CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 13, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

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

For the fiscal year ended December 31, 2016

of

CUMBERLAND PHARMACEUTICALS INC.
A Tennessee Corporation
IRS Employer Identification No. 62-1765329
Commission file number 001-33637

2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
(615) 255-0068

Cumberland Pharmaceuticals Inc. Common Stock, no par value, shares are registered pursuant to Section 12(b) of the Act and are listed on the Nasdaq Global Select Market.

Cumberland Pharmaceuticals Inc. is not a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Cumberland Pharmaceuticals Inc. is required to file reports pursuant to Section 13 or Section 15(d) of the Act. Cumberland Pharmaceuticals Inc. (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Cumberland Pharmaceuticals Inc. has submitted electronically and posted on its corporate Web site every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months.

Disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Cumberland Pharmaceuticals Inc. is a non-accelerated filer as defined in Rule 12b-2 of the Exchange Act and is not a shell company.

The aggregate market value of common stock held by non-affiliates as of June 30, 2016 was $32,029,223. The number of shares of the registrant's Common Stock, no par value, outstanding as of March 6, 2017 was 16,013,407.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of Form 10-K is incorporated by reference from the registrant's Proxy Statement for its 2017 annual meeting of shareholders.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Index

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 and gastroenterology. These medical specialties are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs. We promote our approved products through our hospital and gastroenterology sales forces in the United States and are establishing a network of international partners to bring our products to patients in their countries.

Our portfolio of FDA approved brands includes:

- Acetadote® (acetylcysteine) Injection, for the treatment of acetaminophen poisoning;
- Caldolor® (ibuprofen) Injection, for the treatment of pain and fever; recently approved for use in pediatric patients;
- Kristalose® (lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- Omeclamox®-Pak, (omeprazole, clarithromycin, amoxicillin) for the treatment of Helicobacter pylori (H. pylori) infection and related duodenal ulcer disease;
- Vaprisol® (conivaptan) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- 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;

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) oral formulation, a Phase II candidate for the treatment of patients with portal hypertension ("PH") associated with liver disease;
- Methotrexate (methotrexate) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psoriasis; and
- Totect® (dexrazoxane hydrochloride) Injection for emergency oncology intervention, to reverse the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).

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 six FDA-approved products for sale in the United States. Through our international partners, we are working to bring our products to patients in countries outside the U.S. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to identify and progress promising, early-stage 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 stock and listing on the NASDAQ exchange. Our website address is www.cumberlandpharma.com. We make available through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all other press releases, filings and amendments to those reports as soon as reasonably practicable after their filing with the 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, including pediatric patients	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
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
Methotrexate	Arthritis and psoriasis	Pre-approval
Totect®	Toxic chemotherapy extravasation	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 the 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 2016.

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 during the middle portion of 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. By the end of 2016, Caldolor had been purchased by nearly 1,400 health care facilities in the U.S.

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. Information from these Phase IV studies, including an updated integrated safety database, was submitted to the FDA in early 2015 with a request for updated product labeling.

In late 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 also continue to pursue and evaluate potential improvements to the product's packaging. In March 2016, we began promotion of Caldolor for this pediatric indication. Also in 2016 we reached agreement with the FDA on the design of another Phase IV study evaluating the product in newborns and infants less than six month of age. We then started the implementation of that study. We also continue to pursue and evaluate potential improvements to the product's presentation and continue to support a series of investigator initiated studies with related publications.

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. During 2014, we also entered into a long-term supply agreement and new packaging agreements for the product. By entering into these transactions, we streamlined the supply chain for the product and are exploring opportunities to further develop the brand.

Using the preference data as a cornerstone of our marketing efforts, we have made significant gains following our repositioning of the brand in early 2014. The new marketing strategy includes an enhanced patient coupon program and expanded managed care coverage for the product. During 2015 and 2016, we worked to expand and improve the contract terms for the product's managed care coverage.

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 is now responsible for the supply chain, national accounts and all sales promotion of Omeclamox-Pak as part of the GEL agreement.

Our field sales force promotes Omeclamox-Pak to the gastroenterologist 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. During 2016, we established a series of contracts to provide managed care coverage for Omeclamox-Pak. Cumberland is also seeking a new co-promotion partner to support the product with primary care physicians who were previously covered by Pernix.

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.

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 a 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 August 2016, we began distribution of Ethyol for injection to wholesalers within the U.S. and in September 2016, we launched the national promotional support for the brand. Ethyol is Cumberland's first oncology product and complements our current hospital product line.

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, 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. Furthermore, the Type II patients receiving the higher dose levels of Hepatoren were more likely to experience increases in urine output, a signal of improved kidney function, compared to patients who received placebo.

In 2016, we completed the data analysis and reports from this study and began planning the next steps for this development program which are expected to include a Phase II efficacy trial. With favorable results from that study we would expect to seek orphan drug status for this unmet medical need.

Boxaban®

We have also completed the manufacturing of an oral formulation of ifetroban and the FDA has cleared an IND amendment for this product candidate. We have initiated clinical development under the brand name Boxaban, evaluating this candidate for patients suffering from aspirin-exacerbated respiratory disease (AERD). Also known as Samter’s Triad, AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin or nonsteroidal anti-inflammatory drugs. 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 a Phase II clinical study designed to gather initial safety and tolerability data on Boxaban in AERD patients. It was a multicenter study of sixteen patients with enrollment at several U.S. medical centers including the Scripps Clinic. Results indicate that no adverse events were experienced by patients receiving Boxaban when compared to those receiving placebo. Boxaban was well tolerated and safe for subjects with a history of AERD.

We have completed the data analysis and reports for this study in 2016, while also planning the next steps for this program which are expected to include a follow-on Phase II trial. With favorable results from that study, we would expect to explore orphan drug status to help address this unmet medical need.

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 rare autoimmune disorder that affects the skin and internal organs. It is characterized by vasculopathy, inflammation, and fibrosis. 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.

During 2016, the FDA cleared our investigational new drug application (IND) for a Phase II clinical program for Vasculan in patients with systemic sclerosis. We subsequently began the process of initiating the trial at medical centers across the U.S.

Portaban®

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

The FDA cleared our IND for a Phase II clinical study evaluating Portaban in patients with portal hypertension during 2016. We then began initiating that trial at several medical centers in the U.S.

Methotrexate

In November 2016, we announced that we had entered into an 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 the products, and following FDA approval, commercialize those methotrexate products in the U.S.

Totect®

In January 2017, we announced an exclusive agreement to commercialize the oncology support drug, Totect in the U.S. It is an FDA approved injectable formulation of dexrazoxane hydrochloride used to reverse the toxic effects of extravasation that can result from intravenous anthracycline chemotherapy for certain cancer patients. Extravasation occurs when an injected medicine escapes from the blood vessels and circulates into tissues in the body. This leakage can cause severe tissue damage and result in serious complications for the cancer patients involved. Administration of Totect can reverse such damage caused by anthracycline extravasation, without the requirement for additional surgeries and procedures. The product can enable patients to continue their anti-cancer treatment without significant interruption.

Totect is the second product we have licensed from Clinigen and under the terms of the agreements, we will be responsible for all marketing, promotion, and distribution of the product in the U.S. Clinigen is planning to register a new supplier of the product with the FDA and once that manufacturer is cleared, we expect to receive initial product supplies and launch the product.

OUR STRATEGY

Continue to build a high-performance sales organization to address our target markets

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

Further develop our existing products and develop new late stage product candidates

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

Expand our product portfolio by acquiring rights to additional products and late-stage product candidates

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

Expand our global presence through select international partnerships

We have established our own commercial capabilities, including a sales organization to cover the U.S. market for our products. We are building a network of select international partners to register our products and make them available to patients in their countries. We will continue to expand our network of international partners and continue to support

our partners' registration and commercialization efforts in their respective territories. The launch of Caldolor in Australia by CSL's Seqirus is an example of our international partnerships.

