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, 2015
of

CUMBERLAND PHARMACEUTICALS INC.

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

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Nashville, Tennessee 37203
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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, 2015 was $60,943,000. The number of shares of the registrant's Common Stock, no par value, outstanding as of March 4, 2016 was 16,306,980.

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 2016 annual meeting of shareholders.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

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PART I

Item 1. Business.

THE COMPANY

Cumberland Pharmaceuticals Inc. (“Cumberland,” the “Company,” or as used in the context of “we,” “us,” or “our”), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology. These medical specialties are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs. We market and sell our approved products through our hospital and gastroenterology sales forces in the United States and are establishing a network of international partners to bring our products to patients in their countries.

Our product portfolio includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever; 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;
- **Hepatoren®** (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS"); and
- **Boxaban®** *(ifetroban)* oral capsules, a Phase II candidate for the treatment of patients with aspirin-exacerbated respiratory disease (AERD).

We have both product development and commercial capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, regulatory, manufacturing, sales, marketing and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Our product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our quality and manufacturing professionals oversee the manufacture and release of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our distribution partners to ensure availability and delivery of our products.

Cumberland's growth strategy involves maximizing the potential of our existing brands while continuing to build a portfolio of differentiated products. We currently market five products approved 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 develop 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
Hepatoren®	Hepatorenal Syndrome	Phase II
Boxaban®	Aspirin-Exacerbated Respiratory Disease	Phase II

Acetadote

Acetadote is an intravenous formulation of N-acetylcysteine, or ("NAC"), indicated for the treatment of 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 in 2006 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 formulation 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 (the "Authorized Generic") product. Both Acetadote and our Authorized Generic utilize the new, EDTA-free formulation which accounted for continued significant market share during 2015. We are seeking additional claims to protect our intellectual property associated with Acetadote through patent applications which are pending with the USPTO.

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 Acetadote product before the expiration of Cumberland’s patent in August 2025.

Caldolor

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the United States 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 submission for FDA approval. The FDA approved Caldolor for marketing in the United States during the middle portion of 2009 following a priority review. The product is indicated for use by adults and pediatric patients six months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA-approved intravenous therapy for fever. At December 31, 2015, Caldolor has been purchased by over 1,300 health care facilities in the United States.

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

We completed a series of Phase IV studies to gather additional data to support our Caldolor product. Those completed studies involved another 1,000 patients. The studies included evaluation of the product for the treatment of pediatric pain and pediatric fever in order to address our Phase IV commitment to the FDA for Caldolor. Also included in these studies was an evaluation of a shortened infusion time for the product and pre-surgical administration. The data from these Phase IV studies, including an updated integrated safety database, was submitted to the FDA in early 2015 with a request for updated labeling for the product. In late 2015, we received FDA approval of Caldolor for use 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 pediatric patients. Caldolor’s pediatric approval came after the FDA’s review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. We also continue to pursue and evaluate potential improvements to the product’s packaging.

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 compliance and acceptance. 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 the product 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. 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.

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.

Omeclamox-Pak

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

While there are competing products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the competing branded products, Omeclamox-Pak combines the lowest pill burden and fewest days of therapy. Our involvement with Omeclamox-Pak began in October 2013, through an agreement with Pernix Therapeutics ("Pernix"). In November 2015, Cumberland entered into an exclusive license and supply agreement with Gastro-Entero Logic, LLC (“GEL”) and assumed full commercial responsibility for Omeclamox-Pak in the United States and terminated our Agreement 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. Cumberland will also now seek a new co-promotion partner to support the product with primary care physicians.

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 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 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, which also features our Caldolor and Acetadote products.

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. They 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. We acquired the rights to the ifetroban program from Vanderbilt through CET and intend to develop the product for several potential 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 (*ifetroban*) Injection and are evaluating this candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome ("HRS"), a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment. We would also seek orphan drug status and the associated seven years of marketing exclusivity for this indication.

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 (*ifetroban*) capsules and are evaluating this candidate for patients suffering from aspirin-exacerbated respiratory disease (AERD) a condition for which there is no U.S. approved pharmaceutical treatment. 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.

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. In addition, we may explore further clinical work that could be used to support our sales and marketing activities and maximize their efforts to further penetrate existing markets. 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. We will also 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.

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 2015 launch of Caldolor in Australia by Seqirus is an example of our international partnerships.

Develop a pipeline of early-stage products through 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 and Acetadote 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 Vaprisol as a third acute care product. Our strategy has been to increase the focus of our hospital sales team on targeted, high priority accounts.

In November 2015 we announced a co-promotion agreement with Piramal Critical Care ("Piramal"). Through this agreement, Piramal co-promotes two of Cumberland's branded hospital products, Caldolor and Vaprisol throughout the United States. Piramal will help expand Cumberland's reach for these products by providing coverage to an additional group of hospitals where Piramal's critical care sales force has existing relationships. Cumberland will maintain its promotional efforts supporting the products, continue its focus on its existing group of medical centers across the United States and continue to provide the marketing, national accounts, distribution, and medical support for the brands. The multi-year collaboration will provide expanded sales promotion for the two brands, increased communication to medical professionals and enhanced availability of the products to support patient care.

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 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 a network, which is summarized in the table below, which 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
Alveda Pharmaceuticals, Inc.	Caldolor	Canada	Marketed
DB Pharm Korea Co., Ltd.	Caldolor & Vaprisol	South Korea	Marketed
Alliance Pharm PTE Ltd.	Vaprisol	Singapore	Distributing
Seqirus (a CSL company)	Caldolor	Australia and New Zealand	Marketed
Sandor Medicaids Pvt. Ltd.	Caldolor	India	Registration
GerminMED	Caldolor & Acetadote	Qatar and Arabian Peninsula	Registration
PT. SOHO Industri Pharmasi	Caldolor	Pacific Rim	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
Clinigen Healthcare Limited	Vaprisol	Most territories outside the U.S. and Singapore	Pending
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

Caldolor Approved for Pediatric Use

During November 2015, Caldolor received FDA approval for use in pediatric patients six months and older for management of pain and reduction of fever. The approval was based on data submitted to the U.S. Food and Drug Administration (FDA) as part of a post-marketing commitment following approval of Caldolor in adults in 2009. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.

Caldolor’s pediatric approval came after the FDA’s review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. The pivotal fever study demonstrated a statistically significant greater reduction in temperature for patients receiving Caldolor, as compared to acetaminophen. Seventy-four percent of Caldolor treated patients became afebrile by the end of the first dosing interval. A total of 143 pediatric patients, ages six months and older, have received Caldolor in controlled clinical trials. The most common adverse reactions (incidence greater than or equal to 2%) in pediatric patients treated with Caldolor were infusion site pain, vomiting, nausea, anemia and headache.

The recommended dosing for pediatric patients ages six months to twelve years of age is 10 mg/kg up to a maximum single dose of 400 mg Caldolor every four to six hours as necessary. For patients ages twelve to seventeen years of age, the recommended dosing is 400 mg of Caldolor every four to six hours as necessary for management of pain and/or reduction of fever. The product is diluted and administered intravenously over a ten minute infusion and the maximum daily dose in pediatric patients is 2,400 mg.

Caldolor Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated intravenous ibuprofen safety database combining data from our clinical trials as well as previously published study data. We used this data to support our NDA filing and continue to use and update the data as a part of our ongoing safety evaluation. We continue to use this data in our marketing materials and to support our sales force in promoting Caldolor.

In clinical trials supporting our proposed indications, the number and percentage of all patients in pivotal studies who reported treatment emergent adverse events was comparable between IV ibuprofen and placebo treatment groups. Additionally, there have been no safety related differences between Caldolor and placebo involving side effects sometimes observed with oral Nonsteroidal Anti-Inflammatory Drugs ("NSAIDs"), such as changes in renal function, bleeding events or gastrointestinal disorders.

Publication of Caldolor Shortened Infusion Time Studies

In January 2015, *Clinical Therapeutics, The International Peer-Reviewed Journal of Drug Therapy*, published two articles with data from two Caldolor (*ibuprofen*) registry studies. One study entitled, "*A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety and Efficacy"* provided for eligible enrolled patients to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from thirteen clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The other registry study entitled *"A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety"* was a Phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg of intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from twenty one clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

Publication of Caldolor Integrated Safety Analysis

In October 2015 there was a publication of an integrated safety analysis adding to the growing body of literature that support the safety of Caldolor. The data in this cumulative safety analysis is derived from ten sponsored clinical studies investigating intravenous ibuprofen for the treatment of pain and/or fever in adult patients. Over 1,750 adult patients have been included in safety and efficacy trials over eleven years. The publication is available as an open access article in the *Journal of Pain Research*.

The incidence of adverse events, changes in vital signs and clinically significant laboratory parameters were summarized and compared to patients receiving placebo or active comparator drug. Patients receiving Caldolor required less morphine and experienced fewer adverse events relative to those who received placebo with morphine rescue. Results from the integrated analysis continue to demonstrate the safety of Caldolor, supporting its use in hospitalized patients.

Caldolor Label Safety Update

In July 2015, the FDA decided to strengthen the existing cardiovascular warning for nonsteroidal anti-inflammatory drugs (NSAIDs). This is a class label change for all NSAIDs including over-the-counter and prescription products. It was previously thought that all NSAIDs may have similar cardiovascular risks. While newer information makes it less clear that the cardiovascular risks are similar for all NSAIDs, this information is not sufficient for the FDA to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular

NSAID. While we have not seen a cardiovascular side effect in our extensive Caldolor safety database, we will update our Caldolor label for this requested information once it becomes finalized by the FDA.

Caldolor Continuing Education

We have extended the availability of a web-based, accredited, continuing education seminar featuring the benefits of preoperative use of Caldolor in the hospital setting. The seminar has been distributed to over 60,000 health providers with a growing number of participants completing the seminar for continuing education credit.

Hepatoren Top Line Study Results

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.

We completed the enrollment of Type II patients at the end of 2014. Top line results from these patients indicate that Hepatoren was overall well tolerated with no safety concerns noted. Furthermore, the 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. Based on these results, we will proceed with clinical development of this product candidate.

We subsequently completed enrollment of the Type I patients during the third quarter of 2015 and the analysis of those patient results is underway.

Boxaban Phase II Program

During 2015, Cumberland announced an expansion of its pipeline with another Phase II development program. 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. It 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.

Cumberland completed manufacturing of Boxaban oral capsules and initiated 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. The enrollment in this study was recently completed and top line results indicate that no adverse events were experienced by patients receiving Boxaban when compared to those receiving placebo. Further analysis of the full data set obtained from the study is underway.

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 and Vaprisol 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 our strategic alliance with Clinigen Group plc (AIM: CLIN) ("Clinigen"), a global pharmaceutical and services company. Clinigen is a specialty pharmaceutical and services company focused on providing medicines to patients with high unmet needs through clinical trials, licensed and ethically unlicensed supply.

The alliance will combine the respective strengths, expertise and geographical footprints of Cumberland and Clinigen with respect to potential future products. Under the agreement, we will have the opportunity to support Clinigen products through distribution, marketing and promotion within the United States. Clinigen will be responsible for the marketing, promotion, distribution and sale of our pharmaceutical products in select markets outside of the United States, allowing us to use Clinigen's international reach to enter new markets for our products. During 2016 we entered into an amendment to this strategic alliance agreement that outlines the support Cumberland will provide to one of Clinigen's product in the United States. Cumberland expects to launch the support for the Clinigen product during the second half of 2016.

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 five collaboration agreements with Universities to co-develop promising biomedical technologies, including: Vanderbilt University, Washington University, the University of Virginia, 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 and Boxaban.

CET Financing

In 2014, we organized an equity financing to recapitalize and strengthen the financial position of CET. This financing included an investment of approximately $1.0 million from Harbin Gloria Pharmaceuticals Co., Ltd. ("Gloria") for their participation in CET. As a result, Gloria received shares in CET and joined the CET ownership group. As part of this transaction, Gloria will have the first right to negotiate a license to CET developed products for the Chinese market. The funds from this new investment are being used to support and accelerate the development of CET product candidates. CET's lead product candidate is ifetroban which is being developed by Cumberland under the brand names Hepatoren and Boxaban.

Prior to April 2014, we owned 85% of CET, with the balance of the enterprise owned by Vanderbilt University and the Tennessee Technology Development Corporation. In connection with Gloria's investment in CET, we also provided an additional investment in CET of $1.0 million in cash and $2.4 million in loan forgiveness. Upon completion of the additional investment by Gloria and Cumberland in April 2014, we held an 80% ownership in CET.

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 initiated the manufacturing of Caldolor at two facilities during 2015. Both manufacturers have provided supplies of Caldolor for our international markets. During 2015, we began the process of securing two manufacturers for commercial supply of Caldolor for the United States. All four manufacturers are expected to provide commercial supplies of the product in 2016.

Acetadote

- During the fourth quarter of 2014, we entered into an agreement with a U.S. based manufacturer to supply our Acetadote product. We transferred the Acetadote manufacturing process to this supplier, received FDA clearance and began receiving commercial units from this facility during 2015.

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

- Under the previous agreement, Pernix, was responsible for providing us with the supply of Omeclamox-Pak. Based on our new 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.

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 Amendment primarily serves to extend the term of the Agreement through June 30, 2016 and revises 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. After June 30, 2016, the contract is automatically renewed on a year-to-year basis that is terminable by either party with ninety days' notice. Under the 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.

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 and related litigation

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.

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

We also have additional patent applications relating to Acetadote which are pending with the USPTO.

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. 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.

Remaining Products

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

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.

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 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, and 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.

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 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.

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, 2015, we had 78 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 five products: Acetadote, Caldolor, Kristalose, Vaprisol and Omeclamox-Pak. 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 individuals 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: Caldolor has historically been manufactured at Hospira Australia Pty. Ltd.'s facility in Australia and Bayer's facility in Kansas. We entered into agreements with three manufacturers for the commercial supply of Caldolor. We have successfully transferred the Caldolor manufacturing process to two of these manufacturers and these two suppliers have manufactured inventory under these agreements. During 2015, we began the process of obtaining a third supplier for the manufacture of commercial supply of Caldolor and expect to obtain commercial supply from this manufacturer during 2016. 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: Acetadote was previously manufactured and packaged by two entities: at Bayer's facility in Kansas through January 2014 and in Ireland by Mylan through April 2014. During the fourth quarter of 2014, we entered into an agreement with a U.S. based manufacturer to supply our Acetadote product. We have transferred the Acetadote manufacturing process to this supplier and received and sold commercial units from them during 2015. 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 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: Under the agreement we signed with Pernix, they were responsible for providing Omeclamox-Pak inventory. Effective with the November 2015 agreement with GEL, Cumberland assumes supply chain responsibilities and will now work 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.

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 and Hepatoren. 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 two marketed products to our portfolio of brands: Omeclamox-Pak in the fourth quarter of 2013 and Vaprisol during the first quarter of 2014. We successfully launched our promotional efforts to support both brands during 2014. If we are unable to continue to build on our initial success with these brands or we are unable to successfully integrate the marketing, sale and distribution of any other potential products into our current infrastructure or if they require significantly greater resources than originally anticipated, we may face financial and operational risks and uncertainties. If we are unable to successfully integrate any acquired brands, both current and future, these product acquisitions may not be beneficial to us in the long term.

Our Hepatoren and Boxaban 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 and Boxaban product candidates. Hepatoren (intravenous ifetroban) and Boxaban (oral ifetroban) are candidates used to treat hepatorenal syndrome ("HRS") and aspirin exacerbated respiratory disease ("AERD"), respectively. However, ifetroban has not 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 these 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 Hepatoren and Boxaban 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 PPACA, as amended by the HCERA, constitutes the healthcare reform legislation. 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. Furthermore, future cost control initiatives, legislation and regulations could decrease the price that we receive for any products, which would limit our revenue and profitability.

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, 2015, we had 78 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, 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 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. Despite our security measures, 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. 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 February18, 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.

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, four others expiring in September 2029 and one other expiring in September 2030.

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 Vaprisol and Omeclamox-Pak, increasing market share in Caldolor and Kristalose 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;
- 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, 2015, intangible assets relating to products represented approximately 23% 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, 2016, 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,” “estimate,” “should,” “seek,” “anticipate” and other comparable terms or the negative thereof. In addition, we, through our senior management, from time to time make forward-looking oral and written public statements concerning our expected future operations and other developments. While forward-looking statements reflect our good-faith beliefs and best judgment based upon current information, they are not guarantees of future performance and are subject to known and unknown risks and uncertainties, including those mentioned in Item 1A, “Risk Factors,” Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Form 10-K. 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 development activities and clinical trials; and our ability to successfully commercialize our product candidates;
- The performance of our third-party suppliers and manufacturers; and the retention of key scientific and management personnel;
- Our expectations regarding our ability to provide intellectual property protection for our product candidates; and
- 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of December 31, 2015, 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 by third-party contract groups.

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. CET uses this space to operate the CET Life Sciences Center for product development work to be carried out in collaboration with universities, research institutions and entrepreneurs. The CET Life Sciences Center 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 to another entity or person until April 2016.

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.

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 4, 2016, we had 79 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 4, 2016 was $4.81 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 2015 and 2014:

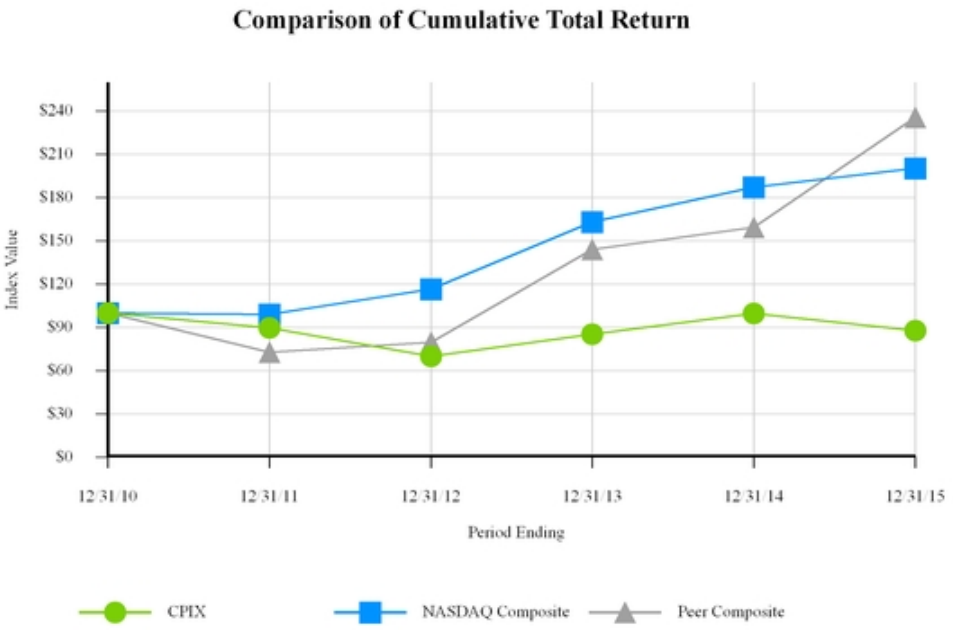
	High	Low
Fiscal year ended December 31, 2015:		
First quarter	$7.09	$5.62
Second quarter	7.78	6.06
Third quarter	7.52	5.50
Fourth quarter	6.50	5.03
Fiscal year ended December 31, 2014:		
First quarter	5.19	4.33
Second quarter	4.59	4.20
Third quarter	5.20	4.42
Fourth quarter	6.20	4.50

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, 2010 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, 2010, 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 829,003 shares, 881,810 shares, and 1,008,105 shares of common stock for approximately $5.3 million, $4.3 million, and $4.8 million during the years ended December 31, 2015, 2014 and 2013, respectively.

The following table summarizes the activity, by month, during the fourth quarter of 2015:

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	43,552	$5.79	43,552	$5,406,839
November	38,978 (1)	5.83	38,978	5,179,445
December	34,339	5.51	34,339	4,990,101
Total	116,869			

(1) Of this amount, 4,783 shares were repurchased directly in a private purchase 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:	**2015**	**2014**	**2013**	**2012**	**2011**
	(in thousands, except per share data)				
Net revenues	$ 33,519	$ 36,902	$ 32,027	$ 48,851	$ 51,143
Costs and expenses	32,407	33,343	35,829	40,033	41,293
Operating income (loss)	1,112	3,559	(3,801)	8,818	9,849
Net income (loss) attributable to common shareholders	731	2,424	(2,105)	5,842	5,658
Earnings (loss) per share – basic	$ 0.04	$ 0.14	$ (0.11)	$ 0.30	$ 0.28
Earnings (loss) per share – diluted	$ 0.04	$ 0.14	$ (0.11)	$ 0.30	$ 0.28

	As of December 31,				
Balance sheet data:	**2015**	**2014**	**2013**	**2012**	**2011**
	(in thousands)				
Cash and cash equivalents	$ 38,203	$ 39,866	$ 40,869	$ 54,349	$ 70,599
Marketable securities	14,564	14,841	14,020	16,686	—
Working capital	54,700	57,065	61,134	79,177	80,708
Total assets	91,919	95,405	87,614	98,594	95,518
Total long-term debt and other long-term obligations (including current portion)	2,687	1,032	869	5,042	5,485
Retained earnings	19,550	18,818	16,395	18,499	12,657
Total equity	76,820	80,753	79,292	85,566	82,835

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 growing 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 product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection for the treatment for pain and fever, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, 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, Hepatoren (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome ("HRS") and Boxaban® *(ifetroban)* oral capsules, a Phase II candidate for the treatment of patients with aspirin-exacerbated respiratory disease (AERD).

We market and sell our approved products through our hospital and field sales forces in the United States, which together comprised approximately 50 sales representatives and managers as of December 31, 2015.

We have both product development and commercial capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, regulatory, manufacturing, sales, marketing and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Our product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our quality and manufacturing professionals oversee the manufacture and release of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our distribution partners to ensure availability and delivery of our products.

The following is a summary of our 2015 highlights and recent developments. For more information, please see Part I, Item I, *Business*, of this Form 10-K.

- In September 2015, we announced our strategic alliance with Clinigen Group plc (AIM: CLIN) ("Clinigen"), a global pharmaceutical and services company. Under the agreement, we will have the opportunity to support Clinigen products through distribution, marketing and promotion within the United States. During 2016 we entered into an amendment to this strategic alliance agreement that outlines the support Cumberland will provide to one of Clinigen's product in the United States. Cumberland expects to launch the support for the Clinigen product during the second half of 2016.
- We obtained a favorable court ruling upholding the validity and enforceability of our key Acetadote patent in September 2015. By ruling in our 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 Acetadote before the expiration of our patent in August 2025.

- We continued our international expansion during 2015, and Caldolor became our fastest growing brand with increased revenue contributions from international sales following the product's launch in Australia.
- After its new positioning a year earlier, Kristalose continued as our largest selling brand and we were able to improve the product's gross sales deductions from managed care contracts.
- We maintained a significant market share for Acetadote through the combined sales of our branded and Authorized Generic products.
- 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 October 2015, we executed a Strategic Alliance Agreement with Piramal Enterprises Limited ("Piramal") for the manufacture and supply of Active Pharmaceutical Ingredients ("API"). Under the this agreement, we will collaborate with Pirarmal on the manufacture and supply of API for New Chemical Entities ("NCE") in development at CET. Piramal will provide both development and commercial supplies of API for select product candidates. Piramal is a diversified conglomerate with operations in over thirty countries and five API manufacturing plants.
- During October 2015, we announced the publication of an integrated safety analysis adding to the growing body of literature that support the safety of Caldolor. The data in this cumulative safety analysis is derived from ten sponsored clinical studies investigating intravenous ibuprofen for the treatment of pain and/or fever in adult patients. Over 1,750 adult patients have been included in safety and efficacy trials over eleven years. The publication is available as open access articles in the *Journal of Pain Research*.
- We also entered into a co-promotion agreement in November 2015 with Piramal Critical Care to expand the support for our Caldolor and Vaprisol products. Piramal will provide coverage for an additional group of hospitals where Piramal's critical care sales force has existing relationships. The collaboration will provide expanded sales promotion and increased communication to medical professionals, to support patient care throughout the U.S.
- In November 2015, we announced the approval of Caldolor for pediatric patients six months of age and older. The approval was based on data submitted to the U.S. Food and Drug Administration (FDA) as part of a post-marketing commitment following approval of Caldolor in adults in

2009. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.

- In November 2015, we entered into a new agreement with Gastoenterlogics Inc. to assume remaining commercial rights to Omeclamox-Pak for the U.S. We had previously signed an agreement with Pernix to jointly commercialize the product in the U.S. However, Pernix was not able to provide the expected primary care support given the arrival of their newly acquired products. Simultaneous with our new GEL Agreement, Cumberland and Pernix terminated their arrangements. We will continue promotion to the gastroenterology community through its field sales force and seek a new co-promotion partner with national primary care capabilities in the U.S.

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 and Kristalose. 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 1.5% percent of net revenues in 2015, 0.6% in 2014, and 2.9% in 2013.

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 and $0.4 million at December 31, 2015 and 2014, respectively for chargebacks, discounts and allowances for product damaged in shipment.

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

	2015	2014	2013
Balance, January 1	$ 5,234,800	$ 2,437,140	$ 3,371,863
Current provision	10,981,168	14,972,112	4,181,403
Actual product returns and credits issued	(9,439,945)	(12,174,452)	(5,116,126)
Balance, December 31	$ 6,776,023	$ 5,234,800	$ 2,437,140

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. 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 $6.8 million, $5.2 million and $2.4 million as of December 31, 2015, 2014 and 2013, respectively. Of these amounts, our estimated liability for fee for services represented $1.1 million, $0.9 million and $0.5 million, respectively, while our accrual for product returns totaled $2.2 million, $2.1 million and $1.6 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 the year ended December 31, 2015, $0.3 million in the year ended December 31, 2014 and $0.1 million in the year ended December 31, 2013. A change in our product return estimate of one percentage point would have impacted net sales by $0.4 million, $0.5 million and $0.3 million for the years ended December 31, 2015, 2014 and 2013, 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, 2015 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.

The tax benefit associated with the exercise of nonqualified stock options is recognized when the benefit is used to offset income taxes payable. As of December 31, 2015, we have unrecognized federal net operating loss carryforwards associated with the exercise of nonqualified options of $43.0 million. In addition to these unrecognized federal net operating loss carryforwards, as of December 31, 2015, we have recognized federal Orphan Drug and Research and Development tax credits of $1.1 million that expire between 2021 and 2033.

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, 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	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 before income taxes	1,246,937	3,743,209	(2,496,272)
Income tax expense	(575,829)	(1,380,744)	804,915
Net income	$ 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)

Revenue increases in two of our five branded prescription products were offset by decreases in Omeclamox-Pak revenue of $1.1 million, Acetadote product revenue of $3.4 million and Vaprisol product revenue of $0.4 million. Our products with revenue gains were led by increases in Kristalose revenue of $0.8 million and Caldolor 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 the first quarter of 2014 to bring Kristalose more in line with the other marketed branded prescription products in its class. Concurrent with the price increase, we increased our patient focused initiatives to enhance patient affordability and increase demand. During the year ended December 31, 2015, we also experienced improvements in product net revenue per unit as we incurred a lower level of net revenue deductions from managed care contracts.

The 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 distributed by Perrigo, 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 sales 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 sales volume partially offset by improved pricing. The sales 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 sales 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.

