Clinigen to acquire an exclusive license and launch Totect® in the U.S.

During August 2017, we entered into a distribution agreement with Clinigen for their Cardioxane® (dexrazoxane hydrochloride, injection) product which is used to support oncology patients from the cardiac complications associated with certain chemotherapeutic agents. Shipments associated with this distribution agreement have been under a special, expedited clearance from the FDA to address the shortage of dexrazoxane in the United States.

Poly Co-Promotion Agreement

In 2017, we entered into a co-promotion arrangement with Poly Pharmaceuticals, Inc. ("Poly") for our Kristalose product. Poly is a privately held U.S. specialty pharmaceutical company that is featuring Kristalose to an expanded number of physicians. Poly's sales organization is more than doubling the number of nationwide physicians called upon with Kristalose.

2R and Foxland Agreements

During 2018, we entered into another co-promotion arrangement related to our Kristalose product. We have agreements with 2R Investments, LLC and with Foxland Pharmaceuticals, Inc. to package, distribute and promote an authorized generic form of our Kristalose product to physician targets that we do not cover. Cumberland continues to manage the regulatory activities associated with the product.

CET Collaboration Agreements

Through CET, we collaborate with a select group of academic research institutions located in the mid-south region of the U.S. CET is collaborating with Vanderbilt University, the University of Mississippi, the University of Tennessee Research Foundation, Louisiana State University, and the Medical University of South Carolina to identify, co-develop and seek grant funding for promising biomedical technologies emerging from those research institutions.

These arrangements enable CET to team with university-based researchers to advance their scientific discoveries and breakthroughs by designing new product candidates to improve patient care and address unmet medical need.

MANUFACTURING AND DISTRIBUTION

Manufacturing

We partner with third parties for certain non-core, capital-intensive capabilities, including the manufacturing and distribution of our products. We manage these third-party relationships and are responsible for the quality review and release of each lot of our products.

Caldolor®

We have agreements with multiple manufacturers for the supply of Caldolor and during 2018 we obtained commercial supplies from two of these manufacturers for our international and domestic Caldolor requirements.

Acetadote®

For Acetadote we have agreements with two manufacturers, and one manufacturer provided commercial supplies of the product during 2018.

Kristalose®

We have an agreement for the purchase of Kristalose API with an international supplier. We also have manufacturing relationships with two packagers who provided finished supplies of the product for commercial and sampling purposes during 2018.

Omeclamox-Pak®

Prior to our asset purchase agreement with GEL that closed in December 2018, GEL managed the packaging and supply of Omeclamox-Pak commercial and sample units. Following our acquisition of the remaining rights to the brand in late 2018, we assumed responsibility for the packaging and supply of the product.

Vaprisol®

As part of the acquisition of Vaprisol, we purchased a significant existing supply of raw material inventory. In addition, as part of that transaction, we were assigned a commercial supply agreement with the historical Vaprisol manufacturer. In 2018, the manufacturer informed us that they would no longer be able to provide the product following the manufacturing of one final batch which is expected to provide us with a multi-year supply. Therefore, we are evaluating alternatives for a new manufacturer to provide us with long term supplies of the product.

Ethyol®

Under our Ethyol agreement, Clinigen is responsible for the supply of the product and has provided commercial inventory for Cumberland to package and distribute. Clinigen is in the process of establishing a new manufacturer for long term supplies of the product.

Totect®

As part of the Totect agreement, Clinigen is also responsible for overseeing the manufacture of the product and has provided commercial supplies for us to package and distribute.

Vibativ®

Through our acquisition of Vibativ, we acquired a multi-year supply of raw material, work in process and finished goods inventory. As a result of the agreement, we are now responsible for the future manufacture of the product and are in the process of completing the transfer of the product's manufacturing activities to a new supplier.

Distribution

Like many pharmaceutical companies, we engage a third-party with appropriate facilities and logistical expertise to support the U.S. distribution of our products. Cardinal Health has exclusively handled our U.S. product logistics activities, including warehousing, shipping, and various other customer activities. Our primary customers are the wholesalers of pharmaceuticals who provide our products to hospitals, clinics and retail pharmacies in the U.S.

CORPORATE DEVELOPMENT

Cumberland Foundation

In December 2017 we formed the Cumberland Pharma Foundation (the "Foundation") to serve as a vehicle to facilitate the ongoing philanthropic endeavors of Cumberland Pharmaceuticals Inc.

The Foundation was formed as an independent, nonprofit corporation designed to qualify as a tax-exempt organization pursuant to Section 501(a) of the Internal Revenue Code. The Foundation's Board of Directors was initially comprised of Cumberland Pharmaceuticals executives who are responsible for overseeing the Foundation's ongoing activities including charitable contributions.

We provided a grant of 50,000 shares of our common stock to the Foundation. The shares will address the ongoing financial needs of the Foundation, with most of the shares expected to be held for the opportunity to realize long term appreciation to support the Foundation's future. The Foundation will maintain independent financial statements and its contributions will not impact the financial statements of Cumberland Pharmaceuticals. Initial annual grants by the Foundation are expected to equal approximately 5% of the Foundation's total holdings, which is consistent with the historic level of contributions made by Cumberland Pharmaceuticals.

Cumberland Health and Wellness Political Action Committee

In November 2017 we formed the Cumberland Health and Wellness Political Action Committee (PAC). The objective of the PAC is to support candidates and policies that are consistent with Cumberland's mission of advancing patient care. The PAC's activities will be at the local, state and federal level and conducted in a bi-partisan manner. The initial committee membership is comprised of Cumberland Pharmaceuticals employees. The PAC received initial funding from us and future funding will include voluntary individual contributions from Cumberland Pharmaceuticals directors and employees.

SUBSEQUENT EVENTS

Next Generation Caldolor Product

In January 2019, the FDA approved our application of our next generation Caldolor (ibuprofen) injection product. In February 2018, Cumberland completed and filed with the FDA an application for approval. The product features a new, patented formulation in a more convenient to use package.

RediTrex Submission

In January 2019, we received notification from the FDA setting September 2019 as the Prescription Drug User Fee ("PDUFA") action date for an approval decision regarding the New Drug Application ("NDA") for our methotrexate product line. Our new line of methotrexate products is designed for the treatment of adult and pediatric patients with rheumatoid arthritis, as well as adults with psoriasis. The NDA was accepted for filing by the FDA in early January, following its submission to the FDA in November 2018.

PATENTS, TRADEMARKS AND OTHER INTELLECTUAL PROPRIETARY RIGHTS

We own the trademarks for each of our branded pharmaceutical products as well as for our corporate name and logo. We have applied for trademark registration for other various names and logos. Over time, we intend to maintain registrations on trademarks that remain valuable to our business.

We seek to protect our products from competition through a combination of patents, trademarks, trade secrets, FDA exclusivity and contractual restrictions on disclosure. Proprietary rights, including patents, are an important element of our business. We seek to protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute agreements providing for protection of our confidential information upon commencement of their employment or engagement. We also require confidentiality agreements from entities to which we provide our confidential information or materials.

Acetadote®

We developed a new formulation of Acetadote (acetylcysteine) Injection as part of a Phase IV commitment in response to a request by the FDA to evaluate the reduction of EDTA from the product's formulation. In April 2012, the USPTO issued U.S. Patent number 8,148,356 (the "356 Acetadote Patent") which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

Following the issuance of the 356 Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc. ("InnoPharma"), Paddock Laboratories, LLC ("Paddock"), Mylan Institutional LLC ("Mylan"), Sagent Agila LLC ("Sagent") and Perrigo Company ("Perrigo") challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity. We responded by filing five separate infringement lawsuits, in the appropriate United States District Courts, to contest each of the challenges.

On November 12, 2012, we entered into a Settlement Agreement (the "Settlement Agreement") with Paddock and Perrigo to resolve the challenges and the pending litigation with those two companies. On November 1, 2013, the United States District Court filed opinions granting Sagent's and InnoPharma's motions to dismiss our suits and we agreed not to file an appeal or motion to reconsider, thereby resolving the challenges and the pending litigation with those two companies.

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

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

On May 18, 2012, we also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that we evaluate the reduction or removal of EDTA from our original Acetadote formulation.

On November 7, 2012, the FDA responded to the Citizen Petition denying our request and on November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. We brought suit against the FDA contesting the FDA's decision to approve the InnoPharma generic on November 13, 2012. On

September 30, 2013, the United States District Court filed an opinion granting a summary judgment in favor of the FDA regarding this suit.

As noted above, during 2012 the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. Upon this condition, in accordance with the License and Supply agreement with Perrigo, we began to supply Perrigo with our Authorized Generic. On January 7, 2013, Perrigo announced initial distribution of our Authorized Generic acetylcysteine injection product.

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

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

On February 18, 2014, the USPTO issued U.S. Patent number 8,653,061 (the "061 Acetadote Patent") which is assigned to us. The claims of the 061 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. Following its issuance, the 061 Acetadote Patent was listed in the FDA Orange Book. The 061 Acetadote Patent is scheduled to expire in August 2025.

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the "738 Acetadote Patent") which is assigned to us. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, we became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

On February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the "065 Acetadote Patent") which is assigned to us. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in our favor in our lawsuit against Mylan for infringement of 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 May 3, 2016, the USPTO issued U.S. Patent number 9,327,028 (the "028 Acetadote Patent") which is assigned to us. The claims of the 028 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 028 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in July 2031.

On January 26, 2017, the Appeals Court affirmed the District Court ruling in our favor in our lawsuit against Mylan for infringement of the 445 Acetadote Patent. The Appeals Court opinion affirmed the District Court's ruling upholding our 445 Acetadote Patent and expressly rejected Mylan's validity challenge.

On November 3, 2017, we became aware of a Paragraph IV certification notice from Exela Pharma Sciences, LLC challenging the 356, 445, 061, 738, and 028 Acetadote Patents on the basis of non-infringement.

We are considering our legal options and intend to continue to vigorously defend and protect our Acetadote product and related intellectual property rights.

Caldolor®

We are the owner of U.S. Patent No. 6,727,286, which encompasses ibuprofen solution formulations, methods of making the same, and methods of using the same, and which is scheduled to expire in November 2021. This U.S. patent is listed in the FDA Orange Book and is associated with our completed international application No. PCT/US01/42894. We have filed for international patent protection in association with this PCT application in various countries, several of which have been allowed.

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty obligations related to Caldolor. During 2014, we obtained additional patents for the brand. On May 27, 2014, the USPTO issued U.S. Patent number 8,735,452 (the "452 Caldolor Patent") which is assigned to us. The claims of the 452 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 452 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

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

During the third quarter of 2015, we obtained four additional patents for Caldolor. On July 7, 2015, the USPTO issued U.S. Patent number's 9,072,710 (the "710 Caldolor Patent") and 9,072,661 (the "661 Caldolor Patent") which are assigned to us. The claims of the 710 Caldolor Patent and the 661 Caldolor Patent include composition and methods of treating pain, inflammation and fever using intravenous ibuprofen. These Caldolor Patents are scheduled to expire in March 2032. On August 25, 2015, the USPTO issued U.S. Patent number 9,114,068 (the "068 Caldolor Patent") which is assigned to us. The claims of the 068 Caldolor Patent include methods of treating pain using intravenous ibuprofen.

Following its issuance, the 068 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029. On September 22, 2015, the USPTO issued U.S. Patent number 9,138,404 (the "404 Caldolor Patent") which is assigned to us. The claims of the 404 Caldolor Patent include methods of treating pain in critically ill patients with intravenous ibuprofen. Following its issuance, the 404 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

On March 29, 2016, the USPTO issued U.S. Patent number 9,295,639 (the "639 Caldolor Patent") which is assigned to us. The claims of the 639 Caldolor Patent include methods of treating pain in critically ill patients with intravenous ibuprofen. Following its issuance, the 639 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

On May 16, 2017, the USPTO issued U.S. Patent number 9,649,284 (the "284 Caldolor Patent") which is assigned to us. The claims of the 284 Caldolor Patent include methods of treating pain in critically ill patients with intravenous ibuprofen. Following its issuance, the 284 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029. We also have additional patent applications related to Caldolor which are pending with the USPTO.

Vaprisol®

We own numerous U.S. patents and related international patents for Vaprisol. These patents were acquired in our February 2014 acquisition of certain product rights, intellectual property and related assets of Vaprisol from Astellas. The primary patent is U.S. Patent number 5,723,606 (the "606 Vaprisol Patent") which includes composition of matter claims that encompass the Vaprisol formulation as well as methods for the intravenous treatment of patients with euvolemic hyponatremia. The 606 Vaprisol Patent is listed in the FDA Orange Book and is scheduled to expire in December 2019.

Ethyol®

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.

Totect®

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.

Vibativ®

We own numerous U.S. patents and related international patents for Vibativ. These patents were acquired in our November 2018 acquisition of certain product rights, intellectual property and related assets of Vibativ from Theravance. Eleven Vibativ patents are listed in the FDA Orange Book. U.S. Patent number 7,531,623 (the "623 Vibativ Patent") is scheduled to expire in January 2027 and includes composition of matter claims that encompass the Vibativ drug substance as well as methods for preparing the Vibativ drug substance.

Remaining Products

We have no issued patents for our Omeclamox-Pak and Kristalose products. We have patent applications relating to our Hepatoren, Boxaban, Vasculan, and Portaban products pending with the USPTO.

We have licensed the injectable methotrexate products and are not aware of any patents issued for those products.

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. Competitive factors directly affecting our markets include but are not limited to:

- product attributes such as efficacy, safety, ease-of-use and cost-effectiveness;
- brand awareness and recognition driven by sales, marketing and distribution capabilities;
- intellectual property and other exclusivity rights;
- availability of resources to build and maintain developmental and commercial capabilities;
- successful business development activities;
- extent of third-party reimbursements; and
- establishment of advantageous collaborations to conduct development, manufacturing or commercialization efforts.

A number of our competitors possess research and development and sales and marketing capabilities as well as financial resources greater than ours. These competitors, in addition to emerging companies and academic research institutions, may be developing, or in the future could develop, new technologies that could compete with our current and future products or render our products obsolete.

Our products face competition from other branded products, generics, and alternate medical treatments. Our task is to position each brand to feature its competitive advantages, implement a well thought out marketing plan and provide focused sales and other tactical support.

Acetadote®

Acetadote is our injectable formulation of NAC for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC including, but not limited to, Geneva Pharmaceuticals, Inc., Bedford Laboratories division of Hikma Pharnaceuticals, Roxane Laboratories, Inc., InnoPharma Inc. and Hospira Inc.

In November 2012, InnoPharma Inc. was granted approval by the FDA to distribute their generic form of the old formulation of Acetadote containing EDTA. In late 2012, we entered into the Settlement Agreement with Paddock and Perrigo that included the right to distribute our Authorized Generic Acetadote injection product. Our branded Acetadote now competes with both the EDTA free Authorized Generic Acetadote distributed by Paddock and Perrigo along with generic Acetadote products that contain EDTA.

Both Akorn and Aurobindo have received FDA approval for their generic form of the old Acetadote formulation containing EDTA and have launched their versions of that product.

Caldolor®

Caldolor is marketed for the treatment of pain and fever, primarily in a hospital setting. A variety of other products address the acute pain market:

- Morphine, the most commonly used product for the treatment of acute, post-operative pain, is manufactured and distributed by several generic pharmaceutical companies;
- Other generic injectable opioids, including fentanyl, meperidine and hydromorphone, address this market;
- Ketorolac (brand name Toradol®), an injectable NSAID, is also manufactured and distributed by several generic pharmaceutical companies;
- Ofirmev®, an injectable acetaminophen product is sold by Mallinckrodt plc;
- Exparel®, a bupivacaine delivery platform sold by Pacira Pharmaceuticals, Inc.; and

We are aware of other product candidates in development to treat acute pain including injectable NSAIDs, novel opioids, new formulations of existing therapies and extended release anesthetics. We believe non-narcotic analgesics for the treatment of post-surgical pain are the primary potential competitors to Caldolor.

In addition to the injectable analgesic products above, many companies are developing analgesics for specific indications such as migraine and neuropathic pain, oral extended-release forms of existing narcotic and non-narcotic products, and products with new methods of delivery such as transdermal. We are not aware of any approved injectable products indicated for the treatment of fever in the U.S. other than Caldolor and Ofirmev.

There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including ibuprofen, acetaminophen, and aspirin. These drugs are manufactured by numerous pharmaceutical companies.

Kristalose®

Kristalose is a dry powder crystalline prescription formulation of lactulose indicated for the treatment of constipation. The U.S. constipation therapy market includes various prescription and over the counter, or OTC, products. The prescription products which we believe are our primary competitors are:

- Amitiza®, an oral product indicated for the treatment of chronic idiopathic constipation in adults, is sold by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited;
- Movantik™, an oral product indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain;
- Linzess®, an oral product indicated for the treatment of irritable bowel syndrome with constipation and chronic idiopathic constipation. It is sold by Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc; and
- Generic and branded liquid lactulose products are marketed by a number of pharmaceutical companies.

There are several hundred OTC products used to treat constipation marketed by numerous pharmaceutical and consumer health companies. MiraLax (polyethylene glycol 3350), previously a prescription product, was indicated for the treatment of constipation and manufactured and marketed by Braintree Laboratories, Inc. Under an agreement with Braintree, Schering-Plough introduced MiraLax as an OTC product in February 2007. Recently, the FDA rescinded the approval of prescription polyethylene glycol 3350 products.

Omeclamox®-Pak

Omeclamox-Pak is a branded prescription product used for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. It combines three well-known and widely prescribed medications packaged together for patient convenience: omeprazole, clarithromycin, and amoxicillin. The three individual components of Omeclamox-Pak are also available from other suppliers through three separate prescriptions.

While there are several competitor products, Omeclamox-Pak is one of the two actively marketed products for this condition. In addition, compared to the competing products, Omeclamox-Pak has the lowest pill burden, fewest days of therapy and convenient twice daily dosing. The prescription combination products, indicated for treatment of H. pylori, which we believe are our primary competitors are:

- PrevPac®, an oral product sold by Takeda Pharmaceutical Company. There are also approved generic versions of PrevPac;
- Pylera®, an oral product sold by Allergan plc; and
- Helidac®, an oral product sold by Prometheus Therapeutics.

Vaprisol®

Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the first and only intravenously administered branded treatment. The other competing product is Samsca, an oral product sold by Otsuka Pharmaceutical Company.

Ethyol®

Ethyol is a patented, prescription brand 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®

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 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. Both companies indicated that their products may again be available in the U.S. in the future.

Vibativ®

Effective November 12, 2018, Cumberland acquired the worldwide rights to Vibativ (telavancin) from Theravance Biopharma.

Vibativ is a potent, once-daily, injectable antibiotic for the treatment of certain gram-positive infections. Vibativ is approved for the treatment of complicated skin and skin structure infections and hospital-acquired or ventilator-associated bacterial pneumonia caused by susceptible isolates of Staphylococcus aureus when alternative treatments are not suitable. There are several generic and branded antibiotics that compete for these indications.

The major generic competitors are vancomycin, linezolid, and daptomycin. Vancomycin is by far the most widely used agent. Newer branded agents are also available including:

- Teflaro (ceftaroline fosamil) sold by Allergan
- Dalyance (dalbavancin) sold by Allergan
- Orbactiv (oritavancin) sold by Melinta

Antibiotic drug selection is based both on an empiric and susceptibility proven basis. In the hospital setting, cost is an important factor which favors the use of generic agents as long as they are effective. Newer agents are often reserved for two reasons: they are valuable in the treatment of patients that fail to respond to generics and it is considered good practice to conserve the use of these agents to reduce the risk of resistance.

GOVERNMENT REGULATION

The development of new pharmaceutical products can be a long, expensive and risky process. There is no assurance we will obtain successful study results or secure the needed market approvals for our pipeline product candidates. Governmental authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacturing, distribution, marketing and sale of pharmaceutical products. In the U.S., the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act, ("FDCA"), the Public Health Service Act, and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applicaiton ("NDAs") or biologics license applications, ("BLAs"), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

We, our manufacturers and contract research organizations may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, (OSHA), the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries.

FDA Approval Process

The FDA is a regulatory agency within the Department of Health and Human Services. A key responsibility is to regulate the safety and effectiveness of drugs sold in the United States. The FDA divides that responsibility into two phases: pre-approval (premarket) and post approval (post market). The FDA reviews manufacturers' applications to market drugs in the United States; a drug may not be sold unless it has FDA approval. The agency continues its oversight of drug safety and effectiveness as long as the drug is on the market.

To market a prescription drug in the United States, a manufacturer needs FDA approval. To get that approval, the manufacturer must demonstrate the drug's safety and effectiveness according to criteria specified in law and agency regulations, ensure that its manufacturing plant passes FDA inspection, and obtain FDA approval for the drug's labeling, a term that includes all written material about the drug, including, for example, packaging, prescribing information for physicians, promotional materials and patient brochures.

The progression to drug approval begins before FDA involvement. First, scientists work in the laboratory to discover and develop a new compound. Next, basic questions on safety are answered by nonclinical testing with animals and then, a drug or biotechnology company develops a prototype drug. That company must seek clearance from the FDA by way of an IND application to test the product with human subjects. Those tests, called clinical trials, are carried out sequentially in Phase I, II, and III studies, which involve increasing numbers of subjects. The manufacturer then compiles the resulting data and analysis in an NDA. The FDA reviews the NDA with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's identity, strength, quality, and purity.

The FDCA and associated regulations detail the requirements at each step. The FDA uses a few special mechanisms to expedite drug development and the review process when a drug might address an unmet need or a serious disease or condition. Those mechanisms include accelerated approval, fast track and priority reviews and the newer designation, breakthrough therapy.

The sponsor of the drug typically conducts human clinical trials in three sequential phases, but the phases may overlap. Phase I clinical trials are generally conducted in a small number of healthy volunteers, primarily to collect and assess pharmacokinetics and safety data at one or more dosages prior to proceeding into patients.

In Phase II clinical trials, the sponsor evaluates the early efficacy of the product in short term trials on the targeted indication and identifies possible adverse effects and safety risks in a patient population.

Phase III clinical trials typically involve testing for patients in long term trials examining safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

The FDA requires that clinical trials be conducted in accordance with the FDA's Good Clinical Practice GCP requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time

or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The institutional review board ("IRB"), or ethics committee (outside of the U.S.), of each clinical site generally must approve the clinical trial design and patient informed consent and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The results of the nonclinical and clinical trials, together with detailed information on the manufacturing and composition of the product and proposed labeling, are submitted to the FDA in the form of an NDA for marketing approval. The NDA undergoes a 60-day validation review period before it is accepted for filing.

If the NDA is found to be incomplete, it will not be accepted. Once the NDA is validated and accepted for filing, the FDA begins an in-depth review of the NDA.