Develop a pipeline of early-stage products through Cumberland Emerging Technologies ("CET")

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

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, and Ethyol through our dedicated hospital sales team. This team targets key hospitals across the U.S. and is comprised of sales professionals with substantial experience in the hospital market. Outside 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 position within the acute care market and existing hospital sales team provided the rationale for adding Ethyol as our first oncology product and a complementary product to our current 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 focus on the gastroenterology market and our existing field sales infrastructure provided us with the rationale to add Omeclamox-Pak. Our field sales force now features both Kristalose and Omeclamox-Pak during most of their physician calls, expanding our presence in the gastroenterology market.

Our sales and marketing executives conduct ongoing market 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 targeted trade shows to promote broad awareness of our products. Our national accounts group is responsible for key large buyers and related marketing programs. This group supports sales and marketing efforts by maintaining 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.

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 the company, licensed product, territory and status:

International Partner	Product(s)	Territory	Status
Phebra Pty Ltd	Acetadote	Australia and New Zealand	Marketed
Teligent Pharmaceuticals, Inc.	Caldolor	Canada	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 the majority of South America	Development
Gloria Pharmaceuticals Co. Ltd.	Caldolor & Acetadote	China	Development
Laboratorios Valmorca, C.A.	Caldolor	Venezuela	Registration

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.

We are currently working to support our existing international partners and to identify other companies to represent our products in select additional territories.

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

Vasculan Program

In April 2016, we announced the addition of Vasculan to our pipeline. Cumberland has initiated the clinical development of Vasculan for the treatment of systemic sclerosis. The FDA has cleared our IND for a Phase II clinical program for Vasculan in patients with systemic sclerosis.

Caldolor Pediatric Study

We reached agreement with the FDA in 2016 on the design of a study to gather data on the use of Caldolor in infants and newborns less than six months of age. We then started planning for initiation of that trial. That development follows FDA approval for the use of Caldolor for pain and fever in children six months of age and older in late 2015.

Caldolor Pediatric Fever Manuscript

In February 2017, we announced the publication of a multicenter clinical study demonstrating that Caldolor Injection delivered significant fever reduction in hospitalized children. This study, which adds to the growing body of literature supporting Caldolor, evaluated the efficacy and safety of intravenous ibuprofen in pediatric patients, six months and older, with fever. This pivotal data published in the British BMC Pediatrics Journal supported the FDA approval of Caldolor for use in this pediatric patient population.

Vaprisol Dose Comparison Manuscript

In February 2016, we announced the publication of an open label multicenter study that supports Vaprisol injection. The study evaluated both 20 and 40 mg/day doses of conivaptan in hyponatremic patients and was conducted at 26 U.S. and 2 international centers. A total of 251 patients were enrolled in the study. The publication is available in the journal Drug Design, Development and Therapy.

Hepatoren Program

We are developing Hepatoren as a potential treatment for Hepatorenal Syndrome ("HRS") - a life threatening condition, with a high mortality rate and no approved pharmaceutical therapy in this country. We initiated a sixty-four patient Phase II study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study was designed to evaluate escalating dose levels of Hepatoren in HRS patients. Progression to higher dose levels is reviewed and approved by an independent safety committee. The study was stratified into Type I or Type II patients with HRS based upon the progression of their disease.

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

We have completed the data analysis and reports from this study and are planning the next steps for this development program which are expected to include a follow on Phase II efficacy trial.

Boxaban Program

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

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

We have completed the data analysis and reports for this study while also planning the next steps for this program which are expected to also include a follow on Phase II study.

Portaban Program

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 associated with liver disease. The FDA has cleared our IND for a Phase II clinical program for Portaban. Preclinical studies have shown ifetroban can reduce portal pressure, necrosis, inflammation, and fibrosis in multiple models of liver injury.

New Hospital Product Candidate

Cumberland was responsible for the formulation, development and FDA approval of both Acetadote and Caldolor. Our Medical Advisory Board has helped us identify additional opportunities that address unmet or poorly met medical needs. As a result, we have targeted a cholesterol reducing agent for use in the hospital setting. Cumberland has successfully designed, formulated and completed the preclinical studies for this product candidate. In October 2016, the FDA cleared the related IND and we initiated a Phase I study in healthy volunteers to determine the pharmacokinetic and safety profile for this new product candidate.

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, and Totect 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.

Clinigen Strategic Alliance

In September 2015, we announced a strategic alliance with Clinigen, an international firm headquartered in London. Clinigen is a specialty pharmaceutical and services company focused on providing medicines to patients with high unmet needs through registered, clinical trials and compassionate use supply. Under the terms of the alliance, Cumberland will commercialize select Clinigen products in the U.S. and Clinigen will support select Cumberland products in international markets where we do not have a distribution partner. The terms of each such product arrangement will be addressed through an additional agreement.

In May 2016, we announced an agreement with Clinigen under which we acquired exclusive rights to Ethyol® in the U.S. Under the terms of the agreement, we are responsible for all marketing, promotion, and distribution of the product in our territory. This is the first product to be licensed by us from Clinigen") under our strategic alliance.

In January 2017, we announced an exclusive agreement to acquire exclusive rights to Totect® in the U. S. This was the second product Clinigen has licensed to us under our strategic alliance. Under the terms of the agreement, we will be responsible for all marketing, promotion, and distribution of the product in this country.

Nordic Group B.V. 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.

CET Collaboration

Through CET, we collaborate with a select group of academic research institutions located in the mid-south region of the U.S. Our business development team is responsible for identifying appropriate CET product candidates and negotiating with our university partners to secure rights to these candidates. Although we believe that these collaborations may be important to our business in the future, they are not material to our business at this time.

CET currently has collaboration agreements with Universities to co-develop promising biomedical technologies, including: Vanderbilt University, the University of Tennessee and the University of Mississippi.

These agreements allow us to play an important role in fostering and shaping early-stage biomedical research to improve patient care and provide CET and Cumberland with access to promising pipeline candidates such as Hepatoren, Boxaban, Vasculan, and Portaban.

MANUFACTURING AND DISTRIBUTION

We partner with third parties for certain non-core, capital-intensive functions, including manufacturing and distribution. Our executives are experienced in these areas and manage these third-party relationships with a focus on quality assurance and timely delivery.

Manufacturing

Our key manufacturing relationships include:

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 2016 for both our international and domestic Caldolor markets.

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. We recently extended the relationship with the supplier for periods beyond the fourth quarter of 2017.

Kristalose®

- We have an agreement for the purchase of Kristalose API with an international supplier. This written agreement formalized and extended our existing relationship with this raw materials supplier. We also have manufacturing relationships with two Kristalose packagers. Under these agreements, we provide Kristalose API to these manufactures and they package the API (for both commercial sale and samples) into 10 gram and 20 gram finished product units for our purchase and distribution.

Omeclamox®-Pak

- Based on our agreement with GEL, effective in November 2015, Cumberland assumed supply chain responsibilities and now works directly with GEL for the manufacture, packaging and supply of Omeclamox-Pak commercial and sample units.

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 existing manufacturer who provided supplies of Vaprisol. That manufacturer continues to supply commercial inventory to Cumberland under this agreement.

Ethyol®

- As part of the Ethyol transaction, we were assigned a commercial supply agreement with the existing manufacturer used to prepare, package, and inspect the Ethyol product. The manufacturer continues to supply commercial inventory to Cumberland under this agreement.