Year ended December 31, 2014 compared to year ended December 31, 2013

The following table presents the statements of operations for the years ended December 31, 2014 and 2013:

	Years ended December 31,		
	2014	**2013**	**Change**
Net revenues	$ 36,901,871	$ 32,027,462	$ 4,874,409
Costs and expenses:			
Cost of products sold	5,053,165	5,439,422	(386,257)
Selling and marketing	14,902,202	14,387,745	514,457
Research and development	3,389,419	5,615,501	(2,226,082)
General and administrative	8,401,560	9,489,976	(1,088,416)
Amortization	1,596,689	896,156	700,533
Total costs and expenses	33,343,035	35,828,800	(2,485,765)
Operating income (loss)	3,558,836	(3,801,338)	7,360,174
Interest income	251,447	230,291	21,156
Interest expense	(67,074)	(103,422)	36,348
Income (loss) before income taxes	3,743,209	(3,674,469)	7,417,678
Income tax (expense) benefit	(1,380,744)	1,523,051	(2,903,795)
Net income (loss)	$ 2,362,465	$ (2,151,418)	$ 4,513,883

Net revenues. Net revenues for the year ended December 31, 2014 were approximately $36.9 million compared to $32.0 million for the year ended December 31, 2013, representing an increase of $4.9 million or 15.2%. The following table summarizes net revenues by product for the years presented:

	Years ended December 31,		
	2014	**2013**	**Change**
Products:			
Acetadote	$ 11,906,232	$ 18,846,753	$ (6,940,521)
Omeclamox-Pak	4,111,916	1,045,815	3,066,101
Kristalose	14,932,271	9,118,475	5,813,796
Vaprisol	3,011,997	—	3,011,997
Caldolor	2,721,346	2,089,655	631,691
Other	218,109	926,764	(708,655)
Total net product revenues	$ 36,901,871	$ 32,027,462	$ 4,874,409

Net product revenues. The revenue increase was driven primarily by increases in Kristalose product revenue of $5.8 million, Omeclamox-Pak revenue of $3.1 million and Vaprisol revenue of $3.0 million. A decrease in branded Acetadote product revenue of $3.5 million and a decrease in Authorized Generic Acetadote product revenue of $3.4 million partially offset this overall revenue increase.

Kristalose revenue increased 63.8% over the prior year primarily due to new positioning for the product. We increased the price of Kristalose during the first quarter of 2014 to bring Kristalose more in line with the other marketed branded prescription products in its class. Concurrent with the price increase, we increased our patient focused initiatives to enhance patient affordability and increase demand.

The increase in revenue was also attributable to a 30.2% increase in Caldolor through our growth in international and domestic sales. The addition of Vaprisol in early 2014 and the benefit of a full year of Omeclamox-Pak compared to a partial year of sales for the brand during 2013 also contributed to the revenue increase.

The year over year decrease in Acetadote net revenue was primarily due to decreased sales volume of the branded Acetadote and Authorized Generic product largely as a result of generic competition. Acetadote product revenue for 2014 included $5.8 million in sales of the Authorized Generic product compared to prior year sales of $9.2 million.

Other revenue. Other revenue was $0.2 million in 2014 compared to $0.9 million in 2013. The decrease was primarily the result $0.6 million of upfront payments we received during 2013 in connection with out-licensing agreements with international commercial partners.

Cost of products sold. As a percentage of net revenues, cost of products sold decreased to 13.7% during 2014, compared to 17.0% in the prior year. The decrease in costs of sales as a percentage of net revenue was partially attributable to a change in the product sales mix and an increase in our sales prices. The comparative decrease is also attributable to the recognition of $0.9 million in inventory write-downs during 2013 for potentially obsolete inventory.

Selling and marketing. Selling and marketing expense for 2014 was $14.9 million, compared to $14.4 million for the prior year, representing an increase of $0.5 million. The increase was the result of increased sales, including a $0.4 million increase in Omeclamox-Pak product royalties and increased distribution costs of products and product samples.

Research and development. Research and development costs in 2014 were $3.4 million, compared to $5.6 million during 2013, representing a decrease of approximately $2.2 million, or 39.6%. This change was a result of decreased product development and clinical study costs during 2014 following the conclusion of clinical studies related to Caldolor during 2013.

General and administrative. General and administrative expense for 2014 totaled approximately $8.4 million, compared to $9.5 million in 2013. The $1.1 million decrease was attributable to decreases in salary, wages and benefits, travel costs, legal expenses and consulting fees, as we continued to realign the organization to support the mix of brands.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization expense for 2014 was $1.6 million compared to $0.9 million in 2013, representing an increase of $0.7 million. The increase in amortization was attributable to additional product and license rights, capitalized patents and patent defense costs.

Income tax (expense) benefit. Income tax expense for the year ended December 31, 2014 totaled approximately $1.4 million, representing a $2.9 million increase in expense over the prior year income tax benefit of $1.5 million. The primary reason for the increase was the result of pretax income in 2014 compared to a pretax loss in 2013. As a percentage of income before income taxes, income tax expense was 36.9% for 2014 compared to a benefit percentage of 41.4% for 2013. The tax expense for 2014 was positively impacted by the extension of the U.S. research and development tax credit for 2014, along with the reduction in our state tax expense during 2014. The tax benefit for 2013 was positively impacted by the reinstatement of the U.S. research and development tax credit during 2013.

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, 2015, 2014 and 2013, we generated $5.9 million, $6.7 million and $0.7 million in cash flow from operations, respectively, and we borrowed $1.7 million on our line of credit during 2015. 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, 2015 and 2014, we had approximately $14.6 million and $14.8 million invested in marketable securities, respectively.

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

	2015	2014
Cash and cash equivalents	$ 38,203,059	$ 39,866,037
Marketable securities	14,564,115	14,841,418
Total cash, cash equivalents and marketable securities	$ 52,767,174	$ 54,707,455
Working capital (current assets less current liabilities)	$ 54,700,327	$ 57,065,489
Current ratio (multiple of current assets to current liabilities)	5.4	5.2
Revolving line of credit availability	$ 10,300,000	$ 12,000,000

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

	2015	2014	2013
Cash provided by (used in):			
Operating activities	$ 5,876,865	$ 6,693,431	$ 746,126
Investing activities	(2,344,972)	(6,034,440)	(5,071,939)
Financing activities	(5,194,871)	(1,662,411)	(9,154,111)
Net (decrease) increase in cash and cash equivalents	$ (1,662,978)	$ (1,003,420)	$ (13,479,924)

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.

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 $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.

The net use of cash and cash equivalents for the year ended December 31, 2013 was partly attributable to net investing and repayment of financing activities during the year. Net investing activities which used cash included $0.1 million in purchases of equipment and investment in intangible assets of $7.5 million. The investment in intangible assets includes our $4.0 million investment in Omeclamox-Pak. The cash used in investing activities was offset by our decrease of $2.5 million in net investment in marketable securities, with the decrease primarily in our VRDN's. We also repaid the outstanding balance of our revolving line of credit of $4.4 million during 2013. While net cash provided by operating activities was $0.7 million, the net loss of $2.2 million contributed to the net decrease in cash equivalents.

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 our previous primary lender which was to expire on December 31, 2014. There are $1.7 million in borrowings under the Loan Agreement at December 31, 2015. The Loan Agreement provides for an aggregate principal amount of up to $20 million and it has a three year term expiring on June 26, 2017. The initial revolving line of credit is up to $12 million, an increase from the $10 million under the previous agreement. We have the ability to increase the borrowing amount up to $20 million, upon the satisfaction of certain conditions.

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 1.2% at December 31, 2015). In addition, a fee of 0.25% per year is charged on the unused line of credit. Interest and the unused line fee are payable quarterly. Borrowings under the line of credit are collateralized by substantially all of the Company's assets. Under the Loan Agreement, we are subject to certain financial covenants, including, but not limited to, maintaining an EBIT to Interest Expense Ratio and a Funded Debt Ratio (as such terms are defined in the Loan Agreement) that are determined on a quarterly basis. We were in compliance with all covenants at December 31, 2015.

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, 2015:

		Payments Due by Year				
Contractual obligations[1]	**Total [2]**	**2016**	**2017**	**2018**	**2019**	**2020**
Amounts reflected in the balance sheet:						
Line of credit[3]	$ 38,625	$ 25,750	$ 12,875	$ —	$ —	$ —
Estimated interest on debt [3]	30,600	20,400	10,200	—	—	—
Other cash obligations not reflected on the balance sheet:						
Operating leases	6,324,377	1,075,243	1,039,618	901,568	838,896	2,469,052
Purchase obligations [4]	—	—	—	—	—	—
Total [1]	$ 6,393,602	$ 1,121,393	$ 1,062,693	$ 901,568	$ 838,896	$ 2,469,052

(1) The table of contractual obligations excludes amounts due under the Kristalose purchase agreement and the Omeclamox-Pak 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 includes a royalty expense as part of the period costs of the agreement.

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

(3) The line of credit payments represent the estimated unused line of credit payments and the 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 $1.7 million balance outstanding on December 31, 2015 is consistently outstanding through June 2017. 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 2015, 2014 and 2013, we did not engage in any off-balance sheet arrangements.

RECENTLY ISSUED BUT NOT YET ADOPTED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (the "FASB") issued amended guidance in the form of a FASB Accounting Standards Update ("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. Adoption prior to January 1, 2017, the original effective date, is not permitted. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application. We are assessing the potential impact of the new standard on financial reporting and have not yet selected a transition method by which we will adopt the standard.

In April 2015, the FASB issued amended guidance in a FASB ASU, "Interest-Imputation of Interest", which simplifies the balance sheet presentation of debt issuance costs. Under the new guidance, debt issuance costs related to a recognized debt liability will be presented on the balance sheet as a direct deduction from the liability. This treatment is consistent with the presentation of debt discounts. The new guidance is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted, and the new guidance should be applied retrospectively. In August 2015, The FASB issued additional related guidance in the form of another ASU "Interest-Imputation of Interest" that specifically addressed "Line -of-Credit Arrangements". The new guidance allows the presentation of deferred debt issuance costs as an asset and subsequently amortizing these costs over the term of the line-of-credit arrangement. This guidance applies whether or not there are any borrowings on the line-of-credit. We do not anticipate adoption of either ASU to have a material effect on our consolidated financial statements and disclosures.

In July 2015, the FASB issued amended guidance in the form of a FASB ASU on, “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 are evaluating the potential impact of this adoption on our consolidated financial statements and disclosures.

In November 2015, the FASB amended guidance in the form of a FASB ASU on, ″Balance Sheet Classification of Deferred Taxes", which requires that all deferred tax assets and liabilities be classified as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The FASB determined that this simplification could reduce cost and complexity without decreasing the usefulness of information provided to financial statement users. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance may be applied prospectively or retrospectively and early adoption is permitted. We do not anticipate adoption of this balance sheet classification ASU to have a material effect on our consolidated financial statements and disclosures.

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 the impact of our pending adoption of the new standard on our consolidated financial statements and disclosures.

There are no other recently issued but not yet adopted accounting pronouncements that would materially impact our financial condition or results of operations.

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 $14.6 million in marketable securities outstanding at December 31, 2015, 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 1.2% at December 31, 2015). As of December 31, 2015, we had $1.7 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 2015, 2014 and 2013. 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, 2015. Based on that evaluation, they have concluded that our disclosure controls and procedures were effective as of December 31, 2015 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 2015, 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.

Dr. Amy D. Rock, who had been serving as Cumberland's Vice President, Regulatory & Scientific Affairs, transitioned out of that role effective March 8, 2016 as she pursues interests outside of the Company. She will continue as an adviser to the Company.

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 2016 annual meeting of shareholders, which is expected to be filed with the SEC on or around March 11, 2016.

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
4.2	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on October 21, 2003, 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
4.3	Stock Purchase Warrant, issued to S.C.O.U.T. Healthcare Fund L.P. on April 15, 2004, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on June 22, 2007
4.4	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on April 6, 2006, 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
4.5#	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
10.1†	Manufacturing and Supply Agreement for N-Acetylcysteine, dated January 15, 2002, by and between Bioniche Life Sciences, Inc. and 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

Exhibit Number	Description
10.2	Novation Agreement, dated January 27, 2006, by and among Bioniche Life Sciences, Inc., Bioniche Pharma Group Ltd., and 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
10.3†	First Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated November 16, 2006, by and between Bioniche Teoranta 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
10.3.1†	Second Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated March 25, 2008, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.3.2†	Third Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, effective April 25, 2011, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on June 24, 2011
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
10.8†	Strategic Alliance Agreement, dated July 21, 2000, by and between F.H. Faulding & Co. Limited and Cumberland Pharmaceuticals Inc., including notification of assignment from F.H. Faulding & Co. Limited to Mayne Pharma Pty Ltd., dated April 16, 2002, incorporated herein by reference to the corresponding exhibit to Amendment No. 4 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 23, 2007
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 9, 2016, effective as of January 1, 2016, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10 .12#	Employment Agreement dated March 9, 2016, effective as of January 1, 2016, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement dated March 9, 2016, effective as of January 1, 2016, by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.
10.14#	Employment Agreement dated March 10, 2016, effective as of March 10, 2016, by and between Michael Bonner and Cumberland Pharmaceuticals Inc.
10.15#	Employment Agreement dated March 9, 2016, effective as of January 1, 2016, by and between James L. Herman and Cumberland Pharmaceuticals Inc.

Exhibit Number	Description
10.17#	1999 Stock Option Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.18#	Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to Appendix A of the Registrant's Schedule 14A as filed with the SEC on March 12, 2012 and approved by the Registrant's shareholders on April 17, 2012
10.19#	Amended and Restated 2007 Directors' Incentive Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to Appendix B of the Registrant's Schedule 14A as filed with the SEC on March 12, 2012 and approved by the Registrant's shareholders on April 17, 2012
10.20	Form of Indemnification Agreement between Cumberland Pharmaceuticals Inc. and all members of its Board of Directors, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.21†	Lease Agreement, dated September 10, 2005, by and between Nashville Hines Development, LLC and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.21.1†	First Amendment to Office Lease Agreement, dated April 25, 2008, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.21.2†	Second Amendment to Office Lease Agreement, dated March 2, 2010, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on May 17, 2010
10.21.3††	Third Amendment to Office Lease Agreement, dated September 29, 2015, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on November 6, 2015
10.23†	Amended and Restated Lease Agreement, dated November 11, 2004, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.24	First Amendment to Amended and Restated Lease Agreement, dated August 23, 2005, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.24.1	Second Amendment to Amended and Restated Lease Agreement, dated January 9, 2006, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.24.2†	Third Amendment to Amended and Restated Lease Agreement, dated July 3, 2012, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on August 9, 2012

Exhibit Number	Description
10.25††	License and Supply Agreement, dated November 16, 2015, by and between Cumberland Pharmaceuticals Inc. and Gastro-Entero Logic, LLC
10.28†	Asset Purchase and Royalty Agreement for Kristalose dated November 15, 2011 by and between Mylan Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on November 22, 2011
10.29†	Packaging Agreement effective November 1, 2011 by and among Mylan Institutional Inc., Mylan Pharmaceuticals Inc. and 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 7, 2012
10.30#	Supplemental Executive Retirement and Savings Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on May 24, 2012
10.31†	Settlement Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.32†	License and Supply Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.33	Revolving Credit Loan Agreement, dated June 26, 2014, by and between Cumberland Pharmaceuticals Inc. and SunTrust Bank incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on August 8, 2014
21	Subsidiaries of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
23.1	Consent of KPMG LLP
31.1	Certification of Chief Executive Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

# Indicates a management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

†† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 14, 2016.

Cumberland Pharmaceuticals, Inc.

/s/ A. J. Kazimi

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

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

Signature	Title	Date
/s/ A. J. Kazimi A. J. Kazimi	Chairman and CEO *(Principal Executive Officer and Director)*	March 14, 2016
/s/ Michael Bonner Michael Bonner	Senior Director and CFO *(Principal Financial and Accounting Officer*	March 14, 2016
/s/ Thomas R. Lawrence Thomas R. Lawrence	Director	March 14, 2016
/s/ Martin E. Cearnal Martin E. Cearnal	Director	March 14, 2016
/s/ Gordon R. Bernard Gordon R. Bernard	Director	March 14, 2016
/s/ Jonathan I. Griggs Jonathan I. Griggs	Director	March 14, 2016
/s/ James R. Jones James R. Jones	Director	March 14, 2016
/s/ Joey A. Jacobs Joey A. Jacobs	Director	March 14, 2016

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Cumberland Pharmaceuticals Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework (2013)*.

Based on its assessment, management has concluded that, as of December 31, 2015, the Company's internal control over financial reporting was effective based on those criteria.

/s/ A. J. Kazimi

A. J. Kazimi
Chief Executive Officer
March 14, 2016

/s/ Michael Bonner

Michael Bonner
Chief Financial Officer
March 14, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors

Cumberland Pharmaceuticals Inc.:

We have audited the accompanying consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive (loss) income, equity, and cash flows for each of the years in the three-year period ended December 31, 2015. In connection with our audit of the consolidated financial statements, we have also audited the financial statement Schedule II - Valuation and Qualifying Accounts for each of the years in the three-year period ended December 31, 2015. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

/s/ KPMG LLP
Nashville, Tennessee
March 14, 2016

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2015 and 2014

	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,203,059	$ 39,866,037
Marketable securities	14,564,115	14,841,418
Accounts receivable, net of allowances	6,077,120	5,504,728
Inventories	4,270,143	5,600,319
Prepaid and other current assets	1,468,913	1,351,324
Deferred tax assets	2,528,724	3,651,145
Total current assets	67,112,074	70,814,971
Property and equipment, net	536,450	651,030
Intangible assets, net	21,168,596	21,568,541
Deferred tax assets	1,210,786	578,592
Other assets	1,891,053	1,791,980
Total assets	$ 91,918,959	$ 95,405,114
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 2,877,479	$ 3,242,713
Other current liabilities	9,534,268	10,506,769
Total current liabilities	12,411,747	13,749,482
Revolving line of credit	1,700,000	—
Other long-term liabilities	987,429	902,841
Total liabilities	15,099,176	14,652,323
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock – no par value; 100,000,000 shares authorized; 16,379,501 and 17,118,993 shares issued and outstanding as of December 31, 2015 and 2014, respectively	57,338,294	61,942,410
Retained earnings	19,549,614	18,818,263
Total shareholders' equity	76,887,908	80,760,673
Noncontrolling interests	(68,125)	(7,882)
Total equity	76,819,783	80,752,791
Total liabilities and equity	$ 91,918,959	$ 95,405,114

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)

Years ended December 31, 2015, 2014 and 2013

	2015	2014	2013
Revenues:			
Net product revenue	$ 33,013,184	$ 36,683,762	$ 31,100,698
Other revenue	505,867	218,109	926,764
Net revenues	33,519,051	36,901,871	32,027,462
Costs and expenses:			
Cost of products sold	4,968,170	5,053,165	5,439,422
Selling and marketing	13,994,768	14,902,202	14,387,745
Research and development	3,847,651	3,389,419	5,615,501
General and administrative	7,607,588	8,401,560	9,489,976
Amortization	1,989,264	1,596,689	896,156
Total costs and expenses	32,407,441	33,343,035	35,828,800
Operating income (loss)	1,111,610	3,558,836	(3,801,338)
Interest income	209,183	251,447	230,291
Interest expense	(73,856)	(67,074)	(103,422)
Income (loss) before income taxes	1,246,937	3,743,209	(3,674,469)
Income tax (expense) benefit	(575,829)	(1,380,744)	1,523,051
Net income (loss)	671,108	2,362,465	(2,151,418)
Net loss at subsidiary attributable to noncontrolling interests	60,243	61,258	46,804
Net income (loss) attributable to common shareholders	$ 731,351	$ 2,423,723	$ (2,104,614)
Earnings (loss) per share attributable to common shareholders:			
Basic	$ 0.04	$ 0.14	$ (0.11)
Diluted	$ 0.04	$ 0.14	$ (0.11)
Weighted-average common shares outstanding:			
Basic	16,715,970	17,617,765	18,332,997
Diluted	17,094,754	17,899,632	18,332,997
Comprehensive income (loss) attributable to common shareholders	$ 731,351	$ 2,423,723	$ (2,104,614)
Net loss at subsidiary attributable to noncontrolling interests	60,243	61,258	46,804
Total comprehensive income (loss)	$ 671,108	$ 2,362,465	$ (2,151,418)

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years ended December 31, 2015, 2014 and 2013

	2015	2014	2013
Cash flows from operating activities:			
Net income (loss)	$ 671,108	$ 2,362,465	$ (2,151,418)
Adjustments to reconcile net income (loss) to net cash flows provided by operating activities:			
Depreciation and amortization expense	2,246,809	1,989,564	1,301,835
Deferred tax expense (benefit)	490,227	(309,330)	(1,579,918)
Share-based compensation	622,503	761,663	674,955
Excess tax benefit derived from exercise of stock options	(90,982)	(1,653,028)	(48,024)
Noncash interest expense	46,422	38,634	24,075
Noncash investment (gains) losses	(77,155)	(52,040)	178,822
Net changes in assets and liabilities affecting operating activities, net of effect of business combination:			
Accounts receivable	(572,392)	(974,304)	1,486,777
Inventories	1,330,176	1,532,563	495,473
Prepaid, other current assets and other assets	(263,084)	(1,011,365)	117,021
Accounts payable and other current liabilities	1,475,964	3,846,482	58,855
Other long-term liabilities	(2,731)	162,127	187,673
Net cash provided by operating activities	5,876,865	6,693,431	746,126
Cash flows from investing activities:			
Additions to property and equipment	(142,965)	(163,258)	(97,412)
Cash paid for acquisitions	—	(2,000,000)	—
Additions to intangible assets	(2,556,465)	(3,101,565)	(7,462,080)
Proceeds from sale of marketable securities	7,883,171	3,437,645	6,859,061
Purchases of marketable securities	(7,528,713)	(4,207,262)	(4,371,508)
Net cash used in investing activities	(2,344,972)	(6,034,440)	(5,071,939)
Cash flows from financing activities:			
Net (repayments) borrowings on line of credit	1,700,000	—	(4,359,951)
Repurchase of common shares	(5,338,967)	(4,315,444)	(4,800,908)
Cash settlement of contingent consideration	(1,668,252)	—	—
Exercise of stock options	21,366	—	(41,276)
Sale of subsidiary shares to noncontrolling interest	—	1,000,005	—
Excess tax benefit derived from exercise of stock options	90,982	1,653,028	48,024
Net cash used in financing activities	(5,194,871)	(1,662,411)	(9,154,111)
Net decrease in cash and cash equivalents	(1,662,978)	(1,003,420)	(13,479,924)
Cash and cash equivalents, beginning of year	39,866,037	40,869,457	54,349,381
Cash and cash equivalents, end of year	$ 38,203,059	$ 39,866,037	$ 40,869,457
Supplemental disclosure of cash flow information:			
Net cash paid (refunded) during the year for:			
Interest	$ 27,434	$ 28,440	$ 79,347
Income taxes	52,238	17,077	(129,509)
Noncash investing and financing activities:			
Change in unpaid invoices for purchases of intangibles	967,146	(1,574,847)	543,905

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Equity

Years ended December 31, 2015, 2014 and 2013

	Cumberland Pharmaceuticals Inc. Shareholders				
	Common stock				
	Shares	Amount	Retained earnings	Non-controlling interest	Total equity
Balance, December 31, 2012	18,937,107	67,197,167	18,499,154	(129,834)	85,566,487
Net loss			(2,104,614)	(46,804)	(2,151,418)
Share-based compensation	19,743	670,934			670,934
Exercise of options and related tax benefit	36,758	6,748			6,748
Repurchase of common shares	(1,008,105)	(4,800,908)			(4,800,908)
Balance, December 31, 2013	17,985,503	63,073,941	16,394,540	(176,638)	79,291,843
Net income			2,423,723	(61,258)	2,362,465
Share-based compensation	15,300	760,894			760,894
Exercise of options and related tax benefit	—	1,653,028			1,653,028
Sale of subsidiary shares to noncontrolling interest	—	769,991	—	230,014	1,000,005
Repurchase of common shares	(881,810)	(4,315,444)			(4,315,444)
Balance, December 31, 2014	17,118,993	$ 61,942,410	$ 18,818,263	$ (7,882)	$ 80,752,791
Net income			731,351	(60,243)	671,108
Share-based compensation	86,102	622,503			622,503
Exercise of options and related tax benefit	3,409	112,348			112,348
Repurchase of common shares	(829,003)	(5,338,967)			(5,338,967)
Balance, December 31, 2015	16,379,501	$ 57,338,294	$ 19,549,614	$ (68,125)	$ 76,819,783

See accompanying notes to consolidated financial statements.

(1) Organization

Cumberland Pharmaceuticals Inc. and its subsidiaries (the "Company," "Cumberland," or in certain context "our" or "we") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets are hospital acute care and gastroenterology. These medical specialties are characterized by relatively concentrated prescriber bases that the Company believes can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs.

Cumberland focuses its resources on maximizing the commercial potential of it's products, as well as developing new product candidates, and has both internal development and commercial capabilities. The Company's products are manufactured by third parties, which are overseen by Cumberland's quality control and manufacturing professionals. The Company works closely with its third-party distribution partner to make its products available in the United States.

In order to expand its portfolio of early-stage product candidates, the Company formed a subsidiary, Cumberland Emerging Technologies, Inc. ("CET"), which assists universities and other research organizations to help bring biomedical projects from the laboratory to the marketplace. The Company's ownership in CET is 80%. In 2014, the Company organized equity financing to recapitalize and strengthen the financial position of CET. This financing included an investment of approximately $1.0 million from Harbin Gloria Pharmaceuticals Co., Ltd. ("Gloria") for their participation in CET. As a result, Gloria received shares in CET and joined the CET ownership group. As noted above, the ownership interests of CET includes Gloria and Cumberland, while the remaining interest is owned by Vanderbilt University and the Tennessee Technology Development Corporation. The operating results of CET are allocated to noncontrolling interests in the consolidated statements of operations were approximately $60,243, $61,258 and $46,804 for the years ended December 31, 2015, 2014 and 2013, respectively.

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

(2) Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

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

Segment Reporting

The Company has one operating segment which is specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Operating segments are identified as components of an enterprise about which separate discrete financial information is evaluated by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company, which uses consolidated financial information in determining how to allocate resources and assess performance, evaluated that our specialty pharmaceutical products compete in similar economic markets and similar circumstances. Substantially all of the Company's assets are located in the United States. Total revenues are primarily attributable to U.S. customers. Net revenues from customers outside the United States were approximately $0.9 million, $0.6 million and $0.8 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Fair Value of Financial Instruments

Fair value of financial assets and liabilities is the price the Company would receive to sell an asset or pay to transfer a liability in an orderly transaction with a market participant at the measurement date. The Company's fair value measurements follow the appropriate rules as well as the fair value hierarchy that prioritizes the information used to develop the measurements. It applies whenever other guidance requires (or permits) assets or liabilities to be measured at fair value and gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

A summary of the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels is described below:

Level 1 - Quoted prices for identical instruments in active markets.

Level 2 - Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 - Significant inputs to the valuation model are unobservable.

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

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

The Company's fair values of marketable securities are determined based on valuations provided by a third-party pricing service, as derived from such services' pricing models, and are considered either Level 1 or Level 2 measurements, depending on the nature of the investment. The Company has no marketable securities in which the fair value is determined based on Level 3. The level of management judgment required in evaluating fair value for Level 1 investments is minimal. Similarly, there is little subjectivity or judgment required for Level 2 investments valued using valuation models that are standard across the industry and whose parameter inputs are quoted in active markets. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. Based on the information available, the Company

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

Cash and Cash Equivalents

Cash and cash equivalents include highly liquid investments with original maturities of three months or less. As of December 31, 2015 and 2014, cash equivalents consist primarily of money market funds.

Marketable Securities

The Company invests in marketable debt securities in order to maximize its return on cash. Marketable securities consist of U.S. Treasury notes and bonds, U.S. Government Agency notes and bonds and bank-guaranteed, variable rate demand notes (VRDN). At the time of purchase, the Company classifies marketable securities as either trading securities or available-for-sale securities, depending on the intent at that time. As of December 31, 2015 and 2014, marketable securities were comprised solely of trading securities. Trading securities are carried at fair value with unrealized gains and losses recognized as a component of interest income in the consolidated statements of operations.