Under policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA (currently PDUFA VI - effective October 1, 2017), the FDA has a target timeline of 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by two months to address deficiencies, or by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission at any time during the review clock period. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an approval letter. Priority Review is reserved for drugs that represent a “significant improvement in safety or efficacy” over existing treatments and FDA endeavors to complete these reviews in six months.

If the NDA meets with FDA approval, a letter will be sent out indicating approval and final labeling recommendations. If not, a Complete Response letter will be sent to applicants indicating that the review cycle for an application is complete and that the application is not ready for approval. The complete response letter will describe the specific deficiencies that the agency has identified in an application and what changes must be made before the application can be approved, with no implication regarding whether the application will ultimately be approved. An approval letter authorizes commercial marketing of the drug for the proposed indication(s) under study. FDA reported that NDAs showed a steadier increase with the percentage of first-cycle approval letters rising from 31% for FY 2000 applications to 91% for FY 2017 applications. The time and cost of completing these steps and obtaining FDA approval can vary dramatically depending on the drug. However, to complete these steps for a novel drug can take many years and cost millions of dollars.

Section 505(b) New Drug Applications

An NDA may be submitted under different methods, a 505(b)(1), 505(b)(2) or 505(j). Section 505(b) provides for the submission of an NDA to support the approval of a drug. Upon approval, a drug may be marketed only for the FDA-approved indication(s) in the approved dosage form. Further clinical trials may be necessary to gain approval for the use of the product for any additional indications or dosage forms.

The FDA also requires post market safety surveillance reporting to monitor the side effects of the drug, which may result in withdrawal of approval after marketing begins.

Section 505(b)(1) or the 'full' NDA is used for new chemical entities ("NCEs") and requires full clinical and nonclinical development of a compound. Marketing exclusivity assigned to a 505(b)(1) approval is five years. A 505(b)(2) NDA permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant using previously reported safety and efficacy data, and for which the applicant has not obtained a right of reference. Generally new studies are required to provide data on the proposed change.

Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs which have a new dosage form, strength, route of administration, formulation or indication or combination drugs. Marketing exclusivity for a 505(b)(2) submission is three years. Both 505 (b)(1) and (b)(2) are eligible for seven years of exclusivity for orphan drugs and/or six months for pediatric exclusivity. Any marketing exclusivity is independent of patent exclusivity. We successfully secured FDA approvals for Acetadote in January 2004 and for Caldolor in June 2009 pursuant to the 505(b)(2) pathway.

Orphan drug designation

The Orphan Drug Act of 1983, ("Orphan Drug Act"), encourages manufacturers to seek approval of products intended to treat “rare diseases and conditions” with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval.

Acetadote received Orphan Drug designation in October 2001 and in 2004 the FDA approved the product to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetadote was entitled to marketing exclusivity until January 2011 for the treatment of this approved indication.

Section 505(j) abbreviated new drug applications

An ANDA is a type of NDA where approval of a generic drug is based on demonstrating comparability to an innovator drug product (the RLD or Reference Listed Drug). Applications are "abbreviated" because they generally don't include preclinical and clinical data to establish safety and effectiveness. Generics must demonstrate that the product is bioequivalent (i.e., performs in the same manner and is comparable to the 'innovator' product in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use). Abbreviated applications may be submitted for drug products that are the same as a listed drug and must be identical in active ingredient(s), form, strength, route of administration, and identical in conditions of use (non-exclusive uses). Products are declared suitable based on a suitability petition to the FDA. If the petition is approved, the Sponsor may then submit the ANDA.

The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act", is a 1984 United States federal law which established the modern system of generic drugs.

Hatch-Waxman amended the Federal Food, Drug, and Cosmetic Act. Section 505(j) 21 U.S.C. 355(j) sets forth the process by which would-be marketers of generic drugs can file ANDAs to seek FDA approval of the generic. Section 505(j)(2)(A)(vii)(IV), the so-called Paragraph IV, allows 180-day exclusivity to companies that are the "first-to-file" an ANDA against holders of patents for branded counterparts.

Hatch-Waxman Amendments grant generic manufacturers the ability to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Hatch-Waxman gives generics considerable leverage in patent litigation.

Health care legislation

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010, or HCERA, was enacted into law, which modified the revenue provisions of the PPACA. The PPACA as amended by the HCERA constitutes the healthcare reform legislation. The following highlights certain provisions of the legislation that may affect us.

Pharmaceutical Industry Fee: Beginning in calendar-year 2011, an annual fee was imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs (e.g., Medicare Part D, Medicare Part B, Medicaid, Department of Veterans Affairs programs, Department of Defense programs and TRICARE).

The annual fee is allocated to companies based on their previous calendar-year market share using sales data that the government agencies that purchase the pharmaceuticals will provide to the Treasury Department. Although we participate in governmental programs that subject us to this fee, our sales volume in such programs is less than $10 million, with the first $5 million of sales being exempt from the fee. This fee has not had a material impact and is not expected to have a material impact on our results of operations.

Physician Payments Sunshine Act: The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, or Sunshine Act, which require manufacturers of pharmaceuticals and medical devices covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services, or CMS, for aggregation and subsequent public disclosure. Under the Sunshine Act, beginning August 1, 2013, we have collected data regarding reportable transfers of value and have reported such data to CMS. Failure to report appropriate data may result in civil or criminal fines and/or penalties. In addition to the Federal Sunshine Act, similar reporting requirements have also been enacted on the state level requiring transparency of interactions with health care professionals.

Medicaid Rebate Rate: We currently provide rebates for products sold to Medicaid beneficiaries.

Product Serialization: In November of 2013, the FDA passed the Drug Supply Chain Security Act (DSCSA). The DSCSA was created to strengthen the security of the drug distribution supply chain by adding controls such as a national pharmaceutical track and trace system and establishing national standards for licensing of prescription drug wholesale distributors and third-party logistics providers. DSCSA requires trading partners, including manufacturers, repackagers, wholesale distributors and dispensers to provide transaction information to subsequent purchasers for certain prescription drugs. We have taken necessary steps to implement this program and are in compliance with all requirements by the November 2018 deadline.

21st Century Cures Act: The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently. The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances FDA's ability to modernize clinical trial designs and clinical outcome assessments, which will speed the development and review of novel medical products, including medical countermeasures.

Specifically, the Cures Act enables us to work with FDA in the development of new biomarkers, clinical outcome assessments, surrogate endpoints, and patient reported outcomes. It allows for the use of data summaries rather than full clinical trials for approval and the use of real world evidence to support approval of new indications of approved medical products, or to help satisfy post-approval study requirements for marketed products.

Post Approval Activities

Once a drug is on the U.S. market (following FDA approval of the NDA), the FDA continues to address drug production, distribution, and use. FDA activities are based on ensuring drug safety and effectiveness, and address product integrity, labeling, reporting of research and adverse events, surveillance, drug studies, risk management, information dissemination, off-label use, and direct-to-consumer advertising.

If we amend the NDA for an FDA approved product, such as adding safety or efficacy labeling claims, promoting those new claims, making certain manufacturing changes or product enhancements, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved.

Securing FDA approval for new indications, product enhancements, and manufacturing and labeling changes may require us to conduct additional clinical trials under FDA's IND regulations. Even if such studies are conducted, they are still subject to the same requirements and timelines as an original NDA.

The FDA continuously gathers information about possible adverse reactions to the products it has approved for use. The FDA requires all manufacturers to report adverse events. It also provides a procedure for consumers and physicians to voluntarily report their concerns about drugs. The agency collects those reports through MedWatch and uses its FDA Adverse Event Reporting System (FAERS) to store and analyze them. Because some events may occur after the use of a drug for reasons unrelated to the product, the FDA reviews the events to assess which ones may indicate a problem with that particular drug. They then use information gleaned from the surveillance data to determine a course of action. They might recommend a change in drug labeling to alert users to a potential problem, or, perhaps, to require the manufacturer to study the observed association between the drug and the adverse event.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs.

Federal False Claims Act

The Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid.

A number of pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

ICH - International Committee on Harmonization

Outside of the U.S., our ability to market our products will depend on receiving marketing authorizations from the appropriate regulatory authorities. The International Committee on Harmonization (ICH) provides a set of standards that most Regulatory Authorities adhere to (e.g. U.S., Europe, and Japan) allowing greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines. Regulatory harmonization offers many direct benefits to both regulatory authorities and the pharmaceutical industry with beneficial impact for the protection of public health.

ENVIRONMENTAL MATTERS

We are subject to federal, state and local environmental laws and regulations and we believe that our operations comply with such regulations. We anticipate that the effects of compliance with federal, state and local laws and regulations relating to the discharge of materials into the environment will not have any material effect on our capital expenditures, earnings or competitive position.

SEASONALITY

There are no significant seasonal aspects to our business.

BACKLOG

Due to the relatively short lead-time required to fill orders for our products, backlog of orders is not considered material to our business.

EMPLOYEES

As of December 31, 2018, we had 80 employees. We believe that our future will depend in part on our continued ability to attract, hire, and retain qualified personnel, including hospital and field sales personnel in particular.

Item 1A. Risk Factors.

The risk factors described below and throughout this report should be carefully considered and could materially affect our business. There are also risks that are not presently known or not presently material, as well as the other information set forth in this report that could materially affect our business. In addition, in our periodic filings with the SEC, press releases and other statements, we discuss estimates and projections regarding our future performance and business outlook. By their nature, such "forward-looking statements" involve known and unknown risks, uncertainties and other factors that in some cases are out of our control. For a further discussion of forward-looking statements, please refer to the section entitled "Special Note Regarding Forward-Looking Statements." These factors could cause our actual results to differ materially from our historical results or our present expectations and projections. These risk factors and uncertainties include, but are not limited to the following:

RISKS RELATED TO OUR BUSINESS

An adverse development regarding our products could have a material and adverse impact on our future revenues and profitability.

A number of factors may impact the effectiveness of our marketing and sales activities and the demand for our products, including:

- Changes in intellectual property protection available for our products or competing treatments;
- Any unfavorable publicity concerning us, our products, or the markets for these products such as information concerning product contamination or other safety issues in any of our product markets, whether or not directly involving our products;
- Perception by physicians and other members of the healthcare community of the safety or efficacy of our products or competing products;
- Regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products;
- The prices of our products relative to other drugs or competing treatments;
- The impact of current or additional generic competitors;
- The availability and level of third-party reimbursement for sales of our products; and
- The continued availability of adequate supplies of our products to meet demand.

If demand for our products weaken, our revenues and profitability will likely decline. Known adverse effects of our marketed products are documented in product labeling, including the product package inserts, medical information disclosed to medical professionals and all marketing-related materials. At this time, no unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products.

We currently market and sell eight products: Acetadote, Caldolor, Kristalose, Vaprisol, Omeclamox-Pak, Ethyol, Totect and Vibativ. A product contamination or other safety or regulatory issues, such as a failure to meet certain FDA reporting requirements involving our products could negatively impact us and possibly lead to a product recall. In addition, changes impacting any of our products in areas such as competition, lack of market acceptance or demand, government regulation, intellectual property, reimbursement and manufacturing could have an adverse impact on our future revenues and profitability.

The FDA has requested prescribers and manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. The FDA requested this action to protect consumers from the risk of severe liver damage which can result from excess acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient

intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures.

The FDA also requires manufacturers to appropriately label all prescription combination acetaminophen products to warn of the potential risk for severe liver injury. The actions the FDA is taking for prescription acetaminophen combination products do not affect over-the-counter acetaminophen products. The FDA's regulation of acetaminophen in prescription combination products and over-the-counter products may reduce the number of acetaminophen overdoses which could result in a lower demand for Acetadote. If the demand for Acetadote decreases, it could have an adverse impact on our future revenues and profitability.

The commercial success of Caldolor is dependent on many third-parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P&T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to continue to be administered primarily to hospital and surgery center patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals' formulary lists by their P&T committees. A hospital's P&T committee generally governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. The commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. As with our other products, if Caldolor is not accepted in the marketplace, it could have an adverse impact on our future revenues and profitability.

If any manufacturer or partner we rely upon fails to supply our products in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.

We do not manufacture any of our products, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of products could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to sell our products as planned. Furthermore, if we encounter delays or difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected.

Caldolor: We have agreements with three manufacturers for the commercial supply of Caldolor and two of the three suppliers have manufactured inventory under these agreements. We obtained commercial supply from two of these manufacturers during 2018 for both our international and domestic Caldolor markets. If the manufacturers of Caldolor are unable to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Acetadote: During the fourth quarter of 2014, we entered into a three-year agreement with a U.S. based manufacturer to supply our Acetadote product. We transferred the Acetadote manufacturing process to this supplier and we have received and sold commercial units from this supplier since 2015. During 2017, we extended the relationship with the supplier into 2022. If the manufacturer of Acetadote is unable to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Kristalose: The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy and we have manufacturing agreements with two Kristalose packagers. If these facilities are damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our product. Kristalose is manufactured through a complex process. It would be particularly difficult to find a new manufacturer of Kristalose active pharmaceutical ingredient on an expedited basis. As a result of these factors, our ability to manufacture Kristalose may be substantially impaired if the manufacturer is unable or unwilling to supply sufficient quantities of the product.

Omeclamox-Pak: Based on our agreement with GEL, effective in November 2015, GEL had managed the manufacture, packaging and supply of Omeclamox-Pak commercial and sample units. Following our acquisition of the remaining rights to the brand in late 2018, we will now oversee packaging of the product and transition those activities to a U.S. based manufacturer. If we are unable to obtain marketable inventory in the future, we could suffer an inability to meet demand for our product.

Vaprisol: As part of the acquisition of Vaprisol, we purchased an existing supply of raw material inventory. In addition, as part of this transaction, we were assigned a commercial supply agreement with the manufacturer Astellas used to prepare, package, inspect and label Vaprisol. The manufacturer continues to supply commercial inventory to Cumberland under this agreement. If the manufacturer of Vaprisol is unable to produce additional marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Ethyol: As part of the Ethyol transaction, we are provided with a commercial supply of the product from Clinigen Group Plc. Clinigen has continued to supply commercial inventory of Ethyol to Cumberland under this agreement. We understand that Clinigen is in the process of registering a new Ehtyol manufacture with the FDA. If Clinigen is unable to secure FDA approval for the new manufacture and supply additional marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Totect: As part of the Totect transaction, we were provided with a commercial supply of the product from Clinigen Group Plc. Clinigen has continued to supply commercial inventory of Totect to Cumberland under this agreement. If Clinigen is unable to supply additional marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Vibativ: Under our Vibativ agreement, we acquired a multi-year supply of inventory. We are now responsible for the ongoing manufacture of the product and will complete the transition already underway to a new manufacturer. If we are unable to obtain marketable inventory in the future, we could suffer an inability to meet demand for our product.

In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practices, ("GMPs"), enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with GMP requirements and with other FDA, state and foreign regulatory requirements.

We have no control over our manufacturers' compliance with these regulations and standards. If our third-party manufacturers do not comply with these requirements, we could be subject to:

- Fines and civil penalties;
- Suspension of production or distribution;
- Suspension or delay in product approval;
- Product seizure or recall; and
- Withdrawal of product approval.

We are dependent on a variety of other third parties. If these third parties fail to perform as we expect, our operations could be disrupted and our financial results could suffer.

We have a relatively small internal infrastructure. We rely on a variety of third parties, in addition to our manufacturers, to help us operate our business. Other third parties on which we rely include:

- Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which bills for, collects, warehouses and ships our marketed products; and

- Vanderbilt University, Gloria and the Tennessee Technology Development Corporation, co-owners with us of CET, and the universities that collaborate with us in connection with CET's research and development programs.

If these third parties do not continue to provide services to us, or collaborate with us, we might not be able to obtain others who can serve these functions. This could disrupt our business operations, increase our operating expenses or otherwise adversely affect our operating results.

Competitive pressures could reduce our revenues and profits.

The pharmaceutical industry is intensely competitive. Our strategy is to target differentiated products in specialized markets. However, this strategy does not relieve us from competitive pressures and can entail distinct competitive risks. Certain of our competitors do not aggressively promote their products in our markets. An increase in promotional activity in our markets could result in large shifts in market share, adversely impacting us.

Our competitors may sell or develop drugs that are more effective and useful or less costly than ours, and they may be more successful in manufacturing and marketing their products. Many of our competitors have significantly greater financial and marketing resources than we do. Additional competitors may enter our markets.

The pharmaceutical industry is characterized by constant and significant investment in new product development, which can result in rapid technological change. The introduction of new products could substantially reduce our market share or render our products obsolete. The selling prices of pharmaceutical products tend to decline as competition increases, through new product introduction or otherwise, which could reduce our revenues and profitability.

If generic products that compete with any of our branded pharmaceutical products are approved and sold, sales of our products will be adversely affected.

Generic equivalents for branded pharmaceutical products are typically sold at lower costs than the branded products. The regulatory approval process in the United States exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and rely instead on the safety and efficacy of prior products, manufacturers of generic products can invest far less in research and development. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U.S. states allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Governmental and private healthcare payors also emphasize substitution of branded pharmaceuticals with less expensive generic equivalents. Pursuant to the provisions of the Hatch-Waxman Act, manufacturers of branded products often bring lawsuits to enforce their patent rights against generic products released prior to the expiration of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product, even if subject to an existing patent. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expires or because our patent protection is not sufficiently broad or enforceable. In addition, we may not be successful in our efforts to extend the proprietary protection afforded our branded products through the development and commercialization of proprietary product improvements. Competition from generic equivalents could result in a decrease in revenues of our branded pharmaceuticals or result in a material impairment of our intangible assets or the acceleration of amortization on our non-impaired intangible assets and may have a material adverse impact on our revenues, financial condition, results of operations and cash flows.

Any attempt by us to expand the potential market for any of our products is subject to limitations.

Expansion of the market for our products may be subject to certain limitations. In the past, these limitations have included FDA required Phase IV commitments. We may also experience delays associated with future required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling patients. Such delays

could impact our ability to explore opportunities for label expansion and limit our ability to bring our products to new patient populations.

In addition, we have only obtained regulatory approval to market our products in the United States. Not all foreign jurisdictions may represent attractive opportunities for our products due to pricing, competitive, regulatory or other factors. In certain foreign jurisdictions, we have licensed the right to market some of our products to third parties. These third parties are responsible for seeking regulatory approval for the products in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for our products will be obtained outside the United States.

Our future growth depends on our ability to identify and acquire rights to products. If we do not successfully identify and acquire rights to products, our growth opportunities may be limited.

We acquired rights our products and our product candidates. Our business strategy is to continue to acquire rights to FDA-approved products as well as pharmaceutical product candidates in the late stages of development. We do not plan to conduct basic research or pre-clinical product development, except to the extent of our investment in CET. As compared to large multi-national pharmaceutical companies, we have limited resources to acquire third-party products, businesses and technologies and integrate them into our current infrastructure. Many acquisition opportunities involve competition among several potential purchasers including large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. With future acquisitions, we may face financial and operational risks and uncertainties. We may not be able to engage in future product acquisitions, and those we do complete may not be beneficial to us in the long term.

Furthermore, other products in development may encounter unforeseen issues during their clinical trials. Any unforeseen issues or lack of FDA approval will negatively affect marketing and development plans for those products.

Our future growth depends on our ability to successfully integrate acquired product brands into our operations. If we do not successfully integrate acquired product brands into our operations, our growth opportunities may be limited.

We added five marketed products to our portfolio of brands, roughly one brand per year, beginning in late 2013 through late 2018. If we are unable to continue to optimize our sales of our brands or we are unable to successfully integrate the marketing, sale and distribution of any other potential products into our current infrastructure or if they require significantly greater resources than originally anticipated, we may face financial and operational risks and uncertainties. If we are unable to successfully integrate any acquired brands, both current and future, these product acquisitions may not be beneficial to us in the long term.

Our Hepatoren, Boxaban, Vasculan, Portaban, and RediTrex product candidates have not been approved for sale and may never be successfully commercialized.

We anticipate that a portion of our future revenue growth will come from sales of our Hepatoren, Boxaban, Vasculan, Portaban, and RediTrex product candidates. Hepatoren (intravenous ifetroban) is used to treat hepatorenal syndrome ("HRS"), Boxaban (oral ifetroban) is used to treat aspirin exacerbated respiratory disease ("AERD"), Vasculan (oral ifetroban) is for the treatment of systemic sclerosis ("SSc"), Portaban (injection and oral ifetroban) is for the treatment of portal hypertension associated with liver disease, and methotrexate (injection) is used to treat active rheumatoid, juvenile idiopathic and severe psoriatic arthritis as well as severe disabling psoriasis. However, none of these products have been approved by the FDA for marketing, and these product candidates are still subject to risks associated with their development.

The FDA has cleared our IND's for the ifetroban product candidates as we evaluate them as treatments for these conditions. Delays in the enrollment and completion of the clinical studies could significantly delay commercial launch and affect our product development costs. Moreover, results from the clinical studies may not be favorable.

Even if they are eventually developed and approved by the FDA, they may never gain significant acceptance in the marketplace and therefore never generate substantial revenue or profits for us. Physicians may determine that

existing drugs are adequate to address patients' needs. The extent to which these product candidates will be reimbursed by the U.S. government or third-party payors is also currently unknown.

As a result of the foregoing and other factors, we do not know the extent to which our product candidates will contribute to our future growth.

If we are unable to maintain, train and build an effective sales and marketing infrastructure, we will not be able to commercialize and grow our products and product candidates successfully.

As we grow, we may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully market and sell our products. This risk would be accentuated if we acquire products in areas outside of our current focus areas since our sales forces specialize in our existing areas. If we are unable to expand our sales and marketing capability, train our sales force effectively or provide any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. We must train our employees on proper regulatory compliance, including, but not limited to, “fair balance” promotion of our products and anti-kickback laws. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses and may experience regulatory compliance issues.

If governmental or third-party payors do not provide adequate reimbursement for our products, our revenue and prospects for profitability may be limited.

Our financial success depends, in part, on the availability of adequate reimbursement from third-party healthcare payors. Such third-party payors include governmental health programs such as Medicare and Medicaid, managed care providers and private health insurers. Third-party payors are increasingly challenging the pricing of medical products and services, while governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

In March 2010, the U.S. government passed into law the Patient Protection and Affordable Care Act, ("PPACA") along with the Health Care and Education Reconciliation Act of 2010, ("HCERA"), which modified the revenue provisions of the PPACA. The legislation calls for an increase in certain Medicare drug rebates paid by pharmaceutical manufacturers and an industry fee imposed on pharmaceutical manufacturers according to the individual manufacturer’s relative percentage of total industry sales to specified government programs. At this time no assurances can be given that these measures, or any other measures included in the Healthcare Reform Act, will not have an adverse effect on our revenues in the future. Future cost control initiatives, legislation and regulations could decrease the price that we receive for any products, which would limit our revenue and profitability.