Distribution

Like many other pharmaceutical companies, we engage a third party contractor with appropriate facilities and logistical expertise to support our distribution efforts. Since August 2002, Cardinal Health ("Cardinal") has exclusively handled U.S. product logistics efforts, including warehousing, shipping, customer billing and collections. We extended our distribution relationship with Cardinal during May 2013, when we entered into the First Amendment ("First Amendment") to the Exclusive Distribution Agreement under which we have operated since August 2010. The First Amendment primarily served to extend the term of the Agreement through June 30, 2016 and revised the fee schedule under the Agreement. Under the Amendment, we have also engaged Cardinal to assist with our physician sample orders based on the Prescription Drug Marketing Act of 1987 (the “PDMA”) for samples shipping. On June 30, 2016, the contract automatically renewed on a year-to-year basis and is now terminable by either party with ninety days' notice. Under the First Amendment and Agreement, Cardinal agrees to provide various services, including storage, distribution, returns, customer support, and system access support to us in connection with the distribution of our products under certain guidelines at established fees.

Our primary customers are wholesaler pharmaceutical distributors in the United States. Total gross revenue for our top four customers at December 31, 2016 total 89%.

TRADEMARKS AND PATENTS

We own all 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 various other 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 that receive our confidential data 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 encompasses the Acetadote formulation and includes 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 Acetadote product (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, we entered into a License and Supply Agreement with Paddock and Perrigo (the “License and Supply Agreement”). Under the terms of the License and Supply Agreement, once 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 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 its 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 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.

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.

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 is directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which expires in 2021. This U.S. patent 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, some of which have been allowed and some of which remain pending.

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 three 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 and inflammation 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 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 composition and methods of treating pain and/or fever in critically ill patients with intravenous ibuprofen. This Caldolor Patent 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 No. 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 expires in December 2019.

Ethyol®

We have an exclusive license to patent number 5,994,409 for Ethyol, for treating patient toxicities associated with the administration of chemotherapeutic agents. This Ethyol patent is FDA Orange Book listed with a term until December 9, 2017. We also have a license to several additional Ethyol patents associated with the subcutaneous administration of the product that are not yet Orange Book listed.

Totect®

We have an exclusive license to patent number 6,727,253 for Totect for 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 expires in March 2020.

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.

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 Ben Venue Laboratories, Inc., 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 marketed by Mallinckrodt plc;
- Exparel®, a bupivacaine delivery platform marketed by Pacira Pharmaceuticals, Inc.; and
- Dyloject, an injectable diclofenac product by Pfizer Inc. approved by the FDA during 2015.

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 marketed 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 marketed by Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc; and
- 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.

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 through three separate prescriptions. While there are several competitor products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the branded competing products, Omeclamox-Pak has the lowest pill burden, fewest days of therapy and the lowest cost. The prescription combination products, indicated for treatment of H. pylori, which we believe are our primary competitors are:

- PrevPac®, an oral product marketed by Takeda Pharmaceutical Company. There are also approved generic versions of PrevPac;
- Pylera®, an oral product marketed by Actavis Pharma, Inc. and Forest Laboratories, Inc.; and
- Helidac®, an oral product marketed 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 marketed 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. We launched the product in late 2016, and the authorized generic form of the product was withdrawn by Clinigen who markets branded Ethyol internationally.

GOVERNMENT REGULATION

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 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 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 clinical research organizations may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, 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, basic scientists work in the laboratory and with animals; second, a drug or biotechnology company develops a prototype drug. That company must seek and receive FDA approval, 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 a 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, animal efficacy approval, fast track applications, and priority review.

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 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 manufacture 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 V - effective October 1, 2012), the FDA has 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. If not, a Complete Response letter will be sent informing applicants of changes that 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. The General Accounting Office ("GAO") reported that standard NDAs showed a steadier increase with the percentage of first-cycle approval letters rising from 43% for FY 2000 applications to 69% for FY 2010 applications. The percentage of priority NDAs receiving an approval letter at the end of the first review cycle fluctuated from FY 2000 through FY 2010, ranging between 47% and 80% during this time. 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) (2) 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

20

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. 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.

Special protocol assessment process

The special protocol assessment, or SPA, process is designed to assess whether a planned protocol is adequate to meet scientific and regulatory requirements identified by the sponsor. Three types of protocols related to PDUFA products are eligible for this special protocol assessment under the PDUFA goals: (1) animal carcinogenicity protocols, (2) final product stability protocols, and (3) clinical protocols for phase III trials whose data will form the primary basis for an efficacy claim if the trials had been the subject of discussion at an end-of-phase 2/pre-phase 3 meeting with the review division, or in some cases, if the division agrees to such a review because the division is aware of the developmental context in which the protocol is being reviewed and the questions are being answered. The clinical protocols for phase III trials can relate to efficacy claims that will be part of an original NDA or BLA or that will be part of an efficacy supplement to an approved NDA or BLA.

New section 505(b)(4)(B) of the Modernization Act directs FDA to meet with sponsors, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a marketing application submitted under section 505(b) of the Act or section 351 of the Public Health Service Act (42 U.S.C. 262).3. Such marketing applications include NDAs, BLAs, and efficacy supplements to approved NDAs and BLAs. Under new sections 505(b)(4)(B) and (C) of the Act, if a sponsor makes a reasonable written request to meet with the FDA for the purpose of reaching agreement on the design and size of a clinical trial, the FDA will meet with the sponsor. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. An agreement may not be changed by the sponsor or FDA after the trial begins, except (1) with the written agreement of the sponsor and FDA, or (2) if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug" was identified after the testing began (section 505(b)(4)(C) of the Act). If a sponsor and the FDA meet regarding the design and size of a clinical trial under section 505(b)(4)(B) of the Act and the parties cannot agree that the trial design is adequate to meet the goals of the sponsor, the FDA will clearly state the reasons for the disagreement in a letter to the sponsor. However, the absence of an articulated disagreement on a particular issue should not be assumed to represent an agreement reached on that issue. Final determinations by the FDA with respect to a product candidate, including as to the scope of its “labeling”, are made after a complete review of the applicable NDA and are based on the entire data in the application.

On June 14, 2004, we submitted a request for SPA of our Caldolor Phase III clinical study. During a meeting with the FDA on September 29, 2004, the FDA confirmed that the efficacy data from our study of post-operative pain with a positive outcome was considered sufficient to support a 505(b)(2) application for the pain indication.

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 United States Food and Drug Administration (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 will be in compliance with all requirements by the November 2017 deadline.

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 Adverse Event Reporting System (AERS) 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, 2016, we had 82 full-time 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.

You should carefully consider the risk factors described below and throughout this report, which 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 six products: Acetadote, Caldolor, Kristalose, Vaprisol, Omeclamox-Pak, and Ethyol. 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.

Caldolor was approved by the FDA in June 2009, and we started commercializing Caldolor in the United States in September 2009. 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 we rely upon fails to produce 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 2016 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. We recently extended the relationship with the supplier for periods beyond the fourth quarter of 2017. 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: Pursuant to the November 2015 agreement with GEL, Cumberland assumed supply chain responsibilities and currently works directly with GEL to ensure availability of Omeclamox-Pak. 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 were assigned a commercial supply agreement with the manufacturer used to prepare, package, and inspect Ethyol. The manufacturer continues to supply commercial inventory to Cumberland under this agreement. If the manufacturer of Ethyol 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.

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.

Governmental and private healthcare payors emphasize substitution of branded pharmaceuticals with less expensive generic equivalents. An increase in the sales of generic pharmaceutical products could result in a decrease in revenues of our branded pharmaceuticals.