Accounts Receivable

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

The majority of the Company’s products are distributed through independent pharmaceutical wholesalers. Net product revenues and accounts receivable take into account the sale of the product at the wholesale acquisition cost, and an accrual is recorded to reflect the difference between the wholesale acquisition cost and the estimated average end-user contract price. This accrual is calculated on a product-specific basis and is based on the estimated number of outstanding units sold to wholesalers that will ultimately be sold in end-user contracts. When the wholesaler sells the product to the end-user at the agreed upon end-user contract price, the wholesaler charges the Company for the difference between the wholesale acquisition price and the end-user contract price and this chargeback is offset against the initial accrual balance.

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

At the time a transaction is recognized as a sale, the Company records a reduction in revenues for an estimate of damaged product in the shipment. The Company’s estimate of the allowance for damaged product is based upon historical experience of claims made for damaged product.

Inventories

The Company works closely with third parties to manufacture and package finished goods for sale. Based on the customer relationship with the manufacturer or packager, the Company will either take title to finished goods at the time of shipment or at the time of arrival from the manufacturer. The Company then warehouses such goods until distribution and sale. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method.

The Company continually evaluates inventories for potential losses due to excess, obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value.

Prepaid and Other Current Assets

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

Property and Equipment

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

Intangible Assets

The Company's intangible assets consist of capitalized costs related to product and license rights, patents and trademarks.

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

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

Amortization expense is recognized ratably over the following periods:

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

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If events or circumstances arise that require a long-lived asset to be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by the asset to its carrying value. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment charge is recognized to the extent that the carrying value exceeds the fair value. Fair value is determined through various valuation techniques including quoted market prices, third-party independent appraisals and discounted cash flow models. The Company recorded no impairment charges during 2015, 2014 and 2013.

Revenue Recognition

Revenue is realizable and earned when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed and determinable; and collectibility of the related receivable is reasonably assured. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction.

Product Revenues

The Company's net product revenue reflects the reduction from gross product revenue for estimated allowances for chargebacks, discounts and damaged goods, and reflects sales related accruals for rebates, product returns, and certain administrative and service fees.

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

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

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

The Company has agreements with certain key wholesalers that include a fee for service costs. These costs are netted against product revenues.

Other Revenues

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

The Company is a party to several licensing arrangements with customers that purchase product from the Company. Under these licensing arrangements, the third-party licensee may have access to the Company's FDA registration file. Licensing arrangements typically include an up-front payment for gaining access to the FDA registration file, royalties and milestone payments upon the achievement of specific sales levels. The amounts received for access to the FDA registration file are evaluated and based on the evaluation, the resulting revenue is either recognized upfront or recognized over the term of the arrangement. Royalties and milestones are recognized as revenue when earned. For substantive milestones, the Company uses the milestone method of recognizing revenue if it is commensurate with either the performance to achieve the milestone or the enhancement of the value of the delivered item, it relates solely to past performance and it is reasonable relative to other milestones.

Cost of Products Sold

Cost of products sold consists principally of the cost to acquire each unit of product sold, including in-bound freight expense. Cost of products sold also includes expenses associated with the write-down of slow-moving or expired product.

Selling and Marketing Expense

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

Distribution Costs

Distribution costs are expensed as incurred and totaled $0.8 million in 2015, $1.0 million in 2014 and $0.9 million in 2013. They are included as a component of selling and marketing expenses in the consolidated statements of operations.

Advertising Costs

Advertising costs are expensed as incurred. These costs were $2.6 million, $2.5 million and $2.1 million in 2015, 2014 and 2013, respectively, and are included as a component of selling and marketing expenses in the consolidated statements of operations.

Research and Development

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

Income Taxes

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

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

The tax benefit associated with the exercise of nonqualified stock options is recognized when the benefit is used to offset income taxes payable.

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

Comprehensive Income (Loss)

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

Earnings (Loss) per Share

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

Share-Based Payments

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

Collaborative Agreements

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

Recent Accounting Guidance

In May 2014, the Financial Accounting Standards Board ("FASB") issued amended guidance in the form of a FASB Accounting Standards Update ("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 the Company to January 1, 2018. Adoption prior to January 1, 2017, the original effective date, is not permitted. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing the potential impact of the new standard on financial reporting and has not yet selected a transition method by which it will adopt the standard.

In April 2015, the FASB issued amended guidance in a FASB ASU, "Interest-Imputation of Interest", which simplifies the balance sheet presentation of debt issuance costs. Under the new guidance, debt issuance costs related to a recognized debt liability will be presented on the balance sheet as a direct deduction from the liability. This treatment is consistent with the presentation of debt discounts. The new guidance is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted, and the new guidance should be applied retrospectively. In August 2015, The FASB issued additional related

guidance in the form of another ASU "Interest-Imputation of Interest" that specifically addressed "Line -of-Credit Arrangements". The new guidance allows the presentation of deferred debt issuance costs as an asset and subsequently amortizing these costs over the term of the line-of-credit arrangement. This guidance applies whether or not there are any borrowings on the line-of-credit. The Company does not anticipate adoption of either ASU to have a material effect on its consolidated financial statements and disclosures.

In July 2015, the FASB issued amended guidance in the form of a FASB ASU on, “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. The Company is evaluating the potential impact of this adoption on our consolidated financial statements and disclosures.

In November 2015, the FASB amended guidance in the form of a FASB ASU on, ″Balance Sheet Classification of Deferred Taxes", which requires that all deferred tax assets and liabilities be classified as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The FASB determined that this simplification could reduce cost and complexity without decreasing the usefulness of information provided to financial statement users. The amendments in this update are effective for fiscal years beginning after December 15, 2016. The accounting guidance may be applied prospectively or retrospectively and early adoption is permitted. The Company does not anticipate adoption of this balance sheet classification ASU to have a material effect on its consolidated financial statements and disclosures.

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. The Company is evaluating the impact of its pending adoption of the new standard on Cumberland’s consolidated financial statements and disclosures.

(3) Vaprisol and Omeclamox-Pak

Vaprisol

On February 28, 2014, the Company acquired certain product rights, intellectual property and related assets of Vaprisol from Astellas Pharma US, Inc. ("Astellas"). Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia. Cumberland's acquisition of Vaprisol is accounted for as a business combination and the products sales are included in the results of operations subsequent to the acquisition date.

The Company provided an upfront payment of $2.0 million to Astellas at closing. The business combination provided for an additional milestone payment of up to $2.0 million, dependent upon Cumberland achieving certain first year sales levels for the product. The Company paid Astellas $1.7 million to fulfill the contingent consideration during April 2015. On a year-to-date basis the Company recognized a $0.3 million reduction in expense related to the contingent consideration as the cost of the Vaprisol acquisition was less than anticipated. Cumberland paid

approximately $0.1 million under the acquired contingent liabilities and recognized a $0.3 million reduction in expense during 2015 upon the resolution of the underlying contingency. Cumberland's acquisition of Vaprisol is accounted for as a business combination and the products sales are included in the results of operations subsequent to the acquisition date.

The following table summarizes the allocation of the fair value of the assets acquired and liabilities assumed as of the acquisition date for Vaprisol:

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

The contingent consideration obligation represents the additional milestone payment discussed above. Cumberland prepared the valuations of the contingent consideration obligation and the intangible assets utilizing significant unobservable inputs. As a result, the valuations are classified as Level 3 fair value measurements. Vaprisol contributed $2.6 million and $3.0 million in net revenues during 2015 and 2014, respectively. The pro-forma effects of the acquisition on the consolidated financial statements were not deemed material for disclosure purposes.

Omeclamox-Pak

During November 2015, Cumberland entered into a new agreement with Gastoenterlogics Inc. ("GEL") to assume the remaining commercial rights to Omeclamox-Pak for the United States. Omeclamox-Pak is a branded prescription product that combines omeprazole, amoxicillin and clarithromycin for the treatment of Helicobacter pylori (*H. pylori*) infection and duodenal ulcer disease. The Company had previously signed an agreement with Pernix Therapeutics ("Pernix") to jointly commercialize the product in the U.S. during October 2013. As part of the new GEL Agreement, Cumberland and Pernix terminated their arrangements. The Company will continue to market and sell Omeclamox-Pak and is now responsible for the supply chain, national accounts and all sales promotion as part of the GEL agreement. The Company will continue promotion to the gastroenterology community through its field sales force and seek a new co-promotion partner with national primary care capabilities in the U.S.

The agreement with GEL has a term through November 2035, with no additional upfront payments required. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits are paid by Cumberland to GEL.

Under the Company's previous agreement with Pernix to distribute and promote Omeclamox-Pak it paid an upfront payment of $4.0 million to Pernix in October 2013. The agreement called for additional milestones at the first and second anniversary dates of the execution of the agreement totaling $4.0 million in the aggregate. Cumberland was not required to make either milestone payment to Pernix as all the criteria for these payments were not met, including Pernix's co-promotion obligations. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits were paid by Cumberland to Pernix.

The $4.0 million upfront payment that the Company paid in October 2013 is included in product and license rights and is being amortized over the remaining expected useful life of the acquired asset, currently the life of the original Pernix agreement, June 2032. The agreement with GEL has a term of November 2035 and the Company has decided to maintain the original useful life for amortization purposes. Omeclamox-Pak contributed $3.0 million in net revenues during 2015 and $4.1 million during 2014.

(4) Revenues

Product Revenues

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

	2015	2014	2013
Products:			
Acetadote	$ 8,489,167	$ 11,906,232	$ 18,846,753
Omeclamox-Pak	3,037,078	4,111,916	1,045,815
Kristalose	15,733,327	14,932,271	9,118,475
Vaprisol	2,641,484	3,011,997	—
Caldolor	3,112,128	2,721,346	2,089,655
Total net product revenues	$ 33,013,184	$ 36,683,762	$ 31,100,698

As discussed in Note 3, the Company acquired rights to Omeclamox-Pak and Vaprisol and both products contributed to Cumberland's net revenue during 2015 and 2014. On October 28, 2013, Cumberland entered into an agreement with Pernix to distribute and promote Omeclamox-Pak. Under the terms of the agreement, effective October 1, 2013, the Company began to record the revenue of this product and effective January 2014 Cumberland began distributing Omeclamox-Pak and promoting it to gastroenterologists across the United States. On February 28, 2014, Cumberland entered into an agreement with Astellas to acquire Vaprisol including certain product rights, intellectual property and related assets. The Company began selling Vaprisol in March 2014 and launched promotional efforts for the brand in May 2014.

Cumberland supplies Perrigo Company ("Perrigo") with an Authorized Generic version of the Company's Acetadote product. The Company's revenue generated by sales of its Authorized Generic distributed by Perrigo is included in the Acetadote product revenue presented above. The Company's share of Authorized Generic revenue was $4.5 million, $5.8 million and $9.2 million during 2015, 2014 and 2013, respectively.

In 2011, the Company discontinued sales of the 400mg Caldolor offering domestically and focused on the 800mg Caldolor offering. During 2015 and 2014, Cumberland had total sales of $0.8 million and $0.5 million of its 400mg Caldolor offering outside the United States, respectively.

The allowances in accounts receivable for chargebacks, cash discounts and damaged goods were $0.4 million at December 31, 2015 and $0.4 million at December 31, 2014, and the accruals for rebates, product returns and certain administrative and service fees included in other current liabilities were $6.8 million and $5.2 million, at December 31, 2015 and 2014, respectively.

Other Revenues

The Company has entered into agreements, beginning in 2012, with international partners for commercialization of the Company's products. The international agreements provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, each partner will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulations. Under the international agreements, the Company is entitled to receive non-refundable up-front payments at the time the agreements are entered into and milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company will recognize revenue for these substantive milestones using the milestone method. The Company is also entitled to receive royalties on future sales of the products under the agreements. The international agreements provide for $1.4 million in non-refundable up-front payments and milestone payments of up to $1.7 million related to regulatory approvals and up to $4.7 million in payments related to product sales. As of December 31, 2015, the Company has recognized

a cumulative $1.5 million in upfront payments as other revenue and has not yet recorded any revenue related to the milestone payments associated with these international agreements.

Other revenues during 2015, 2014 and 2013 also includes revenue generated by CET through grant funding from federal Small Business grant programs, and lease income generated by CET's Life Sciences Center and contract services. The Life Sciences Center is a research center that provides scientists with access to flexible lab space and other resources to develop biomedical products. Grant revenue from SBIR/STTR programs totaled approximately $0.2 million for the year ending December 31, 2015 and $0.1 million for each of the years ended December 31, 2014 and 2013.

(5) Inventories

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

	2015	2014
Raw materials and work in process	$ 2,576,621	$ 2,571,465
Finished goods	1,693,522	3,028,854
Total inventories	$ 4,270,143	$ 5,600,319

Caldolor inventory on hand at December 31, 2015 and 2014 had varying original expiration dates ranging from the second quarter of 2014 and extending through January 2016. During 2013 and again in 2014, the Company provided stability data to the Food and Drug Administration ("FDA") supporting the extension of the Caldolor product expiration dates by an additional year. The FDA notified the Company that it had approved both requests to extend the original shelf life of the Caldolor 800mg vials from five to six years years in January 2014 and from six to seven years in March 2015.

At December 31, 2015 and 2014, the Company has recognized and maintained cumulative charges for potential obsolescence and discontinuance losses, primarily for Caldolor, of approximately $2.7 million and $3.2 million, respectively.

In connection with the acquisition of certain product rights related to the Kristalose brand, the Company is responsible for the purchase of the active pharmaceutical ingredient ("API") for Kristalose and maintains the inventory at the third-party manufacturer. As the API is consumed in production, the value of the API is transferred from raw materials to finished goods. API for the Company's Vaprisol brand is also included in the raw materials inventory total at December 31, 2015 and 2014.

(6) Property and Equipment

Property and equipment consisted of the following at December 31:

	Range of useful lives	2015	2014
Computer equipment	3 – 5 years	$ 839,563	$ 792,268
Office equipment	3 – 15 years	332,126	171,649
Furniture and fixtures	5 – 15 years	618,808	703,187
Leasehold improvements	3 – 15 years, or remaining lease term	1,243,025	1,223,453
Total property and equipment, gross		3,033,522	2,890,557
Less: accumulated depreciation and amortization		(2,497,072)	(2,239,527)
Total property and equipment, net		$ 536,450	$ 651,030

Depreciation expense, including amortization expense related to leasehold improvements, was $0.3 million during 2015 and $0.4 million during 2014 and 2013. Depreciation expense is included in general and administrative expense in the consolidated statements of operations.

(7) Intangible Assets

Intangible assets consisted of the following at December 31:

	2015	2014
Product and license rights	$ 18,011,362	$ 16,477,749
Less: accumulated amortization	(3,541,305)	(2,225,949)
Total product and license rights	14,470,057	14,251,800
Patents	8,236,719	8,194,264
Less: accumulated amortization	(1,551,430)	(877,523)
Total patents	6,685,289	7,316,741
Trademarks	22,270	9,020
Less: accumulated amortization	(9,020)	(9,020)
Total trademarks	13,250	—
Total intangible assets	$ 21,168,596	$ 21,568,541

In February 2014, the Company acquired the rights of the branded prescription product Vaprisol from Astellas (discussed more fully in Note 3). The intangible asset value is $3.0 million and is included in product and license rights. The asset will be amortized through February 2022, the remaining expected useful life of the acquired asset, which coincides with the life of the primary intellectual property asset.

During 2013, the Company entered into an agreement with Pernix to distribute and promote the branded prescription product Omeclamox-Pak. The $4.0 million upfront payment the Company paid to Pernix Therapeutics

on October 29, 2013 (discussed more fully in Note 3) is included in product and license rights and will be amortized through June 2032, the remaining expected useful life of the acquired asset. The Company will continue to market and sell Omeclamox-Pak through its agreement with GEL and is now responsible for the supply chain, national accounts and all sales promotion.

In 2011, the Company acquired the Kristalose trademark and FDA registration from Mylan Inc. The agreement requires the Company to make future quarterly payments over a seven-year period equal to a percentage of Kristalose net sales. The payments are being treated as consideration for the assets acquired and are being capitalized and amortized over the remaining expected useful life of the acquired asset, currently the remaining term of the 15 year agreement, through 2026. During 2015 and 2014, the Company paid $1.5 million and $1.3 million, respectively, to Mylan Inc. in Kristalose payments.

During 2015 and 2014 the Company recorded an additional $0.1 million and $3.3 million, respectively, in intangible assets for patents, trademarks and capitalized patent costs, including amounts incurred in the protection of the Company's intellectual property. These costs will be amortized over the remaining expected useful life of the associated patents.

Amortization expense related to product and license rights, trademarks and patents was $2.0 million, $1.6 million and $0.9 million during 2015, 2014 and 2013, respectively. The expected amortization expense for the Company's current balance of intangible assets are as follows:

Year ending December 31:		
2016	$	2,103,553
2017		2,103,553
2018		2,103,553
2019		2,103,553
2020 and thereafter		12,754,384
	$	21,168,596

(8) Other Current Liabilities

Other current liabilities consisted of the following at December 31:

	2015	2014
Rebates, product returns, administrative fees and service fees	$ 6,776,023	$ 5,234,800
Employee wages and benefits	1,034,991	1,154,093
Acquisition related accruals	—	2,360,960
Other	1,723,254	1,756,916
Total other current liabilities	$ 9,534,268	$ 10,506,769

(9) Debt

Debt Agreement

On June 26, 2014, the Company 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. The Company had $1.7 million in borrowings under the Loan Agreement at December 31, 2015. The Loan Agreement has an aggregate principal amount of up to

$20.0 million, and it has a three year term expiring on June 26, 2017. The initial revolving line of credit is up to $12.0 million, an increase from the $10.0 million under the previous agreement. The Company has 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 1.2% at December 31, 2015). 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 our assets.

Under the Loan Agreement, the Company is subject to certain financial covenants, including, but not limited to, maintaining an EBIT to Interest Expense Ratio and a Funded Debt Ratio, determined on a quarterly basis. The Company was in compliance with all covenants at December 31, 2015.

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

Previous Debt Agreement

The August 2011 Fifth Amended and Restated Loan Agreement carried an interest rate of the LIBOR Daily Floating Rate plus an applicable margin, as defined by the agreement (2.17% at December 31, 2013). Interest and an unused line of credit fee (0.25% per annum) were payable quarterly. There were no borrowings outstanding on the credit facility at December 31, 2014 or at any time during 2014.

Under the previous agreement, the Company was subject to certain financial covenants including, but not limited to, maintaining a leverage ratio and interest coverage ratio, as defined in the agreement. In March 2014 and May 2014, the previous agreement was amended for certain provisions related to the aggregate ownership of the Company's common stock over 30% and certain other financial covenants. As a result of the amendments, the Company was in compliance with all covenants.

(10) Shareholders' Equity

(a) Initial Public Offering

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

(b) Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock. The Board of Directors is authorized to divide these shares into classes or series, and to fix and determine the relative rights, preferences, qualifications and limitations of the shares of any class or series so established. At December 31, 2015 and 2014, there was no preferred stock outstanding.

(c) Common Stock

During 2015, 2014 and 2013, the Company issued 86,102 shares, 15,300 shares and 19,743 shares of common stock, respectively, as a result of restricted shares vesting as well as other common share issuances. Cumberland issued 3,409 and 36,758 common shares under option exercise transactions during 2015 and 2013, respectively. There were no option exercise transactions during 2014. The payment of dividends is restricted by the Agreement with the Company's primary lender.

(d) Warrants

In 2006, the Company signed a new line of credit agreement along with a term loan agreement with a financial institution. In conjunction with these agreements, the Company issued warrants to purchase up to 3,958 shares of common stock at $9.00 per share that expire in April 2016. All of these warrants were outstanding and exercisable as of December 31, 2015 and 2014.

In connection with the amendment to the debt agreements in 2009, the Company issued warrants to purchase up to 7,500 shares of common stock at $17.00 per share that expire in July 2019. All of these warrants were outstanding and exercisable as of December 31, 2015 and 2014.

(e) Share Repurchases

On May 13, 2010, the Company announced a share repurchase program to purchase up to $10 million of its common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012, January 2013, January 2015 and January 2016, the Company's Board of Directors replaced the prior authorizations with new $10 million authorizations for repurchases and retirement of the Company's outstanding common stock. The Company repurchased 829,003 shares, 881,810 shares and 1,008,105 shares of common stock for approximately $5.3 million, $4.3 million and $4.8 million during the years ended December 31, 2015, 2014 and 2013, respectively.

(f) Cumberland Emerging Technologies

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

(11) Earnings Per Share

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

	2015	2014	2013
Numerator:			
Net income (loss) attributable to common shareholders	$ 731,351	$ 2,423,723	$ (2,104,614)
Denominator:			
Weighted-average shares outstanding – basic	16,715,970	17,617,765	18,332,997
Dilutive effect of restricted stock and stock options	378,784	281,867	—
Weighted-average shares outstanding – diluted	17,094,754	17,899,632	18,332,997

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

	2015	2014	2013
Anti-dilutive shares	46,633	194,237	407,954

(12) Income Taxes

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

	2015	2014
Deferred Tax Assets		
Net operating loss and tax credits	$ 2,274,994	$ 2,205,260
Property and equipment and intangibles	326,499	300,301
Allowance for accounts receivable	145,200	172,008
Reserve for expired product	849,579	817,736
Inventory	1,154,507	1,412,477
Deferred charges	660,973	1,504,835
Cumulative compensation costs incurred on deductible equity awards	1,675,757	1,676,729
Total deferred tax assets	7,087,509	8,089,346
Deferred Tax Liabilities		
Intangible assets	(3,162,502)	(3,707,535)
Net deferred tax assets, before valuation allowance	3,925,007	4,381,811
Less: deferred tax asset valuation allowance	(185,497)	(152,074)
Net deferred tax assets	$ 3,739,510	$ 4,229,737

The following table summarizes the amount and year of expiration of the Company's federal and state net operating loss carryforwards as of December 31, 2015:

Years of expiration	Federal	State
2016 - 2018	$ —	$ 562,865
2019 - 2028	—	38,585,151
2029	42,973,043	10,266,915
2030 - 2035	1,984,927	1,615,752
Total federal and state net operating loss carryforwards	$ 44,957,970	$ 51,030,683

The Company has total recognized carryforward tax assets of $0.2 million for foreign tax credits and AMT carryforwards. In addition, the Company has recognized as of December 31, 2015 federal Orphan Drug and Research and Development tax credits of $1.1 million that expire between 2021 and 2035.

The Company has unrecognized federal net operating loss carryforwards as a result of the exercise of nonqualified options of approximately $43.0 million. These benefits occurred as a result of the actual tax benefit realized upon an employee's exercise exceeding the cumulative book compensation charge associated with the awards and will be recognized in the year in which they are able to reduce current income taxes payable. Accordingly, deferred tax assets are not recognized for these net operating loss carryforwards or credit carryforwards resulting from the exercise of nonqualified options. The Company's utilization of these net operating loss carryforwards and a net operating loss in 2013, resulted in minimal income taxes paid in each of the years 2009 through 2015. The Company expects to pay minimal income taxes in 2016 through utilization of these net operating loss carryforwards. The Company has $51.0 million of state net operating loss carryforwards. This amount includes $45.1 million from the exercise of nonqualified options during 2009 and 2015. The state net operating loss carryforwards above include approximately $3.9 million that is subject to a valuation allowance at December 31, 2015.

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

	2015	2014	2013
Current:			
Federal	$ (41,326)	$ (1,440,010)	$ (45,287)
State and other	(44,276)	(250,064)	(11,580)
Total current income tax expense	(85,602)	(1,690,074)	(56,867)
Deferred:			
Federal	(385,723)	213,552	1,426,701
State	(104,504)	95,778	153,217
Total deferred income tax benefit (expense)	(490,227)	309,330	1,579,918
Total income tax benefit (expense)	$ (575,829)	$ (1,380,744)	$ 1,523,051

Deferred income tax is comprised of the following components for the years ended December 31:

	2015	2014	2013
Deferred tax (expense) benefit, excluding items below	$ 26,193	$ 85,844	$ 60,739
Inventory	(257,970)	(83,418)	310,477
Operating loss carryforwards	34,465	17,424	788,342
Tax credit carryforwards	35,272	43,398	196,631
Valuation allowance due to changes in net deferred tax asset balances	(33,405)	(20,457)	(23,299)
Deductible equity awards	(972)	298,039	127,308
Allowance for accounts receivable	(26,808)	(63,438)	161,084
Deferred charges	(59,028)	838,556	83,755
Reserve for expired product	31,784	217,330	(106,554)
Intangible assets	(239,758)	(1,023,948)	(18,565)
Deferred income tax benefit (expense)	$ (490,227)	$ 309,330	$ 1,579,918

The valuation allowance at December 31, 2015, 2014 and 2013 is primarily related to state tax benefits at CET and CPSC that will likely not be realized.

The Company's effective income tax rate for 2015, 2014 and 2013 reconciles with the federal statutory tax rate as follows:

	2015	2014	2013
Federal tax expense at statutory rate	34 %	34 %	34 %
State income tax expense (net of federal income tax benefit)	4 %	5 %	4 %
Permanent differences associated with general business credits	(3)%	(1)%	5 %
Other permanent differences	10 %	1 %	— %
Other	1 %	(2)%	(1)%
Net income tax expense	46 %	37 %	42 %

During 2012, the Company's 2009 federal tax return was examined with no significant findings or adjustments. Federal tax years that remain open to examination are 2010 through 2014. Due to a 2009 net operating loss carryback, federal tax years 2006 through 2008 remain open to the extent of net operating losses utilized in those years. State tax years that remain open to examination are 2008 to 2014. The Company has no unrecognized tax benefits in 2015, 2014 and 2013.

Excluding the alternative minimum tax (AMT) tax credits, the Company will need to generate future taxable income in order to realize its deferred tax assets. Based upon the level of taxable income over the last three years and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will realize the benefits of these deductible differences, net of the existing valuation allowances at December 31, 2015. The amount of deferred tax assets considered realizable, however, could be reduced in the future periods if estimates of future taxable income during the carryforward period are reduced.

(13) Stock-Based Compensation Plans

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

The exercise price of stock options is generally 100% of the fair market value of the underlying common stock on the grant date. The exercise price of incentive stock options granted to a shareholder who owns more than 10% of the total combined voting power of all classes of stock must be at least 110% of the fair market value of the underlying common stock on the grant date. The maximum contractual term of stock options is ten years from the date of grant, except for incentive stock options granted to 10% shareholders, which are five years.

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

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

	2015	2014	2013
Share-based compensation - employees	$ 456,749	$ 660,963	$ 614,818
Share-based compensation - nonemployees	165,754	99,931	56,116
Total share-based compensation	$ 622,503	$ 760,894	$ 670,934

At December 31, 2015, there was approximately $1.8 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted-average period of 2.6 years. This amount relates primarily to unrecognized compensation cost for employees.

Stock Options

Stock option activity for 2015 and 2014 was as follows:

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding, December 31, 2013	356,496	$ 6.96	1.0	$ 360
Options granted	—	—		
Options exercised	—	—		
Options forfeited or expired	(198,140)	6.46		
Outstanding, December 31, 2014	158,356	7.62	0.4	2,320
Options granted	—	—		
Options exercised	(5,652)	5.75		
Options forfeited or expired	(140,404)	7.41		
Outstanding, December 31, 2015	12,300	10.89	1.6	$ —
Exercisable at December 31, 2015	12,300	$ 10.89	1.6	$ —

The Company did not grant any stock options during 2015, 2014 and 2013, and no options were exercised during 2014 . Information related to the stock option plans during 2015, 2014 and 2013 was as follows:

	2015	2014	2013
Intrinsic value of options exercised	$ 3,875	$ —	$ 212,444
Weighted-average fair value of options exercised	$ 3.26	$ —	$ 0.12

Restricted Stock Awards

As previously noted, the Company began issuing restricted stock to employees and directors in 2011 under the provisions of the 2007 Plan and the Directors' Plan. Restricted stock issued to employees generally cliff-vests on the fourth anniversary of the date of grant. Restricted stock issued to directors vests on the one year anniversary of the date of grant. Restricted stock activity was as follows:

	Number of shares	Weighted-average grant-date fair value
Nonvested, December 31, 2013	520,584	$ 5.05
Shares granted	219,734	4.68
Shares vested	(11,300)	4.78
Shares forfeited	(36,181)	5.41
Nonvested, December 31, 2014	692,837	4.92
Shares granted	225,661	6.72
Shares vested	(81,270)	5.22
Shares forfeited	(97,179)	5.49
Nonvested, December 31, 2015	740,049	5.36

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

(14) Employee Benefit Plans

The Company sponsors an employee benefit plan that was established on January 1, 2006, the Cumberland Pharmaceuticals 401(k) Plan (the Plan), under Section 401(k) of the Internal Revenue Code of 1986, as amended, for the benefit of all employees over the age of 21, having been employed by the Company for at least six months. The Plan provides that participants may contribute up to the maximum amount of their compensation as set forth by the Internal Revenue Service each year. Employee contributions are invested in various investment funds based upon elections made by the employees. During 2015, 2014 and 2013, the Company contributed approximately $50,000 in each year to the Plan as an employer match of participant contributions.