Since its inception, other legislative changes have been proposed and adopted. These changes included aggregate reductions of Medicare payments to providers of up to two percent per fiscal year. Additionally, in January 2013, the American Taxpayer Relief Act of 2012, was signed into law which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, while the healthcare reform agenda and policies of the current administration are not fully known, it is possible that additional regulatory changes may take place. This includes a repeal of all or portions of the PPACA, and Congress could be asked to replace the current legislation of the PPACA. There is uncertainty with respect to the timing and impact of any changes. These changes could have an impact on coverage and reimbursement for healthcare products and services covered by plans that were authorized by the PPACA. At this time, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Also, reimbursement practices of third-party payors might preclude us from achieving market acceptance for our products or maintaining price levels sufficient to realize an appropriate return on our investment in product acquisition and development. If we cannot obtain adequate reimbursement levels, our business, financial condition and results of operations would be materially and adversely affected.

Our employees have been trained to submit accurate and correct pricing information to payors. If, despite the training, our employees provide incorrect or fraudulent information, then we will be subject to various administrative and judicial investigations and litigation.

"Formulary" practices of third-party payors could adversely affect our competitive position.

Many managed healthcare organizations are now controlling the pharmaceutical products included on their formulary lists. Having products listed on these formulary lists creates competition among pharmaceutical companies which, in turn, has created a trend of downward pricing pressure in our industry. In addition, many managed care organizations are pursuing various ways to reduce pharmaceutical costs and are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. Our products might not be included on the formulary lists of managed care organizations, and downward pricing pressure in our industry generally could negatively impact our operations.

Continued consolidation of distributor networks in the pharmaceutical industry as well as increases in retailer concentration may limit our ability to profitably sell our products.

We sell most of our products to large pharmaceutical wholesalers, who in turn sell to hospitals, surgery centers and retail pharmacies. The distribution network for pharmaceutical products has become increasingly consolidated in recent years. Further consolidation or financial difficulties could also cause our customers to reduce the amounts of our products that they purchase, adversely impacting our business, financial condition and results of operations.

Our CET joint initiative may not result in our gaining access to commercially viable products.

Our CET joint initiative with Vanderbilt University, Gloria and Tennessee Technology Development Corporation is designed to help us investigate, in a cost-effective manner, early-stage products and technologies. However, we may never gain access to commercially viable products from CET for a variety of reasons, including:

- CET investigates early-stage products, which have risk of failure prior to FDA approval and commercialization;
- In some programs, we do not have pre-set rights to product candidates developed by CET. We would need to agree with CET and its collaborators on the terms of any product licensed or acquired by us;
- We rely principally on government grants to fund CET's research and development programs. If these grants were no longer available, we or our co-owners might be unable or unwilling to fund CET operations at current levels or at all;
- We may become involved in disputes with our co-owners regarding CET policy or operations, such as how best to deploy CET assets or which product opportunities to pursue. Disagreement could disrupt or halt product development; and
- CET may disagree with one of the various universities with which CET is collaborating on research. A disagreement could disrupt or halt product development.

We depend on our key personnel, the loss of whom would adversely affect our operations. If we fail to attract and retain the talent required for our business, our business will be materially harmed.

We are a relatively small company, and we depend to a great extent on principal members of our management, scientific staff, and sales representatives and managers. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, or other members of senior management it could have a material adverse effect on our business prospects. Mr. Kazimi, plays a key role in several operational and strategic decisions such that any loss of his services due to death or disability would adversely impact our day-to-day operations. We have a life insurance policy covering the life of Mr. Kazimi. We have entered into agreements with each of our employees that contain restrictive covenants relating to non-competition and non-solicitation of our customers and suppliers for one year after termination of employment. Nevertheless, each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason, and so as a practical matter these agreements do not guarantee the continued service of these employees. Our success depends on our ability to attract and retain highly qualified scientific, technical, sales and managerial personnel and research partners. Competition among pharmaceutical companies for qualified employees is intense, and we may not be able to retain existing personnel or attract and retain qualified staff in the future. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results.

The size of our organization and our potential growth may lead to difficulties in managing operations.

As of December 31, 2018, we had 79 full-time employees. We may need to continue to expand our managerial, operational, financial and other resources in order to increase our marketing efforts with regard to our currently marketed products, continue our business development and product development activities and commercialize our product candidates. We have experienced, and may continue to experience, growth and increased expenses in the scope of our operations in connection with the continued marketing and development of our products. Our financial performance will depend, in part, on our ability to manage any such growth and expenses of the current organization effectively.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products. An individual may bring a liability claim against us if one of our product candidates or products causes, or appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Liability claims may result in:

- Decreased demand for our products;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Significant litigation costs;
- Substantial monetary awards to or costly settlement with patients;
- Product recalls;
- Loss of revenue; and
- The inability to commercialize our product candidates.

We are highly dependent upon medical and patient perceptions of us and the safety and quality of our products. We could be adversely affected if we or our products are subject to negative publicity. We could also be adversely affected if any of our products or any similar products sold by other companies prove to be, or are asserted to be, harmful to patients. Also, because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products sold by other companies could have a material adverse impact on our results of operations.

We have product liability insurance that covers our clinical trials, the marketing and sale of our products up to a $10 million annual aggregate limit, subject to specified deductibles. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us.

Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote

the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or payment of fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

Our business and operations would suffer in the event of system failures, security breaches, including any cybersecurity incidents, adverse events or other disruptions within our information technology infrastructure at our corporate headquarters.

Despite the implementation of security measures, our internal computer systems, including those at our corporate headquarters, are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In the ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information and that of our customers. We also maintain personally identifiable information of our employees in our data centers and on our networks. The secure processing and maintenance of this information is critical to our operations. In the event that our corporate headquarters and/or our computer systems are disabled or materially damaged, it would have a substantial and material negative effect on our operations. Furthermore, any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. While we continue to invest in data protection and information technology, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our products or product candidates may be delayed.

We may develop internationally and license our products globally; therefore, we may have an increased exposure to foreign regulatory requirements and fluctuations in foreign currency exchange rates.

While we currently have only obtained regulatory approval to market our products in the United States, in the future we may seek global opportunities for our products and to develop product candidates internationally in the future. Such opportunities and development will inherently subject us to a number of risks and uncertainties, including:

- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability or sanctions in areas in which we operate;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- regulations related to customs and import/export matters (including sanctions);
- tax issues, such as tax law changes and variations in tax laws;
- challenges in collecting accounts receivable from customers in the jurisdictions in which we operate;
- complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of pharmaceutical products in the jurisdictions in which we do or will operate;

- operating under regulations in jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale/retail level;
- competition from local, regional and international competitors;
- difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act;
- difficulties protecting or procuring intellectual property rights; and
- fluctuations in foreign currency exchange rates.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. These or other similar risks could adversely affect our revenue and profitability. As we develop internationally, our exposure to these factors will increase.

Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more capital and time than we are willing to invest.

Even if any of our drug candidates receives regulatory approval, it could be subject to post-regulatory surveillance, and may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing, and the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive or because third parties, such as insurance companies or Medicare, have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if competitors develop and commercialize similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

Any approved drug product that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community.

Even if we are successful in gaining regulatory approval of any of our drug candidates or acquire rights to approved drug products, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until longerterm clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third-party payors and the effectiveness of our competitors in marketing their products.
Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including:

- the willingness and ability of patients and the healthcare community to use our drug products;
- the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;
- the label and promotional claims allowed by the FDA; and
- the pricing and reimbursement of our drug products relative to existing treatments.

We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management's attention and harm our operating results and prospects.

As part of our business strategy, we may pursue additional acquisitions of what we believe to be complementary businesses or assets or seek to enter into joint ventures. We also may pursue strategic alliances in an effort to leverage our existing infrastructure and industry experience to expand our product offerings or distribution, or make investments in other companies. The success of our acquisitions, joint ventures, strategic alliances and investments will depend on our ability to identify, negotiate, complete and, in the case of acquisitions, integrate those transactions and, if necessary, obtain satisfactory debt or equity financing to fund those transactions. We may not realize the anticipated benefits of any acquisition, joint venture, strategic alliance or investment. We may not be able to integrate acquisitions successfully into our existing business, maintain the key business relationships of businesses we acquire, or retain key personnel of an acquired business, and we could assume unknown or contingent liabilities or incur unanticipated expenses. Integration of acquired companies or businesses also may require management resources that otherwise would be available for ongoing development of our existing business. Any acquisitions or investments made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. In addition, if we choose to issue shares of our stock as consideration for any acquisition, dilution to our shareholders could result.

The acquisitions we have made or make in the future may make us the subject of lawsuits from either an acquired company's shareholders, an acquired company's previous shareholders, or our current shareholders.

We may be the subject of lawsuits from either an acquired company's shareholders, an acquired company's previous shareholders, or our current shareholders. These lawsuits could result from the actions of the acquisition target prior to the date of the acquisition, from the acquisition transaction itself, or from actions after the acquisition. Defending potential lawsuits could cost us significant expense and distract management's attention from the operation of the business. Additionally, these lawsuits could result in the cancellation of, or the inability to renew, certain insurance coverage that would be necessary to protect our assets.

We may be required to modify our business practices, pay fines and significant expenses or experience other losses due to governmental investigations or other enforcement activities.

We may become subject to litigation or governmental investigations in the United States and foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we have from time to time received inquiries and other types of information requests from government authorities.

While the ultimate outcomes of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters could result in, among other things:

- significant damage awards, fines, penalties or other payments, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that preclude us from operating our business in a certain manner;
- changes and additional costs to our business operations to avoid risks associated with such litigation or investigations;
- product recalls;
- reputational damage and decreased demand for our products; and
- expenditure of significant time and resources that would otherwise be available for operating our business.

RISKS RELATING TO GOVERNMENT REGULATION

We are subject to stringent government regulation. All of our products face regulatory challenges.

Virtually all aspects of our business activities are regulated by government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution, promotion and sampling, advertising of our products, and disposal of waste products arising from such activities are subject to governmental regulation. These activities are regulated by one or more of the FDA, the Federal Trade Commission, ("FTC"), the Consumer Product Safety Commission, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency, ("EPA"), as well as by comparable agencies in foreign countries. These activities are also regulated by various agencies of the states and localities in which our products are sold. For more information, see "*Business—Government Regulation"*.

Like all pharmaceutical manufacturers, we are subject to regulation by the FDA under the FDCA. All new drugs must be the subject of an FDA-approved new drug application, ("NDA"), before they may be marketed in the United States. The FDA has the authority to withdraw existing NDA approvals and to review the regulatory status of products marketed under the enforcement policy. The FDA may require an approved NDA for any drug product marketed under the enforcement policy if new information reveals questions about the drug's safety and effectiveness. All drugs must be manufactured in conformity with GMP, and drug products subject to an approved NDA must be manufactured, processed, packaged, held and labeled in accordance with information contained in the NDA. Since we rely on third parties to manufacture our products, GMP requirements directly affect our third party manufacturers and indirectly affect us. The manufacturing facilities of our third-party manufacturers are continually subject to inspection by such governmental agencies, and manufacturing operations could be interrupted or halted in any such facilities if such inspections prove unsatisfactory. Our third-party manufacturers are subject to periodic inspection by the FDA to assure such compliance.

Even after regulatory approval, certain developments may decrease demand for our products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of our products, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes.

In addition, certain health authorities, regulators and agencies have increased their focus on safety when assessing the balance of benefits and risks of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the U.S., on advertising, and promotion (in particular, direct-to-consumer advertising) and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and other applicable regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated

severity or frequency, or problems with a facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including withdrawal of the product from the market or suspension of manufacturing. If we, our partners or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory agency may take the following actions, among others:

- issue warning letters or untitled letters;
- impose civil or criminal penalties
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

Any change in the FDA's enforcement policy could have a material adverse effect on our business, financial condition and results of operations. We cannot determine what effect changes in regulations or statutes or legal interpretation, when and if promulgated or enacted, may have on our business in the future. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations.

Proposed legislation may permit re-importation of drugs from other countries into the U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., which could materially and adversely affect our operating results and our overall financial condition.

In previous years, legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Based on recent election results, there could be a renewed effort for legislation permitting the re-importation of prescription drugs as a means of lowering drug costs. Such legislation, or similar regulatory changes, if enacted, could decrease the price we receive for any approved products which, in turn, could materially and adversely affect our operating results and our overall financial condition.

We must comply with the Foreign Corrupt Practices Act.

We are required to comply with the United States Foreign Corrupt Practices Act, which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some of our competitors, are not subject to these prohibitions. If our competitors engage in these practices, they may receive preferential treatment from officials or agencies in some countries, giving our competitors an advantage in securing business from government officials who might give them priority in obtaining new licenses, which would put us at a disadvantage. We have established formal policies or procedures for prohibiting or monitoring this conduct, but we cannot assure you that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties.

We must comply with the Physician Payment Sunshine Act.

We are required to comply with the United States Physician Payment Sunshine Act, which requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals. Manufacturers are required to report this information annually to The Centers for Medicare & Medicaid Services (CMS). Cumberland has implemented a series of policies and procedures for every employee involved in the data collection process, and has systems in place to capture the data, which is verified by an outside firm that specializes in reporting the payments. Cumberland has also established a system to ensure that data was reported completely, in the correct format, and on

time. Despite these policies, procedures and systems, we cannot assure you that we will collect and report all data accurately. If we fail to accurately report this information, we could suffer severe penalties.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program.

Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the US in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The Healthcare Reform Act also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. The issuance of the final regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act obligates the Secretary of the HHS to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration ("HRSA"), the federal agency that administers the 340B program, recently updated the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling

price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations. Also, the Medicare Part B drug payment methodology is subject to change based on potential demonstration projects undertaken by CMS or potential legislation enacted by Congress.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs we are required to participate in the VA Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992.

Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

RISKS RELATING TO INTELLECTUAL PROPERTY

Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited or no protection from competition.

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

As discussed in Part I, Item 1, *Business - Patents, Trademarks, and Other Intellectual Proprietary Rights,* of this report on Form 10-K, we have several patents for formulations of Acetadote, and have previously engaged in litigation to enforce our patent rights.

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

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patents, we rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation where we do not believe patent protection is appropriate or attainable. For example, the manufacturing process for Kristalose involves substantial trade secrets and proprietary know-how. We have entered into confidentiality agreements with certain key employees and consultants pursuant to which such employees and consultants must assign to us any inventions relating to our business if made by them while they are our employees, as well as certain confidentiality agreements relating to the acquisition of rights to products. Confidentiality agreements can be breached, though, and we might not have adequate remedies for any breach. Also, others could acquire or independently develop similar technology.

We may depend on certain licensors for the maintenance and enforcement of intellectual property rights and have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf.

When we license products, we often depend on our licensors to protect the proprietary rights covering those products. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining patent or other rights and prosecuting patent applications to our advantage. While any such licensor is expected to be contractually obligated to diligently pursue its patent applications and allow us the opportunity to consult, review and comment on patent office communications, we cannot be sure that it will perform as required. If a licensor does not perform and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights.

If the use of our technology conflicts with the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to commercialize products based on this technology in a profitable manner or at all.

If our products conflict with the intellectual property rights of others, they could bring legal action against us or our licensors, licensees, manufacturers, customers or collaborators. If we were found to be infringing a patent or other intellectual property rights held by a third party, we could be forced to seek a license to use the patented or otherwise protected technology. We might not be able to obtain such a license on terms acceptable to us or at all. If legal action involving an alleged infringement or misappropriation were to be brought against us or our licensors, we would incur substantial costs in defending the action. If such a dispute were to be resolved against us, we could be subject to significant damages, and the manufacturing or sale of one or more of our products could be enjoined.

We may be involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be costly and time consuming.

We have been involved in lawsuits for infringement of the Acetadote Patents as previously described. Because of their nature, these lawsuits can be costly and time-consuming, and we only experience limited benefits and patent protection. A significant adverse ruling in any such lawsuit could put the Acetadote Patents at risk of being invalidated or interpreted narrowly and could compromise the issuance of our existing patent applications.

Competitors may infringe on our other patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

If we breach any of the agreements under which we license rights to our products and product candidates from others, we could lose the ability to continue commercialization of our products and development and commercialization of our product candidates.

We have exclusive licenses for the marketing and sale of certain products and may acquire additional licenses. Such licenses may terminate prior to expiration if we breach our obligations under the license agreement related to these pharmaceutical products. For example, the licenses may terminate if we fail to meet specified quality control standards, including GMP with respect to the products, or commit a material breach of other terms and conditions of the licenses. Such early termination could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Our operating results are likely to fluctuate from period to period.

We are a company actively seeking to deliver significant growth. As we execute our business strategy of adding new products, increasing market share in our existing growth products and striving to maintain market share in our other products, we anticipate that there may be fluctuations in our future operating results. We may not be able to maintain or improve our current levels of revenue or income. Potential causes of future fluctuations in our operating results may include:

- New product launches, which could increase revenues but also increase sales and marketing expenses;
- Acquisition activity and other charges;
- Increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional studies and development;
- Ability to utilize unrecognized federal and state net operating loss carryforwards as a result of the exercise of nonqualified options
- Changes in the competitive, regulatory or reimbursement environment, which could drive down revenues or drive up sales and marketing or compliance costs; and
- Unexpected product liability or intellectual property claims and lawsuits.

See also “Management’s discussion and analysis of financial condition and results of operations—Liquidity and capital resources.” Fluctuation in operating results, particularly if not anticipated by investors and other members of the financial community, could add to volatility in our stock price.

Our focus on acquisitions as a growth strategy has created intangible assets whose amortization could negatively affect our results of operations.

Our total assets include intangible assets related to our acquisitions. As of December 31, 2018, intangible assets relating to products represented approximately 30% of our total assets. We may never realize the value of these assets. U.S. Generally Accepted Accounting Principles ("GAAP") require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any determination requiring the write-off of a significant portion of unamortized intangible assets would adversely affect our results of operations.

We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our product development or commercialization and marketing efforts.

We may need to raise additional funds in order to meet the capital requirements of running our business and acquiring and developing new pharmaceutical products. If we require additional funding, we may seek to sell common stock or other equity or equity-linked securities, which could result in dilution to our shareholders. We may also seek to raise capital through a debt financing, which would result in ongoing debt-service payments and increased interest expense. Any financings would also likely involve operational and financial restrictions being imposed on us. We might also seek to sell assets or rights in one or more commercial products or product

development programs. Additional capital might not be available to us when we need it. We are unable to predict the impact of global credit market trends, and if economic conditions deteriorate, our business, results of operations and ability to raise needed capital could be materially and adversely affected. If we are unable to raise additional capital when needed due to the reasons listed above and lack of creditworthiness, bank failures, or price decline in market investments, we could be forced to scale back our operations to conserve cash.

If we are unable to maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock.

Effective internal controls are necessary for us to provide reliable financial reports and mitigate the risk of fraud. We maintain a system of internal control over financial reporting, which is defined as a process designed by, or under the supervision of, our principal executive officer and principal financial officer, and affected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

We cannot assure you that we will not, in the future, identify areas requiring improvement in our internal control over financial reporting. We cannot assure you that the measures we will take to improve these controls will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue to expand. If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock.

In addition, we maintain a system of internal controls and provide training to employees designed to provide reasonable assurance that unlawful and fraudulent activity, including misappropriation of assets, fraudulent financial reporting, and unauthorized access to sensitive or confidential data is either prevented or timely detected. However, in the event that our employees engage in such fraudulent behavior, we could suffer material adverse consequences.

Changes in, or interpretations of, accounting principles and tax laws could have a significant impact on our financial position and results of operations.

We prepare our consolidated financial statements in accordance with GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions.

For example, in recent years, the U.S.-based Financial Accounting Standards Board, ("FASB"), has worked together with the International Accounting Standards Board, ("IASB"), on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards, ("IFRS"), outside of the U.S. These efforts by the FASB and IASB may result in different accounting principles under GAAP that may result in materially different financial results for us in certain areas.

We may incur losses in the future and we may not achieve or maintain profitability.

We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we may incur losses in future periods.

We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product.

The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing.

We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we are successful in obtaining regulatory approvals for manufacturing and commercializing additional drug products, we may incur losses if our drug products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability.

We may seek to obtain future financing through the issuance of debt or equity, which may have an adverse effect on our shareholders or may otherwise adversely affect our business.

If we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of our current shareholders that do not participate in the issuance. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to develop and/or commercialize products or technologies that we would otherwise seek to develop and/or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of any additional debt securities we may issue in the future may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our share capital, or make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

Our officers, directors, and principal shareholders, acting as a group, could significantly influence corporate actions.

As of December 31, 2018, our officers and directors control approximately 40 percent of our common stock. Acting together, these shareholders could significantly influence any matter requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other shareholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling shareholders.

Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports.

The market for our common stock may be affected by the reports financial analysts publish about us. If one of the analysts covering us downgrades our stock, its price could decline rapidly and significantly. Securities analysts covering our common stock may discontinue coverage. A lack of research coverage may adversely affect our stock's market price.

RISKS RELATED TO OWNING OUR STOCK

The market price of our common stock may fluctuate substantially.

The price for the shares of our common stock sold in our initial public offering was determined by negotiation between the representatives of the underwriters and us. This price may not have reflected the market price of our common stock following our initial public offering. Through March 1, 2019, the closing price of our common stock since our initial public offering has ranged from a low of $4.08 to a high of $17.05 per share. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock. In addition, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such securities litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could negatively impact our business, operating results and financial condition. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

Unstable market conditions may have serious adverse consequences on our business.

Our general business strategy may be adversely affected by unpredictable and unstable market conditions. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a radical economic downturn or increase in our expenses could require additional financing on less than attractive rates or on terms that are dilutive to existing shareholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical developments plans. There is a risk that one or more of our current service providers, manufacturers and other partners may encounter difficult economic circumstances, which would directly affect our ability to attain our operating goals on schedule and on budget.

We experience costs and regulatory risk as a result of operating as a public company, and our management is required to devote time to compliance initiatives.

We have and will continue to incur costs as a result of operating as a public company, and our management is required to devote time to compliance initiatives. As a public company, we have and will continue to incur legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and other rules and regulations subsequently implemented by the SEC and NASDAQ, have imposed various requirements on public companies, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have and will continue to result in legal and financial compliance costs and render some activities more time-consuming and costly. Despite the internal controls and procedures put in place to maintain compliance with securities laws and regulations, our employees may still fail to comply with all SEC disclosure and reporting requirements. Such failure could lead to administrative and civil penalties, criminal penalties, and private litigation with shareholders. The consequences could have a material effect on our ability to effectively market our products and operate our business.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Some provisions of our third amended and restated charter, bylaws and Tennessee law may inhibit potential acquisition bids that you may consider favorable.