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 to Caldolor, Acetadote, Omeclamox-Pak, Vaprisol, Kristalose, Ethyol, Totect, our four Ifetroban product candidates and the methotrexate 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 one marketed product to our portfolio of brands: Ethyol in the third quarter of 2016. We successfully launched our promotional efforts to support the brand during 2016. If we are unable to continue to build on our initial sales of this brand 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, Totect and methotrexate 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, Totect and methotrexate 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 (oral ifetroban) is for the treatment of portal hypertension associated with liver disease, Totect (dexrazoxane hydrochloride) reverses the toxic effects of anthracycline chemotherapy in the case of extravasation and methotrexate 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 hospital acute care and gastroenterology since our sales forces specialize in these 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, there have been judicial and Congressional challenges to certain aspects of the PPACA. Additionally, recent elections results could lead to a repeal of all or portions of the PPACA, and Congress could be asked to replace the current legislation with new legislation. 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, which would materially and adversely impact 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 the greatest 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 to, 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, 2016, we had 82 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.

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.

Pharmaceutical products must be distributed, sampled and promoted in accordance with FDA requirements. We must train our employees on proper regulatory compliance, including, but not limited to, “fair balance” promotion of our products and anti-kickback laws. The FDA also regulates the advertising of prescription drugs. The FDA has the authority to request post-approval commitments that can be time-consuming and expensive.

Under the FDCA, the federal government has extensive enforcement powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to, the authority to initiate court action to seize unapproved or non-complying products, to enjoin non-complying activities, to halt manufacturing operations that are not in compliance with GMP, and to seek civil monetary and criminal penalties. The initiation of any of these enforcement activities, including the restriction or prohibition on sales of our products, could materially and adversely affect our business, financial condition and results of operations.

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 personnel of some companies, 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 redundant 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.

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.

Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. As discussed in Part I, Item 1, Business - Trademarks, Patents and Proprietary Rights, of this Form 10-K, during April 2012, the United States Patent and Trademark Office (the “USPTO”) issued U.S. Patent number 8,148,356 (the “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

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

notice from Perrigo. On August 9, 2012, we filed a lawsuit for infringement of the 356 Acetadote Patent against Perrigo in the United States District Court for the Northern District of Illinois, Eastern Division.

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

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

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

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

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

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

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

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

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.

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 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.

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.

We have U.S. patents and related international patents which include composition of matter claims that encompass the Caldolor formulation, including methods of treating pain using intravenous ibuprofen and claims directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor, ibuprofen, is in the public domain, and a competitor could try to develop, test and seek FDA approval for a sufficiently distinct formulation for another ibuprofen product that competes with Caldolor. The U.S. patents are listed in the FDA Orange Book, with one expiring in November 2021, five others expiring in September 2029 and one other expiring in September 2030. On November 20, 2015, the FDA awarded three years of marketing

exclusivity to Caldolor in connection with the approval of the Caldolor supplemental new drug application. Such exclusivity extends through November 20, 2018.

We have 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 No. 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 expires in December 2019.

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, like Ethyol, increasing market share in Caldolor, Kristalose, Vaprisol and Omeclamox-Pak and striving to maintain market share in our Acetadote product, 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 (such as for inventory expiration);
- 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, 2016, intangible assets relating to products represented approximately 24% 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 areas including, but not limited to, principles for revenue recognition and lease accounting.

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, 2017, the closing price of our common stock since our initial public offering has ranged from a low of $4.03 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 are experiencing increased costs and regulatory risk as a result of operating as a public company, and our management will be required to devote additional time to new compliance initiatives.

We have and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote additional time to new 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 increase our legal and financial compliance costs and will 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.

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,” “esti “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, 2016, 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. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us through contracts with third-party organizations.

Under an agreement amended in July 2012 and expiring in April 2018, CET leases approximately14,200 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 -Trademarks and Patents, of this Form 10-K, which is incorporated by reference herein.

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 6, 2017, we had 100 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 6, 2017 was $5.58 per share. The following table sets forth the high and low trading sales prices for our common stock as reported on the Nasdaq Global Select Market for the full quarterly periods during 2016 and 2015:

	High	Low
Fiscal year ended December 31, 2016:		
First quarter	$5.38	$4.20
Second quarter	4.89	4.27
Third quarter	5.14	4.40
Fourth quarter	6.00	4.60
Fiscal year ended December 31, 2015:		
First quarter	$7.09	$5.62
Second quarter	7.78	6.06
Third quarter	7.52	5.50
Fourth quarter	6.50	5.03

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. The payment of dividends by us on our common stock is limited by our loan agreement. 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, 2011 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, 2011, and that all dividends were reinvested.

Purchases of Equity Securities

On May 13, 2010, we announced a share repurchase program to purchase up to $10 million of our common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012, January 2013, January 2015 and January 2016, our Board of Directors replaced the prior authorizations with $10 million authorizations for repurchases of our outstanding common stock. We repurchased 529,312 shares, 829,003 shares, and 881,810 shares of common stock for approximately $2.5 million, $5.3 million, and $4.3 million during the years ended December 31, 2016, 2015 and 2014, respectively.

The following table summarizes the activity, by month, during the fourth quarter of 2016:

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	14,027	$4.89	14,027	$8,113,276
November	72,431 (1)	5.20	72,431	7,736,568
December	35,397	5.54	35,397	7,540,565
Total	121,855			

(1) Of this amount, 27,336 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:	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Net revenues	$33,026	$33,519	$36,902	$32,027	$48,851
Costs and expenses	34,459	32,407	33,343	35,829	40,033
Operating income (loss)	(1,433)	1,112	3,559	(3,801)	8,818
Net income (loss) attributable to common shareholders	(945)	731	2,424	(2,105)	5,842
Earnings (loss) per share – basic	$(0.06)	$0.04	$0.14	$(0.11)	$0.30
Earnings (loss) per share – diluted	$(0.06)	$0.04	$0.14	$(0.11)	$0.30

	As of December 31,				
Balance sheet data:	2016	2015	2014	2013	2012
	(in thousands)				
Cash and cash equivalents	$34,510	$38,203	$39,866	$40,869	$54,349
Marketable securities	15,622	14,564	14,841	14,020	16,686
Working capital	50,753	52,172	57,065	61,134	79,177
Total assets	93,405	91,919	95,405	87,614	98,594
Total long-term debt and other long-term obligations (including current portion)	5,491	2,687	1,032	869	5,042
Retained earnings	18,605	19,550	18,818	16,395	18,499
Total equity	73,121	76,820	80,753	79,292	85,566

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 and gastroenterology. These markets are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs.

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; recently approved for use in pediatric patients, Kristalose® (lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation, Omeclamox®-Pak, (omeprazole, clarithromycin, amoxicillin) for the treatment of Helicobacter pylori (H. pylori) infection and related duodenal ulcer disease, Vaprisol® (conivaptan) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia, and 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.

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 form of autoimmune disease ("SSc"), Portaban™ (ifetroban) oral formulation, a Phase II candidate for the treatment of patients with portal hypertension ("PH") associated with liver disease, Methotrexate (methotrexate) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psorias, and Totect® (dexrazoxane hydrochloride) Injection for emergency oncology intervention, to reverse the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).

We promote our approved products through our hospital and field sales forces in the United States, which together comprised approximately 40 sales representatives and managers as of December 31, 2016.

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 2016 highlights and recent developments. For more information, please see Part I, Item I, Business, of this Form 10-K.