In 2012 and 2013, the Company established non-qualified unfunded deferred compensation plans that allow participants to defer receipt of a portion of their compensation. The liability under the plans was $0.7 million and $0.6 million as of December 31, 2015 and 2014, respectively. The Company had assets consisting of company-owned life insurance contracts generally designated to pay benefits of the deferred compensation plans of $1.8 million and $1.7 million as of December 31, 2015 and 2014, respectively.

(15) Leases

The Company is obligated under long-term real estate leases for corporate office space that was extended during the third quarter of 2015. Prior to this extension, the lease would have expired in October 2016, the lease is now set to expire in October 2022 . In addition, the research lab space at CET, under an agreement amended in July 2012, is leased through 2018, with an option to extend the lease through April 2028. The Company also subleases a portion of the space under these leases. Rent expense is recognized over the expected term of the lease, including renewal option periods, if applicable, on a straight-line basis. Rent expense for 2015, 2014 and 2013 was approximately $1.0 million, $1.0 million and $0.9 million, respectively, and sublease income was approximately $0.6 million, $0.5 million and $0.5 million. Cumulative future minimum sublease income under noncancelable operating subleases totals approximately $0.1 million and will be paid through the lease ending in October 2016. Future minimum lease payments under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are as follows:

Year ending December 31:		
2016	$	1,075,243
2017		1,039,618
2018		901,568
2019		838,896
2020 and thereafter		2,469,052
Total future minimum lease payments	$	6,324,377

(16) Fair Value of Financial Instruments

The Company owns marketable securities that are solely classified as trading securities as of December 31, 2015. There were no transfers of assets between levels within the fair value hierarchy. The following table summarizes the fair value of these marketable securities by level within the fair value hierarchy:

	December 31, 2015			December 31, 2014		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	$ —	$ —	$ —	$ 1,338,010	$ —	$ 1,338,010
U.S. Agency issued mortgage-backed securities - variable rate	—	5,700,335	5,700,335	—	4,003,375	4,003,375
U.S. Agency notes and bonds - fixed rate	—	2,447,066	2,447,066	—	3,251,336	3,251,336
SBA loan pools - variable rate	—	1,681,714	1,681,714	—	1,413,697	1,413,697
Municipal bonds - VRDN	4,735,000	—	4,735,000	4,835,000	—	4,835,000
Total fair value of marketable securities	$ 4,735,000	$ 9,829,115	$ 14,564,115	$ 6,173,010	$ 8,668,408	$ 14,841,418

The fair values of all other financial instruments outstanding as of December 31, 2015 and 2014 approximate their carrying values. There were no changes to the valuation techniques for the Level 2 marketable securities during 2015 or 2014.

(17) Market Concentrations

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

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

	2015	2014	2013
Customer 1	22%	21%	19%
Customer 2	28%	27%	23%
Customer 3	32%	34%	23%
Customer 4	9%	11%	24%

The Company's accounts receivable, net of allowances, due from these four customers at December 31, 2015 and 2014 was 71% and 91%, respectively.

(18) Manufacturing and Supply Agreements

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

(19) Employment Agreements

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

(20) Commitments and Contingencies

Commitments

In connection with the acquisition of certain Kristalose assets during 2011, the Company is required to make quarterly payments based on a percentage of Kristalose net sales through November 2018. The payments are being treated as consideration for the assets acquired, and are being capitalized and amortized over the remaining expected useful life of the acquired asset, currently the term of the agreement, 15 years.

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

As discussed in Note 3, in connection with the agreements with Pernix and GEL to promote Omeclamox-Pak, the Company is required to make monthly royalty payments based on tiered levels of gross profits. These costs will be period expenses of the Company.

Legal Matters

In April 2012, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,148,356 (the "356 Acetadote Patent") to the Company. 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, the Company received separate Paragraph IV certification notices from InnoPharma, Inc. ("InnoPharma"), Paddock Laboratories, LLC ("Paddock"), Mylan Institutional LLC ("Mylan"), Sagent Agila LLC ("Sagent") and Perrigo Company ("Perrigo") challenging the 356 Acetadote Patent on the basis of non-infringement and/or invalidity. The Company responded by filing five separate infringement lawsuits, in the appropriate United States District Courts, to contest each of the challenges.

On November 12, 2012, the Company entered into a Settlement Agreement (the "Settlement Agreement") with Paddock and Perrigo to resolve the challenges and the pending litigation with those two companies. On November 1, 2013, the United States District Court filed opinions granting Sagent's and InnoPharma's motions to dismiss the Company's suits. In November the Company agreed not to file an appeal or motion to reconsider and 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, Cumberland entered into a License and Supply Agreement with Paddock and Perrigo (the "License and Supply Agreement"). Under the terms of the License and Supply Agreement, 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, the Company supply's Perrigo with an Authorized Generic version of its Acetadote product (the "Authorized Generic").

On May 18, 2012, Cumberland also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that the Company evaluate the reduction or removal of EDTA from its original Acetadote formulation. On November 7, 2012, the FDA responded to the Citizen Petition denying its request and on November 8, 2012, the Company learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. Cumberland 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, the Company began to supply Perrigo with its Authorized Generic. On January 7, 2013, Perrigo announced initial distribution of Cumberland's Authorized Generic acetylcysteine injection product.

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

Pharmaceuticals, Inc., and Mylan Institutional LLC challenging the 445 Acetadote Patent on the basis of non-infringement, unenforceability and/or invalidity.

On June 10, 2013, The Company became aware of a Paragraph IV certification notice from Akorn, Inc. challenging the 445 Acetadote Patent and the 356 Acetadote Patent on the basis of non-infringement. On July 12, 2013, Cumberland filed a lawsuit for infringement of the 356 Acetadote Patent against Akorn, Inc. in 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 Cumberland's favor in its lawsuit against Mylan for infringement of the 445 Acetadote Patent. The opinion upheld Cumberland's 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to the Company 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 Company continues to consider its legal options and intends to continue to vigorously defend and protect its Acetadote product and related intellectual property rights.

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

(21) Quarterly Financial Information (Unaudited)

The following table sets forth the unaudited operating results for each fiscal quarter of 2015 and 2014:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2015:					
Net revenues	$ 8,686,774	$ 8,909,741	$ 7,885,048	$ 8,037,488	$ 33,519,051
Operating income	4,116	673,931	270,884	162,679	1,111,610
Net income attributable to common shareholders	46,281	407,398	126,613	151,059	731,351
Earnings per share attributable to common shareholders [1]					
Basic	$ —	$ 0.02	$ 0.01	$ 0.01	$ 0.04
Diluted	$ —	$ 0.02	$ 0.01	$ 0.01	$ 0.04
2014:					
Net revenues	$ 8,093,244	$ 9,750,168	$ 9,729,047	$ 9,329,412	$ 36,901,871
Operating income	408,051	1,215,609	989,038	946,138	3,558,836
Net income attributable to common shareholders	286,320	722,570	745,920	668,913	2,423,723
Earnings per share attributable to common shareholders [1]					
Basic	$ 0.02	$ 0.04	$ 0.04	$ 0.04	$ 0.14
Diluted	$ 0.02	$ 0.04	$ 0.04	$ 0.04	$ 0.14

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

Schedule II

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Valuation and Qualifying Accounts

Years ended December 31, 2015, 2014 and 2013

Description	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
Allowance for uncollectible amounts, cash discounts, chargebacks, and credits issued for damaged products:					
For the years ended December 31:					
2013	$ 188,587	$ 2,498,170	$ —	$ (2,093,641) [1]	$ 593,116
2014	593,116	5,166,568	—	(5,321,327) [1]	438,357
2015	438,357	3,903,285	—	(3,960,402) [1]	381,240
Valuation allowance for deferred tax assets:					
For the years ended December 31:					
2013	$ 108,318	$ 23,299	$ —	$ —	$ 131,617
2014	131,617	20,457	—	—	152,074
2015	152,074	33,423	—	—	185,497

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

March 9, 2016

Mr. A.J. Kazimi
2525 West End Avenue, Suite 950
Nashville, TN 37203

Re: Employment of A.J. Kazimi as Chief Executive Officer by Cumberland Pharmaceuticals Inc.

Dear A.J.:

Effective January 1, 2016, this letter agreement (the "Agreement") will evidence the terms and conditions under which you will be employed by Cumberland Pharmaceuticals Inc. (the "Company") In consideration of your appointment as Chief Executive Officer of the Company, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Compensation. The Company agrees to compensate you as follows:

(a) The Company agrees to pay you on a salary basis for services performed based on an annual rate of four hundred ninety-eight thousand dollars ($498,000.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2016. For each year, thereafter, you will be paid on a salary basis for services performed based on an annual rate determined by the Company in its sole discretion; provided, however, that any obligation to make payments under this Section 1(a) will cease upon termination of your employment for any reason. Notwithstanding the foregoing, nothing in this Section 1(a) alters or is intended to alter the at-will nature of your employment as described in Section 3 of this Agreement.

(b) You will be eligible to participate in any Company-wide employee benefits as approved by the Board of Directors. The terms of your eligibility and participation will be governed by the provisions of the employee benefit plans, as such plans may be amended from time to time in the discretion of the Company's Board of Directors.

(c) You may be eligible for any Company bonus program, based upon performance in meeting your individual objectives and the Company's overall performance, both as determined and approved by the Board of Directors of the Company. Any such bonus will be discretionary and will be subject to the terms of the applicable bonus program, the terms of which program may be modified from year to year in the sole discretion of the Company's Board of Directors.

(d) You will receive a grant of Cumberland Pharmaceuticals common stock, pursuant to a restricted stock agreement (RSA). Such shares will be subject to the RSA and the terms set forth in the incentive compensation plan under which they are awarded. You may, at the Company's sole discretion, receive additional awards of Company equity, which will be subject to their designated agreements and the incentive compensation plans under which they are awarded.

(e) Except as set forth in Section 2, the Company shall not be liable to you for any expense incurred by you unless you receive the Company's prior written consent to reimburse you for such expense.

2. Additional Payments. During the term hereof, you shall be entitled to receive prompt reimbursement for all reasonable and documented expenses incurred in the performance of services in accordance with the expense reimbursement policy of the Company. Such reimbursement policy shall require adequate documentation by you of the expenses and payment by the Company of such amounts shall be made within a reasonable period after the close of the year in which the expenses were incurred.

3. Employment at Will. This Agreement is not intended to and shall not be understood in any manner as affecting or modifying the at-will status of your employment with the Company. As an at-will employee either you or the Company may terminate the employment relationship at any time with or without cause or notice. The obligations of Sections 4, 5, 6, 7, 8, 10, 11 and 12 herein shall survive the termination of the employment relationship or of this Agreement.

4. Confidentiality. All knowledge and information, not already available to the public, which you acquire, have acquired, or will acquire in the course of your employment with the Company with respect to the Company's business, work methods, or pending regulatory matters, or other Company matters that are treated by the Company as confidential, shall be regarded by you as trade secrets, whether or not they are classifiable legally as trade secrets, and shall be treated by you as strictly confidential. Such knowledge and information shall not either directly or indirectly be used, disclosed, or made accessible to anyone by you for any purpose, except in the ordinary course of the Company's business under circumstances in which you are authorized to use or disclose such information. No disclosures of such confidential information shall be made outside of those you are authorized to make in the regular and ordinary course of your duties unless and until you receive prior written permission of the Board of Directors of the Company to make such disclosure.

5. Discoveries and Improvements. During the time that you are employed by the Company, all confidential information, trade secrets, or proprietary information and all other discoveries, inventions, software programs, processes, methods and improvements that are conceived, developed, or otherwise made by you, alone or with others, that relate in any way to the Company's present or planned business or products (collectively the "Developments"), whether or not patentable or subject to copyright protection and whether or not reduced to tangible form or reduced to practice, shall be the sole property of the Company. You agree to disclose all Developments promptly, fully and in writing to the Company. You agree to keep and maintain adequate and current dated and witnessed written records of all such Developments, in the form of notes, sketches, drawings, or reports, which records shall be promptly submitted to the Company and shall be and remain the

property of the Company at all times. You agree to assign, and hereby do assign, to, the Company all your right, title and interest throughout the world in and to all Developments. You agree that all Developments shall constitute "Works for Hire" (as such are defined under the U.S. Copyright Laws) and hereby assign to the Company all copyrights, patents and other proprietary rights you may have in any Developments without any obligation on the part of the Company to pay royalties or any other consideration to you for such Developments.

6. Publication. All documents and other writings produced by you during the period of your employment, which relate to work you are doing or have done for the Company or to the business of the Company or its affiliates, shall belong to the Company. You will not publish outside of the Company any such writing without the prior written consent of the Board of Directors of the Company. You will, without further compensation, execute at any time (whether or not you are still employed by the Company) all documents requested of you relating to the protection of such rights, including the assignment of such rights to the Company.

7. Litigation. You shall notify the Company within three business days if no longer employed and immediately if still employed by the Company if you are contacted by any person relating to any claim or litigation against the Company. You shall not communicate in any manner with any person related to any claim or litigation against the Company without the prior consent of the Board of Directors of the Company unless compelled to do so by law.

8. Competition. For so long as you are employed by the Company or any Affiliate (as defined below) and for a period of one year after you cease to be employed by the Company or any Affiliate, you shall not, directly or indirectly, engage in any work or other activity--whether as owner, stockholder, partner, officer, consultant, or otherwise--involving a trademark, product, or process that, in the opinion of the Company's President, is similar to a trademark, product or process on which you worked for the Company (or any Affiliate) or obtained knowledge about while working for the Company at any time during the period of employment, if such work or other activity is then, or reasonably expected to become, competitive with that of the Company (or any Affiliate). The restriction in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such work or activity and have received a release in writing from the Board of Directors of the Company allowing you to engage in such work or activity. The Company's President shall have sole discretion to determine whether your work or activity for another employer involves trademarks, products, or processes that are similar to trademarks, products, or processes that you worked on for the Company. Ownership by you of five percent (5%) or less of the outstanding shares of stock of any company either (i) listed on a national securities exchange, or (ii) having at least one hundred (100) stockholders shall not make you a "stockholder" within the meaning of that term as used in this paragraph. For one year after you cease to work for the Company, you will not engage in any work or activity that will cause you to inevitably disclose to anyone not employed by the Company (or an Affiliate) any trade secret or confidential information that belongs to the Company or one of its Affiliates. Nothing in this paragraph shall limit the rights or remedies of the Company arising, directly or indirectly, from such competitive employment, including, without limitation, claims based upon breach of fiduciary duty, misappropriation, or theft of confidential information. The term "Affiliate" shall mean the Company and any entity controlling, controlled by, or under common control with the Company.

9. Conflicting Contracts. You represent and warrant that you are not now under any obligation resulting from any contract or arrangement, to any person, firm, or corporation, which is inconsistent or in conflict with this Agreement. Likewise you represent and warrant that you are not now under any obligation resulting from any contract or arrangement to any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your obligations to the Company.

10. Solicitation. After you cease to be employed by the Company (or a Company affiliate):

(a) You agree not to solicit, directly or indirectly, business related to the development or sales of pharmaceutical products from any entity, organization, or person which is contracted with the Company, which has been doing business with the Company or from which the Company was soliciting at the time of your termination, or a firm which you knew or had reason to know that the Company was going to solicit business at the time you ceased to be employed by the Company. The restriction set forth in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such solicitation and have received a release in writing from the Board of Directors of the Company to engage in such solicitation.

(b) You agree not to solicit, recruit, hire, or assist in the hiring of any employee of the Company to work for you or another person, firm, corporation, or business.

11. Return of Documents. Upon termination of your employment for any reason, you shall immediately return to the Company all documents and things belonging to the Company. This includes, but is not limited to, trade secrets, confidential information, knowledge, data or know-how, and software containing such information, whether or not the documents are marked "Confidential."

12. Remedies. You acknowledge that in the event of breach of this Agreement by you, actual damages to the Company will be impossible to calculate, the Company's remedies at law will be inadequate, and the Company will suffer irreparable harm. Therefore, you agree that any of the covenants contained in this Agreement may be specifically enforced through injunctive relief, but such right to injunctive relief shall not preclude the Company from other remedies which may be available to it. You further agree that should you fail to keep any of the promises made by you in this Agreement, or any way violate this Agreement, the Company shall be entitled to recover all monies the Company is required to spend, including attorneys' fees, to enforce the provisions of this Agreement.

13. Best Efforts and Conflicts of Interest: You are hired with the understanding that Cumberland is your sole employer and you will provide a full-time work effort. You agree to devote your entire professional and business-related time and best efforts to the services required of you by the express and implicit terms of this Agreement, to the reasonable satisfaction of Cumberland in its sole and complete discretion. Engaging in activities outside of work that create a conflict of interest, or detract from your ability to perform your assigned responsibilities or meet your defined goals and objectives with Cumberland, is a problem and may lead to disciplinary action up to and including termination of employment. If you believe that you are potentially involved in a situation that could

create a conflict of interest and affect your ability to adequately perform your job with Cumberland, you should inform your direct supervisor and Cumberland's Human Resources Department immediately.

14. Standards of Business Conduct and Ethics. Cumberland's commitment to a culture of integrity, ethics and compliance with the law is comprised in this policy, which will be provided to you as part of the conditions of your employment. You will have the opportunity to read, discuss and understand this policy prior to accepting and signing its Letter of Agreement.

15. Debarment. You represent and warrant that you have not been debarred and will notify the Company immediately if you are debarred, pursuant to subsection 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act.

16. Notice. Any notice required or permitted to be given under this Agreement shall be sufficient if in writing and if sent by registered or certified mail to your residence or to the Company's principal office in the case of the Company.

17 Waiver. The waiver by either party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

18. Entire Agreement. This Agreement contains the entire agreement of the parties and may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

19. Governance. This Agreement shall be governed by the laws of the State of Tennessee. Any dispute arising out of this Agreement shall be resolved, at the Company's sole option, by courts sitting in Nashville, Tennessee, and you waive any objection to such venue.

20. Enforceability. In the event that any provision of this Agreement shall be held by a court to be unenforceable, such provision will be enforced to the maximum extent permissible, and the remaining portions of this Agreement shall remain in full force and effect.

21. Survival. Notwithstanding any termination of your employment, this Agreement shall survive and remain in effect in accordance with its terms.

# # # #

This letter agreement may be signed in one or more counterparts, each of which shall be an original and all of which will constitute one and the same instrument.

Sincerely yours,

CUMBERLAND PHARMACEUTICALS INC.

/s/ Jean W. Marstiller

By: Jean W. Marstiller
Corporate Secretary

Accepted as to all terms and conditions
as of the 9th of March, 2016:

/s/ A.J. Kazimi

A.J. Kazimi

March 9, 2016

Mr. Martin E. Cearnal
2525 West End Avenue, Suite 950
Nashville, TN 37203

Re: Employment of Martin E. Cearnal as Senior Vice President, Chief Commercial Officer by Cumberland Pharmaceuticals Inc.

Dear Martin:

Effective January 1, 2016, this letter agreement (the "Agreement") will evidence the terms and conditions under which you will be employed by Cumberland Pharmaceuticals Inc. (the "Company") In consideration of your appointment as Senior Vice President, Chief Commercial Officer of the Company, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Compensation. The Company agrees to compensate you as follows:

(a) The Company agrees to pay you on a salary basis for services performed based on an annual rate of two hundred seventy-five thousand one hundred dollars ($275,100.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2016. For each year, thereafter, you will be paid on a salary basis for services performed based on an annual rate determined by the Company in its sole discretion; provided, however, that any obligation to make payments under this Section 1(a) will cease upon termination of your employment for any reason. Notwithstanding the foregoing, nothing in this Section 1(a) alters or is intended to alter the at-will nature of your employment as described in Section 3 of this Agreement.

(b) You will be eligible to participate in any Company-wide employee benefits as approved by the Board of Directors. The terms of your eligibility and participation will be governed by the provisions of the employee benefit plans, as such plans may be amended from time to time in the discretion of the Company's Board of Directors.

(c) You may be eligible for any Company bonus program, based upon performance in meeting your individual objectives and the Company's overall performance, both as determined and approved by the Board of Directors of the Company. Any such bonus will be discretionary and will be subject to the terms of the applicable bonus program, the terms of which program may be modified from year to year in the sole discretion of the Company's Board of Directors.

(d) You will receive a grant of Cumberland Pharmaceuticals common stock, pursuant to a restricted stock agreement (RSA). Such shares will be subject to the RSA and the terms set forth in the incentive compensation plan under which they are awarded. You may, at the Company's sole discretion, receive additional awards of Company equity, which will be subject to their designated agreements and the incentive compensation plans under which they are awarded.

(e) Except as set forth in Section 2, the Company shall not be liable to you for any expense incurred by you unless you receive the Company's prior written consent to reimburse you for such expense.

2. Additional Payments. During the term hereof, you shall be entitled to receive prompt reimbursement for all reasonable and documented expenses incurred in the performance of services in accordance with the expense reimbursement policy of the Company. Such reimbursement policy shall require adequate documentation by you of the expenses and payment by the Company of such amounts shall be made within a reasonable period after the close of the year in which the expenses were incurred.

3. Employment at Will. This Agreement is not intended to and shall not be understood in any manner as affecting or modifying the at-will status of your employment with the Company. As an at-will employee either you or the Company may terminate the employment relationship at any time with or without cause or notice. The obligations of Sections 4, 5, 6, 7, 8, 10, 11 and 12 herein shall survive the termination of the employment relationship or of this Agreement.

4. Confidentiality. All knowledge and information, not already available to the public, which you acquire, have acquired, or will acquire in the course of your employment with the Company with respect to the Company's business, work methods, or pending regulatory matters, or other Company matters that are treated by the Company as confidential, shall be regarded by you as trade secrets, whether or not they are classifiable legally as trade secrets, and shall be treated by you as strictly confidential. Such knowledge and information shall not either directly or indirectly be used, disclosed, or made accessible to anyone by you for any purpose, except in the ordinary course of the Company's business under circumstances in which you are authorized to use or disclose such information. No disclosures of such confidential information shall be made outside of those you are authorized to make in the regular and ordinary course of your duties unless and until you receive prior written permission of the Board of Directors of the Company to make such disclosure.

5. Discoveries and Improvements. During the time that you are employed by the Company, all confidential information, trade secrets, or proprietary information and all other discoveries, inventions, software programs, processes, methods and improvements that are conceived, developed, or otherwise made by you, alone or with others, that relate in any way to the Company's present or planned business or products (collectively the "Developments"), whether or not patentable or subject to copyright protection and whether or not reduced to tangible form or reduced to practice, shall be the sole property of the Company. You agree to disclose all Developments promptly, fully and in writing to the Company. You agree to keep and maintain adequate and current dated and witnessed written records of all such Developments, in the form of notes, sketches, drawings, or reports, which records shall be promptly submitted to the Company and shall be and remain the

property of the Company at all times. You agree to assign, and hereby do assign, to, the Company all your right, title and interest throughout the world in and to all Developments. You agree that all Developments shall constitute "Works for Hire" (as such are defined under the U.S. Copyright Laws) and hereby assign to the Company all copyrights, patents and other proprietary rights you may have in any Developments without any obligation on the part of the Company to pay royalties or any other consideration to you for such Developments.

6. Publication. All documents and other writings produced by you during the period of your employment, which relate to work you are doing or have done for the Company or to the business of the Company or its affiliates, shall belong to the Company. You will not publish outside of the Company any such writing without the prior written consent of the Board of Directors of the Company. You will, without further compensation, execute at any time (whether or not you are still employed by the Company) all documents requested of you relating to the protection of such rights, including the assignment of such rights to the Company.

7. Litigation. You shall notify the Company within three business days if no longer employed and immediately if still employed by the Company if you are contacted by any person relating to any claim or litigation against the Company. You shall not communicate in any manner with any person related to any claim or litigation against the Company without the prior consent of the Board of Directors of the Company unless compelled to do so by law.

8. Competition. For so long as you are employed by the Company or any Affiliate (as defined below) and for a period of one year after you cease to be employed by the Company or any Affiliate, you shall not, directly or indirectly, engage in any work or other activity--whether as owner, stockholder, partner, officer, consultant, or otherwise--involving a trademark, product, or process that, in the opinion of the Company's President, is similar to a trademark, product or process on which you worked for the Company (or any Affiliate) or obtained knowledge about while working for the Company at any time during the period of employment, if such work or other activity is then, or reasonably expected to become, competitive with that of the Company (or any Affiliate). The restriction in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such work or activity and have received a release in writing from the Board of Directors of the Company allowing you to engage in such work or activity. The Company's President shall have sole discretion to determine whether your work or activity for another employer involves trademarks, products, or processes that are similar to trademarks, products, or processes that you worked on for the Company. Ownership by you of five percent (5%) or less of the outstanding shares of stock of any company either (i) listed on a national securities exchange, or (ii) having at least one hundred (100) stockholders shall not make you a "stockholder" within the meaning of that term as used in this paragraph. For one year after you cease to work for the Company, you will not engage in any work or activity that will cause you to inevitably disclose to anyone not employed by the Company (or an Affiliate) any trade secret or confidential information that belongs to the Company or one of its Affiliates. Nothing in this paragraph shall limit the rights or remedies of the Company arising, directly or indirectly, from such competitive employment, including, without limitation, claims based upon breach of fiduciary duty, misappropriation, or theft of confidential information. The term "Affiliate" shall mean the Company and any entity controlling, controlled by, or under common control with the Company.

9. Conflicting Contracts. You represent and warrant that you are not now under any obligation resulting from any contract or arrangement, to any person, firm, or corporation, which is inconsistent or in conflict with this Agreement. Likewise you represent and warrant that you are not now under any obligation resulting from any contract or arrangement to any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your obligations to the Company.

10. Solicitation. After you cease to be employed by the Company (or a Company affiliate):

(a) You agree not to solicit, directly or indirectly, business related to the development or sales of pharmaceutical products from any entity, organization, or person which is contracted with the Company, which has been doing business with the Company or from which the Company was soliciting at the time of your termination, or a firm which you knew or had reason to know that the Company was going to solicit business at the time you ceased to be employed by the Company. The restriction set forth in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such solicitation and have received a release in writing from the Board of Directors of the Company to engage in such solicitation.

(b) You agree not to solicit, recruit, hire, or assist in the hiring of any employee of the Company to work for you or another person, firm, corporation, or business.

11. Return of Documents. Upon termination of your employment for any reason, you shall immediately return to the Company all documents and things belonging to the Company. This includes, but is not limited to, trade secrets, confidential information, knowledge, data or know-how, and software containing such information, whether or not the documents are marked "Confidential."

12. Remedies. You acknowledge that in the event of breach of this Agreement by you, actual damages to the Company will be impossible to calculate, the Company's remedies at law will be inadequate, and the Company will suffer irreparable harm. Therefore, you agree that any of the covenants contained in this Agreement may be specifically enforced through injunctive relief, but such right to injunctive relief shall not preclude the Company from other remedies which may be available to it. You further agree that should you fail to keep any of the promises made by you in this Agreement, or any way violate this Agreement, the Company shall be entitled to recover all monies the Company is required to spend, including attorneys' fees, to enforce the provisions of this Agreement.