Our corporate documents contain provisions that may enable our board of directors to resist a change in control of our company even if a change in control were to be considered favorable by you and other shareholders. These provisions include:

- The authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval;
- Advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders;
- Limitations on persons authorized to call a special meeting of shareholders;
- A staggered board of directors;
- A restriction prohibiting shareholders from removing directors without cause;
- A requirement that vacancies in directorships are to be filled by a majority of the directors then in office and the number of directors is to be fixed by the board of directors; and
- No cumulative voting.

These and other provisions contained in our third amended and restated charter and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our shareholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of shareholders to remove our current management or approve transactions that our shareholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

In addition, we are subject to control share acquisitions provisions and affiliated transaction provisions of the Tennessee Business Corporation Act, the applications of which may have the effect of delaying or preventing a merger, takeover or other change in control of us and therefore could discourage attempts to acquire our company.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never paid cash dividends on our capital stock. We do not anticipate paying cash dividends to our shareholders in the foreseeable future. The availability of funds for distributions to shareholders will depend substantially on our earnings.

DEBT-RELATED RISKS

Our Revolving Credit Agreement impose restrictive and financial covenants on us. Our failure to comply with these covenants could trigger events that would have a material adverse effect on our business.

Our Revolving Credit Agreement contains covenants that restrict the way we conduct business and require us to satisfy certain financial tests in order to incur debt or take other actions. Additionally, our Revolving Credit Agreement contains financial covenants that, for example, require us to maintain certain financial ratios which are measured at the end of each fiscal quarter.

Our Revolving Credit Agreement contains specified quarterly financial maintenance covenants. As of December 31, 2018, we achieved compliance with the financial covenant through the utilization of the covenant cure section of the Revolving Credit Agreement. However, we can make no assurance that we will be able to comply with the restrictive and financial covenants contained in the Revolving Credit Agreement in the future.

Our inability to comply with the covenants in our debt instruments could lead to a default or an event of default under the terms thereof, for which we may need to seek relief from our lender in order to waive the associated default or event of default and avoid a potential acceleration of the related indebtedness or cross-default or cross-acceleration to other debt. There can be no assurance that we would be able to obtain such relief on commercially reasonable terms or otherwise and we may be required to incur significant additional costs. In addition, the lender under our Revolving Credit Agreement may impose additional operating and financial restrictions on us as a condition to granting any such waiver. If an event of default is not cured or is not otherwise waived, the lender under our Revolving Credit Agreement may accelerate the maturity of the related debt, foreclose upon any collateral securing the debt and terminate any commitments to lend, any of which would have a material adverse effect on our business, financial condition, cash flows and results of operations and would cause the market value of our securities to decline.

We have risks related to interest rates.

Our revolving credit facility bears interest based on variable interest. Thus, a change in the short-term interest rate environment (especially a material change) could have a material adverse effect on our business, financial condition, cash flows and results of operations. As of December 31, 2018, we did not have any outstanding interest rate swap contracts.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K that are not historical factual statements are "forward-looking statements." Forward-looking statements include, among other things, statements regarding our intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate" and other comparable terms or the negative thereof. In addition, we, through our senior management, from time to time make forward-looking oral and written public statements concerning our expected future operations and other developments. While forward-looking statements reflect our good-faith beliefs and best judgment based upon current information, they are not guarantees of future performance and are subject to known and unknown risks and uncertainties, including those mentioned in Item 1A, "Risk Factors," Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 10-K. Accordingly, investors are cautioned not to place undue reliance on any forward-looking statements. Actual results may differ materially from the expectations contained in the forward-looking statements as a result of various factors. Such factors include, but are not limited to:

- The possible or assumed future results of operations, including the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- Changes in national or regional economic conditions, including changes in interest rates and the availability and the cost of capital to us;
- Our competitive position and competitors, including the size and growth potential of the markets for our products and product candidates;
- The success, cost and timing of our product acquisition and development activities and clinical trials; and our ability to successfully commercialize our product candidates;
- Product efficacy or safety concerns, whether or not based on scientific evidence, resulting in product withdrawals, recalls, regulatory action on the part of the FDA (or international counterparts) or declining sales;
- The performance of our third-party suppliers and manufacturers which impacts our supply chain and could create business shutdowns or product shortages; and the retention of key scientific and management personnel;
- Challenges to our patents and the introduction of generic versions of our products and product candidates, which could negatively impact our ability to commercialize and sell our products and product candidates and decrease sales a result of market exclusivity;
- Changes in reimbursement available to us, including changes in Medicare and Medicaid payment levels and availability of third-party insurance coverage and the effects of future legislation or regulations, including changes to regulatory approval of new products, licensing and patent rights, environmental protection and possible drug re-importation legislation;
- Interruptions and breaches of our computer and communications systems, and those of our vendors, including computer viruses, hacking and cyber-attacks, that could impair our ability to conduct business and communicate internally and with our customers, or result in the theft of trade secrets or other misappropriation of assets, or otherwise compromise privacy of sensitive information belonging to us, our customers or other business partners; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and the Securities and Exchange Commission.

The list above contains many, but not all, of the factors that could impact our ability to achieve results described in any forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider this list to be a complete statement of all potential risks and uncertainties. We have identified the factors on this list as permitted by the Private Securities Litigation Reform Act of 1995.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of December 31, 2018, we leased approximately 25,500 square feet of office space in Nashville, Tennessee for our corporate headquarters. The lease expires in October 2022. We believe these facilities are adequate to meet our current needs for office space. Manufacturing, packaging or warehousing services are provided to us through contracts with third-party organizations.

The laboratory space at CET, under an agreement amended in July 2012, is leased through April 2023, with an option to extend the lease through April 2028. CET leases approximately 14,200 square feet of office and wet laboratory space in Nashville, Tennessee to operate the CET Life Sciences Center. Cumberland's product formulation and testing laboratories are located at this facility, along with CET's offices. The CET Life Sciences Center also provides laboratory and office space, equipment and infrastructure to early-stage life sciences companies and university spin-outs.

Item 3. Legal Proceedings.

On April 14, 2014, we filed with the American Arbitration Association a request for arbitration with Mylan Inc., Mylan Institutional LLC, Mylan Pharma Group Limited, and Mylan Teoranta (collectively, "Mylan"). We are seeking to arbitrate claims against Mylan in connection with our Alliance Agreement dated January 15, 2002, and Manufacturing and Supply Agreement as amended April 25, 2011, which require that Mylan and its affiliates manufacture and supply acetylcysteine drug product, including Acetadote, for us exclusively until April 2016. We have asserted in the request for arbitration claims against Mylan for breach of contract, breach of implied covenant of good faith and fair dealing, and unjust enrichment and seek monetary damages or to enjoin Mylan and its affiliates from selling or supplying acetylcysteine drug product.

On September 14, 2015, the arbitrator issued a final award in our favor, enjoining Mylan Pharma Group Limited and Mylan Teoranta, together with all their affiliates, from selling, delivering, or giving away any acetylcysteine injectable drug product to another entity or person until April 30, 2018. The award notes that as the prevailing party, we are entitled to reimbursement of our attorney's fees and related costs associated with the arbitration.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in our favor in our lawsuit against Mylan for infringement of 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 our favor in our lawsuit against Mylan for infringement of the 445 Acetadote Patent. The Appeals Court opinion affirmed the District Court's ruling upholding our 445 Acetadote Patent and expressly rejected Mylan's validity challenge.

Also see the discussion of our Acetadote patent defense legal proceedings contained in Part 1, Item 1, *Business - Patents, Trademarks and Other Intellectual Proprietary Rights*, of this Form 10-K, which is incorporated by reference herein.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

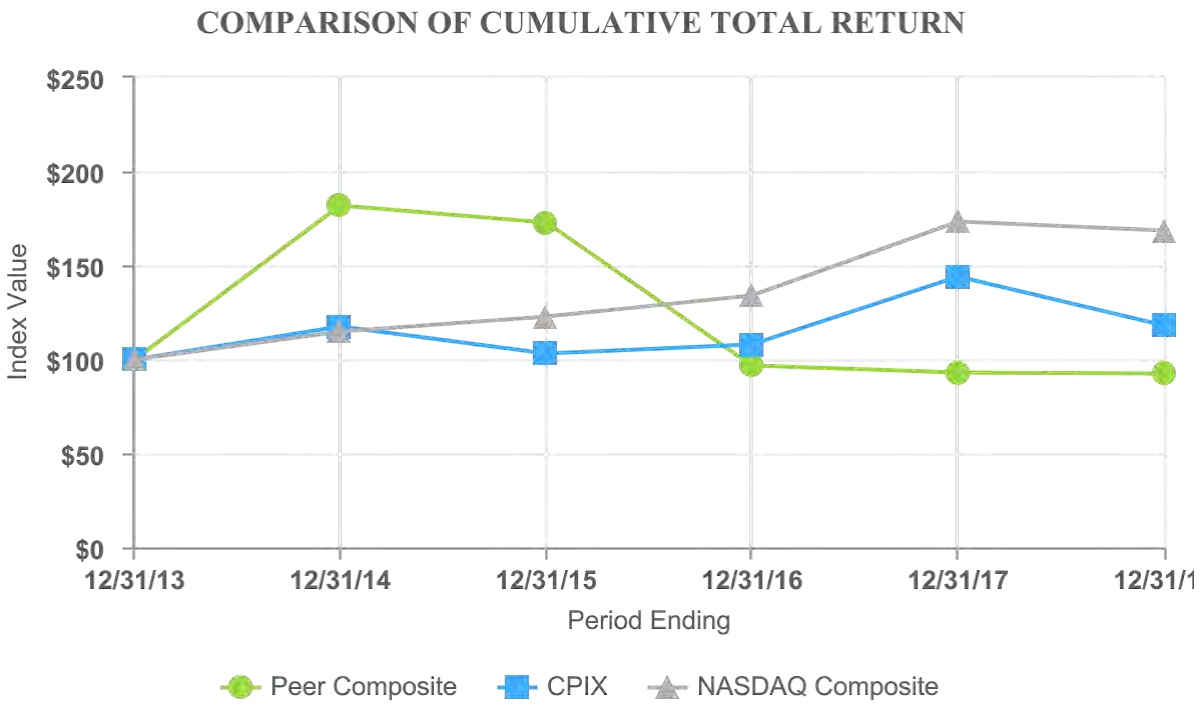
Our common stock, no par value, has been traded on the Nasdaq Global Select Market since August 11, 2009 under the symbol "CPIX." As of March 5, 2019, we had 77 shareholders of record of our common stock. This excludes shareholders whose shares are held by brokers and other institutions on behalf of shareholders. The closing price of our common stock on the Nasdaq Global Select Market on March 5, 2019 was $5.88 per share.

Dividend Policy

We have not declared or paid any cash dividends on our common stock nor do we anticipate paying dividends for the foreseeable future. We currently intend to retain any future earnings for use in the operation of our business and to fund future growth. Any future decision to declare or pay dividends will be at the sole discretion of our Board of Directors.

Performance Graph

The stock performance graph below illustrates a comparison of the total cumulative stockholder return on our common stock since December 31, 2013 to the Nasdaq Composite and a composite of ten Nasdaq Pharmaceutical and Specialty Pharmaceutical Stocks which most closely compare to our Company. The graph assumes an initial investment of $100 on December 31, 2013, and that all dividends were reinvested.



Purchases of Equity Securities

We currently have a share repurchase program to purchase up to $10.0 million of our common stock pursuant to Rule 10b-18 of the Securities Act. In January 2016 and again during January 2019, our Board of Directors established the current $10.0 million repurchase program to replace the prior authorizations for repurchases of our outstanding common stock. We repurchased 443,041 shares, 547,376 shares and 529,312 shares of common stock for approximately $2.9 million, $3.7 million, and $2.5 million during the years ended December 31, 2018, 2017 and 2016, respectively.

The following table summarizes the activity, by month, during the fourth quarter of 2018:

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October	15,242	$5.61	15,242	$1,770,963
November	36,069 (1)	$6.40	36,069	$1,540,169
December	26,082	$6.40	26,082	$1,373,215
Total	77,393			

(1) Of this amount, 6,255 shares were repurchased directly in private purchases at the then-current fair market value of common stock.

Item 6. Selected Financial Data.

The selected consolidated financial data set forth below should be read in conjunction with the audited consolidated financial statements and related notes and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information appearing elsewhere in this Form 10-K. The historical results are not necessarily indicative of the results to be expected for any future periods.

	Years Ended December 31,				
Statement of income data:	**2018**	**2017**	**2016**	**2015**	**2014**
	(in thousands, except per share data)				
Net revenues	$ 40,742	$ 41,150	$ 33,026	$ 33,519	$ 36,902
Costs and expenses	48,133	45,231	34,459	32,407	33,343
Operating income (loss)	(7,391)	(4,081)	(1,433)	1,112	3,559
Net income (loss) attributable to common shareholders	(6,963)	(7,979)	(945)	731	2,424
Earnings (loss) per share – basic	$ (0.45)	$ (0.50)	$ (0.06)	$ 0.04	$ 0.14
Earnings (loss) per share – diluted	$ (0.45)	$ (0.50)	$ (0.06)	$ 0.04	$ 0.14

	As of December 31,				
Balance sheet data:	**2018**	**2017**	**2016**	**2015**	**2014**
	(in thousands)				
Cash and cash equivalents	$ 27,939	$ 45,413	$ 34,510	$ 38,203	$ 39,866
Marketable securities	8,291	4,672	15,622	14,561	14,841
Working capital	31,312	50,990	50,753	52,172	57,065
Total assets	112,694	93,232	93,405	91,919	95,405
Total long-term debt and other long-term obligations (including current portion)	29,319	11,616	5,491	2,687	1,032
Retained earnings	4,746	11,709	18,605	19,550	18,818
Total equity	55,571	63,922	73,121	76,820	80,753

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial position and results of operations should be read together with our audited consolidated financial statements and related notes appearing elsewhere in this Form 10-K. This discussion and analysis may contain forward-looking statements that involve risks and uncertainties – please refer to the section entitled, "Special Note Regarding Forward-Looking Statements," contained in Part I, Item 1A, "Risk Factors," of this Form 10-K. You should review the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

EXECUTIVE SUMMARY

We are 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 field sales forces in the United States and are establishing a network of international partners to bring our medicines to patients in their countries.

Our portfolio of FDA approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **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;
- **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); and
- **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");
- **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™** (*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 promote our approved products through our hospital and gastroenterology sales forces in the United States, which together comprised approximately 40 sales representatives and managers as of December 31, 2018.

We have both product development and commercial capabilities and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, regulatory, manufacturing, sales marketing and finance. Our business development team identifies, evaluates and negotiates product acquisition, licensing and co-promotion opportunities. Our product development team creates proprietary product formulations, manages our clinical studies, prepares all regulatory submissions and manages our medical call center. Our 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.

The following is a summary of our 2018 highlights and recent developments. For more information, please see Part I, Item I, *Business*, of this Form 10-K.

- Caldolor continued to grow, with increases in both our domestic and international customers. The product was also approved for use in India during 2018.
- Net revenue from sales of each of Kristalose, Ethyol and Vaprisol grew in 2018 compared to 2017.
- During 2018, we entered into a co-promotion agreement in support of Kristalose. Under the terms of the agreement, 2R Pharmaceuticals will repackage and promote Kristalose to physician targets that we do not cover.
- CET was named a recipient of a National Institute of Health grant of $2 million for a CET oncology program. CET also entered into two new collaboration agreements with Louisiana State University and the Medical University of South Carolina.
- During 2018, 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.
- During 2017, we completed a Phase I study which defined the pharmacokinetic properties and provided a favorable safety profile for a new hospital product candidate. The study results and a proposed clinical development plan were discussed with the FDA and, as a result, in 2018 a Phase II study was initiated.
- In January 2018, we announced a new publication in *Leukemia & Lymphoma*, with results from an investigator initiated study showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma.
- 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.
- In September 2018 Cumberland announced a publication of a contemporary retrospective study showing that subcutaneous amifostine administered before radiotherapy postponed the onset of acute esophagitis in stage three small cell lung cancer patients.
- 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

- In October 2018, Cumberland announced a favorable Caldolor study publications. An investigator initiated study at The Ohio State Wexner Medical Center, revealed more effective pain control and opioid-sparing activity with Caldolor when compared to ketorolac in patients undergoing arthroscopic knee surgery.

- In 2018 an investigator initiated trial conducted at Tufts University School of Dental Medicine was published. The study concluded that preemptive analgesia with Caldolor (IV ibuprofen) is more effective than Ofirmev® (IV acetaminophen) in reducing post-surgical pain and opioid use.

- In October 2018, we signed an amendment to our Revolving Credit Loan Agreement with Pinnacle Bank increasing the maximum aggregate principal available for borrowing under the Pinnacle Agreement to $20 million.

- In November 2018, Cumberland announced the acquisition of Vibativ from Theravance Biopharma and assumed global responsibility for the product. Immediately after the closing we initiated shipments of Vibativ and assumed responsibility for the supply chain and distribution of the product in the U.S.

- In January 2019, we received notification from the FDA setting September 2019 as the Prescription Drug User Fee (“PDUFA”) action date for an approval decision for the Company’s New Drug Application (“NDA”) for our methotrexate product line. Our new line of methotrexate products is designed for the treatment of adult and pediatric patients with rheumatoid arthritis, as well as adults with psoriasis. The NDA was accepted for filing by the FDA in early January 2019, following its submission to the FDA in November 2018.

- In January 2019, the FDA approved our application of our next generation Caldolor injection product. In February 2018, Cumberland completed and filed with the FDA an application for approval. The product features a new, patented formulation in a more convenient to use package.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Accounting Estimates and Judgments

The preparation of the consolidated financial statements in conformity with GAAP 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 are not 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, marketable securities, inventory, intangible assets, research and development accounting, contingent consideration liability, provision for income taxes and share-based payments.

Revenue Recognition

We recognize revenue in accordance with the Accounting Standards Codification (ASC) Topic 606. Effective January 1, 2018, we 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.

Our revenue is derived primarily from the product sales of our eight FDA approved pharmaceutical brands. 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. Our 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. Other revenue, which is a component of net revenues, includes non-refundable upfront payments and milestone payments under licensing agreements along with grant and rental income. Other income was approximately 1.3% percent of net revenues in 2018, 1.9% in 2017, and 1.7% in 2016 respectively.

Our financial statements reflect accounts receivable allowances of $0.9 million and $0.5 million at December 31, 2018 and 2017, respectively, for chargebacks, discounts and allowances for product damaged in shipment.

The following table reflects our sales-related accrual activity for the periods indicated below:

	2018	2017	2016
Balance, January 1	$ 4,683,694	$ 4,051,029	$ 6,776,023
Current provision	13,609,017	12,318,312	9,837,063
Actual product returns and credits issued	(12,656,739)	(11,685,647)	(12,562,057)
Balance, December 31	$ 5,635,972	$ 4,683,694	$ 4,051,029

The allowances for chargebacks, discounts, and damaged products and sales related accruals for rebates and product returns are determined on a product-by-product basis. We establish them using our 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.
- The contractual terms with direct and indirect customers.
- analyses of historical levels of chargebacks, discounts and credits claimed for damaged and expired product.
- Communications with customers;
- Purchased information about the rate of prescriptions being written and the level of inventory remaining in the distribution channel, if known; and
- Expectations about the market for each product, including any anticipated introduction of competitive products.

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

The allowances for chargebacks and accruals for rebates and product returns are the most significant estimates used in the recognition of our revenue from product sales. Of the accounts receivable allowances and our sales related accruals, our accrual for fee for services and product returns represents the majority of the balance. Sales related accrued liabilities for rebates, product returns, service fees, and administrative fees totaled $5.6 million, $4.7 million and $4.1 million as of December 31, 2018, 2017 and 2016, respectively. Of these amounts, our estimated liability for fee for services represented $2.0 million, $1.5 million and $1.3 million, respectively, while our accrual for product returns totaled $2.2 million, $2.1 million and $2.0 million, respectively. If the actual amount of cash discounts, chargebacks, rebates, and product returns differs from the amounts estimated by management, material differences may result from the amount of our revenue recognized from product sales. A change in our rebate estimate of one percentage point would have impacted net sales by approximately $0.3 million in each of the years ended December 31, 2018, 2017, and 2016. A change in our product return estimate of one percentage point would have impacted net sales by $0.5 million, $0.5 million and $0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Fair Value of Marketable Securities

We have historically invested a portion of our cash reserves in 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 in order to maximize our return on cash. We classify these investments as trading securities, and mark the investments to fair value at the end of each reporting period, with the adjustment being recognized in the statement of income as a component of interest income. These investments are generally valued using observable market prices by third-party pricing services, or are derived from such services' pricing models. The level of management judgment required in establishing fair value of financial instruments for which there is a quoted price in an active market is minimal. Similarly, there is little subjectivity or judgment required for instruments valued using valuation models that are standard across the industry and where all 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.

Inventories

We record amounts for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the net realizable value based upon assumptions about remaining shelf life, future demand and market conditions. The estimated inventory obsolescence amounts are calculated based upon specific review of the inventory expiration dates and the quantity on-hand at December 31, 2018 in comparison to our expected inventory usage. The amount of actual inventory obsolescence and unmarketable inventory could differ (either higher or lower) in the near term from the estimated amounts. Changes in our estimates would be recorded in our statement of operations in the period of the change.

Income Taxes

We provide for deferred taxes using the asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to operating loss and tax credit carry-forwards and differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Our principal differences are related to the timing of deductibility of certain items such as depreciation, amortization and expense for options issued to nonemployees. Deferred tax assets and liabilities are measured using management's estimate of tax rates expected to apply to taxable income in the years in which management believes those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in our results of operations in the period that includes the enactment date.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment.

We adopted FASB ASU 2016-09, "Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting" effective January 1, 2017. The impact of adoption on our consolidated financial statements included the recording of $44.1 million in previously unrecognized net operating loss carryforwards, net of valuation allowances, generated from the exercise of nonqualified options during 2009. These net operating loss carryforwards occurred as a result of the actual tax benefit realized upon employee exercise exceeding the cumulative book compensation charge associated with the options. The adoption resulted in the recording of $1.1 million in net non-current deferred tax assets and retained earnings effective as of January 1, 2017. The $1.1 million in net non-current deferred tax assets was the result of a deferred tax asset of $17.0 million, net of a related valuation allowance of $15.9 million. Under the previous accounting guidance, these benefits had been recognized in the year in which they were able to reduce current income taxes payable. As part of our adoption of the FASB guidance and its continued evaluation of our utilization of net operating loss carryforwards and other deferred tax assets, including updates to our forecasts of future taxable income, we also recorded an additional valuation allowance of $1.0 million for our federal Orphan Drug and Research and Development tax credits that expire between 2021 and 2036. This additional valuation allowance impacted our effective tax rate during 2017.