- Kristalose was our largest selling brand in 2016, and we continued to improve the product’s insurance coverage and contract terms with national managed care organizations.
- Caldolor continued as our fastest growing brand in 2016 with contributions from both our domestic and international customers.
- We also continued to maintain a significant market share for Acetadote through the combined sales of our branded and Authorized Generic products in 2016.
- We reached agreement with the FDA in 2016 on the design of a study to gather data on the use of Caldolor in infants and newborns less than six months of age. We then started planning for initiation of that trial. That development follows FDA approval for the use of Caldolor to reduce pain and fever in children six months of age and older in late 2015.
- In February 2016, we announced the publication of an open label multicenter study that supports Vaprisol injection. The study evaluated both 20 and 40 mg/day doses of conivaptan in hyponatremic patients and was conducted at 26 U.S. and 2 international centers. A total of 251 patients were enrolled in the study. The publication is available in the journal Drug Design, Development and Therapy.
- We completed initial Phase II studies for our Hepatoren and Boxaban product candidates. The Company is developing Boxaban for the treatment of Aspirin-Exacerbated Respiratory Disease ("AERD"). AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin.
- In April 2016, we announced the addition of Vasculan to our pipeline. Cumberland has initiated the clinical development of Vasculan for the treatment of systemic sclerosis. The FDA has cleared our IND for a Phase II clinical program for Vasculan in patients with systemic sclerosis.
- In May 2016, we announced our agreement to commercialize the oncology support drug, Ethyol, in the U.S. In August 2016, we began distributing Ethyol to wholesalers within the U.S. and in September 2016, we launched the national promotional support for the brand. Ethyol is Cumberland's first oncology product and complements our current hospital product line.
- In June 2016, Cumberland announced the addition of Caroline Young to its Board of Directors. Caroline is the prior President of the Nashville Health Care Council and founding Executive Director of the Tennessee Biotechnology Association. Caroline’s appointment to Cumberland’s Board was effective September 13, 2016.
- 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 associated with liver disease. The FDA has cleared our IND for a Phase II clinical program for Portaban. Preclinical studies have shown ifetroban can reduce portal pressure, necrosis, inflammation, and fibrosis in multiple models of liver injury.
- In October 2016, the FDA cleared the related IND and we initiated a Phase I study in healthy volunteers to determine the pharmacokinetic and safety profile for a new hospital product candidate.
- 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.
- In January 2017, we announced an exclusive agreement to acquire exclusive rights to Totect® in the U.S. This is the second product Clinigen has licensed to us under our strategic alliance. Under the terms of the agreement, we will be responsible for all marketing, promotion, and distribution of the product in this country.

- In January 2017, Cumberland announced the addition of Kenneth J. Krogulski, CFA to its Board of Directors. Kenneth is the President and Chief Executive Officer of Berkshire Asset Management LLC ("Berkshire"). He is also the Chief Investment Officer of Berkshire, a 30-year-old independent SEC registered investment advisory firm with over $1.5 billion under management. Kenneth's appointment to Cumberland's Board was effective January 18, 2017.
- 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.
- In February 2017, we announced the publication of a multicenter clinical study demonstrating that Caldolor Injection delivered significant fever reduction in hospitalized children. This study, which adds to the growing body of literature supporting Caldolor, evaluated the efficacy and safety of intravenous ibuprofen in pediatric patients, six months and older, with fever. This pivotal data published in the British BMC Pediatrics Journal supported the FDA approval of Caldolor for use in this pediatric patient population.

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, provision for income taxes and share-based payment.

Revenue Recognition

We recognize revenue in accordance with the SEC’s Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104 (together, SAB 101), and Topic 605-15 of the Accounting Standards Codification.

Our revenue is derived primarily from the product sales of Acetadote, Vaprisol, Caldolor, Omeclamox-Pak, Kristalose, and Ethyol. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our wholesalers for a particular product. Other revenue, which is a component of net revenues, includes upfront payments under licensing agreements along with grant and rental income. Other income was 1.7% percent of net revenues in 2016, 1.5% in 2015, and 0.6% in 2014.

Our net product revenue reflects the reduction of gross product revenue at the time of initial sales recognition for estimated accounts receivable allowances for chargebacks, cash discounts and damaged product as well as provisions for sales related accruals of rebates, product returns and administrative fees and fee for services. Our financial statements reflect accounts receivable allowances of $0.4 million at December 31, 2016 and 2015, for chargebacks, discounts and allowances for product damaged in shipment.

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

	2016	2015	2014
Balance, January 1	$6,776,023	$5,234,800	$2,437,140
Current provision	9,837,063	10,981,168	14,972,112
Actual product returns and credits issued	(12,562,057)	(9,439,945)	(12,174,452)
Balance, December 31	$4,051,029	$6,776,023	$5,234,800

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 and are established by management as 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 and accruals as well as payments and credits issued. Additionally, these allowances and accruals are established based on the following:

- The contractual terms with customers;
- Analysis of historical levels of discounts, returns, chargebacks and rebates;
- 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.

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 $4.1 million, $6.8 million and $5.2 million as of December 31, 2016, 2015 and 2014, respectively. Of these amounts, our estimated liability for fee for services represented $1.3 million, $1.1 million and $0.9 million, respectively, while our accrual for product returns totaled $2.0 million, $2.2 million and $2.1 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, 2016, 2015, and 2014. A change in our product return estimate of one percentage point would have impacted net sales by $0.4 million, $0.4 million and $0.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Fair Value of Marketable Securities

We invest in variable rate demand notes and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate mortgage-backed securities), 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. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security.

Inventories

We record amounts for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market 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, 2016 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 the income statement 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.

As of December 31, 2016, we have unrecognized federal net operating loss carryforwards associated with the exercise of nonqualified options of $44.1 million. In addition to these unrecognized federal net operating loss carryforwards, as of December 31, 2016, we have recognized federal Orphan Drug and Research and Development tax credits of $1.2 million that expire between 2021 and 2036. As of December 31, 2016, we have a valuation allowance recorded on Orphan Drug and Research and Development tax credits of $0.2 million.

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.

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

Intangible assets include product rights, license agreements and other identifiable intangible assets. We assess the impairment of 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, 2016 compared to year ended December 31, 2015

The following table presents the statements of operations for the years ended December 31, 2016 and 2015:

	Years ended December 31,		
	2016	2015	Change
Net revenues	$33,025,560	$33,519,051	$(493,491)
Costs and expenses:			
Cost of products sold	5,958,660	4,968,170	990,490
Selling and marketing	14,553,481	13,994,768	558,713
Research and development	3,190,700	3,847,651	(656,951)
General and administrative	8,561,811	7,607,588	954,223
Amortization	2,194,039	1,989,264	204,775
Total costs and expenses	34,458,691	32,407,441	2,051,250
Operating income (loss)	(1,433,131)	1,111,610	(2,544,741)
Interest income	204,661	209,183	(4,522)
Interest expense	(106,392)	(73,856)	(32,536)
Income (loss) before income taxes	(1,334,862)	1,246,937	(2,581,799)
Income tax (expense) benefit	330,924	(575,829)	906,753
Net income (loss)	$(1,003,938)	$671,108	$(1,675,046)

Net revenues. Net revenues for the year ended December 31, 2016 were approximately $33.0 million compared to $33.5 million for the year ended December 31, 2015, representing a decrease of $0.5 million or 1.5%. The following table summarizes net revenues by product for the years presented:

	Years ended December 31,		
	2016	2015	Change
Products:			
Acetadote	$7,214,341	$8,489,167	$(1,274,826)
Omeclamox-Pak	2,536,027	3,037,078	(501,051)
Kristalose	15,898,760	15,733,327	165,433
Vaprisol	1,857,838	2,641,484	(783,646)
Caldolor	4,132,833	3,112,128	1,020,705
Ethyol	838,386	—	838,386
Other	547,375	505,867	41,508
Total net product revenues	$33,025,560	$33,519,051	$(493,491)

Product revenue from Caldolor increased $1.0 million and Kristalose increased $0.2 million. Ethyol, our newest product, provided product revenue of $0.8 million. Acetadote revenue decreased $1.3 million, Vaprisol decreased $0.8 million, and Omeclamox decreased $0.5 million.