13. Best Efforts and Conflicts of Interest: You are hired with the understanding that Cumberland is your sole employer and you will provide a full-time work effort. You agree to devote your entire professional and business-related time and best efforts to the services required of you by the express and implicit terms of this Agreement, to the reasonable satisfaction of Cumberland in its sole and complete discretion. Engaging in activities outside of work that create a conflict of interest, or detract from your ability to perform your assigned responsibilities or meet your defined goals and objectives with Cumberland, is a problem and may lead to disciplinary action up to and including termination of employment. If you believe that you are potentially involved in a situation that could

create a conflict of interest and affect your ability to adequately perform your job with Cumberland, you should inform your direct supervisor and Cumberland's Human Resources Department immediately.

14. Standards of Business Conduct and Ethics. Cumberland's commitment to a culture of integrity, ethics and compliance with the law is comprised in this policy, which will be provided to you as part of the conditions of your employment. You will have the opportunity to read, discuss and understand this policy prior to accepting and signing its Letter of Agreement.

15. Debarment. You represent and warrant that you have not been debarred and will notify the Company immediately if you are debarred, pursuant to subsection 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act.

16. Notice. Any notice required or permitted to be given under this Agreement shall be sufficient if in writing and if sent by registered or certified mail to your residence or to the Company's principal office in the case of the Company.

17 Waiver. The waiver by either party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

18. Entire Agreement. This Agreement contains the entire agreement of the parties and may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

19. Governance. This Agreement shall be governed by the laws of the State of Tennessee. Any dispute arising out of this Agreement shall be resolved, at the Company's sole option, by courts sitting in Nashville, Tennessee, and you waive any objection to such venue.

20. Enforceability. In the event that any provision of this Agreement shall be held by a court to be unenforceable, such provision will be enforced to the maximum extent permissible, and the remaining portions of this Agreement shall remain in full force and effect.

21. Survival. Notwithstanding any termination of your employment, this Agreement shall survive and remain in effect in accordance with its terms.

# # # #

This letter agreement may be signed in one or more counterparts, each of which shall be an original and all of which will constitute one and the same instrument.

Sincerely yours,

CUMBERLAND PHARMACEUTICALS INC.

/s/ A.J. Kazimi

By: A.J. Kazimi
Chief Executive Officer

Accepted as to all terms and conditions
as of the 9th of March, 2016:

/s/ Martin E. Cearnal

Martin E. Cearnal

March 9, 2016

Mr. Leo Pavliv
2525 West End Avenue, Suite 950
Nashville, TN 37203

Re: Employment of Leo Pavliv as Senior Vice President, Operations and Chief Development Officer by Cumberland Pharmaceuticals Inc.

Dear Leo,

Effective January 1, 2016, this letter agreement (the "Agreement") will evidence the terms and conditions under which you will be employed by Cumberland Pharmaceuticals Inc. (the "Company") In consideration of your appointment as Senior Vice President, Operations and Chief Development Officer of the Company, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Compensation. The Company agrees to compensate you as follows:

(a) The Company agrees to pay you on a salary basis for services performed based on an annual rate of three hundred fifty-eight thousand five hundred dollars ($358,500.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2016. For each year, thereafter, you will be paid on a salary basis for services performed based on an annual rate determined by the Company in its sole discretion; provided, however, that any obligation to make payments under this Section 1(a) will cease upon termination of your employment for any reason. Notwithstanding the foregoing, nothing in this Section 1(a) alters or is intended to alter the at-will nature of your employment as described in Section 3 of this Agreement.

(b) You will be eligible to participate in any Company-wide employee benefits as approved by the Board of Directors. The terms of your eligibility and participation will be governed by the provisions of the employee benefit plans, as such plans may be amended from time to time in the discretion of the Company's Board of Directors.

(c) You may be eligible for any Company bonus program, based upon performance in meeting your individual objectives and the Company's overall performance, both as determined and approved by the Board of Directors of the Company. Any such bonus will be discretionary and will

be subject to the terms of the applicable bonus program, the terms of which program may be modified from year to year in the sole discretion of the Company's Board of Directors.

(d) You will receive a grant of Cumberland Pharmaceuticals common stock, pursuant to a restricted stock agreement (RSA). Such shares will be subject to the RSA and the terms set forth in the incentive compensation plan under which they are awarded. You may, at the Company's sole discretion, receive additional awards of Company equity, which will be subject to their designated agreements and the incentive compensation plans under which they are awarded.

(e) Except as set forth in Section 2, the Company shall not be liable to you for any expense incurred by you unless you receive the Company's prior written consent to reimburse you for such expense.

2. Additional Payments. During the term hereof, you shall be entitled to receive prompt reimbursement for all reasonable and documented expenses incurred in the performance of services in accordance with the expense reimbursement policy of the Company. Such reimbursement policy shall require adequate documentation by you of the expenses and payment by the Company of such amounts shall be made within a reasonable period after the close of the year in which the expenses were incurred.

3. Employment at Will. This Agreement is not intended to and shall not be understood in any manner as affecting or modifying the at-will status of your employment with the Company. As an at-will employee either you or the Company may terminate the employment relationship at any time with or without cause or notice. The obligations of Sections 4, 5, 6, 7, 8, 10, 11 and 12 herein shall survive the termination of the employment relationship or of this Agreement.

4. Confidentiality. All knowledge and information, not already available to the public, which you acquire, have acquired, or will acquire in the course of your employment with the Company with respect to the Company's business, work methods, or pending regulatory matters, or other Company matters that are treated by the Company as confidential, shall be regarded by you as trade secrets, whether or not they are classifiable legally as trade secrets, and shall be treated by you as strictly confidential. Such knowledge and information shall not either directly or indirectly be used, disclosed, or made accessible to anyone by you for any purpose, except in the ordinary course of the Company's business under circumstances in which you are authorized to use or disclose such information. No disclosures of such confidential information shall be made outside of those you are authorized to make in the regular and ordinary course of your duties unless and until you receive prior written permission of the Board of Directors of the Company to make such disclosure.

5. Discoveries and Improvements. During the time that you are employed by the Company, all confidential information, trade secrets, or proprietary information and all other discoveries, inventions, software programs, processes, methods and improvements that are conceived, developed, or otherwise made by you, alone or with others, that relate in any way to the Company's present or planned business or products (collectively the "Developments"), whether or not patentable or subject to copyright protection and whether or not reduced to tangible form or reduced to practice, shall be the sole property of the Company. You agree to disclose all Developments promptly, fully and in writing to the Company. You agree to keep and maintain adequate and current dated and

witnessed written records of all such Developments, in the form of notes, sketches, drawings, or reports, which records shall be promptly submitted to the Company and shall be and remain the property of the Company at all times. You agree to assign, and hereby do assign, to, the Company all your right, title and interest throughout the world in and to all Developments. You agree that all Developments shall constitute "Works for Hire" (as such are defined under the U.S. Copyright Laws) and hereby assign to the Company all copyrights, patents and other proprietary rights you may have in any Developments without any obligation on the part of the Company to pay royalties or any other consideration to you for such Developments.

6. Publication. All documents and other writings produced by you during the period of your employment, which relate to work you are doing or have done for the Company or to the business of the Company or its affiliates, shall belong to the Company. You will not publish outside of the Company any such writing without the prior written consent of the Board of Directors of the Company. You will, without further compensation, execute at any time (whether or not you are still employed by the Company) all documents requested of you relating to the protection of such rights, including the assignment of such rights to the Company.

7. Litigation. You shall notify the Company within three business days if no longer employed and immediately if still employed by the Company if you are contacted by any person relating to any claim or litigation against the Company. You shall not communicate in any manner with any person related to any claim or litigation against the Company without the prior consent of the Board of Directors of the Company unless compelled to do so by law.

8. Competition. For so long as you are employed by the Company or any Affiliate (as defined below) and for a period of one year after you cease to be employed by the Company or any Affiliate, you shall not, directly or indirectly, engage in any work or other activity--whether as owner, stockholder, partner, officer, consultant, or otherwise--involving a trademark, product, or process that, in the opinion of the Company's President, is similar to a trademark, product or process on which you worked for the Company (or any Affiliate) or obtained knowledge about while working for the Company at any time during the period of employment, if such work or other activity is then, or reasonably expected to become, competitive with that of the Company (or any Affiliate). The restriction in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such work or activity and have received a release in writing from the Board of Directors of the Company allowing you to engage in such work or activity. The Company's President shall have sole discretion to determine whether your work or activity for another employer involves trademarks, products, or processes that are similar to trademarks, products, or processes that you worked on for the Company. Ownership by you of five percent (5%) or less of the outstanding shares of stock of any company either (i) listed on a national securities exchange, or (ii) having at least one hundred (100) stockholders shall not make you a "stockholder" within the meaning of that term as used in this paragraph. For one year after you cease to work for the Company, you will not engage in any work or activity that will cause you to inevitably disclose to anyone not employed by the Company (or an Affiliate) any trade secret or confidential information that belongs to the Company or one of its Affiliates. Nothing in this paragraph shall limit the rights or remedies of the Company arising, directly or indirectly, from such competitive employment, including, without limitation, claims based upon breach of fiduciary duty, misappropriation, or theft

of confidential information. The term "Affiliate" shall mean the Company and any entity controlling, controlled by, or under common control with the Company.

9. Conflicting Contracts. You represent and warrant that you are not now under any obligation resulting from any contract or arrangement, to any person, firm, or corporation, which is inconsistent or in conflict with this Agreement. Likewise you represent and warrant that you are not now under any obligation resulting from any contract or arrangement to any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your obligations to the Company.

10. Solicitation. After you cease to be employed by the Company (or a Company affiliate):

(a) You agree not to solicit, directly or indirectly, business related to the development or sales of pharmaceutical products from any entity, organization, or person which is contracted with the Company, which has been doing business with the Company or from which the Company was soliciting at the time of your termination, or a firm which you knew or had reason to know that the Company was going to solicit business at the time you ceased to be employed by the Company. The restriction set forth in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such solicitation and have received a release in writing from the Board of Directors of the Company to engage in such solicitation.

(b) You agree not to solicit, recruit, hire, or assist in the hiring of any employee of the Company to work for you or another person, firm, corporation, or business.

11. Return of Documents. Upon termination of your employment for any reason, you shall immediately return to the Company all documents and things belonging to the Company. This includes, but is not limited to, trade secrets, confidential information, knowledge, data or know-how, and software containing such information, whether or not the documents are marked "Confidential."

12. Remedies. You acknowledge that in the event of breach of this Agreement by you, actual damages to the Company will be impossible to calculate, the Company's remedies at law will be inadequate, and the Company will suffer irreparable harm. Therefore, you agree that any of the covenants contained in this Agreement may be specifically enforced through injunctive relief, but such right to injunctive relief shall not preclude the Company from other remedies which may be available to it. You further agree that should you fail to keep any of the promises made by you in this Agreement, or any way violate this Agreement, the Company shall be entitled to recover all monies the Company is required to spend, including attorneys' fees, to enforce the provisions of this Agreement.

13. Best Efforts and Conflicts of Interest: You are hired with the understanding that Cumberland is your sole employer and you will provide a full-time work effort. You agree to devote your entire professional and business-related time and best efforts to the services required of you by the express and implicit terms of this Agreement, to the reasonable satisfaction of Cumberland in its sole and complete discretion. Engaging in activities outside of work that create a conflict of interest, or detract from your ability to perform your assigned responsibilities or meet your defined goals and

objectives with Cumberland, is a problem and may lead to disciplinary action up to and including termination of employment. If you believe that you are potentially involved in a situation that could create a conflict of interest and affect your ability to adequately perform your job with Cumberland, you should inform your direct supervisor and Cumberland's Human Resources Department immediately.

14. Standards of Business Conduct and Ethics. Cumberland's commitment to a culture of integrity, ethics and compliance with the law is comprised in this policy, which will be provided to you as part of the conditions of your employment. You will have the opportunity to read, discuss and understand this policy prior to accepting and signing its Letter of Agreement.

15. Debarment. You represent and warrant that you have not been debarred and will notify the Company immediately if you are debarred, pursuant to subsection 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act.

16. Notice. Any notice required or permitted to be given under this Agreement shall be sufficient if in writing and if sent by registered or certified mail to your residence or to the Company's principal office in the case of the Company.

17 Waiver. The waiver by either party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

18. Entire Agreement. This Agreement contains the entire agreement of the parties and may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

19. Governance. This Agreement shall be governed by the laws of the State of Tennessee. Any dispute arising out of this Agreement shall be resolved, at the Company's sole option, by courts sitting in Nashville, Tennessee, and you waive any objection to such venue.

20. Enforceability. In the event that any provision of this Agreement shall be held by a court to be unenforceable, such provision will be enforced to the maximum extent permissible, and the remaining portions of this Agreement shall remain in full force and effect.

21. Survival. Notwithstanding any termination of your employment, this Agreement shall survive and remain in effect in accordance with its terms.

# # # #

This letter agreement may be signed in one or more counterparts, each of which shall be an original and all of which will constitute one and the same instrument.

Sincerely yours,

CUMBERLAND PHARMACEUTICALS INC.

/s/ A.J. Kazimi

By: A.J. Kazimi
Chief Executive Officer

Accepted as to all terms and conditions
as of the 9th of March, 2016:

/s/ Leo Pavliv

Leo Pavliv

March 10, 2016

Mr. Michael Bonner
2525 West End Avenue, Suite 950
Nashville, TN 37203

Re: Employment of Michael Bonner as Senior Director, Finance & Accounting; Chief Financial Officer by Cumberland Pharmaceuticals Inc.

Dear Michael:

Effective March 10, 2016, this letter agreement (the "Agreement") will evidence the terms and conditions under which you will be employed by Cumberland Pharmaceuticals Inc. (the "Company") In consideration of your appointment as Senior Director, Finance & Accounting; Chief Financial Officer of the Company, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Compensation. The Company agrees to compensate you as follows:

(a) The Company agrees to pay you on a salary basis for services performed based on an annual rate of one hundred seventy-five thousand one hundred dollars ($175,100.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2016. For each year, thereafter, you will be paid on a salary basis for services performed based on an annual rate determined by the Company in its sole discretion; provided, however, that any obligation to make payments under this Section 1(a) will cease upon termination of your employment for any reason. Notwithstanding the foregoing, nothing in this Section 1(a) alters or is intended to alter the at-will nature of your employment as described in Section 3 of this Agreement.

(b) You will be eligible to participate in any Company-wide employee benefits as approved by the Board of Directors. The terms of your eligibility and participation will be governed by the provisions of the employee benefit plans, as such plans may be amended from time to time in the discretion of the Company's Board of Directors.

(c) You may be eligible for any Company bonus program, based upon performance in meeting your individual objectives and the Company's overall performance, both as determined and approved by the Board of Directors of the Company. Any such bonus will be discretionary and will

be subject to the terms of the applicable bonus program, the terms of which program may be modified from year to year in the sole discretion of the Company's Board of Directors.

(d) You will receive a grant of Cumberland Pharmaceuticals common stock, pursuant to a restricted stock agreement (RSA). Such shares will be subject to the RSA and the terms set forth in the incentive compensation plan under which they are awarded. You may, at the Company's sole discretion, receive additional awards of Company equity, which will be subject to their designated agreements and the incentive compensation plans under which they are awarded.

(e) Except as set forth in Section 2, the Company shall not be liable to you for any expense incurred by you unless you receive the Company's prior written consent to reimburse you for such expense.

2. Additional Payments. During the term hereof, you shall be entitled to receive prompt reimbursement for all reasonable and documented expenses incurred in the performance of services in accordance with the expense reimbursement policy of the Company. Such reimbursement policy shall require adequate documentation by you of the expenses and payment by the Company of such amounts shall be made within a reasonable period after the close of the year in which the expenses were incurred.

3. Employment at Will. This Agreement is not intended to and shall not be understood in any manner as affecting or modifying the at-will status of your employment with the Company. As an at-will employee either you or the Company may terminate the employment relationship at any time with or without cause or notice. The obligations of Sections 4, 5, 6, 7, 8, 10, 11 and 12 herein shall survive the termination of the employment relationship or of this Agreement.

4. Confidentiality. All knowledge and information, not already available to the public, which you acquire, have acquired, or will acquire in the course of your employment with the Company with respect to the Company's business, work methods, or pending regulatory matters, or other Company matters that are treated by the Company as confidential, shall be regarded by you as trade secrets, whether or not they are classifiable legally as trade secrets, and shall be treated by you as strictly confidential. Such knowledge and information shall not either directly or indirectly be used, disclosed, or made accessible to anyone by you for any purpose, except in the ordinary course of the Company's business under circumstances in which you are authorized to use or disclose such information. No disclosures of such confidential information shall be made outside of those you are authorized to make in the regular and ordinary course of your duties unless and until you receive prior written permission of the Board of Directors of the Company to make such disclosure.

5. Discoveries and Improvements. During the time that you are employed by the Company, all confidential information, trade secrets, or proprietary information and all other discoveries, inventions, software programs, processes, methods and improvements that are conceived, developed, or otherwise made by you, alone or with others, that relate in any way to the Company's present or planned business or products (collectively the "Developments"), whether or not patentable or subject to copyright protection and whether or not reduced to tangible form or reduced to practice, shall be the sole property of the Company. You agree to disclose all Developments promptly, fully and in writing to the Company. You agree to keep and maintain adequate and current dated and

witnessed written records of all such Developments, in the form of notes, sketches, drawings, or reports, which records shall be promptly submitted to the Company and shall be and remain the property of the Company at all times. You agree to assign, and hereby do assign, to, the Company all your right, title and interest throughout the world in and to all Developments. You agree that all Developments shall constitute "Works for Hire" (as such are defined under the U.S. Copyright Laws) and hereby assign to the Company all copyrights, patents and other proprietary rights you may have in any Developments without any obligation on the part of the Company to pay royalties or any other consideration to you for such Developments.

6. Publication. All documents and other writings produced by you during the period of your employment, which relate to work you are doing or have done for the Company or to the business of the Company or its affiliates, shall belong to the Company. You will not publish outside of the Company any such writing without the prior written consent of the Board of Directors of the Company. You will, without further compensation, execute at any time (whether or not you are still employed by the Company) all documents requested of you relating to the protection of such rights, including the assignment of such rights to the Company.

7. Litigation. You shall notify the Company within three business days if no longer employed and immediately if still employed by the Company if you are contacted by any person relating to any claim or litigation against the Company. You shall not communicate in any manner with any person related to any claim or litigation against the Company without the prior consent of the Board of Directors of the Company unless compelled to do so by law.

8. Competition. For so long as you are employed by the Company or any Affiliate (as defined below) and for a period of one year after you cease to be employed by the Company or any Affiliate, you shall not, directly or indirectly, engage in any work or other activity--whether as owner, stockholder, partner, officer, consultant, or otherwise--involving a trademark, product, or process that, in the opinion of the Company's President, is similar to a trademark, product or process on which you worked for the Company (or any Affiliate) or obtained knowledge about while working for the Company at any time during the period of employment, if such work or other activity is then, or reasonably expected to become, competitive with that of the Company (or any Affiliate). The restriction in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such work or activity and have received a release in writing from the Board of Directors of the Company allowing you to engage in such work or activity. The Company's President shall have sole discretion to determine whether your work or activity for another employer involves trademarks, products, or processes that are similar to trademarks, products, or processes that you worked on for the Company. Ownership by you of five percent (5%) or less of the outstanding shares of stock of any company either (i) listed on a national securities exchange, or (ii) having at least one hundred (100) stockholders shall not make you a "stockholder" within the meaning of that term as used in this paragraph. For one year after you cease to work for the Company, you will not engage in any work or activity that will cause you to inevitably disclose to anyone not employed by the Company (or an Affiliate) any trade secret or confidential information that belongs to the Company or one of its Affiliates. Nothing in this paragraph shall limit the rights or remedies of the Company arising, directly or indirectly, from such competitive employment, including, without limitation, claims based upon breach of fiduciary duty, misappropriation, or theft

of confidential information. The term "Affiliate" shall mean the Company and any entity controlling, controlled by, or under common control with the Company.

9. Conflicting Contracts. You represent and warrant that you are not now under any obligation resulting from any contract or arrangement, to any person, firm, or corporation, which is inconsistent or in conflict with this Agreement. Likewise you represent and warrant that you are not now under any obligation resulting from any contract or arrangement to any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your obligations to the Company.

10. Solicitation. After you cease to be employed by the Company (or a Company affiliate):

(a) You agree not to solicit, directly or indirectly, business related to the development or sales of pharmaceutical products from any entity, organization, or person which is contracted with the Company, which has been doing business with the Company or from which the Company was soliciting at the time of your termination, or a firm which you knew or had reason to know that the Company was going to solicit business at the time you ceased to be employed by the Company. The restriction set forth in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such solicitation and have received a release in writing from the Board of Directors of the Company to engage in such solicitation.

(b) You agree not to solicit, recruit, hire, or assist in the hiring of any employee of the Company to work for you or another person, firm, corporation, or business.

11. Return of Documents. Upon termination of your employment for any reason, you shall immediately return to the Company all documents and things belonging to the Company. This includes, but is not limited to, trade secrets, confidential information, knowledge, data or know-how, and software containing such information, whether or not the documents are marked "Confidential."

12. Remedies. You acknowledge that in the event of breach of this Agreement by you, actual damages to the Company will be impossible to calculate, the Company's remedies at law will be inadequate, and the Company will suffer irreparable harm. Therefore, you agree that any of the covenants contained in this Agreement may be specifically enforced through injunctive relief, but such right to injunctive relief shall not preclude the Company from other remedies which may be available to it. You further agree that should you fail to keep any of the promises made by you in this Agreement, or any way violate this Agreement, the Company shall be entitled to recover all monies the Company is required to spend, including attorneys' fees, to enforce the provisions of this Agreement.

13. Best Efforts and Conflicts of Interest: You are hired with the understanding that Cumberland is your sole employer and you will provide a full-time work effort. You agree to devote your entire professional and business-related time and best efforts to the services required of you by the express and implicit terms of this Agreement, to the reasonable satisfaction of Cumberland in its sole and complete discretion. Engaging in activities outside of work that create a conflict of interest, or detract from your ability to perform your assigned responsibilities or meet your defined goals and

objectives with Cumberland, is a problem and may lead to disciplinary action up to and including termination of employment. If you believe that you are potentially involved in a situation that could create a conflict of interest and affect your ability to adequately perform your job with Cumberland, you should inform your direct supervisor and Cumberland's Human Resources Department immediately.

14. Standards of Business Conduct and Ethics. Cumberland's commitment to a culture of integrity, ethics and compliance with the law is comprised in this policy, which will be provided to you as part of the conditions of your employment. You will have the opportunity to read, discuss and understand this policy prior to accepting and signing its Letter of Agreement.

15. Debarment. You represent and warrant that you have not been debarred and will notify the Company immediately if you are debarred, pursuant to subsection 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act.

16. Notice. Any notice required or permitted to be given under this Agreement shall be sufficient if in writing and if sent by registered or certified mail to your residence or to the Company's principal office in the case of the Company.

17 Waiver. The waiver by either party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

18. Entire Agreement. This Agreement contains the entire agreement of the parties and may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

19. Governance. This Agreement shall be governed by the laws of the State of Tennessee. Any dispute arising out of this Agreement shall be resolved, at the Company's sole option, by courts sitting in Nashville, Tennessee, and you waive any objection to such venue.

20. Enforceability. In the event that any provision of this Agreement shall be held by a court to be unenforceable, such provision will be enforced to the maximum extent permissible, and the remaining portions of this Agreement shall remain in full force and effect.

21. Survival. Notwithstanding any termination of your employment, this Agreement shall survive and remain in effect in accordance with its terms.

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This letter agreement may be signed in one or more counterparts, each of which shall be an original and all of which will constitute one and the same instrument.

Sincerely yours,

CUMBERLAND PHARMACEUTICALS INC.

/s/ A.J. Kazimi

By: A.J. Kazimi
Chief Executive Officer

Accepted as to all terms and conditions
as of the 10th of March, 2016:

/s/ Michael Bonner

Michael Bonner

Exhibit 10.15

March 9, 2016

Mr. James L. Herman
2525 West End Avenue, Suite 950
Nashville, TN 37203

Re: Employment of James L. Herman as Vice President, National Accounts and Chief Compliance Officer by Cumberland Pharmaceuticals Inc.

Dear Jim:

Effective January 1, 2016, this letter agreement (the "Agreement") will evidence the terms and conditions under which you will be employed by Cumberland Pharmaceuticals Inc. (the "Company") In consideration of your appointment as Vice President, National Accounts and Chief Compliance Officer of the Company, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Compensation. The Company agrees to compensate you as follows:

(a) The Company agrees to pay you on a salary basis for services performed based on an annual rate of two hundred twenty thousand dollars ($220,000.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2016. For each year, thereafter, you will be paid on a salary basis for services performed based on an annual rate determined by the Company in its sole discretion; provided, however, that any obligation to make payments under this Section 1(a) will cease upon termination of your employment for any reason. Notwithstanding the foregoing, nothing in this Section 1(a) alters or is intended to alter the at-will nature of your employment as described in Section 3 of this Agreement.

(b) You will be eligible to participate in any Company-wide employee benefits as approved by the Board of Directors. The terms of your eligibility and participation will be governed by the provisions of the employee benefit plans, as such plans may be amended from time to time in the discretion of the Company's Board of Directors.

(c) You may be eligible for any Company bonus program, based upon performance in meeting your individual objectives and the Company's overall performance, both as determined and approved by the Board of Directors of the Company. Any such bonus will be discretionary and will be subject to the terms of the applicable bonus program, the terms of which program may be modified from year to year in the sole discretion of the Company's Board of Directors.

(d) You will receive a grant of Cumberland Pharmaceuticals common stock, pursuant to a restricted stock agreement (RSA). Such shares will be subject to the RSA and the terms set forth in the incentive compensation plan under which they are awarded. You may, at the Company's sole discretion, receive additional awards of Company equity, which will be subject to their designated agreements and the incentive compensation plans under which they are awarded.

(e) Except as set forth in Section 2, the Company shall not be liable to you for any expense incurred by you unless you receive the Company's prior written consent to reimburse you for such expense.

2. Additional Payments. During the term hereof, you shall be entitled to receive prompt reimbursement for all reasonable and documented expenses incurred in the performance of services in accordance with the expense reimbursement policy of the Company. Such reimbursement policy shall require adequate documentation by you of the expenses and payment by the Company of such amounts shall be made within a reasonable period after the close of the year in which the expenses were incurred.

3. Employment at Will. This Agreement is not intended to and shall not be understood in any manner as affecting or modifying the at-will status of your employment with the Company. As an at-will employee either you or the Company may terminate the employment relationship at any time with or without cause or notice. The obligations of Sections 4, 5, 6, 7, 8, 10, 11 and 12 herein shall survive the termination of the employment relationship or of this Agreement.

4. Confidentiality. All knowledge and information, not already available to the public, which you acquire, have acquired, or will acquire in the course of your employment with the Company with respect to the Company's business, work methods, or pending regulatory matters, or other Company matters that are treated by the Company as confidential, shall be regarded by you as trade secrets, whether or not they are classifiable legally as trade secrets, and shall be treated by you as strictly confidential. Such knowledge and information shall not either directly or indirectly be used, disclosed, or made accessible to anyone by you for any purpose, except in the ordinary course of the Company's business under circumstances in which you are authorized to use or disclose such information. No disclosures of such confidential information shall be made outside of those you are authorized to make in the regular and ordinary course of your duties unless and until you receive prior written permission of the Board of Directors of the Company to make such disclosure.

5. Discoveries and Improvements. During the time that you are employed by the Company, all confidential information, trade secrets, or proprietary information and all other discoveries, inventions, software programs, processes, methods and improvements that are conceived, developed, or otherwise made by you, alone or with others, that relate in any way to the Company's present or planned business or products (collectively the "Developments"), whether or not patentable or subject to copyright protection and whether or not reduced to tangible form or reduced to practice, shall be the sole property of the Company. You agree to disclose all Developments promptly, fully and in writing to the Company. You agree to keep and maintain adequate and current dated and witnessed written records of all such Developments, in the form of notes, sketches, drawings, or reports, which records shall be promptly submitted to the Company and shall be and remain the property of the Company at all times. You agree to assign, and hereby do assign, to, the Company all your right, title and interest throughout the world in and to all Developments. You agree that all Developments shall constitute "Works for Hire" (as such are defined under the U.S. Copyright Laws) and hereby assign to the Company all copyrights, patents and other proprietary rights you may have in any Developments without any obligation on the part of the Company to pay royalties or any other consideration to you for such Developments.