During the second quarter of 2017, as part of our continued evaluation of the utilization of our net operating loss carryforwards we recorded an additional valuation allowance of $3.5 million for our remaining deferred tax assets. This additional valuation allowance impacted our effective tax rate during the second quarter of 2017 and all deferred tax assets have a full valuation allowance.

The net operating loss carryforwards generated during 2009 consisted of $44.1 million in federal and $45.4 million in state amounts. Since they were generated, we have utilized these net operating loss carryforwards to pay minimal income taxes. We will continue to experience a reduction in income taxes paid in future years, through the continued utilization of these net operating loss carryforwards, as we are able to achieve taxable income through our operations.

The newly adopted FASB guidance also results in any changes in the tax benefit being recognized in the provision for taxes on income during the period incurred. Previously, we recorded these benefits directly to equity. The Company's accounting policy with respect to interest and penalties arising from income tax settlements is to recognize them as part of the provision for income taxes.

On December 22, 2017, the Tax Cut and Jobs Act (the "Tax Act") was signed into law. The Tax Act provides for significant changes in the U.S. Internal Revenue Code of 1986, as amended. The Tax Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. Certain provisions of the Tax Act were effective during our fiscal year ending December 31, 2018 with all provisions of the Tax Act effective as of the beginning of our fiscal year ending December 31, 2019.

Under ASC Topic 740, Income Taxes ("ASC 740"), we are required to revalue any deferred tax assets or liabilities in the period of enactment of change in tax rates. The Tax Act lowers the corporate income tax rate from 35% to 21%. As a result of the Tax Act discussed above, we will experience a positive impact to our future results of operations to the extent we achieve taxable income through our operations.

Share-Based Payments

We recognize compensation expense for all share-based payments based on the fair value of the award on the date of grant. In addition, incremental compensation expense is recognized upon the modification of equity awards.

During 2011, we began issuing restricted stock awards at no cost in lieu of stock options to employees, directors and consultants. Compensation expense for restricted stock granted to employees and directors is generally equal to the fair market value of the underlying common stock on the date of grant. If a sufficient disincentive for nonperformance does not exist at the date of grant, the compensation cost is remeasured at each reporting date at the then-current fair market value of the underlying common stock until the award vests.

Research and Development

We accrue for and expense research and development costs based on estimates of work performed, patient enrollment or fixed-fee-for-services. As work is performed and/or invoices are received, we adjust our estimates and accruals. To date, our accruals have not differed materially from our estimates. Total research and development costs are a function of studies being conducted and will increase or decrease based on the level of activity in any particular year.

Intangible Assets and Goodwill

Intangible assets include product rights, license agreements, other identifiable intangible assets and goodwill associated with the Vibativ acquisition. We assess the impairment of goodwill at least annually and identifiable intangible assets whenever events or changes in circumstances indicate the carrying value may not be recoverable. In determining the recoverability of our intangible assets, we make assumptions regarding estimated future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets, we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than the carrying value, an impairment loss will be recognized in an amount equal to the difference. Fair value is determined through various valuation techniques including quoted market prices, third-party independent appraisals and discounted cash flow models, as considered necessary.

RESULTS OF OPERATIONS

Year ended December 31, 2018 compared to year ended December 31, 2017

The following table presents the statements of operations for the years ended December 31, 2018 and 2017:

	Years ended December 31,		
	2018	2017	Change
Net revenues	$ 40,741,765	$ 41,150,131	$ (408,366)
Costs and expenses:			
Cost of products sold	7,378,095	7,370,585	7,510
Selling and marketing	20,258,307	21,492,937	(1,234,630)
Research and development	7,320,797	3,901,365	3,419,432
General and administrative	10,405,872	10,030,370	375,502
Amortization	2,769,466	2,436,222	333,244
Total costs and expenses	48,132,537	45,231,479	2,901,058
Operating income (loss)	(7,390,772)	(4,081,348)	(3,309,424)
Interest income	564,484	299,326	265,158
Interest expense	(195,848)	(92,904)	(102,944)
Income (loss) before income taxes	(7,022,136)	(3,874,926)	(3,147,210)
Income tax (expense) benefit	(16,636)	(4,174,889)	4,158,253
Net income (loss)	$ (7,038,772)	$ (8,049,815)	$ 1,011,043

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

	Years ended December 31,		
	2018	2017	Change
Products:			
Acetadote	$ 4,284,111	$ 6,576,720	$ (2,292,609)
Omeclamox-Pak	623,297	1,761,868	(1,138,571)
Kristalose	12,055,625	11,455,805	599,820
Vaprisol	1,763,874	1,576,222	187,652
Caldolor	5,001,997	4,178,443	823,554
Ethyol	10,545,906	10,835,038	(289,132)
Totect	850,965	3,992,467	(3,141,502)
Vibativ	5,075,057	—	5,075,057
Other	540,933	773,568	(232,635)
Total net revenues	$ 40,741,765	$ 41,150,131	$ (408,366)

Net revenues. Net revenues for the year ended December 31, 2018 were approximately $40.7 million compared to $41.2 million for the year ended December 31, 2017, representing a decrease of $0.4 million or 1.0%. Three of our products: Acetadote, Omeclamox Pak and Totect experienced a decrease in revenue during 2018, with the largest decrease coming from our Totect product. 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.

These decreases were partially offset by the initial product sales of our newest product, Vibativ and as well as three of our marketed products experiencing increases in net revenue during the period: Kristalose, Vaprisol and Caldolor.

Kristalose revenue increased by $0.6 million, or 5.2%, compared to December 31, 2017 primarily as a result of increased sales volume. The product's net revenue was positively impacted by increased sales volumes and lower managed care and Medicare rebates, resulting in improved net pricing for the product for the year ended December 31, 2018.

Caldolor revenue experienced a 20% increase to $5.0 million during the year ended December 31, 2018 compared to $4.2 million in the same period last year. This increase in Caldolor revenue for the year ended December 31, 2018 was positively impacted by increased domestic and international shipments. Domestic net revenue improved from increased sales volumes and improved pricing.

Vaprisol revenue increased $0.2 million during the year ended December 31, 2018 compared to the prior year period due to increased sales of the product. Sales of Vaprisol 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 product. During April 2018, the Vaprisol supply issue was resolved as we received new shipments from our manufacturer. This 12% net revenue increase was partially offset by an increase in expired product sales returns during the period.

Ethyol revenue for the year ended December 31, 2018 was $10.5 million, which is a decrease of $0.3 million from the year ended December 31, 2017. The decrease in net revenue is primarily a result of increases in chargeback deductions related to the Public Health Service's 340B drug pricing program.

Totect revenue decreased $3.1 million for the year ended December 31, 2018 compared to the prior year. The decrease is primarily due to a decrease in product sales volume compared to the prior year period. As noted above, we began shipments of Totect during a national shortage of dexrazoxane, resulting in strong initial demand for the product.

Omeclamox-Pak revenue decreased $1.1 million during the year ended December 31, 2018 compared to the prior year. The decrease was largely the result of lower sales volume and much higher expired product sales returns.

Acetadote revenue included net sales of our branded product and our share of net sales from our Authorized Generic. For the year ended December 31, 2018, the Acetadote net revenue decreased $2.3 million compared to the prior year due to a reduction in sales volume as a result of generic competition.

Cost of products sold. Cost of products sold for the year ended December 31, 2018 were $7.4 million, remaining consistent with the prior year. As a percentage of net revenues, cost of products sold were 18.1% compared to 17.9% during the prior year. The change 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 expense for the year ended December 31, 2018 were $20.3 million, which was a decrease of $1.2 million compared to the prior year's expense of $21.5 million. This decrease was primarily attributable to lower royalty expense related to product sales as well as lower promotional spending for the year ended December 31, 2018.

Research and development. Research and development costs for the year ended December 31, 2018 were $7.3 million, compared to $3.9 million last year, representing an increase of $3.4 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 partially the result of additional investments in our ongoing clinical initiatives associated with our pipeline products of $1.6 million. There was also an increase in our products FDA program fees including the $1.3 million fee associated with our RediTrex submission. Research and development costs also increased for salary, wages and benefits.

General and administrative. General and administrative expense for the year ended December 31, 2018 was $10.4 million for 2018, compared to $10.0 million last year. The $0.4 million or, 3.7%, increase from the prior year was primarily driven by an increase in compensation and benefits along with increases in legal and consulting expenses.

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 2018 totaled approximately $2.8 million, which was an increase of $0.3 million over the prior year. The increase in amortization was attributable to additional product and license rights and capitalized patents.

Income tax expense. Income tax expense for the year ended December 31, 2018 was $16,636, compared to approximately $4.2 million in the year ended December 31, 2017. As a percentage of income (loss) before income taxes, income taxes were 0.2% for the year ended December 31, 2018 compared to 107.7% for the year ended December 31, 2017. As discussed in our consolidated financial statements, the effective tax rate for the year ended December 31, 2017 was primarily impacted by recording a valuation allowance of $1.0 million for our federal Orphan Drug and Research and Development tax credits and an additional valuation allowance of $3.5 million for our remaining deferred tax assets. These non-cash valuation allowance adjustments impacted our effective tax rate during the year ended December 31, 2017 .

Year ended December 31, 2017 compared to year ended December 31, 2016

The following table presents the statements of operations for the years ended December 31, 2017 and 2016:

	Years ended December 31,		
	2017	**2016**	**Change**
Net revenues	$ 41,150,131	$ 33,025,560	$ 8,124,571
Costs and expenses:			
Cost of products sold	7,370,585	5,958,660	1,411,925
Selling and marketing	21,492,937	14,553,481	6,939,456
Research and development	3,901,365	3,190,700	710,665
General and administrative	10,030,370	8,561,811	1,468,559
Amortization	2,436,222	2,194,039	242,183
Total costs and expenses	45,231,479	34,458,691	10,772,788
Operating income (loss)	(4,081,348)	(1,433,131)	(2,648,217)
Interest income	299,326	204,661	94,665
Interest expense	(92,904)	(106,392)	13,488
Income (loss) before income taxes	(3,874,926)	(1,334,862)	(2,540,064)
Income tax (expense) benefit	(4,174,889)	330,924	(4,505,813)
Net income (loss)	$ (8,049,815)	$ (1,003,938)	$ (7,045,877)

Net revenues. Net revenues for the year ended December 31, 2017 were approximately $41.2 million compared to $33.0 million for the year ended December 31, 2016, representing an increase of $8.1 million or 24.6%. The following table summarizes net revenues by product for the years presented:

	Years ended December 31,		
	2017	2016	Change
Products:			
Acetadote	$ 6,576,720	$ 7,214,341	$ (637,621)
Omeclamox-Pak	1,761,868	2,536,027	(774,159)
Kristalose	11,455,805	15,898,760	(4,442,955)
Vaprisol	1,576,222	1,857,838	(281,616)
Caldolor	4,178,443	4,132,833	45,610
Ethyol	10,835,038	838,386	9,996,652
Totect	3,992,467	—	3,992,467
Other	773,568	547,375	226,193
Total net revenues	$ 41,150,131	$ 33,025,560	$ 8,124,571

Ethyol revenue for the year ended December 31, 2017 was $10.8 million, which is an increase of $10.0 million from the year ended December 31, 2016. The Company began generating revenue from the sale of Ethyol during the third quarter of 2016. The increase resulted from a full year of sales of the product as well as increased demand for our branded Ethyol product during 2017.

The Company began shipments of Totect in July of 2017, resulting in $4.0 million in sales during the year ended December 31, 2017 with Cardioxane contributing $0.3 million. The launch of Totect was impacted by a national shortage of dexrazoxane, resulting in strong initial demand for the product.

Caldolor revenue experienced an increase to $4.2 million during the year ended December 31, 2017 compared to $4.1 million in the same period last year. Caldolor revenue in the year ended December 31, 2017 was primarily impacted by increased domestic net revenue as a result of improved pricing and lower expired product sales returns. The increase in domestic net revenue was partially offset by declines in international sales revenue.

Kristalose revenue decreased by $4.4 million primarily as a result of reduced sales volume. The product's net revenue was negatively impacted by higher Medicaid rebates due to changes to this product's reimbursement. This reduction was partially offset by improved pricing during the year ended December 31, 2017.

Omeclamox-Pak revenue decreased $0.8 million during the year ended December 31, 2017 compared to the prior year. The decrease was primarily the result of lower sales volume and higher expired product sales returns. These decreases were partially offset by improved pricing.

Acetadote revenue included net sales of our branded product and our share of net sales from our Authorized Generic. During the year ended December 31, 2017, the Acetadote net revenue included $4.6 million in revenue from sales of our Authorized Generic, compared to $4.8 million for the same period last year. Our branded Acetadote product net revenue decreased $0.5 million due to a reduction in sales volume as a result of generic competition during the year ended December 31, 2017.

Vaprisol revenue decreased $0.3 million during the year ended December 31, 2017 compared to the prior year period due to increases in our fee for service paid to wholesalers and sales returns related to short-dated product. We experienced decreased sales volume during a portion of the fourth quarter as the manufacturer was unable to provide requested supplies of Vaprisol which led to limited inventory and sales of the product.

Cost of products sold. Cost of products sold for the year ended December 31, 2017 were $7.4 million, compared to $6.0 million in the prior year, representing an increase of $1.4 million, or 23.7%. As a percentage of net revenues, cost of products sold were 17.9% compared to 18.0% during the prior year. This improvement in costs of products sold as a percentage of revenue was attributable to changes in the product sales mix during the period compared to the prior year.

Selling and marketing. Selling and marketing expense for the year ended December 31, 2017 were $21.5 million, which was an increase of $6.9 million compared to the prior year's expense of $14.6 million. This increase was the result of $6.7 million in additional royalties, related to increased product sales, primarily associated with Ethyol and Totect, for the year ended December 31, 2017.

Research and development. Research and development costs for the year ended December 31, 2017 were $3.9 million, compared to $3.2 million last year, representing an increase of $0.7 million, or 22.3%. 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 the result of additional investments in our ongoing clinical initiatives associated with our pipeline products and an increase in our products FDA program fees.

General and administrative. General and administrative expense for the year ended December 31, 2017 was $10.0 million for 2017, compared to $8.6 million last year. The $1.4 million increase from the prior year was primarily driven by a $0.6 million increase in non-cash stock based compensation which included $0.4 million in expense related to the contribution of 50,000 shares of our common stock in connection with the creation of the Cumberland Pharma charitable foundation. We also experienced an increase in compensation as well as benefits and increases in legal and other professional fees associated with our business development initiatives.

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 2017 totaled approximately $2.4 million, which was an increase of $0.2 million over the prior year. The increase in amortization was attributable to additional product and license rights, capitalized patents and patent defense costs.

Income tax expense. Income tax expense for the year ended December 31, 2017 was $4.2 million, compared to income tax benefit of $0.3 million in the year ended December 31, 2016. As a percentage of income (loss) before income taxes, income taxes were 107.7% for the year ended December 31, 2017 compared to 24.8% for the year ended December 31, 2016. As discussed in our consolidated financial statements, the effective tax rate for the year ended December 31, 2017 was primarily impacted by a valuation allowance of $1.0 million for our federal Orphan Drug and Research and Development tax credits and an additional valuation allowance of $3.5 million for our remaining deferred tax assets. These non-cash valuation allowance adjustments impacted our effective tax rate during the year ended December 31, 2017. The rate for the year ended December 31, 2016 was impacted by the valuation allowance recorded for our federal Orphan Drug and Research and Development tax credits of $0.2 million.

LIQUIDITY AND CAPITAL RESOURCES

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 December 31, 2018 and 2017, we had approximately $8.3 million and $4.7 million invested in marketable securities, respectively.

The following table summarizes our liquidity and working capital as of the years ended December 31:

	2018	2017
Cash and cash equivalents	$ 27,938,960	$ 45,412,868
Marketable securities	8,290,679	4,672,476
Total cash, cash equivalents and marketable securities	$ 36,229,639	$ 50,085,344
Working capital (current assets less current liabilities)	$ 31,311,813	$ 50,990,102
Current ratio (multiple of current assets to current liabilities)	2.1	3.9
Revolving line of credit availability	$ —	$ 2,200,000

The following table summarizes our net changes in cash and cash equivalents for the years ended December 31:

	2018	2017	2016
Cash provided by (used in):			
Operating activities	$ 3,112,737	$ (557,714)	$ 569,478
Investing activities	(27,724,818)	9,512,577	(3,115,079)
Financing activities	7,138,173	1,947,675	(1,147,128)
Net (decrease) increase in cash and cash equivalents	$ (17,473,908)	$ 10,902,538	$ (3,692,729)

The net $17.5 million decrease in cash and cash equivalents for the year ended December 31, 2018 was attributable to cash used by investing activities offset by cash provided by operating and financing activities. Cash provided by operating activities of $3.1 million was impacted by a net loss for the period of $7.0 million. This use of operating cash was offset by non-cash expenses of depreciation and amortization and share-based compensation expense totaling $4.3 million. Changes in our working capital provided net cash of $5.9 million. Cash used in investing activities included $20 million in cash paid for the acquisition of Vibativ during 2018, the use of cash to complete a net increase in marketable securities of $3.4 million, and the addition to intangibles of $3.8 million. Our financing activities included $10.2 million in net cash provided by borrowings under our line of credit net of $2.9 million in cash used to repurchase shares of our common stock.

As noted above, we continue to repurchase shares of our common stock, as discussed in Part II, Item 5, "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities", of this Form 10-K.

The net $10.9 million increase in cash and cash equivalents for the year ended December 31, 2017 was attributable to cash provided by investing and financing activities offset by cash used in operating activities. Cash used in operating activities of $0.6 million was primarily impacted by a net loss for the period of $8.0 million. These uses of operating cash were offset by deferred tax expenses of $4.2 million and non-cash expenses of depreciation and amortization and share-based compensation expense totaling $4.1 million. Changes in our working capital used net cash of $0.8 million, including accounts receivable, inventory and other current assets of $3.5 million offset by cash provided by accounts payable increases of $2.3 million. Cash provided by investing activities included net proceeds from marketable securities of $11.0 million offset by additions to intangibles of $1.2 million. Our financing activities included $24.5 million in cash provided by borrowings under our line of credit and $3.7 million in cash used to repurchase shares of our common stock.

Operating activities provided $0.6 million in cash during the year ended December 31, 2016. The net $3.7 million decrease in cash and cash equivalents for 2016 was attributable to cash used in investing and financing activities, which was partly offset by the $0.6 million in cash generated from operations. Cash used in investing activities included a net cash investment in our intangible assets of $2.0 million and net purchases of $1.0 million associated with our investing activities in marketable securities. Our financing activities included $2.5 million in cash used to repurchase shares of our common stock and $2.4 million in cash provided by borrowings under our line of credit. Cash provided by operating activities benefited from the non-cash expenses of depreciation, amortization and share-based compensation costs totaling $3.2 million offset by cash used through changes in our working capital of $3.3 million. During 2016, we recognized approximately $1.0 million of excess tax expense derived from the previous exercise of nonqualified stock options.

Shelf Registration

In November 2017, the Company filed its Shelf Registration on Form S-3 with the SEC associated with the sale of up to $100 million in corporate securities. The Shelf Registration which was declared effective in January 2018. It also included an At the Market ("ATM") feature that allows the Company to sell common shares at market prices, along with an agreement with B. Riley FBR to support such a placement of shares. We issued $0.2 million in shares under this ATM during the year ended December 31, 2018.

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 increased the maximum aggregate principal available for borrowing under the Pinnacle Agreement to $20 million. We had $20 million in borrowings under that agreement at December 31, 2018. For a summary of the material terms of the Pinnacle Agreement, as amended, see Note 9 to the accompanying notes to 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 achieved compliance with the financial covenant as of December 31, 2018 through the utilization of the covenant cure section of the agreement.

Minimum Product Purchase Requirements

Our manufacturing and supply agreements do not require minimum annual purchase obligations.

Contractual cash obligations

The following table summarizes our contractual cash obligations as of December 31, 2018:

		Payments Due by Year				
Contractual obligations[1]	**Total [2]**	**2019**	**2020**	**2021**	**2022**	**2023 and thereafter**
Line of credit[3]	$20,000,000	$ —	$20,000,000	$ —	$ —	$ —
Estimated interest on debt [3]	1,290,000	860,000	430,000	—	—	—
Contingent consideration liability payments [4]	9,502,000	2,290,000	1,661,800	1,454,200	1,072,260	3,023,740
Operating leases	3,858,702	959,902	980,720	1,001,603	871,969	44,508
Purchase obligations [5]	—	—	—	—	—	—
Total [1]	$34,650,702	$ 4,109,902	$23,072,520	$ 2,455,803	$1,944,229	$3,068,248

1. The table of contractual obligations excludes amounts due under the Ethyol and Totect royalty agreements. We exclude these amounts as they are not determined until sales of these products have occurred. As consideration for the purchase of certain Kristalose assets in November 2011, we agreed to pay the seller a percentage of net sales for a seven-year period beginning November 15, 2011. These payments were due quarterly, in arrears and the sales term subject to payments ended in November 2018. Ethyol and Totect include a royalty expense as part of the period costs of the agreement.

2. The sum of the individual amounts may not agree due to rounding.

3. The line of credit payments represent the estimated unused line of credit payments and the amount due at maturity. The estimated interest on debt represents the interest on the principal outstanding on the line of credit. These amounts are based on the $20.0 million line of credit assuming the current $20.0 million balance outstanding on December 31, 2018 is consistently outstanding through maturity of July 2020. Interest and unused line of credit payments are due and payable quarterly in arrears.

4. The contingent consideration liability represents the fair value of the royalty payments of up to 20% of future net sales as part of the Vibativ acquisition.

5. Represents minimum purchase obligations under our manufacturing agreements.

OFF-BALANCE SHEET ARRANGEMENTS

During 2018, 2017 and 2016, we did not engage in any off-balance sheet arrangements.

RECENT ACCOUNTING PRONOUNCEMENTS

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 and an effective date approach are provided for lessees of 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 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 of between $3.6 million and $4.2 million.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

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

We believe that our interest rate risk related to our cash and cash equivalents is not material. The risk related to interest rates for these accounts would produce less income than expected if market interest rates fall. Based on current interest rates, we do not believe we are exposed to significant downside risk related to a change in interest on our money market accounts. Based on the $8.3 million in marketable securities outstanding at December 31, 2018, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income 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 1.75% to 2.75% (representing an interest rate of 4.3% at December 31, 2018). As of December 31, 2018, we had $20.0 million in borrowings outstanding under our revolving line of credit.

Exchange Rate Risk

While we operate primarily in the U.S., we are exposed to foreign currency risk. A portion of our research and development is performed abroad.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange losses were immaterial for 2018, 2017 and 2016. Neither a five percent increase nor decrease from current exchange rates would have had a material effect on our operating results or financial condition.

Item 8. Financial Statements and Supplementary Data.