Caldolor product revenue experienced a $1.0 million improvement, which represents an increase of 32.8% during 2016 compared to 2015. Caldolor sales volumes and net revenue were positively impacted by the efforts of our sales force and marketing initiatives. Caldolor sales were also positively impacted by international contributions.

We began generating revenue from the sale of Ethyol during the third quarter of 2016, which resulted in Ethyol revenue of $0.8 million for 2016.

Kristalose revenue increased by $0.2 million or 1.1% over the prior year period. Since re-positioning Kristalose during the first quarter of 2014 we launched initiatives to enhance patient affordability and increase demand. During the year ended December 31, 2016, we also experienced improvements in product net revenue per unit as we incurred a lower level of rebates from managed care contracts.

Our branded Acetadote product net revenue decreased $1.5 million when compared to 2015 due to a shift in demand to our Authorized Generic product as well as generic competition. The reduced branded sales volume was partially offset by a $0.2 million increase in the Authorized Generic. For the year ended December 31, 2016, revenues from our Authorized Generic were $4.8 million, compared to $4.5 million in 2015.

Omeclamox-Pak revenue declined 16.5% during 2016 compared to the prior year. The decrease was the result of lower shipment volume partially offset by improved pricing. The shipment volume decrease was impacted by the lack of a co-promotion partner supporting the product in 2016.

Vaprisol revenue decreased 29.7% during 2016 compared to the prior year primarily due to lower shipment volume during the twelve months ended December 31, 2016, which was partially offset by improved pricing.

Cost of products sold. Cost of products sold for the year ended December 31, 2016 were $6.0 million, compared to $5.0 million in the prior year, representing an increase of $1.0 million, or 19.9%. As a percentage of net revenues, cost of products sold were 18.0% compared to 14.8% during the prior year. This increase in costs of products sold as a percentage of revenue was attributable to a change in the product sales mix during the period compared to the prior year. The costs of products sold during a portion of 2016 were impacted by short term increases in the costs to manufacture inventory for the domestic Caldolor market.

Selling and marketing. Selling and marketing expense for 2016 totaled approximately $14.6 million, which was an increase of $0.6 million, or 4.0%, compared to the prior year's expense of $14.0 million. The increase was the result of non-personal promotional spending including print materials and product samples as well as $0.6 million in additional royalty expense.

Research and development. Research and development costs for the year ended December 31, 2016 were $3.2 million, compared to $3.8 million last year, representing a decrease of $0.7 million, or 17%. This change was primarily the result of a $1.2 million required fee that accompanied the Caldolor sNDA filed with the FDA in 2015. This submission was successful and the FDA approved Caldolor for a pediatric indication.

General and administrative. General and administrative expense for the year ended December 31, 2016 was $8.6 million for 2016, compared to $7.6 million last year, representing an increase of $1.0 million. This increase was primarily due to a $0.3 million decrease in contingent consideration during 2015 as the result of a reduction in the cost of the Vaprisol acquisition. Also, there was a $0.1 million increase in compensation and benefit expense, including stock based compensation, and a $0.3 million increase in professional and consulting fees during the year ended December 31, 2016.

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 2016 totaled approximately $2.2 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 benefit for the year ended December 31, 2016 was $0.3 million, compared to income tax expense of $0.6 million in 2015. The change was the result of a pretax loss for 2016 as compared to pretax income last year. As a percentage of income before income taxes, income tax benefit was 24.8% in 2016 compared to 46.2% in 2015. The rate as of December 31, 2016 was impacted by the valuation allowance recorded on Orphan Drug and Research and Development tax credits of $0.2 million.

Year ended December 31, 2015 compared to year ended December 31, 2014

The following table presents the statements of operations for the years ended December 31, 2015 and 2014:

	Years ended December 31,		
	2015	2014	Change
Net revenues	$33,519,051	$36,901,871	$(3,382,820)
Costs and expenses:			
Cost of products sold	4,968,170	5,053,165	(84,995)
Selling and marketing	13,994,768	14,902,202	(907,434)
Research and development	3,847,651	3,389,419	458,232
General and administrative	7,607,588	8,401,560	(793,972)
Amortization	1,989,264	1,596,689	392,575
Total costs and expenses	32,407,441	33,343,035	(935,594)
Operating income (loss)	1,111,610	3,558,836	(2,447,226)
Interest income	209,183	251,447	(42,264)
Interest expense	(73,856)	(67,074)	(6,782)
Income (loss) before income taxes	1,246,937	3,743,209	(2,496,272)
Income tax (expense) benefit	(575,829)	(1,380,744)	804,915
Net income (loss)	$671,108	$2,362,465	$(1,691,357)

Net revenues. Net revenues for the year ended December 31, 2015 were approximately $33.5 million compared to $36.9 million for the year ended December 31, 2014, representing a decrease of $3.4 million or 9.2%. The following table summarizes net revenues by product for the years presented:

	Years ended December 31,		
	2015	2014	Change
Products:			
Acetadote	$8,489,167	$11,906,232	$(3,417,065)
Omeclamox-Pak	3,037,078	4,111,916	(1,074,838)
Kristalose	15,733,327	14,932,271	801,056
Vaprisol	2,641,484	3,011,997	(370,513)
Caldolor	3,112,128	2,721,346	390,782
Other	505,867	218,109	287,758
Total net product revenues	$33,519,051	$36,901,871	$(3,382,820)

Our products with revenue increases from 2014 to 2015 were Kristalose, with a revenue increase of $0.8 million and Caldolor, with a revenue increase of $0.4 million. We experienced revenue decreases in Omeclamox-Pak revenue of $1.1 million, Acetadote product revenue of $3.4 million and Vaprisol product revenue of $0.4 million.

Kristalose revenue increased by $0.8 million, or 5.4%, over the prior year period primarily due to new positioning for the product. We increased the price of Kristalose during 2014 to bring Kristalose more in line with the other marketed branded prescription products in its class. Concurrent with the price increase, we launched initiatives to enhance patient affordability and increase demand. During the year ended December 31, 2015, we also experienced improvements in product net revenue per unit as we incurred a lower level of rebates from managed care contracts.

Caldolor product revenue experienced a $0.4 million improvement, which represents an increase of 14.4% during 2015 compared to 2014. Caldolor sales volumes and net revenue were positively impacted by the efforts of our sales force, marketing initiatives and a temporary shortage of a competing product. Caldolor sales were also positively impacted by the return of international sales in South Korea as well the product's launch in Australia. While we expect 2016 Caldolor annual product revenue to continue to grow compared to 2015, we continue to anticipate quarterly fluctuations due to wholesaler buying patterns and other factors.

Acetadote net revenue for the year ended December 31, 2015 included $4.5 million in revenue from sales of our Authorized Generic, compared to $5.8 million last year. This decrease in sales of our Authorized Generic product accounted for approximately 37.2% of the decline in total Acetadote revenue. The Authorized Generic sales were impacted by a temporary packaging delay and resulting shortage of marketable product that impacted revenue during a portion of the year. Our branded Acetadote product net revenue decreased $2.1 million due to a reduction in shipment volume as a result of generic competition, along with an increase in revenue deductions related to an increase in expired product during the first quarter of 2015. It is likely that there will be further reductions in our revenue generated by Acetadote and our Authorized Generic as a result of generic competition.

Omeclamox-Pak revenue declined 26.1% during 2015 compared to the prior year. The decrease was the result of lower shipment volume partially offset by improved pricing. The shipment volume decrease was impacted by the lack of sales calls supporting the product by our co-promotion partner for this period.

Vaprisol revenue decreased 12.3% during 2015 compared to the prior year primarily due to lower shipment volume during a portion of the twelve months ended December 31, 2015, which was partially offset by improved pricing. A portion of the sales volume decrease was attributable to the period in which we transitioned our marketable inventory from the Astellas labeled product to our Cumberland labeled product.