6. Publication. All documents and other writings produced by you during the period of your employment, which relate to work you are doing or have done for the Company or to the business of the Company or its affiliates, shall belong to the Company. You will not publish outside of the Company any such writing without the prior written consent of the Board of Directors of the Company. You will, without further compensation, execute at any time (whether or not you are still employed by the Company) all documents requested of you relating to the protection of such rights, including the assignment of such rights to the Company.

7. Litigation. You shall notify the Company within three business days if no longer employed and immediately if still employed by the Company if you are contacted by any person relating to any claim or litigation against the Company. You shall not communicate in any manner with any person related to any claim or litigation against the Company without the prior consent of the Board of Directors of the Company unless compelled to do so by law.

8. Competition. For so long as you are employed by the Company or any Affiliate (as defined below) and for a period of one year after you cease to be employed by the Company or any Affiliate, you shall not, directly or indirectly, engage in any work or other activity--whether as owner, stockholder, partner, officer, consultant, or otherwise--involving a trademark, product, or process that, in the opinion of the Company's President, is similar to a trademark, product or process on which you worked for the Company (or any Affiliate) or obtained knowledge about while working for the Company at any time during the period of employment, if such work or other activity is then, or reasonably expected to become, competitive with that of the Company (or any Affiliate). The restriction in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such work or activity and have received a release in writing from the Board of Directors of the Company allowing you to engage in such work or activity. The Company's President shall have sole discretion to determine whether your work or activity for another employer involves trademarks, products, or processes that are similar to trademarks, products, or processes that you worked on for the Company. Ownership by you of five percent (5%) or less of the outstanding shares of stock of any company either (i) listed on a national securities exchange, or (ii) having at least one hundred (100) stockholders shall not make you a "stockholder" within the meaning of that term as used in this paragraph. For one year after you cease to work for the Company, you will not engage in any work or activity that will cause you to inevitably disclose to anyone not employed by the Company (or an Affiliate) any trade secret or confidential information that belongs to the Company or one of its Affiliates. Nothing in this paragraph shall limit the rights or remedies of the Company arising, directly or indirectly, from such competitive employment, including, without limitation, claims based upon breach of fiduciary duty, misappropriation, or theft of confidential information. The term "Affiliate" shall mean the Company and any entity controlling, controlled by, or under common control with the Company.

9. Conflicting Contracts. You represent and warrant that you are not now under any obligation resulting from any contract or arrangement, to any person, firm, or corporation, which is inconsistent or in conflict with this Agreement. Likewise you represent and warrant that you are not now under any obligation resulting from any contract or arrangement to any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your obligations to the Company.

10. Solicitation. After you cease to be employed by the Company (or a Company affiliate):

(a) You agree not to solicit, directly or indirectly, business related to the development or sales of pharmaceutical products from any entity, organization, or person which is contracted with the Company, which has been doing business with the Company or from which the Company was soliciting at the time of your termination, or a firm which you knew or had reason to know that the Company was going to solicit business at the time you ceased to be employed by the Company. The restriction set forth in the preceding sentence shall not apply if you have disclosed to the Company in writing all the known facts relating to such

solicitation and have received a release in writing from the Board of Directors of the Company to engage in such solicitation.

(b) You agree not to solicit, recruit, hire, or assist in the hiring of any employee of the Company to work for you or another person, firm, corporation, or business.

11. Return of Documents. Upon termination of your employment for any reason, you shall immediately return to the Company all documents and things belonging to the Company. This includes, but is not limited to, trade secrets, confidential information, knowledge, data or know-how, and software containing such information, whether or not the documents are marked "Confidential."

12. Remedies. You acknowledge that in the event of breach of this Agreement by you, actual damages to the Company will be impossible to calculate, the Company's remedies at law will be inadequate, and the Company will suffer irreparable harm. Therefore, you agree that any of the covenants contained in this Agreement may be specifically enforced through injunctive relief, but such right to injunctive relief shall not preclude the Company from other remedies which may be available to it. You further agree that should you fail to keep any of the promises made by you in this Agreement, or any way violate this Agreement, the Company shall be entitled to recover all monies the Company is required to spend, including attorneys' fees, to enforce the provisions of this Agreement.

13. Best Efforts and Conflicts of Interest: You are hired with the understanding that Cumberland is your sole employer and you will provide a full-time work effort. You agree to devote your entire professional and business-related time and best efforts to the services required of you by the express and implicit terms of this Agreement, to the reasonable satisfaction of Cumberland in its sole and complete discretion. Engaging in activities outside of work that create a conflict of interest, or detract from your ability to perform your assigned responsibilities or meet your defined goals and objectives with Cumberland, is a problem and may lead to disciplinary action up to and including termination of employment. If you believe that you are potentially involved in a situation that could create a conflict of interest and affect your ability to adequately perform your job with Cumberland, you should inform your direct supervisor and Cumberland's Human Resources Department immediately.

14. Standards of Business Conduct and Ethics. Cumberland's commitment to a culture of integrity, ethics and compliance with the law is comprised in this policy, which will be provided to you as part of the conditions of your employment. You will have the opportunity to read, discuss and understand this policy prior to accepting and signing its Letter of Agreement.

15. Debarment. You represent and warrant that you have not been debarred and will notify the Company immediately if you are debarred, pursuant to subsection 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act.

16. Notice. Any notice required or permitted to be given under this Agreement shall be sufficient if in writing and if sent by registered or certified mail to your residence or to the Company's principal office in the case of the Company.

17 Waiver. The waiver by either party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

18. Entire Agreement. This Agreement contains the entire agreement of the parties and may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

19. Governance. This Agreement shall be governed by the laws of the State of Tennessee. Any dispute arising out of this Agreement shall be resolved, at the Company's sole option, by courts sitting in Nashville, Tennessee, and you waive any objection to such venue.

20. Enforceability. In the event that any provision of this Agreement shall be held by a court to be unenforceable, such provision will be enforced to the maximum extent permissible, and the remaining portions of this Agreement shall remain in full force and effect.

21. Survival. Notwithstanding any termination of your employment, this Agreement shall survive and remain in effect in accordance with its terms.

# # # #

This letter agreement may be signed in one or more counterparts, each of which shall be an original and all of which will constitute one and the same instrument.

Sincerely yours,

CUMBERLAND PHARMACEUTICALS INC.

/s/ *A.J. Kazimi*

By: A.J. Kazimi
Chief Executive Officer

Accepted as to all terms and conditions
as of the 9th of March, 2016:

/s/ James L. Herman

James L. Herman

Exhibit 10.25

*Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment which has been filed separately with the SEC

LICENSE AND SUPPLY AGREEMENT

by and between

GASTRO-ENTERO LOGIC, LLC,

and

CUMBERLAND PHARMACEUTICALS INC.

Dated as of November 16, 2015

This **LICENSE AND SUPPLY AGREEMENT** ("Agreement") is entered into this 16th day of November, 2015 ("Effective Date"), by and between **Cumberland Pharmaceuticals Inc.**, a Tennessee corporation having a place of business at 2525 West End Avenue, Suite 950, Nashville, TN 37203 ("CPI") and **Gastro-Entero Logic, LLC**, a Delaware limited liability company, having a registered office located at 3500 South DuPont Highway, Dover, County of Kent, Delaware, 19901 ("GEL"). CPI and GEL are referred to herein collectively as the "Parties" and sometimes individually as a "Party".

RECITALS:

WHEREAS, GEL controls certain patents, know-how and other rights related to the Product (as defined below);

WHEREAS, GEL believes that a license and supply arrangement with CPI regarding the Product would be desirable and CPI believes that CPI's participation in this arrangement with GEL would be of economic benefit to both Parties;

WHEREAS, CPI wishes to obtain the exclusive right to commercialize the Product in the Territory and GEL desires to grant such an exclusive right to CPI, pursuant to the terms and subject to the conditions set forth in this Agreement.

WHEREAS, in consideration of the foregoing recitals, the mutual representations, warranties and covenants contained herein, and other good and valuable consideration, the Parties agree as follows:

SECTION 1. DEFINITIONS

1.1. Interpretation and Construction. The headings of Sections in this Agreement are provided for convenience only and shall not affect its construction or interpretation. All references

to “Section” or “Sections” refer to the corresponding Section or Sections of this Agreement. All words used in this Agreement shall be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided in this Agreement, the word “including” does not limit the preceding words or terms and shall be deemed to be followed by the words “without limitation.” Unless otherwise expressly provided in this Agreement, the terms “shall have responsibility for”, “shall be responsible for” or the like, shall be deemed to be followed by “and shall be obligated to duly carry out such responsibility.”

1.2. Definitions. As used herein, the following terms shall have the following meanings:

1.2.1 “Act” means, as applicable, the United States Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. §§ 301 et seq.).

1.2.2 “Adverse Drug Experience” means any of: an “adverse drug experience,” a “life-threatening adverse drug experience,” a “serious adverse drug experience,” or an “unexpected adverse drug experience,” as those terms are defined at either 21 C.F.R. §312.32 or 21 C.F.R. §314.80, and any other applicable regulations promulgated by the FDA, as related to the use of the Product which requires reporting to a Regulatory Authority.

1.2.3 “Affiliate” means, with respect to a Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. “Control” and, with correlative meanings, the terms “controlled by” and “under common control with,” shall mean to possess the power to direct the management or policies of a Person, whether through: (a) direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in such entity; (b) the right to appoint fifty percent (50%) or more of the directors or management of such entity; or (c) by contract or otherwise. The Parties acknowledge and agree that under no circumstances shall the term “Affiliate” as defined herein mean as to GEL, for any purpose, any (i) Venture Entity having, directly or indirectly, an interest in or controlling, alone or with others, GEL, or (ii) other Persons in which such Venture Entity have an interest or are controlled by, controlling or are under common control with such Person, unless GEL directly possesses the power to control and direct management of such other Persons.

1.2.4 “Agency” has the meaning set forth in Section 12.1.

1.2.5 “Agreement” has the meaning set forth in the Preamble of this Agreement.

1.2.6 “Annual Net Sales” means the Net Sales achieved by CPI during any Net Sales Fiscal Year.

1.2.7 “API” means the active pharmaceutical ingredient in each Component.

1.2.8 “Applicable Law” means all laws, rules and regulations, including any rules, regulations, guidelines, or other requirements of Regulatory Authorities, applicable to the Development, Commercialization or Supply of the Product, as the case may be, that may be in effect from time to time in the Territory.

1.2.9 "Batch Size" means, for each Net Sales Year, [***] Units for commercial sale or [***] Units for sample distribution or any combination thereof where the amount of individual blisters allocated to Units for commercial sales is in increments of [***]. GEL will use its commercially reasonable efforts to reduce or increase the Batch Size to meet CPI's reasonable request.

1.2.10 "Branded Royalty Rate" has the meaning set forth in Section 7.4.

1.2.11 "Business Day" means any day on which banking institutions in New York, New York, United States are open for business.

1.2.12 "Calendar Quarter" means the three-month period in any given calendar year ending on March 31, June 30, September 30 and December 31.

1.2.13 "Certificate of Analysis" means a certificate evidencing the analytical tests conducted on a specific lot of Product reflecting that such Product and any Raw Materials used therein conform to the relevant Specifications and setting forth, *inter alia*, the items tested and test results, and accompanied by all documentation required by Applicable Law and/or a Regulatory Authority to Commercialize the Product in the Territory.

1.2.14 "Certificate of Compliance" means a certificate evidencing that the Product delivered to CPI was manufactured in accordance with cGMP and any applicable Regulatory Approvals.

1.2.15 "cGCP" means the applicable regulatory requirements for current good clinical practices promulgated by the FDA under 21 C.F.R. § 50, as the same may be amended from time to time.

1.2.16 "cGLP" means the applicable regulatory requirements for current good laboratory practices promulgated by the FDA under 21 C.F.R. § 58, as the same may be amended from time to time.

1.2.17 "cGMP" means the applicable regulatory requirements for current good manufacturing practices promulgated by the FDA under 21 C.F.R. §§ 210, 211, as the same may be amended from time to time.

1.2.18 "Commercialization" means any and all activities directed to marketing, promoting, distributing, offering for sale and selling the Product. When used as a verb, "Commercialize" means to engage in Commercialization.

1.2.19 "Commercially Reasonable Efforts" means, with respect to a Party, the efforts and resources which would be used (including, without limitation, the promptness in which such efforts and resources would be applied) by that Party relating to a certain activity or activities, consistent with its normal business practices, which are equivalent to the general level of effort and resources which would be used in the pharmaceutical industry by a company similar in size and scope, with respect to a product having a similar market potential and at a similar stage in life cycle,

taking into account, as applicable, the competitiveness of the marketplace and any legal and regulatory issues involved, the profitability of the applicable products and other relevant factors, including technical, legal, scientific, medical, sales performance, and/or marketing factors.

1.2.20 "Competitive Generic Product" has the meaning set forth in Section 7.4.1

1.2.21 "Component" or "Components" means each of, or, if referred to as a group, all of, Omeprazole Delayed-Release Capsules, USP, 20 mg; Clarithromycin Tablets, USP, 500 mg; and Amoxicillin Capsules, USP, 500 mg.

1.2.22 "Confidential Information" has the meaning set forth in Section 9.1

1.2.23 "Control" or "Controlled" means, with respect to any Intellectual Property (as defined below) or other intangible property, the possession (whether by license or ownership, or by control over an Affiliate having possession by license or ownership) by a Party of the ability to grant to the other Party access, a license or sublicense (or all of the foregoing) as provided herein without violating any agreement with any Third Party (as defined below).

1.2.24 "CPI" has the meaning set forth in the Preamble to this Agreement.

1.2.25 "CPI Trademark" means collectively the name and logo of CPI or any of its Affiliates as identified on "**Exhibit "B**" attached hereto and made a part hereof.

1.2.26 "Detail" means a face-to-face presentation by a sales representative to a physician (or other health care practitioner who is permitted under applicable laws to prescribe the Product) in a setting appropriate for meaningful medical dialogue, during which presentation such sales representative makes a presentation relating to the Product. When used as a verb "Detail" or "Detailing" means to engage in a Detail.

1.2.27 "Development" means pre-clinical and clinical drug development activities that occur prior to or as a condition of Regulatory Approval including, among other things: test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, cGMP audits, cGCP audits, cGLP audits, analytical method validation, manufacturing process validation, cleaning validation, scale-up, quality assurance/quality control development, statistical analysis and report writing, pre-clinical and clinical studies, regulatory filing submissions and pre-approvals, and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in Development.

1.2.28 "Disclosing Party" has the meaning set forth in Section 9.1.

1.2.29 Intentionally Omitted

1.2.30 Intentionally Omitted

1.2.31 "Distribution Costs" include (a) in-bound freight to receive Product, (b) outbound freight to ship Product, (c) warehouse costs to store Product, and (d) costs charged by a Third Party Logistics company to perform distribution activities.

1.2.32 "Drug Product" means a drug product as defined in 21 C.F.R. § 314.3 for administration to human subjects.

1.2.33 "Effective Date" has the meaning set forth in the Preamble of this Agreement.

1.2.34 "FDA" means the United States Food and Drug Administration, and any of its successor agencies or departments.

1.2.35 "Force Majeure" has the meaning set forth in Section 14.7.

1.2.36 "GAAP" means United States' generally accepted accounting principles, consistently applied.

1.2.37 "GEL" has the meaning set forth in the Preamble to this Agreement.

1.2.38 "GEL IP" means any and all Intellectual Property and Regulatory Approvals Controlled by GEL or its Affiliates and which are useful or necessary to Manufacture, Develop, Supply or Commercialize the Product.

1.2.39 "GEL Patents" means any and all patents, patent applications, and any and all provisional applications, divisions, continuations, continuations-in-part, reexaminations, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, all inventions disclosed therein, including extensions and complementary or supplementary certificates of protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications Controlled by GEL or its Affiliates and which are useful or necessary to Manufacture, Develop, Supply or Commercialize the Product.

1.2.40 "GEL Trademark" means collectively the name and logo of GEL or any of its Affiliates as identified on **Exhibit "A"** attached hereto and by this reference made a part hereof.

1.2.41 "Gross Profit" means, for any period of determination, [***].

1.2.42 "Indemnitee" has the meaning set forth in Section 10.3.1.

1.2.43 "Indemnitor" has the meaning set forth in Section 10.3.1.

1.2.44 "Intellectual Property" means all: (a) all patents, patent applications, and any and all provisional applications, divisions, continuations, continuations-in-part, reexaminations, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, all inventions disclosed therein, including extensions and complementary or supplementary certificates of protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications; (b) copyrightable works, copyrights in works of authorship of any type, including computer software and industrial designs, registrations and applications for registration thereof; (c) trade secrets, know-how, processes, specifications, product designs, manufacturing information, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality assurance, quality control and clinical data, technical

information, data, research records, supplier lists and similar data and information and other material confidential or proprietary technical, business and other information necessary or useful to Manufacture, Develop, Supply or Commercialize the Product in the Territory, and all rights in any jurisdiction to limit the use or disclosure thereof with respect to the Development, Supply or Commercialization of the Product in the Territory; (d) including with respect to extensions and the like; (e) any and all rights of application regarding any of the foregoing; and (f) as further provided in Section 13.2, rights to sue and recover damages or obtain injunctive relief for infringement, or misappropriation thereof.

1.2.45 "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 3.1.1.

1.2.46 "Latent Defect" means any instance where: (i) a Product fails to conform to the Specifications, Applicable Law, cGMP, the Quality Agreement and the terms and conditions set forth in this Agreement; and (ii) such failure could not reasonably have been discovered upon receipt and careful inspection of the Product during the Review Period or such failure occurred after the Review Period; and (iii) the assignable cause for such failure can be properly attributed to the actions or omissions of GEL prior to delivery of the Product to CPI.

1.2.47 "Launch Date" means the date of the First Commercial Sale.

1.2.48 "Manufacture" means the process of packaging the Components into Product in accordance with the Specifications, Applicable Law, cGMP, the Quality Agreement and the terms and conditions set forth in this Agreement. When used as a verb, "Manufacture" means to engage in Manufacturing.

1.2.49 "Marketing Expenses" means all costs and expenses incurred in connection with the Commercialization of the Product in the Territory, including, without limitation: (a) marketing, advertising, sampling, and promotional activities; (b) marketing studies; (c) primary and secondary market research; (d) promotional materials; and (e) samples. Marketing Expenses shall not include any deductions allowed under the definition of Net Sales.

1.2.50 "Material Adverse Event" means any event that materially affects the demand of the Product. For purposes of this section, materiality is defined as more than a 20% reduction in prescription demand, as determined by IMS (or comparable) monthly prescription data, from one three-month period to the next.

1.2.51 "NDA" means a new drug application for the Product, including a new drug application filed under Section 505(b)(2) of the Act, 21 U.S.C. § 355(b)(2), which has been filed with the FDA under the Act to obtain Regulatory Approval in the United States, including all amendments and supplements thereto and all documentation submitted to the FDA in connection therewith.

1.2.52 "Net Sales" means, for any period of determination, the aggregate amount invoiced by CPI (or any Affiliate, successor, sublicensee, subcontractor, or agent of CPI) to a Third Party distributor, agent, contractor or end user for the sale of Product during such period less the

following amounts: (a) credits, refunds, allowances, charge-backs, rebates, fees, patient vouchers, coupons, reimbursements, and similar payments provided to wholesalers, chains, mass merchandisers, group purchasing organizations and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations, any governmental, quasi-governmental or regulatory body, agency or authority in respect of any federal, state, provincial and/or local Medicare, Medicaid or similar programs or other customers; (b) credits or discounts related to sales promotions, samples, trade show discounts and stocking allowances and trade volume and cash discounts and rebates (including coupons and government charge-backs) in amounts that are usual and customary; (c) any price adjustments, shelf stock or floor stock adjustments, billing errors, rejected goods, product recalls, damaged goods and returns, allowances, adjustments, reimbursements, Third Party administration fees, distribution services agreement fees allowed or paid to third party distributors, discounts, rebates or other price reductions provided to any customer; (d) any invoiced charge for freight, insurance, handling, or other transportation costs, to the extent included in the gross amount invoiced to the customer; (e) rebates or other price reductions provided any governmental, quasi-governmental or regulatory body, agency or authority in respect of any state or federal Medicare, Medicaid or similar programs; (f) sales, use, value-added, and other like taxes, duties or excises, excluding income tax; and (g) any other mutually agreed upon items that reduce Net Sales as required by GAAP in the United States applied on a consistent basis; it being understood between the Parties that the amounts of any deductions accrued pursuant to clauses (a) through (g) of this Section shall be determined in accordance with GAAP and shall only be deducted once and only to the extent not otherwise deducted from the aggregate amount invoiced. "Net Sales" shall not include revenue received by CPI (or any of its Affiliates) from transactions with an Affiliate, where the Product in question will be resold to an independent Third Party distributor, agent or end user by the Affiliate where such revenue received by the Affiliate from such resale is included in Net Sales. For the avoidance of doubt, distribution of the Product in connection with clinical studies and as samples shall not be included in this definition.

1.2.53 "Net Sales Fiscal Year" has the meaning set forth in Section 7.3.

1.2.54 "Net Sales Milestone" has the meaning set forth in Section 7.3.

1.2.55 "Overpayment" has the meaning set forth in Section 7.10.

1.2.56 "Party" or "Parties" has the meaning set forth in the Preamble to this Agreement.

1.2.57 "Patent Claims" has the meaning set forth in Section 13.3.

1.2.58 "PDM Act" has the meaning set forth in Section 6.11.

1.2.59 "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other legal entity or organization, including a government or political subdivision, department or agency of a government.

1.2.60 "Product" means the pharmaceutical product known as Omeclamox-Pak®: Omeprazole, Clarithromycin and Amoxicillin Triple-Therapy Pack, plus any other formulations approved under the Product's NDA or applicable supplement(s) thereto.

1.2.61 "Quality Agreement" has the meaning set forth in Section 6.13.

1.2.62 "Raw Materials" has the meaning set forth in Section 6.3.

1.2.63 "Recall" has the meaning set forth in Section 12.5.1.

1.2.64 "Recall Expenses" has the meaning set forth in Section 12.5.1.

1.2.65 "Recall Objection Notice" has the meaning set forth in Section 12.5.1.

1.2.66 "Receiving Party" has the meaning set forth in Section 9.1.

1.2.67 "Regulatory Approval" means any approvals (including applications therefor, supplements and amendments including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the Commercialization, Development, Supply, Manufacture, testing, labeling, packaging, or shipping of the Product in the Territory, including the NDA for the Product.

1.2.68 "Regulatory Authority" means any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental authority in the Territory involved in the granting of approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations for the marketing, sale, manufacturing, testing, labeling, packaging, shipping or supply of Drug Products, including the FDA.

1.2.69 "Specifications" means the written specifications for the Product mutually agreed upon by the Parties including, without limitation, the expiry period of such Product and the specifications as set forth in the NDA for the Product. The Specifications, and any modifications or supplements thereto, as are mutually agreed in writing by the Parties from time to time after the Effective Date and during the Term, are hereby incorporated by reference in this Agreement.

1.2.70 "Supply" means the manufacture, processing, testing, storing, labeling and packaging (as specified in this Agreement) for sale and delivery of the Product.

1.2.71"Supply Failure" has the meaning set forth in Section 6.5.2.

1.2.72 "Term" has the meaning set forth in Section 11.1.

1.2.73 "Territory" means the United States of America and its territories and possessions.

1.2.74 "Third Party" means any Person other than GEL and CPI and their respective Affiliates.

1.2.75"Third Party Claim" has the meaning set forth in Section 10.3.1.

1.2.76"Underpayment" has the meaning set forth in Section 7.10.

1.2.77 "Unit" shall, in the case of a Unit for sale, mean a single box containing ten blister cards of the Product and, in the case of a Unit for sample, a single box containing one blister card with a single day treatment, as applicable.

1.2.78 "Venture Entity" shall mean a Person for which its primary business is the investment of capital in other Persons, and shall explicitly exclude any Person that markets, sells, promotes, develops or manufactures Drug Products and any Person for which its primary business is owning or controlling Intellectual Property.

SECTION 2. RIGHTS AND OBLIGATIONS

2.1. Commercialization License. Subject to the terms and conditions of this Agreement, GEL hereby grants to CPI and its Affiliates, and CPI and its Affiliates accept, an exclusive (even as to GEL and its Affiliates), royalty-bearing, sublicensable (solely in accordance with and subject to, Section 2.4 below) license under GEL's IP to Commercialize the Product in the Territory in accordance with the terms of this Agreement. Such license shall also include the right to access and use: (a) any and all Product-related clinical and non-clinical data and safety information, (b) applicable domain name registrations and uniform resource locators, and (c) exclusive supplies of trade and sample inventories for sale in the Territory indirectly from third party contract manufacturers. GEL covenants and agrees with CPI that during the Term (or extension or renewal thereof), GEL will not grant, transfer, convey or assign any license or similar right with respect to the Product to any Third Party in the Territory. CPI shall be responsible for the actions of it Affiliates with respect to their activities under the license granted hereunder.

2.2. Manufacturing Exclusivity. Unless otherwise agreed to in writing by both Parties, GEL will be responsible for the Development and Manufacture of the Product under this Agreement. Notwithstanding the foregoing, in the event GEL is unable to timely supply CPI with Product that conforms with the Specifications, Applicable Law, cGMP, the Quality Agreement and the terms and conditions set forth in this Agreement [***].

2.3. Trademark Licenses.

2.3.1 Subject to the terms and conditions of this Agreement, CPI hereby grants to GEL, and GEL accepts, a non-exclusive, fully-paid license to use the CPI Trademarks in the Territory solely in conjunction with the labeling and specified packaging of Product and solely as such are approved by CPI.

2.3.2 Subject to the terms and conditions of this Agreement, GEL hereby grants to CPI, and CPI accepts, a non-exclusive, non-transferable (except in accordance with Section 2.4), fully-paid, perpetual license to use the GEL Trademarks in the Territory, to the extent required, solely in conjunction with the Product and solely as such are approved by GEL.

2.4. CPI Sublicensing or Subcontracting to Third Parties. CPI shall have the right to sublicense or subcontract to any Third Party any of CPI's rights and responsibilities under this Agreement with the prior written consent of GEL, such consent not to be unreasonably withheld. CPI shall be responsible for each such sublicensee's or subcontractor's performance of CPI's obligations under this Agreement.

2.5. Marking of Promotional Materials. Subject to Section 2.3.2, the label for the Product shall be a CPI label in accordance with CPI's customary practices. All promotional materials, package inserts or outserts and packaging for the Product or samples of Product used during the Term shall be consistent with the label of the Product. Neither Party shall have any rights to the other Party's trademarks, names or logos for any use other than as contemplated in this Agreement.

2.6. Exclusivity. Except as set forth in this Agreement, the Parties agree that they shall not, directly, or indirectly (whether through an Affiliate, Third Party or otherwise), in the Territory during the Term, make, have made, use, develop, import/export, register, file, promote, market, manufacture, distribute, offer to sell, sell or otherwise Commercialize: (a) the Product or (b) any competitive H. Pylori product having the same Components, or assist any Third Party in the foregoing with respect to 2.6(a) or (b) above.