See consolidated financial statements, including the reports of the independent registered public accounting firm, starting on page F-1, which is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018. Based on that evaluation, they have concluded that our disclosure controls and procedures were effective as of December 31, 2018 to ensure that material information relating to us and our consolidated subsidiaries is made known to officers within these entities in order to allow for timely decisions regarding required disclosure.

Management's report on internal control over financial reporting is included on page F-1 of this annual report on Form 10-K, and incorporated herein by reference. During our fourth quarter of 2018, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f)).

Item 9B. Other Information.

None.

PART III

The information called for by Part III of Form 10-K (Item 10 – Directors, Executive Officers and Corporate Governance, Item 11 – Executive Compensation, Item 12 – Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13 – Certain Relationships and Related Transactions, and Director Independence, Item 14 – Principal Accounting Fees and Services), is incorporated by reference from our proxy statement related to our 2018 annual meeting of shareholders, which is expected to be filed with the SEC on or around March 15, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

a. Documents filed as part of this report:

1. Financial Statements

	Page Number
Management's Report on Internal Control over Financial Reporting	83
Report of Independent Registered Public Accounting Firm – Consolidated Financial Statements	1
Consolidated Balance Sheets	3
Consolidated Statements of Operations and Comprehensive Income (Loss)	4
Consolidated Statements of Cash Flows	5
Consolidated Statements of Equity	6
Notes to the Consolidated Financial Statements	7

(2) Financial Statement Schedule

Valuation and Qualifying Accounts	36

b. Exhibits

Exhibit Number	Description
3.1	Third Amended and Restated Charter of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
3.2	Second Amended and Restated Bylaws of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
4.1	Specimen Common Stock Certificate of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 5 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on August 6, 2007
4.2	Preferred Stock Terms, Rights, and Provisions, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-221402) as filed with the SEC on December 19, 2017
4.3	Form of Senior Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-221402) as filed with the SEC on November 7, 2017
4.4	Form of Subordinated Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-221402) as filed with the SEC on November 7, 2017
4.5#	Form of Option Agreement under 1999 Stock Option Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007

4.6.1#	Form of Incentive Stock Option Agreement under the Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.6.2#	Form of Non-Statutory Stock Option Agreement under the Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.7#	Form of Non-Statutory Stock Option Agreement under the Amended and Restated 2007 Directors' Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.8	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on July 22, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 19, 2010
4.9	Form of Senior Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-184091) as filed with the SEC on September 25, 2012.
4.10	Form of Subordinated Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-184091) as filed with the SEC on September 25, 2012
10.35	Amendment to Revolving Credit Loan Agreement, by and between Pinnacle Bank and Cumberland Pharmaceuticals Inc., dated August 14, 2018, incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report Form 10-Q (File No. 001-33637) as filed with the SEC on August 14, 2018
10.36	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 Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on October 19, 2018
10.7†	Exclusive Distribution Agreement, effective as of July 1, 2010, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on August 13, 2010
10.7.1†	First Amendment to Exclusive Distribution Agreement, dated March 31, 2013, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report of Form 8-K (File No. 001-33637) as filed with the SEC on June 3, 2013
10.10†	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.11#	Employment Agreement dated March 8, 2019, effective as of January 1, 2019, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10 .12#	Employment Agreement dated March 8, 2019, effective as of January 1, 2019, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement dated March 8, 2019, effective as of January 1, 2019, by and between Leo B. Pavliv and Cumberland Pharmaceuticals Inc.
10.14#	Employment Agreement dated March 8, 2019, effective as of January 1, 2019, by and between Michael P. Bonner and Cumberland Pharmaceuticals Inc.
10.15#	Employment Agreement dated March 8, 2019, effective as of January 1, 2019, by and between James L. Herman and Cumberland Pharmaceuticals Inc.
10.17#	1999 Stock Option Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007

10.18#	Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to Appendix A of the Registrant's Schedule 14A as filed with the SEC on March 12, 2012 and approved by the Registrant's shareholders on April 17, 2012
10.19#	Amended and Restated 2007 Directors' Incentive Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to Appendix B of the Registrant's Schedule 14A as filed with the SEC on March 12, 2012 and approved by the Registrant's shareholders on April 17, 2012
10.2	Form of Indemnification Agreement between Cumberland Pharmaceuticals Inc. and all members of its Board of Directors, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.21†	Lease Agreement, dated September 10, 2005, by and between Nashville Hines Development, LLC and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.21.1†	First Amendment to Office Lease Agreement, dated April 25, 2008, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.21.2†	Second Amendment to Office Lease Agreement, dated March 2, 2010, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on May 17, 2010
10.21.3†	Third Amendment to Office Lease Agreement, dated September 29, 2015, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on November 6, 2015
10.23†	Amended and Restated Lease Agreement, dated November 11, 2004, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007

10.24	First Amendment to Amended and Restated Lease Agreement, dated August 23, 2005, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.24.1	Second Amendment to Amended and Restated Lease Agreement, dated January 9, 2006, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.24.2†	Third Amendment to Amended and Restated Lease Agreement, dated July 3, 2012, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on August 9, 2012
10.25†	License and Supply Agreement, dated November 16, 2015, by and between Cumberland Pharmaceuticals Inc. and Gastro-Entero Logic, LLC incorporated herein by reference to the corresponding exhibit of the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 14, 2016
10.28†	Asset Purchase and Royalty Agreement for Kristalose dated November 15, 2011 by and between Mylan Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on November 22, 2011
10.30#	Supplemental Executive Retirement and Savings Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on May 24, 2012
10.31†	Settlement Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.32†	License and Supply Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.33	Revolving Credit Loan Agreement, dated June 26, 2014, by and between Cumberland Pharmaceuticals Inc. and SunTrust Bank incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on August 8, 2014
10.33.1	First Amendment to Revolving Credit Loan Agreement, dated July 29, 2016, by and between Cumberland Pharmaceuticals Inc. and SunTrust Bank incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on November 3, 2016
10.33.2	Waiver and Second Amendment to Revolving Credit Loan Agreement, dated October 28, 2016, by and between Cumberland Pharmaceuticals Inc. and SunTrust Bank incorporated herein by reference to the corresponding exhibit of the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 13, 2017
10.34	Revolving Credit Loan Agreement, dated July 31, 2017, by and between Cumberland Pharmaceuticals Inc. and Pinnacle Bank incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on November 8, 2017

21	Subsidiaries of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
23.1	Consent of KPMG LLP
23.2	Consent of BDO USA, LLP
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 Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

#	Indicates a management contract or compensatory plan.
†	Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.
††	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

Item 16. Form 10-K Summary

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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, on March 11, 2019.

Cumberland Pharmaceuticals, Inc.

/s/ A. J. Kazimi

By: A. J. Kazimi
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. J. Kazimi A. J. Kazimi	Chairman and CEO *(Principal Executive Officer and Director)*	March 11, 2019
/s/ Michael P. Bonner Michael P. Bonner	Senior Director and CFO *(Principal Financial and Accounting Officer*	March 11, 2019
/s/ Martin E. Cearnal Martin E. Cearnal	Director	March 11, 2019
/s/ Gordon R. Bernard Gordon R. Bernard	Director	March 11, 2019
/s/ Jonathan I. Griggs Jonathan I. Griggs	Director	March 11, 2019
/s/ James R. Jones James R. Jones	Director	March 11, 2019
/s/ Joey A. Jacobs Joey A. Jacobs	Director	March 11, 2019
/s/ Caroline R. Young Caroline R. Young	Director	March 11, 2019
/s/ Kenneth J. Krogulski Kenneth J. Krogulski	Director	March 11, 2019
/s/ Joseph C. Galante Joseph C. Galante	Director	March 11, 2019

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Cumberland Pharmaceuticals Inc. and its subsidiaries (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Cumberland Pharmaceuticals Inc.'s internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Cumberland Pharmaceuticals Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework (2013)*.

Based on its assessment, management has concluded that, as of December 31, 2018, the Company's internal control over financial reporting was effective based on those criteria.

/s/ A. J. Kazimi
A. J. Kazimi
Chief Executive Officer
March 11, 2019

/s/ Michael Bonner
Michael Bonner
Chief Financial Officer
March 11, 2019

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Cumberland Pharmaceuticals Inc.
Nashville, Tennessee

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for the years then ended, and the related notes and financial statement schedule as of December 31, 2018 and 2017 and for the years then ended listed in the accompanying index (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017.

Nashville, Tennessee
March 11, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors

Cumberland Pharmaceuticals Inc.:

We have audited the accompanying consolidated balance sheet of Cumberland Pharmaceuticals Inc. and subsidiaries (the Company) as of December 31, 2016, and the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for each of the years in the two-year period ended December 31, 2016. In connection with our audit of the consolidated financial statements, we have also audited the financial statement Schedule II - Valuation and Qualifying Accounts for each of the years in the two-year period ended December 31, 2016. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2016, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

/s/ KPMG LLP
Nashville, Tennessee
March 10, 2017

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2018 and 2017

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,938,960	$ 45,412,868
Marketable securities	8,290,679	4,672,476
Accounts receivable, net	7,844,249	8,395,112
Inventories, net	12,078,343	6,737,848
Prepaid and other current assets	2,963,806	3,466,541
Total current assets	59,116,037	68,684,845
Non-current inventories	15,749,000	—
Property and equipment, net	771,213	528,882
Intangible assets, net	33,655,099	21,444,545
Goodwill	784,000	—
Deferred tax assets, net	87,210	87,210
Other assets	2,531,309	2,486,830
Total assets	$ 112,693,868	$ 93,232,312
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 11,093,297	$ 8,979,929
Other current liabilities	16,710,927	8,714,814
Total current liabilities	27,804,224	17,694,743
Revolving line of credit	20,000,000	9,800,000
Other long-term liabilities	9,319,143	1,815,968
Total liabilities	57,123,367	29,310,711
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock – no par value; 100,000,000 shares authorized; 15,481,497 and 15,723,075 shares issued and outstanding as of December 31, 2018 and 2017, respectively	51,098,613	52,410,941
Retained earnings	4,746,154	11,709,222
Total shareholders' equity	55,844,767	64,120,163
Noncontrolling interests	(274,266)	(198,562)
Total equity	55,570,501	63,921,601
Total liabilities and equity	$ 112,693,868	$ 93,232,312

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)

Years ended December 31, 2018, 2017 and 2016

	2018	2017	2016
Revenues:			
Net product revenue	$ 40,200,832	$ 40,376,563	$ 32,478,185
Other revenue	540,933	773,568	547,375
Net revenues	40,741,765	41,150,131	33,025,560
Costs and expenses:			
Cost of products sold	7,378,095	7,370,585	5,958,660
Selling and marketing	20,258,307	21,492,937	14,553,481
Research and development	7,320,797	3,901,365	3,190,700
General and administrative	10,405,872	10,030,370	8,561,811
Amortization	2,769,466	2,436,222	2,194,039
Total costs and expenses	48,132,537	45,231,479	34,458,691
Operating income (loss)	(7,390,772)	(4,081,348)	(1,433,131)
Interest income	564,484	299,326	204,661
Interest expense	(195,848)	(92,904)	(106,392)
Income (loss) before income taxes	(7,022,136)	(3,874,926)	(1,334,862)
Income tax (expense) benefit	(16,636)	(4,174,889)	330,924
Net income (loss)	(7,038,772)	(8,049,815)	(1,003,938)
Net loss at subsidiary attributable to noncontrolling interests	75,704	71,182	59,255
Net income (loss) attributable to common shareholders	$ (6,963,068)	$ (7,978,633)	$ (944,683)
Earnings (loss) per share attributable to common shareholders:			
Basic	$ (0.45)	$ (0.50)	$ (0.06)
Diluted	$ (0.45)	$ (0.50)	$ (0.06)
Weighted-average common shares outstanding:			
Basic	15,614,052	15,911,577	16,236,525
Diluted	15,614,052	15,911,577	16,236,525
Comprehensive income (loss) attributable to common shareholders	$ (6,963,068)	$ (7,978,633)	$ (944,683)
Net loss at subsidiary attributable to noncontrolling interests	75,704	71,182	59,255
Total comprehensive income (loss)	$ (7,038,772)	$ (8,049,815)	$ (1,003,938)

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years ended December 31, 2018, 2017 and 2016

	2018	2017	2016
Cash flows from operating activities:			
Net income (loss)	$ (7,038,772)	$ (8,049,815)	$ (1,003,938)
Adjustments to reconcile net income (loss) to net cash flows provided by (used in) operating activities:			
Depreciation and amortization expense	2,982,703	2,647,753	2,396,908
Deferred tax expense	81,886	4,206,753	619,580
Share-based compensation	1,364,698	1,115,063	852,102
Share-based compensation (foundation contribution)	—	372,500	—
Excess tax (benefit) expense derived from exercise of stock options	(81,886)	(91,109)	1,026,413
Noncash interest expense	99,883	77,911	84,539
Noncash investment gains	(168,440)	(52,012)	(74,015)
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	550,863	(1,064,985)	(1,253,007)
Inventories	460,505	(1,366,118)	(1,101,586)
Prepaid, other current assets and other assets	712,149	(1,074,369)	(1,556,282)
Accounts payable and other current liabilities	4,308,706	2,307,617	191,901
Other long-term liabilities	(159,558)	413,097	386,863
Net cash provided by (used in) operating activities	3,112,737	(557,714)	569,478
Cash flows from investing activities:			
Additions to property and equipment	(455,569)	(275,960)	(130,872)
Additions to intangible assets	(3,819,486)	(1,213,110)	(2,000,226)
Cash paid for acquisition	(20,000,000)	—	—
Proceeds from sale of marketable securities	16,663,232	13,381,061	4,489,111
Purchases of marketable securities	(20,112,995)	(2,379,414)	(5,473,092)
Net cash provided by (used in) investing activities	(27,724,818)	9,512,577	(3,115,079)
Cash flows from financing activities:			
Borrowings on line of credit	56,000,000	24,500,000	2,400,000
Repayments on line of credit	(45,800,000)	(18,800,000)	—
Repurchase of common shares	(2,879,426)	(3,724,375)	(2,520,715)
Payments of deferred equity offering costs	(383,310)	(27,950)	—
Sale of shares of common stock, net of offering costs	200,909	—	—
Excess tax (expense) benefit derived from exercise of stock options	—	—	(1,026,413)
Net cash provided by (used in) financing activities	7,138,173	1,947,675	(1,147,128)
Net increase (decrease) in cash and cash equivalents	(17,473,908)	10,902,538	(3,692,729)
Cash and cash equivalents, beginning of year	45,412,868	34,510,330	38,203,059
Cash and cash equivalents, end of year	$ 27,938,960	$ 45,412,868	$ 34,510,330
Supplemental disclosure of cash flow information:			
Net cash paid (refunded) during the year for:			
Interest	$ 95,965	$ 14,993	$ 21,853
Income taxes	15,441	18,000	(8,359)
Noncash investing and financing activities:			
Change in unpaid invoices for purchases of intangibles	$ (539,467)	$ (513,481)	$ (1,179,394)
Deferred offering costs included in accounts payable and other accrued expenses	—	97,254	—
Non cash increase in liabilities related to acquisition (see Note 3)	14,034,000	—	—

See accompanying notes to consolidated financial statements

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Equity

Years ended December 31, 2018, 2017 and 2016

	Cumberland Pharmaceuticals Inc. Shareholders				
	Common stock		Retained earnings	Non-controlling interest	Total equity
	Shares	Amount			
Balance, December 31, 2015	16,379,501	$ 57,338,294	$ 19,549,614	$ (68,125)	$ 76,819,783
Net income (loss)			(944,683)	(59,255)	(1,003,938)
Share-based compensation	223,987	852,102	—	—	852,102
Exercise of options and related tax benefit	—	(1,026,413)	—	—	(1,026,413)
Repurchase of common shares	(529,312)	(2,520,715)	—	—	(2,520,715)
Balance, December 31, 2016	16,074,176	54,643,268	18,604,931	(127,380)	73,120,819
Net income (loss)			(7,978,633)	(71,182)	73,120,819
Cumulative effect from change in accounting principle (Note 12)	—	—	1,082,924	—	1,115,063
Share-based compensation	146,275	1,115,063	—	—	1,115,063
Charitable contribution of shares	50,000	372,500	—	—	372,500
Repurchase of common shares	(547,376)	(3,719,890)	—	—	(3,719,890)
Balance, December 31, 2017	15,723,075	52,410,941	11,709,222	(198,562)	63,921,601
Net income (loss)			(6,963,068)	(75,704)	(7,038,772)
Share-based compensation	170,759	1,364,698	—	—	1,364,698
Proceeds from sale of common stock, net of offering costs	30,704	200,909	—	—	200,909
Repurchase of common shares	(443,041)	(2,877,935)	—	—	(2,877,935)
Balance, December 31, 2018	15,481,497	$ 51,098,613	$ 4,746,154	$ (274,266)	$ 55,570,501

See accompanying notes to consolidated financial statements.

(1) Organization

Cumberland Pharmaceuticals Inc. and its subsidiaries ("Cumberland," the "Company," or as used in the context "our" or "we") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets are hospital acute care, 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 order to build a pipeline of early-stage product candidates, the Company formed a subsidiary, Cumberland Emerging Technologies, Inc. ("CET"), which teams with universities and other research organizations to help advance scientific discoveries from the laboratory to the marketplace. The Company's ownership in CET is 80%. In 2014, the Company organized equity financing to recapitalize and strengthen the financial position of CET. This financing included an investment of approximately $1.0 million from Gloria Pharmaceuticals Co., Ltd. ("Gloria"). As a result, Gloria received shares in CET and joined the CET ownership group. As noted above, the ownership interests of CET includes Gloria and Cumberland, while the remaining interest is owned by Vanderbilt University and the Tennessee Technology Development Corporation. The operating results of CET allocated to noncontrolling interests in the consolidated statements of operations were $75,704, $71,182 and $59,255 for the years ended December 31, 2018, 2017 and 2016, respectively.

Effective January 1, 2007, the Company formed a wholly-owned subsidiary, Cumberland Pharma Sales Corp. ("CPSC"). CPSC is the subsidiary that employs the Company's hospital and field sales force personnel.

(2) Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements of the Company are stated in U.S. dollars and are prepared using U.S. generally accepted accounting principles. These financial statements include the accounts of the Company and its wholly and majority-owned subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates under different assumptions and conditions. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns (2) the allowances for obsolescent or unmarketable inventory (3) assumptions used in estimating acquisition date fair value of assets acquired in business combinations and (4) valuation of contingent consideration liability associated with business combinations.

Segment Reporting

The Company has one operating segment which is specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Operating segments are identified as components of an enterprise about which separate discrete financial information is evaluated by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company, which uses consolidated financial information in determining how to allocate resources and assess performance, evaluated that our specialty pharmaceutical products compete in similar economic markets and similar circumstances. Substantially all of the Company's assets are located in the United States. Total revenues are primarily attributable to U.S. customers. Net revenues from customers outside the United States were approximately $2.1 million, $1.6 million and $2.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Fair Value of Financial Instruments

Fair value of financial assets and liabilities is the price the Company would receive to sell an asset or pay to transfer a liability in an orderly transaction with a market participant at the measurement date. 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.

We maintain policies and procedures to value instruments using the best and most relevant data available. The following section describes the valuation methodologies we use to measure different financial instruments at fair value on a recurring basis.

The Company's financial instruments include cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities, contingent consideration liability and a revolving line of credit. The carrying values for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short-term nature. The revolving line of credit has a variable interest rate, which approximates the current market rate.

The Company's fair values of marketable securities are determined based on valuations provided by a third-party pricing service, as derived from such services' pricing models, and are considered either Level 1 or Level 2 measurements, depending on the nature of the investment. The Company has no marketable securities in which the fair value is determined based on Level 3. 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. The

Company believes that the valuations provided by the third-party pricing service, as derived from such services' pricing models, represent prices that would be received to sell the assets at the measurement date (exit prices).

The Company's contingent consideration liability is a Level 3 fair value measurement that is updated on a recurring basis at each reporting period using a valuation model. Consist with Level 3 fair value measurements there are significant inputs to the valuation model that are unobservable.

Cash and Cash Equivalents

Cash and cash equivalents include highly liquid investments with original maturities of three months or less. As of December 31, 2018 and 2017, cash equivalents consist primarily of money market funds.

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 December 31, 2018 and 2017, marketable securities were 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 consolidated statements of operations.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount. The Company records allowances for amounts that could become uncollectible in the future based on historical experience, including amounts related to chargebacks, cash discounts and credits for damaged product. The Company reviews each customer balance to assess collection status.

The majority of the Company's products are distributed through independent pharmaceutical wholesalers. 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.

Cash discounts are reductions to invoiced amounts offered to customers for payment within a specified period of time from the date of the invoice.

Inventories

The Company works closely with third parties to manufacture and package finished goods for sale. Based on the customer relationship with the manufacturer or packager, the Company will either take title to 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. As discussed below, effective January 1, 2017, 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 inventories for potential losses due to expired, short-dated or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value. The Company classifies the Vibativ inventories that it does not expect to sell within one year as non-current inventories.

Prepaid and Other Current Assets

Prepaid and other current assets consist of deferred offering costs, prepaid insurance premiums, prepaid consulting services, deposits and annual fees paid to the U.S. Food and Drug Administration ("FDA"). The Company expenses all prepaid and other current asset amounts as used or over the period of benefit primarily on a straight-line basis, as applicable.

Deferred offering costs are expenses directly related to the Form S-3 or Shelf Registration filed with the SEC on November 11, 2017 and declared effective on January 16, 2018. These costs consist of legal, accounting, printing, and filing fees that the Company has capitalized. Deferred costs associated with the Shelf Registration will be reclassified to additional paid in capital on a pro-rata basis as the Company completes sales of shares under the Shelf Registration, with any remaining deferred offering costs to be charged to the results of operations at the end of the three-year life of the Shelf Registration. During the year ended December 31, 2018, the Company has not expensed any deferred offering costs associated with the Shelf Registration.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the initial lease term plus renewal options, if reasonably assured, or the remaining useful life of the asset. Upon retirement or disposal of assets, any gain or loss is reflected as a component of operating income (loss) in the consolidated statement of operations. Improvements that extend an asset’s useful life are capitalized. Repairs and maintenance costs are expensed as incurred.

Intangible Assets and Goodwill

The Company’s intangible assets and goodwill consist of capitalized costs related to product and license rights, patents, trademarks and goodwill obtained in the Vibativ acquisition. Goodwill is not amortized for financial reporting purposes.

The cost of acquiring product and license rights are capitalized at fair value at the date of acquisition for products that are approved by the FDA for commercial use. These costs are amortized ratably over the estimated economic life of the product. The economic life is estimated based upon several factors. This includes the term of the license agreement, the patent life or market exclusivity of the product and as well as management's expectations of continued involvement with the product and the assessment of future sales, the future periods under which the product will be sold and the profitability of the product. This estimate is evaluated on a regular basis during the amortization period and adjusted if appropriate. If there are any changes made to the useful life of the product and license rights, the costs associated with such a change, if any, will be capitalized and amortized over the revised useful life.