Cost of products sold. Cost of products sold for the year ended December 31, 2015 decreased 1.7% as compared to the same period in the prior year. As a percentage of net revenues, cost of products sold increased to 14.8% compared to 13.7% during the prior year. This results partially from a change in the product sales mix as well as $0.3 million in inventory write-downs during 2015 for potentially obsolete inventory.

Selling and marketing. Selling and marketing expense for 2015 totaled approximately $14.0 million, which was a decrease of $0.9 million compared to the prior year's expense of $14.9 million. The decrease was the result of a $0.3 million reduction in Omeclamox product royalties as well as decreases in sales force salaries and related costs. These

decreases were partially offset by an increase in non-personal promotional spending. We continue to actively manage our selling and marketing efforts and expenses under our strategy to efficiently support our five commercial brands.
Research and development. Research and development costs for the year ended December 31, 2015 were $3.8 million, compared to $3.4 million last year, representing an increase of $0.5 million, or 13.5%. This change was the result of a $1.2 million required fee that accompanied the Caldolor sNDA filed with the FDA during the first quarter of 2015. This submission was successful and the FDA approved Caldolor for a pediatric indication. This increase was offset by a $0.3 million reduction in costs as we were able to reduce our acquired contingent study liabilities related to the Vaprisol acquisition. We continued to fund clinical studies for both our Boxaban and Hepatoren product candidates during 2015. A portion of our research and development costs are variable based on the number of studies, sites and participants involved in our product development activities.
General and administrative. General and administrative expense was $7.6 million for 2015, compared to $8.4 million during 2014. The $0.8 million decrease was primarily driven by a $0.3 million decrease in contingent consideration as the result of a reduction in the cost of the Vaprisol acquisition. General and administrative expense was also benefited by a reduction in our travel and legal fees along with a $0.3 million decrease in compensation and benefit expense during the period.
Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for 2015 totaled approximately $2.0 million, which was an increase of $0.4 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, 2015 was $0.6 million, compared to income tax expense of $1.4 million in 2014. The change was the result of the reduction in pretax income for 2015 as compared to last year. As a percentage of income before income taxes, income tax expense was 46.2% in 2015 compared to 36.9% in 2014. The income tax rate for the year ended December 31, 2015 was primarily a result of other permanently non-deductible differences, including adjustments to our valuation allowance and increases in our state income tax rate, including changes from legislation. Our recurring expenses that are non-deductible for tax purposes grew during 2015, but the primary impact was the result of these costs being a higher percentage of income before income taxes. The income tax rate for the year ended December 31, 2014 was positively impacted by a reduction in our state tax expense.

LIQUIDITY AND CAPITAL RESOURCES
Our primary sources of liquidity are cash flows provided by our operations, our availability under our line of credit and the cash proceeds from our initial public offering of common stock that was completed in August 2009. For the years ended December 31, 2016, 2015 and 2014, we generated $0.6 million, $5.9 million and $6.7 million in cash flow from operations, respectively, and we borrowed $2.4 million on our line of credit during 2016. We believe that our internally generated cash flows and amounts available under our line of credit will be adequate to finance internal growth and fund capital expenditures.
We invest a portion of our cash reserves in variable rate demand notes ("VRDNs") and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate, mortgage-backed securities). The VRDNs are generally issued by municipal governments and are backed by a financial institution letter of credit. We hold a put right on the VRDNs, which allows us to liquidate the investments relatively quickly (less than one week). The government-backed securities have an active secondary market that generally provides for liquidity in less than one week. At December 31, 2016 and 2015, we had approximately $15.6 million and $14.6 million invested in marketable securities, respectively.
The following table summarizes our liquidity and working capital as of the years ended December 31:

	2016	2015
Cash and cash equivalents	$34,510,330	$38,203,059
Marketable securities	15,622,111	14,564,115
Total cash, cash equivalents and marketable securities	$50,132,441	$52,767,174
Working capital (current assets less current liabilities)	$50,753,001	$52,171,603
Current ratio (multiple of current assets to current liabilities)	4.4	5.2
Revolving line of credit availability	$7,900,000	$10,300,000

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

	2016	2015	2014
Cash provided by (used in):			
Operating activities	$569,478	$5,876,865	$6,693,431
Investing activities	(3,115,079)	(2,344,972)	(6,034,440)
Financing activities	(1,147,128)	(5,194,871)	(1,662,411)
Net (decrease) increase in cash and cash equivalents	$(3,692,729)	$(1,662,978)	$(1,003,420)

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.

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.

Operating activities provided $5.9 million in cash during the year ended December 31, 2015. The net $1.7 million decrease in cash and cash equivalents for 2015 was attributable to cash used in investing and financing activities, which was partly offset by the $5.9 million in cash generated from operations. Cash used in investing activities included a net cash investment in our intangible assets of $2.6 million, which was partially offset by net proceeds of $0.4 million associated with our investing activities in marketable securities. Our financing activities included $5.3 million in cash used to repurchase shares of our common stock, $1.7 million used to settle the remaining cash consideration for Vaprisol and $1.7 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 $2.8 million and included positive changes in our working capital of $2.0 million. During 2015, we recognized approximately $0.1 million of excess tax benefits. The excess tax benefit represented the income taxes that would have been paid if not for the tax deductions created upon the exercise of nonqualified stock options.

Operating activities provided $6.7 million in cash during the year ended 2014, with the net decrease in cash and cash equivalents for 2014 mainly attributable to cash used in our investing activities. Cash used in investing activities included a $2.0 million up-front payment for the acquisition of Vaprisol, a $3.1 million increase in intangible assets,

and a net investment in marketable securities of $0.8 million. Our financing activities included the repurchase of shares of our common stock totaling $4.3 million partially offset by the $1.0 million investment Gloria made in CET. During 2014, we recognized approximately $1.7 million of excess tax benefits. The excess tax benefit represented the income taxes that would have been paid if not for the tax deductions created upon the exercise of nonqualified stock options.

Debt Agreement

On June 26, 2014, we entered into a Revolving Credit Loan Agreement ("Loan Agreement") with SunTrust Bank. The agreement replaced the August 2011 Fifth Amended and Restated Loan Agreement with a previous lender which was to expire on December 31, 2014. We had $4.1 million in borrowings under the Loan Agreement at December 31, 2016. On July 29, 2016, Cumberland amended the agreement to extend the original three-year term by an additional year. The initial revolving line of credit is up to $12.0 million, an increase from the $10.0 million under the previous agreement. We have the ability to increase the borrowing amount up to $20.0 million, upon the satisfaction of certain conditions.

The interest rate on the Loan Agreement is based on LIBOR plus an interest rate spread. There is no LIBOR minimum and the LIBOR pricing provides for an interest rate spread of 1.0% to 2.85% (representing an interest rate of 1.6% at December 31, 2016). In addition, a fee of 0.25% per year is charged on the unused line of credit. Interest expense and the unused line fee are payable quarterly. Borrowings under the line of credit are collateralized by substantially all of the Company's assets.

Under the Loan Agreement, Cumberland is subject to certain financial covenants, including, but not limited to, maintaining a Funded Debt Ratio, as such term is defined in the Loan Agreement and determined on a quarterly basis. On July 29, 2016, we obtained a compliance waiver for a financial covenant as of June 30, 2016. On October 28, 2016, we obtained a compliance waiver and amended the agreement to modify a financial covenant, replacing the EBIT to interest ratio covenant with a minimum liquidity requirement. As a result of the covenant waiver and modification in the October 28, 2016 amendment, Cumberland achieved compliance with all covenants as of September 30, 2016. We are in compliance with all covenants at December 31, 2016.