SECTION 3. COMMITTEES

3.1 Joint Commercialization Committee.

3.1.1 Within sixty (60) days after the Effective Date the Parties shall establish a Joint Commercialization Committee ("JCC"), which shall provide a forum for open communication between the Parties regarding Product Commercialization activities, and which shall be responsible for such matters related to Commercialization of the Products in the Territory as may be described below. The JCC shall consist of two (2) individuals from each of the Parties. Each Party shall have the right at any time and from time to time to designate a replacement, on a permanent or temporary basis, for any or all of its previously-designated members of the JCC. CPI shall appoint one of its designees to serve as the Chair of the JCC. The JCC shall meet at least once per Calendar Quarter, and more frequently as mutually agreed by the Parties, on such dates and at such places and times as the Parties shall agree. The Party hosting any JCC meeting shall appoint one person (who need not be a member of the JCC) to attend the meeting and record the minutes of the meeting in writing. Such minutes shall be circulated to the members of the JCC in a time frame to be agreed upon by the JCC after the meeting and the members agree to review and comment on such minutes in a time frame to be agreed upon by the JCC. The Parties agree to use Commercially Reasonable Efforts to promptly finalize any dispute regarding minutes of any meeting.

3.1.2 CPI agrees to keep the JCC reasonably informed in respect of its Commercialization of the Product in the Territory pursuant to its authority and responsibility set forth in Section 5.1, and in particular CPI shall: (a) provide the JCC with copies of CPI's annual Product marketing plans on a quarterly basis, information regarding CPI's Commercialization strategy, and updates regarding the foregoing and the progress of CPI's Commercialization activities; (b) promptly advise the JCC of any unforeseen material problems or delays encountered since the date of its last report in connection with the Commercialization activities; and (c) provide GEL as

soon as reasonably practicable with such other documentation and information as GEL's JCC members may reasonably request in writing from time to time with respect to the status of the Commercialization activities and progress. CPI will reasonably and in good faith consider any comments and recommendations provided pursuant to this Section that the JCC may have with respect to the Commercialization of the Product.

3.1.3 The JCC shall: (a) review and make recommendations (or decline to make recommendations), regarding the overall progress of the Commercialization of the Product, managed care strategy and managed care access regarding the Product; and (b) perform such other activities and discharge such other responsibilities as may be assigned to the JCC by the Parties pursuant to this Agreement or as may be mutually agreed upon in writing by the Parties from time to time. CPI will reasonably and in good faith consider any comments and recommendations that the JCC may have pursuant to this Section with respect to the Commercialization of the Product.

3.1.4 The JCC shall establish the initial WAC and AWP for the Product based on information provided by CPI. CPI shall not make changes to the WAC or the AWP without consulting with and receiving approval of the JCC. CPI shall have the discretion to apply discounts to AWP in the ordinary course of business; provided that these discounts will be reviewed periodically by the JCC.

3.1.5 The JCC has no decision-making authority except as expressly set forth herein. All decisions of the JCC shall be made by unanimous vote or unanimous written consent of both Parties, with each Party having, collectively among its respective designees, one vote in all decisions. The members of the JCC shall use Commercially Reasonable Efforts to decide all matters assigned to the JCC under this Agreement or otherwise referred to it by mutual written agreement of the Parties; provided, however, that if the members of the JCC are unable to make a decision by unanimous vote or unanimous written consent within ten (10) days after commencing discussions regarding such decision, then, any JCC member may submit it to the Executive Officers of the Parties for resolution. Each Party shall designate an "Executive Officer" of its company as the designee in the event of any dispute that has not been resolved by the JCC in accordance with this Section. The Executive Officer must be at least at the level of an officer of the respective Party. The Executive Officers of the Parties shall discuss in good faith the issue to be resolved and make a decision based on an assessment of the objectives for the Commercialization of the Product.

3.2 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and approved invitees to attend meetings of, and otherwise participate on, the JCC.

SECTION 4. DEVELOPMENT

4.1 Right of First Refusal. In the event GEL and/or its Affiliates Develops and obtains one or more Regulatory Approvals for: (a) any improvement, extension or reformulation of the Product: (b) any new product that links the Product in any pharmaceutical drug database, including, without limitation, First DataBank, Medi-Span and Gold Standard; (c) any product that otherwise competes with the Product (in either case, a "New Product") then GEL and/or its Affiliates, as applicable, shall offer CPI a right of first refusal for the exclusive right (even as to GEL and/or its Affiliates) to Commercialize such New Product in the Territory. The Parties shall use Commercially

Reasonable Efforts in good faith for a period of no less than Sixty (60) days following CPI's receipt of notice from GEL that a New Product is available to reach a definitive agreement or an amendment to this Agreement with respect to the Commercialization rights for such New Product before GEL is permitted to seek an alternate partner for the Commercialization of such New Product. The foregoing notwithstanding, in the event GEL notifies CPI of its intent to develop a New Product, CPI shall have the right to elect, within 3 Business Days, to request information regarding the New Product from GEL. Within 10 Business Days of its receipt of the requested information regarding the New Product, CPI may elect, in its sole discretion, to share in the development costs for such New Product, at a rate equivalent to CPI's share of Net Sales provided in Section 7.4, in exchange for GEL adding the new product to this agreement at the same royalty terms indicated under section 7.4.

4.2 Development Responsibilities of GEL. To the extent applicable to the Product or any New Product, GEL shall have overall responsibility for the performance of all Development activities, including formulation development, analytical method development and validation, Component and Product specifications, commercial scale-up and process validation, Manufacturing of registration and validation batches, pre-approval inspection and approval of GEL's contract Manufacturing facilities, monitoring that the Manufacturers of the Components maintain cGMP processes and procedures in conjunction with Manufacturing, packaging, storage and stability of the Product, and other manufacturing-related activities required for Regulatory Approval. GEL shall have overall responsibility for the performance of the selected Development activities of clinical trial design and conduct, bioanalytical assay method validation, bioanalytical sample shipping, pharmacokinetic and bioequivalent evaluation, data management and clinical study report writing.

4.3 Clinical Costs. GEL shall be responsible and pay for one hundred percent (100%) of the costs of clinical studies necessary for the FDA's approval of the NDA for the New Product.

4.4 Changes.

4.4.1 In the event that CPI is required to change the labeling, packaging or Specifications for the Product pursuant to Applicable Law, or in response to an order or request of a Regulatory Authority, CPI shall advise GEL in writing of any such change, as well as any scheduling adjustments which may result from such change. CPI shall be responsible for the costs of implementing any such change; provided, however, that if such change results from the fault or negligence of a Party or the breach by a Party of its obligations under this Agreement, then such Party shall be solely responsible for all such costs or, if such change relates to GEL's contract Manufacturing facilities generally or to equipment which is not specifically dedicated to the Product, then GEL shall be solely responsible for all such costs. Upon request, each of the Parties shall provide to the other Party reasonable advance notice of and documentation of such Party's costs related to such change and permit the other Party to review and audit such costs under the same audit guidelines as set forth in Sections 7.9 and 7.10.

4.4.2 Subject to Section 2.3.2, CPI shall have the right, upon prior written notice to GEL, to change the labeling or packaging for the Product. Such changes shall be at CPI's sole cost and expense (including paying GEL for the cost of any and all inventory, work-in-process, Raw Materials and packaging materials of GEL which becomes obsolete or unusable as a result of

such request) and the Parties shall agree in good faith on a reasonable timeframe for implementation of such changes. GEL shall not be required to make any such change if: (a) it results in the need for any un-reimbursable capital investment by GEL; (b) it results in any un-reimbursable cost increases (including manpower allocations or resources) to GEL; or (c) it is not consistent with the Specifications the Regulatory Approvals or any Applicable Laws.

4.4.3 Both Parties shall have the right to request that a change be made to the Specifications for the Product at its expense and upon prior written notice and approval to the other Party and, if approved, the Parties shall agree on a reasonable timeframe for implementation of such changes. No change shall be made to the Specifications without the mutual agreement of the Parties and neither Party shall be required to make or accept any such change if: (a) it results in the need for any un-reimbursable capital investment by such Party; (b) it results in any un-reimbursable cost increases (including manpower allocations or resources) to such Party; or (c) it requires any changes to the Regulatory Approvals or could have a material adverse effect on the Commercialization of the Product.

SECTION 5. COMMERCIALIZATION

5.1 CPI Responsibility and Control. Except as otherwise expressly set forth herein, and subject to the oversight of the JCC as provided in Section 3.2, CPI shall have responsibility for all Commercialization activities for the Product in the Territory, including developing strategies and tactics related to the advertising, promotion, pricing, marketing and selling the Product. CPI shall have final decision-making authority and primary responsibility for all Commercialization strategies, plans and activities regarding the Product in the Territory. CPI shall include GEL in such efforts in an advisory and consultative capacity. CPI shall comply, shall cause its sublicensees to comply, and shall require all of its Third Party agents and contractors, if any, to comply, with all Applicable Laws in Commercializing the Product in accordance with this Agreement.

5.2 Specific Commercialization Rights and Obligations of CPI. CPI shall use Commercially Reasonable Efforts to Commercialize the Product in a manner consistent with the then-current Commercialization plan. Subject to any conditions or limitations set forth herein, it shall be CPI's sole right and responsibility to: (a) determine the commercially reasonable launch dates for the Product; (b) develop advertising and promotional materials related to the Product; (c) book sales for the Product; (d) handle all returns of the Product; (e) handle all aspects of order processing, invoicing and collection of receivables for the Product; (f) maintain managed care and similar types of reimbursements; (g) collect data regarding sales to hospitals and other end users of the Product; (h) monitor inventory levels of the Product; (i) provide first line customer support and pharmacovigilance; (j) warehouse the Product; and (k) determine the prices for the Product and any discounts and rebates that may be offered thereto, including decisions relating to customer allowances and credits. CPI shall determine the Commercialization plan(s) and Commercialization activities, and the execution thereof shall be within CPI's decision-making authority and control.

5.3 Marketing Expenses. CPI shall be responsible and pay for one hundred percent (100%) of the Marketing Expenses for the Product in the Territory, including the costs and expenses incurred in connection with CPI's responsibilities under this Section 5.

5.4 Sales Forecast. CPI shall use Commercially Reasonable Efforts to effectuate sales of the Product commensurate with an estimated forecast "Sales Forecast"; it being understood that the Sales Forecast is merely a good faith, reasonable, non-binding, twelve (12) month sales and prescription forecast for the Product and not a binding obligation.

5.5 Sales Representatives,

5.5.1 CPI shall have sole responsibility for employing or retaining a sufficient number of sales representatives who are qualified to Detail the Product, in accordance with customary standards in the pharmaceuticals industry. Following the Effective Date, CPI shall promote, market or Detail to [***].

5.5.2 CPI shall have sole responsibility for all salary and other compensation and benefits with respect to its sales representatives and shall ensure the filing of all appropriate business registrations, and compliance with the requirements of tax withholding and reporting occasioned by the engagement of such sales representatives.

SECTION 6. MANUFACTURING & SUPPLY

6.1 Supply Obligations. Subject to the terms and conditions hereof, during the Term, GEL shall exclusively Supply CPI and CPI's Affiliates and their permitted sublicensees with, and CPI shall exclusively purchase from GEL, all of CPI's and its Affiliates' or their permitted sublicensees' requirements for the Product in the Territory during the Term, pursuant to purchase orders delivered by CPI or its Affiliate or CPI's permitted sublicensees to GEL in accordance with Section 6.5. GEL shall Supply the Product in Units, each with a shelf life and expiration date of at least twenty (20) months from the date of shipment, in accordance with the terms and conditions of this Agreement, Applicable Law, the Specifications and cGMP.

6.2 Supply Price. With respect to Product supplied to CPI under this Agreement: (a) GEL shall supply quantities of each Unit of the Product to CPI at the lesser of [***] or [***]. GEL shall have the right to increase the Purchase Price for the Product once annually by the rate of price change indicated in the Producer Price Index applicable to pharmaceutical preparations published by the U.S. Bureau of Labor Statistics, Department of Labor (or any applicable successor index to be agreed to by the Parties in good faith in the event of the discontinuation of same) over the prior twelve (12) month period. If the cost increase for the prior twelve (12) month period in GEL's actual documented cost of manufacturing and Supplying Product is greater than the price change indicated by the Producer Price Index applicable to pharmaceutical preparations, then the Parties will meet to discuss if additional price increases are appropriate.

6.3 Raw Materials. GEL, at its sole cost and expense, shall have responsibility for the procurement, manufacture, quality control, processing, testing, storage, treatment and handling of all packaging, Components and other raw materials, chemicals, work-in-process and other materials used for Supply (collectively, "Raw Materials"). GEL shall be solely responsible for causing its contract Manufacturers to dispose of all Components and Raw Materials and wastes arising from its performance hereunder and for performance of its obligations hereunder in accordance with Applicable Law in effect at the time and place of Manufacture of the Product.

6.4 Quality Control. All quality control processes and procedures relating to the Product shall be the sole cost and responsibility of GEL. GEL shall conduct quality control testing of Product prior to shipment in accordance with the Product's NDA and Applicable Law. GEL shall prepare and retain records pertaining to such testing as required by Applicable Law, GEL's standard operating procedures and the Quality Agreement.

6.5 Forecasts, Order and Delivery of Products. In order to assist GEL in planning production, CPI shall deliver to GEL a Supply forecast on a monthly basis by the 15th business day of the current month. The supply forecast will include the quantities of Product by strength (including samples) required by CPI (and/or its Affiliates or their permitted sublicensees, subcontractors and distributors) by month for the next twelve (12) months. The first four (4) months of such forecast shall constitute a binding order for the quantities of Products specified therein ("Firm Commitment") and the following eight (8) months of the forecast shall be non-binding, good faith estimates, provided however that in each forecast, the new fourth and fifth months of such forecast shall be no greater than one hundred and twenty five percent (125%) and no less than seventy-five percent (75%) of the amount that was forecast in the previously submitted forecast for such months provided there has been no Material Adverse Event that affects the demand of the Product.

6.5.1 CPI shall furnish to GEL binding purchase orders on an as needed basis. Each such purchase order shall conform to the Firm Commitment indicated in the forecast provided in Section 6.5.1 and shall specify the requested date of delivery of the Product to CPI or to CPI's Affiliates or any Third Party designated by CPI. CPI shall furnish purchase orders a minimum of one hundred twenty (120) days prior to the requested delivery date. Each purchase order shall be for amounts of Products in whole Batch Size increments. The Parties agree that no provision of any purchase order, invoice or of any confirmation or acknowledgement or any other documentation or forms submitted by either Party to the other Party shall be controlling to the extent it sets forth any terms or conditions that are additional to, or in conflict or inconsistent with, the terms or conditions of this Agreement.

6.5.2 GEL shall ensure its ability to Supply Product covered under binding purchase orders furnished by CPI in accordance with the terms of this Agreement. GEL and CPI will consider a purchase order filled as long as no less than 90% of the quantities are delivered against the purchase order; such failure to so fill at least 90% of the quantity of a purchase order referred to herein as a "Supply Failure". CPI agrees to accept delivery of up to 110% of the requested purchase order.

GEL shall deliver Product set forth in each purchase order Ex Works (Incoterms 2010 edition, published by the International Chamber of Commerce) at the applicable Manufacturing facility to CPI's designated carrier as specified by CPI in the applicable purchase order or otherwise notified in writing to GEL by CPI. CPI reserves the right to designate the carrier for shipment from the GEL facility provided that GEL has approved such carrier for the facility, such approval not to be unreasonably withheld, conditioned or delayed. Costs incurred by CPI in relation to acquiring Product inventory from GEL shall be part of CPI's distribution costs and included in the cost of goods sold.

6.6 Intentionally Omitted.

6.7 Invoice. Each binding purchase order shall be accompanied by a payment equal to sixty-six percent (66%) of the estimated value of the Product ordered therein ("Prepayment"). The Prepayment shall, initially be determined using a purchase price based on annual purchase volumes as follows:

Annual Commercial Volume	Unit Commercial Unit Price	Annual Sample Volume	Unit Sample Unit Price
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

In addition, the Commercial Unit Prices shall be increased by (i) [***] for individual orders in an amount equal to two or three times the Batch Size or (ii) [***] for individual orders equal to one times the Batch Size. For all orders equal in amount to four or more times the Batch Size, the above pricing shall apply.

The Prepayment prices for a particular Net Sales Fiscal Year shall be based on the Sales Forecast prepared by CPI pursuant to Section 5.4. GEL shall invoice CPI at the Purchase Price for all quantities of Product delivered in accordance herewith. Each invoice shall be delivered concurrently with each shipment of Product and be accompanied by a Certificate of Analysis, Certificate of Compliance and any other documentation required by the applicable Regulatory Authorities or by Applicable Law to Commercialize the Product in the Territory. The amount payable with respect to an invoice issued hereunder shall (i) reflect the actual number of units of Product shipped to CPI and GEL's direct costs and (ii) be reduced by a credit issued by GEL in the amount of the Prepayment. Payments shall be made in accordance with Section 7.6, and shall be due within thirty (30) days after delivery of the invoice with respect thereto, subject to the procedure for rejected shipments set forth in Section 6.8. Within forty-five (45) days of the end of each Net Sales Fiscal Year, CPI will prepare a reconciliation of actual unit volume for that period versus the Sales Forecast for that period. Any overpayment or underpayment of Purchase Price shall be remitted within thirty (30) days of receipt of the reconciliation by GEL from one Party to the other, as appropriate.

6.8 Product Not in Compliance with Purchase Order. Within thirty (30) day after receipt of the Product, CPI or its agent shall perform an examination of the Certificates of Analysis and other documentation, if any, provided with each shipment of Product, and shall determine whether such Product meets the requirements of the applicable purchase order. In the event that CPI determines, within such thirty (30) day period, that any Product Supplied by GEL does not conform to the applicable purchase order, CPI shall give GEL written notice thereof and the reasons(s) therefor within thirty (30) days after receipt thereof. If CPI does not submit written notice of rejection within such thirty (30) day period, such Product shall be deemed accepted by CPI, except to the extent of the presence of Latent Defects. In the event of such rejection or the subsequent discovery of a Latent Defect, GEL shall, at CPI's option, either: (a) correct such shipment to conform

to the applicable purchase order; or (b) grant CPI a credit on that portion of the shipment that is nonconforming.

6.9 Inspection by CPI. At any time during the Term of this Agreement and upon not less than ten (10) Business Days' prior written notice, GEL shall, subject to any limitations in GEL's agreements with its contract Manufacturers, permit CPI to inspect any facility (including any subcontractors' facilities) where the Supply of the Product is carried out in order to assess GEL's (or its designees') compliance with cGMP and other Applicable Law, and to discuss any related issues with GEL's management personnel for prompt resolution.

6.10 Inspections by Regulatory Authorities. GEL shall, subject to any limitations in GEL's agreements with its contract Manufacturers, allow representatives of any Regulatory Authority to inspect the relevant parts of the facility where the Supply of Product is carried out and to inspect the lot, batch and other Manufacturing records to verify compliance with cGMP and other Applicable Law and practices and shall promptly notify CPI of the scheduling of any such inspection relating to Supply. GEL shall promptly send to CPI a copy of any reports, citations, or warning letters received by GEL in connection with an inspection by a Regulatory Authority to the extent such documents relate to or affect Supply.

6.11 Samples. CPI shall order samples in the Territory under purchase orders separate from the Product for sale and/or as otherwise approved by the JCC. CPI agrees that it shall use and distribute samples each Calendar Quarter in compliance with all Applicable Laws, including the requirements of the Prescription Drug Marketing Act of 1987, as amended (the "PDM Act").Without limiting the generality of the foregoing, CPI shall ensure that CPI and its Affiliates and their permitted sublicensees, and subcontractors comply with all requirements of the PDM Act. CPI shall notify GEL promptly upon learning that any samples have been lost or have not been received as scheduled. Each of the Parties shall maintain records as required by the PDM Act and all other Applicable Laws. Each Party shall be responsible for the filing of any necessary reports to the FDA in connection with the PDM Act, and each Party shall provide to the other Party in a timely fashion all necessary information in connection with such reporting under the PDM Act. Upon reasonable advance written notice to CPI, GEL shall be entitled, at GEL's expense, to conduct an inspection and audit of the sample distribution practices by CPI, its Affiliates and/or their permitted sublicensees, and subcontractors and their respective sales representatives, in the Territory. Upon reasonable advance written notice to GEL, CPI shall be entitled, at CPI's expense, and subject to GEL's contractual arrangements with its sample packager, to conduct an inspection and audit of any of GEL's contract facilities where samples are stored. GEL shall cause such samples to be stored in compliance with the Specifications and use its commercially reasonable efforts to arrange for access to CPI for the purpose of conducting such inspection and audit. Each such inspection and audit shall be made in accordance with the applicable provisions of the PDM Act and with the provisions of this Agreement.

6.12 Safety Stock. CPI shall use commercially reasonable efforts during the Term to maintain an inventory of Product in an amount equal to three (3) months of its current requirement of the Product.

6.13 Quality Agreement. Within ninety (90) days from the Effective Date, the Parties will enter into an agreement that details the quality assurance obligations of each Party (the "Quality Agreement"). Notwithstanding the foregoing, neither the Quality Agreement, nor the absence of a Quality Agreement, shall affect the rights and obligations of the Parties under this Agreement. The Parties shall amend the Quality Agreement from time to time as the Parties deem necessary. All Product supplied to CPI be supplied in accordance with the Quality Agreement. The Quality Agreement, as may be amended from time to time, is hereby incorporated by reference into and made part of this Agreement.

SECTION 7. PAYMENTS AND REPORTS

7.1 Intentionally omitted.

7.2 Intentionally omitted.

7.3 Sales Milestone Payments. As consideration to GEL for the rights granted to CPI under this Agreement, CPI shall pay to GEL a one-time payment in consideration of CPI's achievement of each of the following Net Sales milestone events during the Term (each, a "Net Sales Milestone"):

Milestone Event	Milestone Payment (U.S. Dollars)
The First Time Annual Net Sales reach [***]	[***]
The First Time Annual Net Sales reach [***]	[***]
The First Time Annual Net Sales reach [***]	[***]
The First Time Annual Net Sales reach [***]	[***]

Annual Net Sales shall be measured for twelve month periods commencing on the Launch Date and ending on each anniversary of the Launch Date ("Net Sales Fiscal Year"). For each Net Sales Milestone achieved, CPI shall notify GEL in writing and promptly remit payment to GEL against the applicable Net Sales Milestone within forty-five (45) days after the achievement of same. CPI shall only be required to remit payment for one Net Sales Milestone in any calendar year. Accordingly, in the event more than one Net Sales Milestone is achieved in any Net Sales Fiscal Year, CPI shall remit payments in respect of such Net Sales Milestones as follows: Payment in respect of the first Net Sales Milestone achieved shall be remitted within forty-five (45) after the achievement of same; then, in the event a second Net Sales Milestone is achieved in such Net Sales Fiscal Year, then payment shall become due upon the later of (i) ninety (90) days following the achievement of such Net Sales Milestone or (ii) the fifth business day of the following calendar year; then, in the event a third Net Sales Milestone is achieved in such Net Sales Fiscal Year, payment in respect of such Net Sales Milestone shall become due upon the fifth business day of the calendar

year after the payment described in (ii) becomes due. The maximum amount payable to GEL under this section is [***] over the Term of the Agreement.

7.4 Royalties.

As additional consideration for the license and other rights granted to CPI under this Agreement, during the Term and in addition to any payments set forth in this Section 7, CPI shall pay to GEL a royalty payment at a rate ("Branded Royalty Rate") based upon the actual U.S. dollar value, as follows:

Branded Royalty Rate
[***]% of Gross Profit on the first [***] in Net Sales
[***]% of Gross Profit on Net Sales from [***] to [***]
[***]% of Gross Profit on all Net Sales over [***]

7.4.1 Notwithstanding the foregoing, in the event that during the Term a generic pharmaceutical medicinal or nutritional product ("Competitive Generic Product") launches or otherwise commences commercialization in the Territory, CPI shall have the right, but not the obligation, to Commercialize a GEL-supplied authorized generic version of the Product in the Territory upon commercially reasonable business terms to be defined by the Parties in a definitive agreement, and the Parties hereby agree to use Commercially Reasonable Efforts to promptly and diligently enter into such definitive agreement.

7.4.2 [***]. Royalties paid pursuant to this Section 7.4 shall be subject to [***]. Royalties shall be paid in accordance with Section 7.5. At the end of each Net Sales Fiscal Year, the Quarterly Royalty Report (as defined below) shall include a reconciliation of actual royalties paid during the Net Sales Fiscal Year to [***]. To the extent that actual royalties paid are [***].

7.4.3 Intentionally Omitted.

7.5 Royalty Reports and Payments. During the Term, CPI shall make quarterly royalty payment reports ("Quarterly Royalty Reports") to GEL on or before the thirtieth (30th) day following the end of the preceding Calendar Quarter. Each Quarterly Royalty Report shall cover the most recently completed Calendar Quarter and shall show: (a) the Gross Profit and Net Sales of the Product during the most recently completed Calendar Quarter including reasonable detail with respect to the calculation of Net Sales such as units sold, discounts, credits and other components in the calculation of Net Sales; (b) the royalties, in U.S. dollars, payable with respect to such Net Sales; and (c) prescription data for the Product (i.e., Symphony Health data). Each royalty payment shall be due and payable to GEL no later than forty-five (45) days after the expiration of the applicable Calendar Quarter.

7.6. Manner of Payment. All sums due under this Agreement shall be payable in U.S. dollars by bank wire in immediately available funds to such bank account(s) as GEL shall designate.

7.7. Taxes and Withholding. Except with respect to the calculation of Net Sales, all payments under this Agreement will be made without any deduction or withholding for or on account of any tax, duties, levies, or other charges unless such deduction or withholding is required by Applicable Law. If CPI is so required to deduct or withhold, CPI will: (a) notify GEL of such requirement in writing; (b) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required; and (c) forward to GEL an official receipt (or certified copy) or other documentation reasonably acceptable to GEL evidencing such payment to such authorities.

7.8. Accounting. All financial terms and standards defined or used in this Agreement for sales or activities occurring in the Territory shall be governed by and determined in accordance with GAAP, including the calculation of Net Sales and royalties due to GEL hereunder; provided that when the actual results become known relative to any accrued amount, any difference between the actual results and the accrual is reported and accounted for in the next payment due hereunder (subject to customary processing periods). To the extent that the difference between such accruals and the actual results has led to an underpayment, CPI shall pay GEL the amount of such underpayment on the next date payment is due to GEL hereunder. To the extent that the difference between such accruals and the actual results has led to an overpayment to GEL, CPI may set-off such overpayments against subsequent payments to be made to GEL; additionally, if any overpayments remain upon the expiration or termination of this Agreement, GEL shall refund such overpayments to CPI within thirty (30) days of receiving an invoice for such overpayment together with applicable supporting documentation.

7.9. Record Keeping; Audits. CPI and its Affiliates shall keep books and accounts of record in connection with Net Sales of the Product in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder. CPI and its Affiliates shall maintain such records for a period of at least three (3) years after the end of the Calendar Quarter in which they were generated; provided, however, that if any records are in dispute and CPI has received written notice from GEL of the records which are in dispute, CPI and its Affiliates shall keep such records until the later of one (1) year or until such dispute is resolved. [***].

7.10. Underpayments and Overpayments. If an audit conducted by GEL pursuant to Section 7.9 reveals that additional royalties were due to GEL under this Agreement (an "Underpayment") or that GEL was paid royalties in excess of those royalties due to GEL under this Agreement (an "Overpayment"), CPI shall, in the case of an Underpayment, pay to GEL the additional royalties within ten (10) days of the date CPI receives written notice of such underpayment, together with interest thereon from the date such royalty payments were due in the first instance at the rate equal to one percent (1%) per month or at the highest rate permitted by New Jersey law, whichever is less. In the case of an Overpayment, CPI shall deduct such amount from the next royalty payment due GEL under this Agreement, interest will only be due if the underpayment agreed to by the Parties is at least 5%.

SECTION 8. REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1. Representations, Warranties and Covenants of Each Party. Each Party hereby represents, warrants and covenants to the other Party as follows:

8.1.1 Such Party: (a) is duly formed and in good standing under the laws of the jurisdiction of its formation; (b) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; and (c) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

8.1.2 All necessary consents, approvals and authorizations of all Regulatory Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

8.1.3 The execution and delivery of this Agreement, the performance of such Party's obligations hereunder, and any actions or omissions of such Party related to the activities contemplated hereunder and the circumstances surrounding this Agreement: (a) do not and will not conflict with or violate any Applicable Law or any provision of the articles of incorporation, bylaws or other governing charter documents of such Party; and (b) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

8.1.4 Each Party agrees not to engage in any action that is in violation of or inconsistent with the terms and conditions of this Agreement or that interferes with the consummation of the transactions contemplated under this Agreement.