Capitalized patent costs consist of outside legal costs associated with obtaining and protecting patents on products that have been approved for marketing by the FDA. If it becomes probable that a patent will not be issued or a patent has been declared invalid, related costs associated with the patent application are expensed at the time such determination is made. All costs associated with obtaining patents for products that have not been approved for marketing by the FDA are expensed as incurred.

Amortization expense is recognized ratably over the following periods:

Product rights	Estimated economic life
License rights	Term of license agreement
Patents	Life of patent

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If events or circumstances arise that require a long-lived asset to be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by the asset to its carrying value. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment charge is recognized to the extent that the carrying value exceeds the fair value. Fair value is determined through various valuation techniques including quoted market prices, third-party independent appraisals and discounted cash flow models.

Goodwill and other indefinite lived intangible assets that are not subject to amortization are tested at least annually for impairment. The Company's goodwill was acquired in November 2018 with the Vibativ acquisition. The Company recorded no impairment charges during 2018, 2017 and 2016.

Revenue Recognition

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.

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.

Other Revenues

Other revenues primarily consist of income from grant funding programs, licensing agreements, leases and contract services. Revenue related to grants is recognized when all conditions related to such grants have been met. All other revenue is recognized when earned.

Cost of Products Sold

Cost of products sold consists principally of the cost to acquire each unit of product sold, including in-bound freight expense as well as any adjustment in the net realizable value of inventory acquired in acquisitions. Cost of products sold also includes expenses associated with the reduction in the net realizable value of slow-moving or expired product.

Selling and Marketing Expense

Selling and marketing expense consists primarily of expenses relating to the advertising, promotion, distribution and sale of products, including royalty expense, salaries and related costs.

Distribution Costs

Distribution costs are expensed as incurred and are included as a component of selling and marketing expenses in the consolidated statements of operations. Distribution costs were as follows for the years ended December 31:

	2018	2017	2016
Distribution costs	$ 618,756	$ 621,142	$ 703,353

Advertising Costs

Advertising costs are expensed as incurred and are included as a component of selling and marketing expenses in the consolidated statements of operations. Advertising costs were as follows for the years ended December 31:

	2018	2017	2016
Advertising costs	$ 2,219,074	$ 2,589,185	$ 2,626,238

Research and Development

Research and development costs are expensed in the period incurred. Research and development costs are comprised mainly of clinical trial expenses, salaries, wages and other related costs such as materials and supplies. Research and development expense includes activities performed by third-party providers participating in the Company's clinical studies. The Company accounts for these costs based on estimates of work performed, patients enrolled or fixed fees for services over the period of time the clinical trials are performed.

Income Taxes

The Company provides for deferred taxes using the asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for future tax consequences attributable to operating loss and tax credit carryforwards, as well as differences between the carrying amounts of existing assets and liabilities and their respective tax bases. The Company's principal differences are related to the timing of deductibility of certain items, such as inventory, depreciation, amortization and share-based compensation. Deferred tax assets and liabilities are measured using enacted statutory tax rates that are expected to apply to taxable income in the years such temporary differences are anticipated to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company only recognizes income tax benefits associated with an income tax position in which it is "more likely than not" that the position would be sustained upon examination by the taxing authorities.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of existing temporary differences, projected future taxable income and tax planning strategies in making this assessment.

The Company's accounting policy with respect to interest and penalties arising from income tax settlements is to recognize them as part of the provision for income taxes.

Comprehensive Income (Loss)

Total comprehensive income (loss) was comprised solely of net income (loss) for all periods presented.

Earnings (Loss) per Share

Basic earnings per share is calculated by dividing net income (loss) attributable to common shareholders by the weighted-average number of shares outstanding. Except where the result would be antidilutive to income from continuing operations, diluted earnings per share is calculated by assuming the vesting of unvested restricted stock and the exercise of stock options and warrants and unrecognized compensation costs.

Share-Based Payments

The Company recognizes compensation cost for all share-based payments issued, modified, repurchased or canceled. Depending on the nature of the vesting provisions, restricted stock awards are measured using either the fair value on the grant date or the fair value of common stock on the date the vesting provisions lapse. Prior to the lapse for those equity grants not valued on the grant date, the fair value is measured on the last day of the reporting period.

Collaborative Agreements

The Company 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 these collaborative agreements do not meet the criteria for accounting under Accounting Standards Codification 808, Collaborative Agreements. The agreements do not specifically designate each party's rights and obligations to each other under the collaborative arrangements. Except for patent defense costs, expenses incurred by one party are not required to be reimbursed by the other party. The funding for these programs is generally provided through private sector investments or federal Small Business Administration ("SBIR/STTR") grant programs. Expenses incurred under these collaborative agreements are included in research and development expenses in the consolidated statements of operations. Funding received from private sector investments and grants are recorded as net revenues in the consolidated statements of operations.

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 (formerly "capital leases") or operating, with classification affecting the pattern of expense

recognition in the income statement. The standard provides for a modified retrospective transition approach 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. In July 2018, the FASB issued ASU 2018-11, "Leases: Targeted Improvements", allowing for an alternative transition method (the effective date approach). It allows an entity to initially apply the new lease guidance at the adoption date (rather than at the beginning of the earliest period presented). Cumberland adopted the lease guidance effective January 1, 2019 using the practical expedients. This will allow the Company to retain the lease classification for any leases existing prior to adoption, in addition to other benefits.

The Company expects the primary effect of adopting ASU 2016-02 will be to record right-of-use assets and obligations for our leases currently classified as operating leases. 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. These operating leases are expected to result in initial ROU assets and liabilities as of January 1, 2019 of between $3.6 million and $4.2 million.

(3) Omeclamox®-Pak, Ethyol®, RediTrex®, Totect® and Vibativ®

Omeclamox-Pak

In December 2018, Cumberland completed an agreement with Gasto-enterlogics Inc. ("GEL") to acquire the remaining product rights associated with Omeclamox-Pak including the Product's FDA-approved New Drug Application and the domestic and international trademarks. As part of the transaction, which was accounted for as an asset acquisition, Cumberland paid $2.3 million during 2018 and ended Cumberland's payments of royalties and manufacturing fees to GEL. The Company has now assumed responsibility for the maintenance of the Product's FDA approval and for the oversight of the Product's manufacturing and packaging.

This agreement follows the November 2015 agreement between Cumberland and GEL to assume the remaining commercial rights to Omeclamox-Pak for the United States. The Company had previously signed an agreement with Pernix Therapeutics ("Pernix") to jointly commercialize the product in the United States in October 2013. As part of the November 2015 GEL Agreement, Cumberland and Pernix terminated their arrangements.

The $4.0 million upfront payment that the Company paid in October 2013 to Pernix along with the payments made to GEL during 2018 are included in product and license rights and are being amortized over the remaining expected useful life of the acquired asset. The Company evaluated the remaining expected useful life and maintained the existing estimated life of the product, June 2032. Omeclamox-Pak contributed $0.6 million, $1.8 million, and $2.5 million in net revenues during 2018, 2017, and 2016, respectively.

Ethyol

During May 2016, the Company announced an agreement with Clinigen Group Plc ("Clinigen") in which Cumberland acquired the exclusive rights to commercialize Ethyol in the United States. Ethyol is a FDA approved cytoprotective drug indicated as an adjuvant therapy to reduce the incidence of xerostomia (dry mouth) as a side-effect in patients undergoing post-operative radiation treatment for head and neck cancer. It also reduces the cumulative renal toxicity associated with the repeated administration of cisplatin in patients with advanced ovarian cancer.

Under the terms of the agreement, Cumberland is responsible for all marketing, promotion, and distribution of the product in the United States. There were no upfront payments required under the agreement. Royalty payments ranging from 30% to 50% based on tiered levels of net sales are paid by Cumberland to Clinigen. The Company began generating revenue from the sale of Ethyol during the third quarter of 2016. Ethyol contributed $10.5 million, $10.8 million and $0.8 million in net revenues during 2018, 2017 and 2016, respectively.

RediTrex

In November 2016, the Company announced an Agreement to acquire the exclusive U.S. rights to Nordic Group B.V.'s ("Nordic") injectable methotrexate product line. The products are designed for the treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, severe psoriatic arthritis, and severe disabling psoriasis. The product line is approved for patient use in various European countries and Cumberland is in the process of registering and commercialize the products in the United States.

Under the terms of the Agreement, Cumberland is responsible for the products' FDA submission and registration. The regulatory submission are based on the dossier provided by Nordic. As consideration for the license, Cumberland paid a deposit of $100,000 and recorded an initial liability of $900,000 provided through 180,000 unvested restricted shares of Cumberland stock, valued on November 15, 2016, that will fully vest upon the FDA approval of the first Nordic product. Cumberland will also provide Nordic a series of payments tied to the products' FDA approval, launch and achievement of certain sales milestones. Nordic will be responsible for manufacturing and supply of the products. The 180,000 shares of unvested restricted Cumberland stock was reflected in other current liabilities in the consolidated balance sheet and were valued at $1.1 million and $1.3 million at December 31, 2018 and 2017, respectively.

Totect

During January 2017, the Company announced an agreement with Clinigen in which Cumberland acquired the exclusive rights to commercialize Totect in the United States. Totect is an FDA-approved hospital based emergency oncology intervention drug, indicated to treat the toxic effects of anthracycline chemotherapy. It treats anthracycline extravasation that occurs when the injected medication escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications.

The Company launched Totect during a national shortage of dexrazoxane, resulting in strong initial demand for the product. It's our second oncology support product and the second product licensed to us through our Strategic Alliance with Clinigen.

Under the terms of the agreement, Cumberland is responsible for all marketing, promotion, and distribution of the product in the United States. There are no upfront payments required under the agreement. Royalty payments ranging from 30% to 50% based on tiered levels of net sales are paid by Cumberland to Clinigen. The Company began generating revenue from the sale of Totect during the third quarter of 2017. Totect contributed approximately $0.9 million and $4.0 million in net revenue during 2018. and 2017, respectively.

Vibativ

During November 2018, the Company closed on an agreement with Theravance Biopharma ("Theravance") to acquire the global responsibility for Vibativ including the marketing, distribution, manufacturing and regulatory activities associated with the brand. 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. Cumberland acquired Vibativ to further add to its product offerings, increase its net revenue and positively contribute to the Company's operating results. Cumberland is evaluating the tax deductibility of the goodwill acquired in the acquisition.

Cumberland has accounted for the transaction as a business combination in accordance with ASC 805 and the product sales are included in the results of operations subsequent to the acquisition date. The Company paid an upfront payment of $20.0 million with a $5.0 million cash payment due in early 2019. In addition, Cumberland has agreed to pay a royalty of up to 20% on future net sales of the product. The future royalty payments are required to be recognized at their acquisition-date fair value as part of the contingent consideration transferred in the business combination.

The following table summarizes the initial payments and consideration for the business combination:

Consideration:		
Cash paid at closing	$	20,000,000
Cash payment during early 2019		5,000,000
Fair value of contingent consideration - net sales royalty		9,034,000
Total consideration	$	34,034,000

The contingent consideration liability represents the future net sales royalty payments discussed above. Cumberland prepared the valuations of the contingent consideration liability and the intangible assets utilizing significant unobservable inputs. As a result, the valuations are classified as Level 3 fair value measurements. The Company will continue to evaluate the assets acquired and liabilities assumed during the measurement period. Vibativ contributed $5.1 million in net revenues during 2018. The pro-forma effects of the acquisition on the consolidated financial statements were not deemed meaningful for disclosure purposes.

The following table presents the changes in the Company's Level 3 contingent consideration liability that is measured at fair value on a recurring basis. The current and long-term portions of this liability are disclosed in Note 8. The contingent consideration earned and accrued in operating expenses is paid to the seller quarterly.

		Contingent consideration liability
Balance at November 12, 2018	$	9,034,000
Change in fair value of contingent consideration included in operating expenses		(40,000)
Contingent consideration earned and accrued in operating expenses		508,000
Balance at December 31, 2018	$	9,502,000

The following table summarizes the preliminary allocation of the fair values of the assets acquired as of the acquisition date for Vibativ:

Finished goods inventory	$	6,624,000
Work in process - unlabeled vials		3,970,000
Work in process - validation vials		1,827,000
Raw materials		9,129,000
Total inventory	$	21,550,000
Intellectual property amortizable intangible assets	$	11,700,000
Goodwill		784,000
Total intangibles and goodwill	$	12,484,000
Total assets acquired	$	34,034,000

(4) Revenues

Product Revenues

The Company's net product revenues consisted of the following for the years ended December 31:

	2018	2017	2016
Products:			
Acetadote	$ 4,284,111	$ 6,576,720	$ 7,214,341
Omeclamox-Pak	623,297	1,761,868	2,536,027
Kristalose	12,055,625	11,455,805	15,898,760
Vaprisol	1,763,874	1,576,222	1,857,838
Caldolor	5,001,997	4,178,443	4,132,833
Ethyol	10,545,906	10,835,038	838,386
Totect	850,965	3,992,467	—
Vibativ	5,075,057	—	—
Total net product revenues	$ 40,200,832	$ 40,376,563	$ 32,478,185

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 $3.1 million, $4.6 million and $4.8 million during 2018, 2017 and 2016, respectively.

The allowances in accounts receivable for chargebacks, cash discounts and damaged goods were $0.9 million at December 31, 2018 and $0.5 million at December 31, 2017, and the accruals for rebates, product returns and certain administrative and service fees included in other current liabilities were $5.6 million and $4.7 million, at December 31, 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 payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company will recognize revenue for these achievements once it is probable that these consideration amounts are no longer constrained. The Company is also entitled to receive royalties on future sales of the products under the agreements. The international agreements provide for $1.5 million in non-refundable up-front payments, milestone payments of up to $2.4 million of milestone payments related to regulatory approvals and up to $4.6 million in payments related to product sales. As of December 31, 2018, the Company has recognized a cumulative $1.5 million in upfront payments as other revenue and has recognized $0.1 million in revenue related to the milestone payments associated with these international agreements.

Other revenues during 2018, 2017 and 2016 also includes revenue generated by CET through grant funding from federal Small Business grant programs, and lease income generated by CET's Life Sciences Center and contract services. The Life Sciences Center is a research center that provides scientists with access to flexible lab space and other resources to develop biomedical products. Grant revenue from SBIR/STTR programs totaled approximately $0.1 million, $0.2 million, and $0.1 million for the years ending December 31, 2018, 2017 and 2016, respectively.

(5) Inventories

The Company's net inventories consisted of the following as of December 31:

	2018	2017
Raw materials and work in process	$ 18,378,450	$ 3,156,002
Consigned inventory	937,006	249,964
Finished goods, net of reserve	8,511,887	3,331,882
Total inventories	27,827,343	6,737,848
less non-current inventories	(15,749,000)	—
Total inventories classified as current	$ 12,078,343	$ 6,737,848

The Company continually evaluates inventories for potential losses due to expired, short-dated or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value. At December 31, 2018 and 2017, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses of approximately $0.3 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 packagers. 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 December 31, 2018 and 2017. Consigned inventory represents Authorized Generic inventory stored with Perrigo until shipment. As part of the Vibativ acquisition, Cumberland acquired API and work in process inventories that are classified as non-current and included in the raw materials and work in process inventory at December 31, 2018. Non-current inventories also include $0.8 million in Vibativ finished goods.

(6) Property and Equipment

Property and equipment consisted of the following at December 31:

	Range of useful lives	2018	2017
Computer equipment	3 – 5 years	$ 1,148,140	$ 1,074,172
Office equipment	3 – 15 years	809,153	457,945
Furniture and fixtures	5 – 15 years	639,267	633,577
Leasehold improvements	3 – 15 years, or remaining lease term	1,299,363	1,274,660
Total property and equipment, gross		3,895,923	3,440,354
Less: accumulated depreciation and amortization		(3,124,710)	(2,911,472)
Total property and equipment, net		$ 771,213	$ 528,882

Depreciation expense, including amortization expense related to leasehold improvements, is included in general and administrative expense in the consolidated statements of operations. Depreciation expense was as follows for the years ended December 31:

	2017	2016	2015
Depreciation expense	$ 213,237	$ 211,532	$ 202,868

(7) Intangible Assets and Goodwill

Intangible assets and Goodwill consisted of the following at December 31:

	2018	2017
Product and license rights	$ 36,573,941	$ 21,879,981
Less: accumulated amortization	(8,405,188)	(6,564,007)
Total product and license rights	28,168,753	15,315,974
Patents	9,428,266	9,177,647
Less: accumulated amortization	(4,087,273)	(3,158,990)
Total patents	5,340,993	6,018,657
Trademarks	154,373	118,934
Less: accumulated amortization	(9,020)	(9,020)
Total trademarks	145,353	109,914
Total intangible assets	$ 33,655,099	$ 21,444,545
Goodwill	$ 784,000	$ —

During 2013, the Company entered into an agreement with Pernix to distribute and promote the branded prescription product Omeclamox-Pak. The $4.0 million upfront payment the Company paid to Pernix during October 2013 and the $2.3 million payments made to GEL during 2018 (discussed more fully in Note 3) are included in product and license rights and are being amortized through June 2032, the remaining expected useful life of the acquired asset.

During 2014, the Company acquired the rights of the branded prescription product Vaprisol from Astellas. The intangible asset value is $3.0 million and is included in product and license rights. The asset is being amortized through February 2022, the remaining expected useful life of the acquired asset, which coincides with the life of the primary intellectual property asset.

In November 2016, the Company acquired the U.S. rights to Nordic Group B.V.'s injectable methotrexate product line. The agreement requires the Company to make future milestone payments over a fifteen-year period from the effective grant of the Regulatory Approval of the Methotrexate Pre-Filled Syringe Product in the U.S. The payments are being treated as consideration for the assets acquired and are being capitalized and will be amortized over the expected useful life of the acquired asset, once approval is granted. During 2017, the Company paid a deposit of $100,000 as well as recorded a liability provided through 180,000 unvested restricted shares of Cumberland stock, that will fully vest upon the FDA approval of the first Nordic product. As of December 31, 2018, the 180,000 shares of unvested restricted Cumberland stock are valued at $1.1 million.

As discussed in Note 3, during November 2018, the Company acquired Vibativ from Theravance. This resulted in amortizable intangible assets related to the product rights of $11.7 million and goodwill of $0.8 million. The intangible assets are being amortized through November 2028, the expected useful life of the acquired asset.

During 2018 and 2017, the Company recorded an additional $0.4 million and $0.4 million, respectively, in intangible assets for patents, trademarks and capitalized patent costs, including amounts incurred in the protection of the Company's intellectual property. These costs will be amortized over the remaining expected useful life of the associated patents.

Amortization expense related to product and license rights, trademarks and patents were as follows for the years ended December 31:

	2018	2017	2016
Amortization expense	$ 2,769,466	$ 2,436,222	$ 2,194,039

The expected amortization expense for the Company's current balance of intangible assets are as follows:

Year ending December 31:	
2019	$ 3,658,612
2020	3,737,638
2021	3,737,638
2022	3,426,180
2023 and thereafter	19,095,031
	$ 33,655,099

(8) Other Current and Other Long-term Liabilities

Other current liabilities consisted of the following at December 31:

Other current liabilities	2018	2017
Rebates, product returns, administrative fees and service fees	$ 5,635,972	$ 4,683,694
Employee wages and benefits	1,263,426	1,032,652
Stock payable	1,085,400	1,324,800
Current portion of accrued contingent consideration	2,290,000	—
Deferred acquisition liability	5,000,000	—
Accrued inventory purchases	434,405	1,055,220
Other	1,001,724	618,448
Total other current liabilities	$ 16,710,927	$ 8,714,814

Other long-term liabilities	2018	2017
Noncurrent portion of accrued contingent consideration	$ 7,212,000	$ —
Deferred compensation	1,588,123	1,599,960
Other	519,020	216,008
Total other long-term liabilities	$ 9,319,143	$ 1,815,968

(9) Debt

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 $20.0 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 $12.0 million with the ability to increase the principal amount available for borrowing up to $20.0 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 $20.0 million in borrowings under the Pinnacle Agreement at December 31, 2018 and $9.8 million at December 31, 2017. As of December 31, 2018, the Company had used all of its available borrowing under its revolving line of credit.

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 4.3% at December 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 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 achieved compliance with the financial covenant as of December 31, 2018 through the utilization of the covenant cure section of the Pinnacle Agreement.

(10) Shareholders' Equity

(a) Initial Public Offering

On August 10, 2009, the Company completed its initial public offering of 5,000,000 shares of common stock at a price of $17.00 per share, raising gross proceeds of $85.0 million. After deducting underwriting discounts of approximately $6.0 million and offering costs incurred of approximately $4.2 million, the net proceeds to the Company were approximately $74.8 million. Contemporaneously with the offering, each outstanding share of preferred stock was automatically converted into two million shares of common stock.

(b) Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock. The Board of Directors is authorized to divide these shares into classes or series, and to fix and determine the relative rights, preferences, qualifications and limitations of the shares of any class or series so established. At December 31, 2018 and 2017, there was no preferred stock outstanding.

(c) Common Stock

During 2018, 2017 and 2016, the Company issued 170,759 shares, 146,275 shares, and 223,987 shares of common stock, respectively, as a result of restricted shares vesting as well as other common share issuances. Cumberland issued 3,409 common shares under option exercise transactions during 2016. There were no option exercise transactions during 2018 and 2017. The payment of dividends is restricted by the Agreement with the Company's primary lender.

In January 2018, the Company's Form S-3 or Shelf Registration associated with the sale of up to $100 million in corporate securities was declared effective. The Shelf Registration 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.

(d) Warrants

In 2006, the Company signed a new line of credit agreement along with a term loan agreement with a financial institution. In conjunction with these agreements, the Company issued warrants to purchase up to 3,958 shares of common stock at $9.00 per share within 10 years of issuance. All of these warrants expired during 2017.

In connection with the amendment to the debt agreements in 2009, the Company issued warrants to purchase up to 7,500 shares of common stock at $17.00 per share that expire in July 2019. All of these warrants were outstanding and exercisable as of December 31, 2018 and 2017.

(e) 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 Act. In January 2016 and again during January 2019, the Company's Board of Directors established the current $10 million repurchase program to replace the prior authorizations. The Company repurchased 443,041 shares, 547,376 shares and 529,312 shares of common stock for approximately $2.9 million, $3.7 million, and $2.5 million during the years ended December 31, 2018, 2017 and 2016, respectively.