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, 2016:

		Payments Due by Year				
Contractual obligations[1]	Total [2]	2017	2018	2019	2020	2021
Amounts reflected in the balance sheet:						
Line of credit[3]	$4,129,625	$19,750	$4,109,875	$—	$—	$—
Estimated interest on debt [3]	98,400	65,600	32,800	—	—	—
Other cash obligations not reflected on the balance sheet:						
Operating leases	5,249,135	1,039,618	901,568	838,896	856,084	1,612,969
Purchase obligations [4]	—	—	—	—	—	—
Total [1]	$9,477,160	$1,124,968	$5,044,243	$838,896	$856,084	$1,612,969

(1) The table of contractual obligations excludes amounts due under the Kristalose purchase agreement, and the Omeclamox-Pak and Ethyol royalty agreement as these amounts cannot be 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. Payments are due quarterly, in arrears. Omeclamox-Pak and Ethyol 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 ad 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 $12 million line of credit assuming the current $4.1 million balance outstanding on December 31, 2016 is consistently outstanding through maturity of June 2018. Interest and unused line of credit payments are due and payable quarterly in arrears.

(4) Represents minimum purchase obligations under our manufacturing agreements.

OFF-BALANCE SHEET ARRANGEMENTS

During 2016, 2015 and 2014, we did not engage in any off-balance sheet arrangements.

RECENTLY ISSUED BUT NOT YET ADOPTED ACCOUNTING PRONOUNCEMENTS

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU"), “Statement of Cash Flows—Restricted Cash—a consensus of the FASB Emerging Issues Task Force.” 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 effective date for this standard is for years beginning after December 15, 2017, with early adoption permitted. We are evaluating the potential impact of this adoption on our condensed consolidated financial statements and disclosures.

In August 2016, the FASB issued amended guidance in the form of a FASB ASU, "Classification of Certain Cash Receipts and Cash Payments." The core principle of the new guidance is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments in this update are effective for fiscal years beginning after December 15, 2017. The accounting guidance should be applied retrospectively and early adoption is permitted. We continue to evaluate the potential impact of this adoption on our condensed consolidated financial statements and disclosures but currently we do not anticipate that adoption will have a material impact.

In May 2014, the FASB issued amended guidance in the form of a FASB ASU, "Revenue from Contracts with Customers". The core principle of the new guidance is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The new guidance defines a five-step process to achieve this core principle and, in doing so, additional judgments and estimates may be required within the revenue recognition process. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective. In July 2015, the FASB issued a one-year deferral of the adoption date, which extended the effective date for us to January 1, 2018 at which point the we will adopt the standard. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing the appropriate method for implementing the ASU, as well as the impact the adoption of the ASU will have on its consolidated financial statements and footnote disclosures.

In July 2015, the FASB issued amended guidance in the form of a FASB ASU, “Inventory: Simplifying the Measurement of Inventory.” The amended guidance requires entities to measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The requirement would replace the current lower of cost or market evaluation. Accounting guidance is unchanged for inventory measured using last-in, first-out (“LIFO”) or the retail method. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance should be applied prospectively and early adoption is permitted. We continue to evaluate the potential impact of this adoption on our condensed consolidated financial statements and disclosures but currently, we do not anticipate that adoption will have a material impact.

In February 2016, the FASB issued guidance in the form of a FASB ASU, "Leases." The new standard establishes a right-of-use (ROU) model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain optional practical expedients available. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are evaluating our current lease agreements for the impact of our pending adoption of the new standard on our consolidated financial statements and disclosures. Our material operating leases include the lease of approximately 25,500 square feet of office space in Nashville, Tennessee for our corporate headquarters, with the lease expiring in October 2022. The CET lease, through April 2018, of approximately14,200 square feet of office and wet laboratory space in Nashville, Tennessee is also included to operate the CET Life Sciences Center.

In March 2016, the FASB released in the form of a FASB ASU, "Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting." The ASU includes multiple provisions intended to simplify various aspects of the accounting for share-based payments. While aimed at reducing the cost and complexity of the accounting for share-based payments, the amendments are expected to significantly impact net income, earnings per share ("EPS"), and the statement of cash flows. Implementation and administration may present challenges for companies with significant share-based payment activities. The ASU is effective for public companies in annual periods beginning after December 15, 2016, and interim periods within those years. We are currently evaluating the impact of adoption on the consolidated financial statements including the unrecognized net operating loss carryforwards generated from the exercise of nonqualified options of approximately $44.1 million and the future vesting of shares of restricted stock issued to employees and directors.

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.

We invest in VRDNs and a portfolio of government backed securities (including U.S. Treasuries, government sponsored enterprise debentures and government sponsored adjustable rate mortgage backed securities) to obtain a higher return while preserving our capital. The VRDNs are generally issued by municipal governments and are backed by a financial institution letter of credit. The VRDNs allow us the ability to liquidate the investment relatively quickly (less than one week). The government backed securities have an active secondary market that generally provides for liquidity in less than one week. The primary risk related to interest rates for these accounts are that they will produce less income than expected if market interest rates fall. Based on the $15.6 million in marketable securities outstanding at December 31, 2016, 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 1.0% to 2.85% (representing an interest rate of 1.6% at December 31, 2016). As of December 31, 2016, we had $4.1 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 2016, 2015 and 2014. 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, 2016. Based on that evaluation, they have concluded that our disclosure controls and procedures were effective as of December 31, 2016 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 2016, 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.

Board of Directors Appointments

On June 10, 2016, Cumberland announced the addition of Caroline Young to its Board of Directors. Caroline is the prior President of the Nashville Health Care Council and founding Executive Director of the Tennessee Biotechnology Association. Caroline’s appointment to Cumberland’s Board was effective September 13, 2016.

Caroline was the President of the Nashville Health Care Council from 2008 to 2015. The Council was formed as an association of the largest concentration of healthcare companies in the U.S., which are headquartered in the Nashville area. It is one of the nation’s foremost health care industry associations, and under Caroline’s leadership, membership grew to encompass 300 diverse organizations. There, she oversaw a series of international trade missions and launched one-of-a-kind Health Care Council Fellows program, designed to encompass the healthcare perspective and further develop the skills of senior business executives. Additionally, she expanded the Council’s innovative Leadership Health Care program, dedicated to nurturing the talents of the next generation of health care industry leaders.

On January 16, 2017, Cumberland announced the addition of Kenneth J. Krogulski, CFA to its Board of Directors. Kenneth is the President and Chief Executive Officer of Berkshire Asset Management LLC ("Berkshire"). He is also the Chief Investment Officer of Berkshire, a 30-year-old independent SEC registered investment advisory firm with over $1.5 billion under management. Kenneth's appointment to Cumberland's Board was effective January 18, 2017.

Kenneth has over 37 years' experience in security analysis and portfolio management. He began his career in finance at First Eastern Bank (now PNC Financial) as an investment analysis and portfolio manager. He then served as senior portfolio manager in First Eastern's trust department. Mr. Krogulski then joined Berkshire and later led a

management buy-out acquiring the company from Legg Mason. Under his leadership, Berkshire's assets under supervision have grown from $600 million in 2006 and are now over $1.5 billion.

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 2017 annual meeting of shareholders, which is expected to be filed with the SEC on or around March 14, 2017.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report:

(1) Financial Statements

(2) Financial Statement Schedule

(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
4.5#	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
10.7†	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, 2017, effective as of January 1, 2017, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10 .12#	Employment Agreement dated March 8, 2017, effective as of January 1, 2017, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement dated March 8, 2017, effective as of January 1, 2017, by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.

Exhibit Number	Description
10.14#	Employment Agreement dated March 8, 2017, effective as of January 1, 2017, by and between Michael Bonner and Cumberland Pharmaceuticals Inc.
10.15#	Employment Agreement dated March 8, 2017, effective as of January 1, 2017, 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