(f) Cumberland Emerging Technologies

In April 2014, the Company received approximately $1 million from Gloria for its participation in CET. As a result, Gloria received shares in CET and will have the first right to negotiate a license to CET developed products for the Chinese market. Prior to April 2014, Cumberland owned 85% of CET, with the balance of the enterprise being owned by Vanderbilt University and the Tennessee Technology Development Corporation. In connection with Gloria's investment in CET, the Company also provided an additional investment in CET. Cumberland contributed $1.0 million in cash and provided $2.4 million in loan forgiveness to CET in exchange for newly issued shares. Upon completion of the additional investment by Gloria and Cumberland in April 2014, the Company's ownership in CET is 80%. As CET is a consolidated subsidiary, the Company reports the operating results of CET and allocates the noncontrolling interests to the non-majority partners.

(g) Cumberland Foundation

In December 2017, the Company formed the Cumberland Pharma Foundation (the "Foundation") to serve as a vehicle to facilitate the ongoing philanthropic endeavors of Cumberland Pharmaceuticals Inc.

The Foundation was formed as a nonprofit corporation designed to qualify as a tax-exempt organization pursuant to Section 501(a) of the Internal Revenue Code. The Foundation's Board of Directors was initially comprised of Cumberland Pharmaceuticals executives who are responsible for overseeing the Foundation's ongoing activities including charitable contributions.

Cumberland provided a grant of 50,000 shares of the Company's common stock to the Foundation. The shares will address the ongoing financial needs of the organization, with most of the shares expected to be held for the opportunity to realize long term appreciation to support the Foundation's future. The Foundation will maintain separate financial statements and its ongoing operations will not impact the financial statements of Cumberland Pharmaceuticals. Initial annual grants by the Foundation are expected to equal approximately 5% of the Foundation's total holdings, which is consistent with the historic level of contributions made by Cumberland Pharmaceuticals.

(11) Earnings (Loss) Per Share

The following table shows the computation of the numerator and the denominator used to calculate diluted earnings (loss) per share for the years ended December 31:

	2018	2017	2016
Numerator:			
Net income (loss) attributable to common shareholders	$ (6,963,068)	$ (7,978,633)	$ (944,683)
Denominator:			
Weighted-average shares outstanding – basic	15,614,052	15,911,577	16,236,525
Dilutive effect of restricted stock and stock options	—	—	—
Weighted-average shares outstanding – diluted	15,614,052	15,911,577	16,236,525

The Company's anti-dilutive restricted shares and stock options outstanding were as follows for the years ended December 31:

	2018	2017	2016
Anti-dilutive shares and options	41,650	18,325	13,300

(12) Income Taxes

The components of the Company's net deferred tax assets at December 31 are as follows:

	2018	2017
Deferred Tax Assets		
Net operating loss and tax credits	$ 16,410,403	$ 15,295,547
Property and equipment and intangibles	236,318	232,667
Allowance for accounts receivable	251,068	129,180
Reserve for expired product	558,484	538,141
Inventory	193,150	173,885
Deferred charges	910,577	624,367
Cumulative compensation costs incurred on deductible equity awards	884,049	793,206
Total deferred tax assets	19,444,049	17,786,993
Deferred Tax Liabilities		
Intangible assets	(1,974,787)	(2,067,548)
Net deferred tax assets, before valuation allowance	17,469,262	15,719,445
Less: deferred tax asset valuation allowance	(17,382,052)	(15,632,235)
Net deferred tax assets	$ 87,210	$ 87,210

The following table summarizes the amount and year of expiration of the Company's federal and state net operating loss carryforwards as of December 31, 2018:

Years of expiration	Federal	State
2019	$ —	$ 238,047
2020 - 2028	—	38,886,662
2029	44,153,819	10,508,184
2030 - 2037	7,534,351	9,617,093
Indefinite Period	3,918,317	137,040
Total federal and state net operating loss carryforwards	$ 55,606,487	$ 59,387,026

Income tax (expense) benefit includes the following components for the years ended December 31:

	2018	2017	2016
Current:			
Federal	$ —	$ —	$ 867,041
State and other	(16,636)	(59,243)	83,463
Total current income tax (expense) benefit	(16,636)	(59,243)	950,504
Deferred:			
Federal	—	(3,682,772)	(537,965)
State	—	(432,874)	(81,615)
Total deferred income tax (expense) benefit	—	(4,115,646)	(619,580)
Total income tax (expense) benefit	$ (16,636)	$ (4,174,889)	$ 330,924

The Company's effective income tax rate for 2018, 2017 and 2016 reconciles with the federal statutory tax rate as follows:

	2018	2017	2016
Federal tax expense at statutory rate	21 %	34 %	34 %
State income tax expense (net of federal income tax benefit)	4 %	4 %	4 %
Permanent differences associated with general business credits	1 %	1 %	5 %
Change in valuation allowance	(25)%	(148)%	(15)%
Change in tax rate	— %	2 %	— %
Other permanent differences	(1)%	1 %	(2)%
Other	— %	(2)%	(1)%
Net income tax expense	— %	(108)%	25 %

In 2017, the Company determined that it was not more likely than not that its net deferred tax assets would be realized. As such, the Company's income tax provision for the year ended December 31, 2017 reflected a full valuation allowance against net deferred tax assets with the exception of the deferred tax asset for alternative minimum tax ("AMT") credit carryforwards discussed further below. The Company's position is unchanged as of December 31, 2018.

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.

In connection with our analysis of the impact of the Tax Act, we recorded a net tax benefit of $0.1 million in the period ended December 31, 2017. This net tax benefit consisted 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.

Federal tax years that remain open to examination are 2012 through 2017. Due to a 2009 net operating loss carryback, federal tax years 2006 through 2008 remain open to the extent of net operating losses utilized in those years. During 2012, the 2009 federal tax return was examined by the Internal Revenue Service with no significant findings or adjustments. State tax years that remain open to examination are 2011 to 2017. The Company has no unrecognized tax benefits in 2018, 2017 and 2016.

(13) Stock-Based Compensation Plans

The Company has grants outstanding under three equity compensation plans, with two of the plans available for future grants of equity compensation awards to employees, consultants and directors. All of the equity plans were approved by shareholders. The 2007 Long-Term Incentive Compensation Plan (the 2007 Plan) and the 2007 Directors' Incentive Plan (the "Directors' Plan") superseded the 1999 Stock Option Plan. The 2007 Plan and the Directors' Plan provide for the issuance of stock options, stock appreciation rights and restricted stock. Vesting is determined on a grant-by-grant basis in accordance with the terms of the plans and the related grant agreements. The Company has reserved 2.4 million shares of common stock for issuance under the 2007 Plan and 250,000 shares for issuance under the Directors' Plan.

The exercise price of stock options is generally 100% of the fair market value of the underlying common stock on the grant date. The maximum contractual term of stock options is ten years from the date of grant, except for incentive stock options granted to 10% shareholders, which is five years.

During 2011, the Company began issuing shares of restricted stock with no exercise price to employees and directors. Restricted stock issued to employees generally cliff-vests on the fourth anniversary of the date of grant. Restricted stock issued to directors vests on the one year anniversary of the date of grant.

Stock compensation expense is presented as a component of general and administrative expense in the consolidated statements of operations. Stock compensation expense consisted of the following for the years ended December 31:

	2018	2017	2016
Share-based compensation - employees	$ 1,244,606	$ 1,032,094	$ 833,027
Share-based compensation - nonemployees	120,092	82,969	19,075
Share-based compensation - foundation contribution	$ —	$ 372,500	$ —
Total share-based compensation	$ 1,364,698	$ 1,487,563	$ 852,102

At December 31, 2018, there was approximately $2.4 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted-average period of 2.6 years. This amount relates primarily to unrecognized compensation cost for employee restricted stock awards.

Stock Options

Stock option activity for 2018 and 2017 was as follows:

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding, December 31, 2016	5,800	$ 13.00	1.9	$ —
Options granted	—	—		
Options exercised	—	—		
Options forfeited or expired	—	—		
Outstanding, December 31, 2017	5,800	13.00	0.9	—
Options granted	—	—		
Options exercised	—	—		
Options forfeited or expired	—	—		
Outstanding, December 31, 2018	5,800	13.00	0.1	—
Exercisable at December 31, 2018	5,800	$ 13.00	0.1	$ —

The Company did not grant any stock options during 2018, 2017 and 2016, and no options were exercised during 2018 and 2017. Information related to the stock option plans during 2018, 2017 and 2016 was as follows:

	2018	2017	2016
Intrinsic value of options exercised	$ —	$ —	$ —
Weighted-average fair value of options exercised	$ —	$ —	$ —

Restricted Stock Awards

Restricted stock activity was as follows:

	Number of shares	Weighted-average grant-date fair value
Nonvested, December 31, 2016	703,295	$ 5.13
Shares granted	238,550	6.48
Shares vested	(146,275)	4.74
Shares forfeited	(27,725)	5.34
Nonvested, December 31, 2017	767,845	5.61
Shares granted	261,680	6.66
Shares vested	(170,759)	4.79
Shares forfeited	(25,025)	6.19
Nonvested, December 31, 2018	833,741	$ 6.09

The fair value of restricted stock granted was based on the closing market price of the Company's common stock on the date of grant. The restricted stock grants are included in the diluted weighted shares outstanding computation until they cliff-vest. Once vested they are included in the basic weighted shares outstanding computation.

(14) Employee Benefit Plans

The Company sponsors an employee benefit plan that was established on January 1, 2006, the Cumberland Pharmaceuticals 401(k) Plan (the Plan), under Section 401(k) of the Internal Revenue Code of 1986, as amended, for the benefit of all employees over the age of 21, having been employed by the Company for at least six months. The Plan provides that participants may contribute up to the maximum amount of their compensation as set forth by the Internal Revenue Service each year. Employee contributions are invested in various investment funds based upon elections made by the employees. During 2018, 2017 and 2016, the Company contributed approximately $50,000 in each year to the Plan as an employer match of participant contributions.

In 2012 and 2013, the Company established non-qualified unfunded deferred compensation plans that allow participants to defer receipt of a portion of their compensation. The liability under the plans, reflected in other long term liabilities in the consolidated balance sheet, was $1.6 million and as of December 31, 2018 and 2017. The Company had assets consisting of company-owned life insurance contracts generally designated to pay benefits of the deferred compensation plans reflected in other assets in the consolidated balance sheet of $2.3 million as of December 31, 2018 and 2017, respectively.

(15) Leases

The Company is obligated under long-term real estate leases for corporate office space that was extended during the third quarter of 2015. Prior to this extension, the lease would have expired in October 2016, the lease is now set to expire in October 2022. In addition, the research lab space at CET, under an agreement amended in July 2012, is leased through April 2023, with an option to extend the lease through April 2028. The Company also subleases a portion of the space under these leases.

Rent expense is recognized over the expected term of the lease, including renewal option periods, if applicable, on a straight-line basis. Rent expense and sublease income were as follows for the years ended December 31:

	2018	2017	2016
Rent expense	$ 1,136,610	$ 1,074,437	$ 1,150,614
Sublease income	$ 662,358	$ 573,494	$ 646,235

Cumulative future minimum sublease income under noncancelable operating subleases totals approximately $0.3 million and will be paid through the leases ending in February 2019, March 2019, and October 2022. Future minimum lease payments under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are as follows:

Year ending December 31:	
2019	$ 959,902
2020	980,720
2021	1,001,603
2022	871,969
2023	44,508
2024 and thereafter	—
Total future minimum lease payments	$ 3,858,702

(16) Fair Value of Financial Instruments

The Company owns marketable securities that are solely classified as trading securities as of December 31, 2018. There were no transfers of assets between levels within the fair value hierarchy. The following table summarizes the fair value of these marketable securities by level within the fair value hierarchy:

	December 31, 2018			December 31, 2017		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	$5,034,955	$ —	$ 5,034,955	$ —	$ —	$ —
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	—	2,504,551	2,504,551			
SBA loan pools - variable rate	—	—	—	—	935,081	935,081
Short-term cash investments	—	751,173	751,173	—	—	—
Total fair value of marketable securities	$5,034,955	$3,255,724	$ 8,290,679	$ —	$4,672,476	$ 4,672,476

The fair values of all other financial instruments outstanding as of December 31, 2018 and 2017 approximate their carrying values. There were no changes to the valuation techniques for the Level 2 marketable securities during 2018 or 2017.

(17) Market Concentrations

The Company currently focuses on the acquisition, development and commercialization of branded prescription products for the hospital acute care, gastroenterology, and oncology supportive care markets. The Company's principal financial instruments subject to potential concentration of credit risk are accounts receivable, which are unsecured, and cash equivalents. The Company's cash equivalents consist primarily of money market funds. Certain bank deposits may at times be in excess of the insurance limits provided by the Federal Deposit Insurance Corporation.

The Company's primary customers are wholesale pharmaceutical distributors in the U.S. Total revenues by customer for each customer representing 10% or more of consolidated revenues are summarized below for the years ended December 31:

	2018	2017	2016
Customer 1	26%	25%	22%
Customer 2	24%	22%	28%
Customer 3	25%	25%	29%
Customer 4	*%	*%	10%
Customer 5	11%	*%	*%

**: less than 10% of total*

The Company's accounts receivable, net of allowances, due from the customers representing 10% or more of consolidated revenue was 78% and 53% at December 31, 2018 and 2017, respectively.

(18) Manufacturing and Supply Agreements

The Company utilizes one or two primary suppliers to manufacture each of its products and product candidates. Although there are a limited number of manufacturers of pharmaceutical products, the Company believes it could utilize other suppliers to manufacture its prescription products on comparable terms. A change in suppliers, problems with its third-party manufacturing operations or related production capacity, or contract disputes with suppliers could cause a delay in manufacturing or shipment of finished goods and possible loss of sales, which could adversely affect operating results.

(19) Employment Agreements

The Company has entered into employment agreements with all its full-time employees. Each employment agreement provides for a salary for services performed, a potential annual bonus and, if applicable, a grant of restricted common shares pursuant to a restricted stock agreement.

(20) Commitments and Contingencies

Commitments

In connection with the acquisition of certain Kristalose assets during 2011, the Company was required to make quarterly payments based on a percentage of Kristalose net sales through November 2018. The payments are being treated as consideration for the assets acquired, and are being capitalized and amortized over the remaining expected useful life of the acquired asset, currently through 2026.

In connection with its licensing agreements for Caldolor, Ethyol, and Totect, the Company is required to pay royalties based on net sales over the life of the contracts. Royalty expense is recognized as a component of selling and marketing expense in the period that revenue is recognized.

In connection with the acquisition of Vibativ, the Company is required to pay royalties based on net sales of the product. At the purchase date, Cumberland recorded the fair value of this liability and will continue to evaluate the liability each period and the royalty expense is recognized as a component of selling and marketing expense in the period that the change in fair value is recognized.

Legal Matters

In April 2012, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,148,356 (the "356 Acetadote Patent") which is assigned to the Company. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

Following the issuance of the 356 Acetadote Patent, the Company received separate Paragraph IV certification notices from InnoPharma, Inc. ("InnoPharma"), Paddock Laboratories, LLC ("Paddock"), Mylan Institutional LLC ("Mylan"), Sagent Agila LLC ("Sagent") and Perrigo Company ("Perrigo") challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity. The Company responded by filing five separate infringement lawsuits, in the appropriate United States District Courts, to contest each of the challenges.

On November 12, 2012, the Company entered into a Settlement Agreement (the "Settlement Agreement") with Paddock and Perrigo to resolve the challenges and the pending litigation with those two companies. On November 1, 2013, the United States District Court filed opinions granting Sagent's and InnoPharma's motions to dismiss the Company's suits and the Company agreed not to file an appeal or motion to reconsider, thereby resolving the challenges and the pending litigation with those two companies.

Under the Settlement Agreement, Paddock and Perrigo admit that the 356 Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic version of Acetadote (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, Cumberland entered into a License and Supply Agreement with Paddock and Perrigo (the "License and Supply Agreement"). Under the terms of the License and Supply Agreement, if a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party has made such generic version available for purchase in commercial quantities in the United States, the Company supply's Perrigo with an Authorized Generic version of its Acetadote product.

On May 18, 2012, Cumberland also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that the Company evaluate the reduction or removal of EDTA from its original Acetadote formulation. On November 7, 2012, the FDA responded to the Citizen Petition denying its request and stating that ANDAs referencing Acetadote that contain EDTA may be accepted and approved provided they meet all applicable requirements. The Company believes this response contradicts the FDA's request to evaluate the reduction or removal of EDTA. On November 8, 2012, the Company learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. On November 3, 2012, Cumberland brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of our Citizen Petition and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law.

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

On January 7, 2013, Perrigo announced initial distribution of Cumberland's Authorized Generic acetylcysteine injection product.

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

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

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

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

On February18, 2014, the USPTO issued U.S. Patent number 8,653,061 (the "061 Acetadote Patent") which is assigned to the Company. The claims of the 061 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. Following its issuance, the 061 Acetadote Patent was listed in the FDA Orange Book. The 061 Acetadote Patent is scheduled to expire in August 2025.

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the "738 Acetadote Patent") which is assigned to Cumberland. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, the Company became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

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

On February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the “065 Acetadote Patent”) which is assigned to us. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in our favor in our lawsuit against Mylan for infringement of 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 May 3, 2016, the USPTO issued U.S. Patent number 9,327,028 (the “028 Acetadote Patent”) which is assigned to us. The claims of the 028 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 028 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in July 2031.

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.

On November 3, 2017, the Company became aware of a Paragraph IV certification notice from Exela Pharma Sciences, LLC challenging the 356, 445, 061, 738, and 028 Acetadote Patents on the basis of non-infringement.

The Company continues to consider its legal options and intends to continue to vigorously defend and protect its Acetadote product and related intellectual property rights.

The Company is a party to various other legal proceedings in the ordinary course of its business. In the opinion of management, the liability associated with these matters, other than the issue concerning the Company's Acetadote patents discussed above, will not have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

(21) Quarterly Financial Information (Unaudited)

The following table sets forth the unaudited operating results for each fiscal quarter of 2018 and 2017:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2018:					
Net revenues	$ 8,587,605	$ 10,163,724	$ 8,492,530	$ 13,497,906	$ 40,741,765
Operating income (loss)	(2,452,222)	(868,978)	(1,806,883)	(2,262,689)	(7,390,772)
Net income (loss) attributable to common shareholders	(2,379,239)	(720,688)	(1,643,044)	(2,220,097)	(6,963,068)
Earnings (loss) per share attributable to common shareholders [1]					
Basic	$ (0.15)	$ (0.05)	$ (0.11)	$ (0.14)	$ (0.45)
Diluted	$ (0.15)	$ (0.05)	$ (0.11)	$ (0.14)	$ (0.45)
2017:					
Net revenues	$ 9,636,755	$ 8,667,127	$ 11,196,961	$ 11,649,288	$ 41,150,131
Operating income (loss)	(657,802)	(1,680,871)	(839,349)	(903,326)	(4,081,348)
Net income (loss) attributable to common shareholders	(1,274,446)	(5,160,611)	(743,031)	(800,545)	(7,978,633)
Earnings (loss) per share attributable to common shareholders [1]					
Basic	$ (0.08)	$ (0.32)	$ (0.05)	$ (0.05)	$ (0.50)
Diluted	$ (0.08)	$ (0.32)	$ (0.05)	$ (0.05)	$ (0.50)

(1) Due to the nature of interim earnings per share calculations, the sum of the quarterly earnings (loss) per share amounts may not equal the reported earnings (loss) per share for the full year.

Schedule II

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Valuation and Qualifying Accounts

Years ended December 31, 2018, 2017 and 2016

Description	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
Allowance for uncollectible amounts, cash discounts, chargebacks, and credits issued for damaged products:					
For the years ended December 31:					
2016	$ 381,240	$ 3,755,804	$ —	$ (3,687,185) (1)	$ 449,859
2017	449,859	5,066,526	—	(5,008,851) (1)	507,534
2018	507,534	6,286,581	—	(5,800,775) (1)	993,340
Valuation allowance for deferred tax assets:					
For the years ended December 31:					
2016	$ 185,497	$ 203,003	$ —	$ —	$ 388,500
2017	388,500	(665,039) (2)	15,908,744	—	15,632,235
2018	15,632,235	1,749,817	—	—	17,382,052

(1) Composed of actual returns and credits for chargebacks and cash discounts.

(2) Amount includes $4,202,854 related to increase in the valuation allowance during the year, net of $4,867,893 related to the revaluation of deferred income tax balances for new rates under the Tax Act.

Officers and Directors

Board of Directors

A.J. Kazimi
Chairman
Cumberland Pharmaceuticals

Dr. Gordon R. Bernard
Executive Vice President for Research
Vanderbilt University Medical Center

Martin E. Cearnal
Executive Vice President and
Chief Commercial Officer
Cumberland Pharmaceuticals

Jonathan I. Griggs
Former Vice President Human Resources
Warner Lambert Corporation

Joey A. Jacobs
Former Chairman & CEO
Acadia Healthcare Co. Inc.

James R. Jones
Former Managing Partner
KPMG LLP-Nashville

Kenneth J. Krogulski
President and Chief Investment Officer
Berkshire Asset Management, LLC.

Caroline Young
Executive Director
NashvilleHealth

Former CEO
Nashville Health Care Council

Joseph C. Galante
Former Chairman
Sony Music Nashville

Former President
RCA Records

Management Team

A.J. Kazimi
Chief Executive Officer

Martin E. Cearnal
Executive Vice President, Marketing & Sales and
Chief Commercial Officer

Leo Pavliv, R.Ph.
Executive Vice President, Operations and
Chief Development Officer

James L. Herman
Senior Vice President, National Accounts and
Chief Compliance Officer

Michael P. Bonner
Senior Director, Finance & Accounting and
Chief Financial Officer

Todd M. Anthony
Executive Director, Organizational Development

Tan Cheow Choon
Senior Director, International Business

Barry L. Lee
Senior Director, Hospital Products

Cindy B. Patton
Senior Director, Field Sales & Marketing

Adam Haeberle, Ph.D.
Senior Director, Clinical & Regulatory Affairs

Todd Rice, M.D.
Director, Medical Affairs

Corporate Information

Stock Listing
NASDAQ Global Select
Market Ticker Symbol: CPIX

Annual Meeting
9:30 a.m. Central Time
Tuesday, April 23, 2019
Cumberland Headquarters
2525 West End, Suite 950
Nashville, Tennessee 37203

Independent Registered Public Accounting Firm
BDO USA, LLP
Bank of America Plaza
414 Union St., Suite 1800
Nashville, Tennessee 37219
(615) 248-2125

Transfer Agent and Registrar
Continental Stock Transfer
& Trust Company
1 State Street, 30th Floor
New York, New York 10004
(800) 509-5586
(212) 509-4000
cstmail@continentalstock.com

Forward Looking Statement
This annual report includes forward-looking statements regarding expected future results of the company. A variety of factors could cause actual results to differ materially from expected results. Please see the risk factors more fully described in our Annual Report on Form 10-K for the year ended December 31, 2018, which is filed with the U.S. Securities and Exchange Commission.

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