8.1.5 Neither Party nor any of its Affiliates is a Party to or otherwise bound by any oral or written contract or agreement that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any of the Parties' rights under this Agreement.

8.2. Additional GEL Representations, Warranties and Covenants. GEL represents, warrants and covenants to CPI as follows:

8.2.1 GEL has not received and is not aware of any written notice of any Third Party Claim alleging infringement or misappropriation of any Intellectual Property of any Third Party based on GEL IP or the Product.

8.2.2 GEL and its Affiliates have the right to grant the licenses granted to CPI herein, and GEL owns all right, title and interest in and to, or has a license, sublicense or otherwise permission to use and license, all of the GEL IP.

8.2.3 During the Term, GEL shall comply with and maintain in force all licenses, agreements, consents, permits and authorization that may be required with respect to the Supply of Product and its performance of its obligations hereunder.

8.2.4 During the Term, GEL shall comply with and maintain in force all licenses, agreements, consents, permits and authorization which may be required with respect to its facility and its performance of its obligations hereunder, including without limitation, licenses and permits issued or required by all Regulatory Authorities and those required, if applicable, in relation to the generation, storage, treatment, transport, possession, handling and disposal of any waste and GEL shall Supply Product in compliance with all such licenses, consents, permits and authorization.

8.2.5 GEL shall not during the Term in the Territory: (a) Supply (either directly or indirectly) or arrange for the supply of Product to any Affiliate of GEL or any Third Party or for GEL's own account; or (b) manufacture Product for the account of any Third Party besides CPI or its Affiliates or their permitted Third Party designees.

8.2.6 The Product shall: (a) be Supplied in accordance with the Specifications and cGMP; (b) be in conformity with the applicable Specifications, applicable Regulatory Approval, Applicable Law and the Certificate of Analysis; and (c) be in dosage form labeled, packaged and tested for commercial sale in the Territory and title to such Product shall pass to CPI as provided herein free and clear of any security interest, lien or other encumbrance.

8.3. Additional CPI Representations, Warranties and Covenants. CPI further represents, warrants and covenants to GEL that:

8.3.1 It has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of the Product and has solely relied on such analysis and evaluations in deciding to enter into this Agreement.

8.3.2 Neither CPI nor any of its Affiliates is a Party to or otherwise bound by any oral or written contract or agreement that will result in any Person obtaining any interest in, or that would give to any Person any right to assert any claim in or with respect to, any of CPI's or GEL's rights under this Agreement.

8.3.3 During the Term, CPI shall comply with and maintain in force all licenses, consents, permits and authorizations necessary to perform its obligations under this Agreement.

8.4. Disclaimer. EXCEPT AS OTHERWISE SPECIFICALLY SET FORTH HEREIN, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION BY GEL REGARDING THE EFFECTIVENESS, VALUE, SAFETY, NON-TOXICITY OF THE PRODUCT OR OF ANY INFORMATION OR RESULTS PROVIDED BY GEL PURSUANT TO THIS AGREEMENT. EXCEPT AS SET FORTH HEREIN, GEL HEREBY DISCLAIMS: (I) ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR (II) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.

SECTION 9. CONFIDENTIAL INFORMATION

9.1. General. Pursuant to the terms of this Agreement, each of GEL and CPI (in such capacity, the "Disclosing Party") has disclosed and will be disclosing to the other Party, and to the officers, directors, employees, agents and/or representatives of each (in such capacity, the "Receiving Party") certain secret, confidential or proprietary data, Intellectual Property and related information, including, without limitation, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information ("Confidential Information"). Without limiting the foregoing, it is acknowledged that the GEL IP shall constitute the Confidential Information of GEL (subject to Section 9.2) for purposes of this Agreement. The Receiving Party shall make no use of any Confidential Information of the Disclosing Party except in the exercise of its rights and the performance of its obligations set forth in this Agreement. The Receiving Party: (a) shall keep and hold as confidential, and shall cause its officers, directors, employees, agents and representatives to keep and hold as confidential, all Confidential Information of the Disclosing Party; and (b) shall not disclose, and shall cause its officers, directors, employees, agents and representatives not to disclose, any Confidential Information of the Disclosing Party. Confidential Information disclosed by the Disclosing Party shall remain the sole and absolute property of the Disclosing Party, subject to the rights granted in this Agreement or pursuant to Applicable Law.

9.2. Exceptions. The above restrictions set forth in Section 9.1 on the use and disclosure of Confidential Information shall not apply to any information which: (a) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality); (b) is or becomes generally known or available to the public other than through any act or omission of the Receiving Party in breach of this Agreement; (c) is acquired by the Receiving Party from a Third Party who is not directly or indirectly under an obligation of confidentiality to the Disclosing Party with respect to same, or (d) is developed independently by the Receiving Party without the use, direct or indirect, of the Disclosing Party's Confidential Information. In addition, nothing in this Section 9 shall be interpreted to limit the ability of either Party to disclose its own Confidential Information to any other Person on such terms and subject to such conditions as it deems advisable or appropriate.

9.3. Permitted Disclosures . It shall not be a breach of Section 9.1 if a Receiving Party discloses Confidential Information of a Disclosing Party: (a) pursuant to Applicable Law, including securities laws applicable to a public company, to any Regulatory Authority or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other governmental authority; or (b) in a judicial, administrative, arbitration or other legal proceeding to enforce such Party's rights under this Agreement; provided, however, that the Receiving Party (i) provides the Disclosing Party with as much advance written notice as possible of the required disclosure, (ii) reasonably cooperates with the Disclosing Party in any attempt to prevent, limit or seek confidential treatment for the disclosure and (iii) discloses only the minimum amount of Confidential Information necessary for compliance.

9.4. Confidential Terms. Each Party acknowledges and agrees that the terms and conditions of this Agreement shall be considered Confidential Information of each Party and shall be treated accordingly. Notwithstanding the foregoing, each Party acknowledges and agrees that the other may be required to disclose some or all of the information included in this Agreement in order to comply with its obligations under securities laws or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market, and hereby consents to such disclosure to the extent deemed advisable or appropriate by its respective counsel (but only after consulting with the other to the extent practicable). The Parties may also disclose the existence of this Agreement and terms thereof to their directors, investors, officers, employees, attorneys, accountants, agents and other advisers on a need to know basis and may, upon obtaining a written confidentiality agreement, further disclose the existence and terms of this Agreement to Third Parties to whom it may be relevant in connection with financings, acquisitions and similar transactions.

9.5. Equitable Remedies. Each Party specifically recognizes that any breach by it of this Section 9 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available.

SECTION 10. INDEMNIFICATION; LIMITATION OF LIABILITY

10.1. Indemnification by CPI. CPI shall defend, indemnify and hold harmless GEL and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns from and against all Third Party Claims, and all associated Losses, to the extent arising out of: (a) the gross negligence or willful misconduct of CPI or any of its Affiliates or any permitted sublicensees or subcontractors in performing any of CPI's obligations under this Agreement; or (b) a material breach by CPI or any of its Affiliates or any permitted sublicensees or subcontractors of any of CPI's representations, warranties, covenants or agreements under this Agreement; provided, however, that in all cases referred to in this Section 10.1, CPI shall not be liable to indemnify GEL for any Losses of GEL to the extent that such Losses of GEL were caused by (i) the gross negligence or willful misconduct or intentional wrongdoing of GEL or any of its Affiliates, or (ii) any breach by GEL or any of its Affiliates of GEL's representations, warranties, covenants or agreements under this Agreement.

10.2. Indemnification by GEL. GEL shall defend, indemnify and hold harmless CPI and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns from and against all Third Party Claims, and all associated Losses, to the extent arising out of: (a) the gross negligence or willful misconduct of Gel or any of its Affiliates in performing any of its obligations under this Agreement; (b) a material breach by GEL or any of its Affiliates of any of its representations, warranties, covenants or agreements under this Agreement; or (c) a claim by a Third Party that the Product in the Territory during the Term infringes on the Intellectual Property or other proprietary rights of such Third Party; provided, however, that in all cases referred to in this Section 10.2, GEL shall not be liable to indemnify CPI for any Losses of CPI to the extent

that such Losses of CPI were caused by (i) the gross negligence or willful misconduct or intentional wrongdoing of CPI or any of its Affiliates or any permitted sublicensees or subcontractors or (ii) any breach by CPI or any of its Affiliates or any permitted sublicensees of CPI's representations, warranties, covenants or agreements under this Agreement.

10.3. Procedure for Indemnification.

10.3.1 Notice. In the case of a Third Party Claim or demand, other than Patent Claims which are subject to the procedures set forth in Section 13.3, ("Third Party Claim") made by any Person who is not a Party of this Agreement (or an Affiliate thereof) as to which a Party (the "Indemnitor") may be obligated to provide indemnification pursuant to this Agreement, such Party seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and including, to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually materially prejudiced as a result of such failure.

10.3.2 Defense of Claim. If a Third Party Claim is made against an Indemnitee, the Indemnitor will be entitled, within thirty (30) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof by providing written notice to Indemnitee of its intention to assume the defense of such Third Party Claims within such thirty (30) day period (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of a Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, however, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnitor and the Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided, further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one separate counsel for such Indemnitee. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnitee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnitee (including, without limitation, providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control by written acknowledgement of the defense of any Third Party Claim within the thirty (30) day period set forth

above, or if such good faith and diligent defense is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, after three (3) Business Days' written notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

10.3.3 Settlement of Claims. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee will agree to any settlement, compromise or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all Losses in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise or discharge (including, without limitation, the consent to entry of any judgment), that provides for injunctive or other nonmonetary relief affecting the Indemnitee.

10.4. Assumption of Defense. Notwithstanding anything to the contrary contained herein, an Indemnitee shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnitee upon written notice to the Indemnitor pursuant to this Section 10.4, in which case, the Indemnitor shall be relieved of liability under Section 10.1 or 10.2, as applicable, solely for such Third Party Claim and related Losses.

10.5. Insurance. During the Term and for a period of five (5) years after the termination or expiration of this Agreement, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, product liability insurance in amounts, respectively, which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party but in no event less than three million dollars ($3,000,000). All insurance policies reflecting such insurance shall be written on a "per occurrence" or "claims made" basis with an insurance company rated at least A-3 by Best's rating guide. If requested, each Party shall provide the other with a certificate of insurance and shall keep such policy current. Each Party shall use Commercially Reasonable Efforts to provide the other Party with at least thirty (30) calendar days prior written notice to the other Party of the cancellation or any substantial modification of the terms of coverage. Such product liability insurance shall insure against all liability, including without limitation personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Product. Each Party also agrees to waive, and will require its insurers to waive, all rights of subrogation against the other Party, and its directors, officers, employees, and agents on all the foregoing coverages. Each Party shall provide written proof of the existence of such insurance to the other Party upon written request.

10.6. Limitation of Liability. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT OR TO THE EXTENT CAUSED BY GROSS NEGLIGENCE OR INTENTIONAL ACTS OR OMISSIONS, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION,

LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT APPLY IN CASES OF FRAUD IN THE PERFORMANCE OF A PARTY'S OBLIGATIONS UNDER THIS AGREEMENT AND SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER THIS SECTION 10.

SECTION 11. TERM AND TERMINATION

11.1. Term. This Agreement shall commence as of the Effective Date and, unless earlier terminated or renewed in accordance with the terms hereof, shall expire on the tenth (10^{th}) anniversary of the Effective Date (together with any renewal term, the "Term"). Thereafter this Agreement may be renewed for two (2) additional, consecutive five (5) year terms (each a "Renewal Term") by CPI by delivery of written notice to GEL not less than three (3) months prior to expiration of the initial Term or any Renewal Term, as applicable. At any time after the third anniversary of the Effective Date, CPI shall have the option to purchase the Product (and all Intellectual Property therein and thereto Controlled by GEL) for an amount equal to [***]. Upon the closing of the purchase transaction, CPI shall then have no further obligations to GEL under this Agreement or with respect to the Product, except as set forth in the definitive agreement effectuating such purchase transaction.

11.2. Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement:

11.2.1 this Agreement may be terminated by either Party: (a) immediately upon written notice if the other Party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization (except for the purposes of a bona fide amalgamation or other reorganization) or for an arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors; or (b) if the other Party commits any material misrepresentation or breach of any of its covenants, obligations, representations or warranties under this Agreement to which such action to terminate applies and, in the case of a breach which is capable of remedy, such Party fails to remedy the same within ninety (90) days after receipt of a written notice describing the breach and requiring it to be so remedied;

11.2.2 this Agreement may be terminated by either Party upon ten (10) days' prior written notice to the other Party in the event that any Governmental Authority takes any action or raises any objection that prevents CPI from Commercializing the Product in the Territory or that has the effect of making the Development, Manufacture or Supply of the Product unlawful for a period of not less than sixty (60) days;

11.2.3 this Agreement may be terminated by GEL upon thirty (30) days' prior written notice to CPI in the event that CPI fails to promptly pay milestone, royalty, or other payments as and when due pursuant to Section 7 or pursuant to any other agreement between the Parties and/or their respective Affiliates; provided CPI fails to cure such failure within thirty (30) days after written notice thereof;

11.2.4 Intentionally omitted.

11.2.5 This Agreement may be terminated by CPI upon thirty (30) days' prior written notice to GEL in the event of a Supply Failure; provided GEL fails to cure such failure within thirty (30) days after written notice thereof. However such cure period shall not apply if GEL fails to use commercially reasonable efforts to cure such default upon its receipt of notice. Provided further, that in the event such Supply Failure was caused by the willful misconduct or negligence of GEL, CPI may elect, in lieu of terminating this Agreement, to assume direct responsibility for sourcing the Components and the Product; and

11.2.6 this Agreement may be terminated by CPI upon thirty (30) days' prior written notice to GEL in the event that GEL fails to maintain the Regulatory Approvals for the Product, fails or neglects to comply with all Regulatory Requirements and/or otherwise fails or neglects to keep the Product NDA in force; provided GEL fails to cure such failure within thirty (30) days after written notice thereof. However such cure period shall not apply if GEL fails to use commercially reasonable efforts to cure such default upon its receipt of notice. Provided further, that in the event such failure to maintain the Regulatory Approvals was caused by the willful misconduct or negligence of GEL, CPI may elect, in lieu of terminating this Agreement, to be appointed GEL's regulatory agent with respect to the Product.

11.3. No Waiver. The right of CPI or GEL to terminate this Agreement, as herein above provided, shall not be affected in any way by CPI's or GEL's respective waiver or failure to take action with respect to any prior default or breach.

11.4. Effects of Termination.

11.4.1 Effect of Termination Generally. On the expiration or earlier termination of this Agreement for any reason, except as otherwise expressly provided herein, all rights and obligations of each Party hereunder shall cease.

11.4.2 Disposition and Transfer of Inventory upon Termination; Royalties Due Thereon Not Affected By Termination. On the expiration or earlier termination of this Agreement by GEL due to CPI's material breach of this Agreement: (a) all unpaid royalties for Product sold as of the effective date of termination shall remain due and payable as scheduled; (b) at CPI's option, GEL shall complete all work-in-process and CPI shall purchase at the Purchase Price under this Agreement, all remaining inventory of the Product and, at cost, all Raw Materials relating thereto in GEL's possession or control, and GEL shall use all Commercially Reasonable Efforts to mitigate the cost thereof to CPI and to consult with CPI in connection with such attempts to mitigate; (c) CPI shall have the limited right to sell out such remaining inventory of Product; and (d) CPI shall pay to GEL a royalty, in the same amount and calculated in accordance with the terms set forth in

Section 7.2 and subject to all of the provisions of Sections 7.3 through and including 7.10, on each sale of remaining inventory of Product by CPI and/or its Affiliates and/or their respective permitted sublicensees when and as such Product is sold.

11.4.3 Accrued Rights. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any right that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration including damages arising from any breach under this Agreement. Termination, relinquishment or expiration of this Agreement shall not relieve either Party from any obligation which is expressly or by implication intended to survive such termination, relinquishment or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment or expiration. Remedies for breaches under this Agreement shall also survive any termination, relinquishment or expiration of this Agreement.

11.4.4 Survival. The following Sections of this Agreement, as well as any other provisions in this Agreement which specifically state they will survive termination or expiration of this Agreement, shall survive termination of this Agreement for any reason: Section 1, Section 2.1 through Section 2.4 inclusive (provided that the license granted in Section 2.1 shall be non-exclusive and all such sections shall survive for the sole purpose of selling out remaining inventory of Product as set forth in Section 11.4.2(b), Section 2.5, Section 6.5, Section 6.8, Section 7.1 through and including Section 7.3 with respect to unpaid milestone payments, Section 7.4 with respect to unpaid royalty payments and royalty payments due under Section 11.4.2 above, Sections 7.5 through and including Section 7.10 with respect to royalty payments due after such termination or expiration, Section 8.4, Section 9, Section 10, Section 11.3, this Section 11.4, Section 12.5, and Section 14.

11.4.5 Return of Confidential Information. Within thirty (30) days of any expiration or termination of this Agreement: (a) CPI shall cease to use and shall deliver to GEL, upon written request, all Confidential Information of GEL, except for any documents or records that CPI is required to retain by Applicable Law; and (b) GEL shall cease to use and shall deliver to CPI, upon written request, all Confidential Information of CPI except for any documents or records that GEL is required to retain by Applicable Law.

SECTION 12. REGULATORY MATTERS

12.1 Appointment of CPI as Regulatory Agent. GEL reserves the right to appoint CPI as GEL's exclusive agent in the Territory with respect to dealings with the FDA relating to the Product and the Product ANDA upon terms and conditions to be reasonably agreed upon by GEL and CPI (the "Agency").

12.1.1 Within five (5) days of GEL's notification of CPI that it intends to establish the Agency, GEL will transmit a letter to the FDA, the form of which is attached hereto as **Exhibit "H"**, notifying the FDA that CPI has been appointed GEL's exclusive regulatory agent in the Territory with respect to dealing with the FDA relating to the Product and the Product NDA.

12.1.2 GEL may, at its sole discretion, terminate the Agency upon 15 days written notice.

12.2 Maintenance of the Regulatory Approvals. Subject to the terms of the Agency, GEL shall bear responsibility for, at its sole cost and expense, the regulatory strategies relating to the Product in the Territory, including, without limitation: (a) matters relating to the maintenance of the Regulatory Approvals for the Product, including compliance with all Regulatory Requirements and otherwise keeping the Product NDA in force, and (b) all communications with the Regulatory Authorities associated with the Product NDA including all Adverse Drug Experience reporting and periodic safety update reporting ("PSUR"). CPI shall be responsible for timely providing GEL all necessary documentation needed for all regulatory filings relating to the Commercialization of the Product in the Territory, including all pharmacovigilance data needed for PSUR. CPI will prepare all PSURs for submission by GEL to the Regulatory Authorities.

12.3 Communications with Governmental Authorities and PDUFA Fees.

12.3.1 Communications Regarding Regulatory Approvals. Subject to the provisions of this Section 12, GEL shall be solely responsible for interfacing, corresponding and meeting with all Regulatory Authorities in the Territory with respect to the Development of Product and the Regulatory Approval of the NDA. CPI, to the extent not prohibited by the Regulatory Authority, shall be allowed to attend all meetings between representatives of GEL and/or its agents and Regulatory Authorities relating to the Development and approval of the Product and maintenance of the NDA therefor. GEL shall provide CPI as soon as reasonably possible (but in any event at least five (5) Business Days before any such meeting) with copies of all documents, correspondence and other materials in its possession which are relevant to the matters to be addressed at any such meeting. GEL shall also provide CPI with prompt access to all exchanges of correspondence with a Governmental Authority with respect to the Product.

12.3.2 Communications Regarding Pharmacovigilance. Subject to the provisions of this Section 12, and the Pharmacovigilance Agreement attached hereto as **Exhibit "I"** and by this reference made a part hereof, CPI shall be solely responsible for reporting any and all Adverse Drug Experiences to applicable Regulatory Authorities. CPI shall be responsible for all pharmacovigilance activities in the Territory, including receiving, monitoring, responding promptly to, tracking, or as may otherwise be required by Applicable Law and Regulatory Authority, all Product-related inquiries, Product quality complaints, and Adverse Drug Experience reports received by CPI its Affiliates or subdistributors or by GEL and its affiliates (and which GEL shall have promptly forwarded to CPI) from individuals and/or health care professionals from within the Territory. Immediately upon receipt of any contact with or communication from any Regulatory Authority relating to the Product or becoming aware of any Adverse Drug Experience in the Territory, each of the Parties shall forward a copy or description of the same to the other Party and shall use Commercially Reasonable Efforts to respond to all reasonable inquiries from the other Party relating thereto. Both Parties shall use Commercially Reasonable Efforts to cooperate to provide all reasonable assistance and take all actions that are necessary to comply with any Applicable Law.

12.3.3 Approval of Labeling and Promotional Materials. Subject to the provisions of this Agreement, CPI shall submit to the applicable Regulatory Authorities and obtain any

necessary Regulatory Authority approvals of any promotional materials, label, labeling, package inserts or outserts, monographs and packaging within sixty days of the Effective Date.

12.3.4 PDUFA Product Fees. CPI shall be responsible for paying PDUFA Product fees beginning in FY 2016 when due and, within thirty (30) days of receiving an invoice and a copy of the corresponding FDA invoice(s) from GEL, CPI shall, if applicable, reimburse GEL for any such PDUFA Product fees paid by GEL to the FDA for the period ending with the commencement of FY 2016. For purposes of clarity, GEL will be responsible for any PDUFA Product fees incurred or due for years prior to FY 2016. GEL shall be responsible for paying all PDUFA fees related to the Development, Manufacturing, testing and release of the Product.

12.4 Regulatory Information.

12.4.1 Assistance. Subject to the terms of this Section 12, in the Territory, each Party agrees to use Commercially Reasonable Efforts to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law.

12.4.2 Notice. Each Party or its respective representative shall provide the other Party with notice, in a sufficiently timely basis to enable the other Party to comply in all material respects with Applicable Law, of notification or other information which it receives (directly or indirectly) from, any Regulatory Authority (and providing, as soon as reasonably possible, copies of any associated written requests) that: (a) raises any material concerns regarding the safety or efficacy of the Product; (b) indicates or suggests a Third Party Claim arising in connection with the Product; or (c) is reasonably likely to lead to a recall, market withdrawal or field correction of, field alert report or comparable report with respect to the Product. Information that shall be disclosed pursuant to this Section 12.4.2 shall include, but not be limited to:

(i) inspections by a Regulatory Authority of Manufacturing, distribution or other related facilities concerning the Product;

(ii) inquiries by a Regulatory Authority concerning clinical investigation activities (including, without limitation, inquiries regarding investigators, clinical monitoring organizations and other related Parties) with respect to the Product;

(iii) any communication from a Regulatory Authority involving the manufacture, sale, promotion or distribution of the Product, or any other Regulatory Authority reviews or inquiries relating to any event set forth in this Section 12.3.2(c);

(iv) any receipt of a FDA Warning Letter relating to the Product;

(v) any initiation of any Regulatory Authority investigation, detention, seizure or injunction concerning the Product; and

(vi) any other regulatory action (e.g., proposed labeling or other registrational dossier changes and recalls) that would affect the Product.

12.5 Recalls or Other Corrective Action.

12.5.1 Notice of Action. As soon as reasonably possible, CPI shall notify GEL of any actions to be taken by CPI or its Affiliates or permitted sublicensees, subcontractors or agents with respect to any recall or market withdrawal or field correction of, field alert report or comparable report or any matter which is suspected or likely to be the subject of a complaint which may require a recall, market correction or similar action relating to the Product in the Territory (a "Recall") prior to (but in any event at least ten (10) Business Days prior to) any such action so as to permit GEL a reasonable opportunity to consult with CPI with respect thereto. CPI agrees to consider GEL's consultation in good faith; provided, however, nothing in this Section 12.4 is intended to limit CPI's ability to recall, withdraw or take any other corrective action relating to the Product. At CPI's reasonably written request and cost (except as set forth in this Section 12.4), GEL shall provide reasonable assistance to CPI in conducting such Recall. The cost of any Recall, including, the costs of notifying customers and the costs associated with the shipment of the Product from customers and all reasonable credits extended to customers as a result thereof, and the costs of replacing the Product ("Recall Expenses"), occasioned or required as part of a general Recall of the products of a Party, shall be borne by that Party. Any Recall Expenses caused by GEL or the failure of GEL to Supply the Product conforming to the Specifications or applicable Regulatory Approvals or other breach of this Agreement by GEL, shall be borne by GEL, except to the extent such Recall Expenses are caused in whole or in part by CPI of any of its Affiliates or licensees, or subcontractors. Any Recall Expenses caused by CPI shall be borne by CPI except to the extent caused in whole or in part by GEL or any of its Affiliates. In the event that either Party disputes that it is the cause of a Recall, the Parties agree to use their Commercially Reasonable Efforts to resolve such dispute within ten (10) days after receipt of a notice of objection regarding such recall (the "Recall Objection Notice"). If CPI and GEL fail within ten (10) days after delivery of the Recall Objection Notice to agree as to the Party that is the cause of such Recall, the issue, and as applicable, any representative samples of the Product, shall be submitted to a mutually acceptable independent laboratory or consultant (if not a laboratory analysis issue) for analysis or review. The results of such evaluation shall be binding upon the Parties. The Party that is determined to have been incorrect in its determination of the Party that is the cause of such Recall shall pay the Recall Expenses including the cost of any such evaluation. If the fees of the independent laboratory or consultant are due in advance, CPI and GEL shall each pay fifty percent (50%) of such fees; provided that promptly after the independent laboratory or consultant completes its evaluation, the Party that was incorrect in its determination shall reimburse the other Party for its fifty percent (50%) share of such fees. If the results of such evaluation are inconclusive, CPI and GEL shall each pay fifty percent (50%) of the direct, out-of-pocket Recall Expenses relating to such Recall including the cost of any such evaluation and destruction of any recalled Product.

12.5.2 Recall Information Received. Each Party shall, as soon as reasonably practicable, notify the other Party of any recall, market withdrawal or field correction of, field alert report or comparable report or complaint with respect to the Product and supply all information

received by it relating thereto in sufficient detail to allow the Parties to comply with Applicable Law.

12.6 Events Affecting Integrity or Reputation. During the Term, the Parties shall notify each other immediately of any circumstances of which they are aware and which could materially impair the integrity and reputation of the Product or if a Party is threatened by the unlawful activity of any Third Party in relation to the Product, which circumstances shall include, by way of illustration, deliberate tampering with or contamination of the Product by any Third Party as a means of extorting payment from the Parties or another Third Party. In any such circumstances, the Parties shall use Commercially Reasonable Efforts to limit any damage to the Parties and/or to the Product. The Parties shall promptly call a JCC meeting to discuss and resolve such circumstances.

SECTION 13. INTELLECTUAL PROPERTY

13.1. Patent Prosecution and Maintenance.

13.1.1 GEL IP. GEL shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of any patents under the GEL IP (the "GEL Patents"). The cost of such preparation, filing, prosecution and maintenance of the GEL Patents shall be borne by GEL. GEL shall consider in good faith the requests and suggestions of CPI with respect to strategies for prosecution and maintenance of GEL Patents in the Territory and revisions to correspondence with the U.S. Patent Office.

13.1.2 Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of any GEL Patents under this Agreement and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to any GEL Patent claiming the composition or use of a Product being commercialized pursuant to this Agreement.

13.2. Infringement by Third Parties. The Parties shall promptly notify the other in writing of any alleged or threatened infringement or misappropriation of any GEL Patent of which they become aware. Either Party shall have the right (though CPI shall have the first right) but not the obligation, to bring, at its own expense, an action against such infringing or misappropriating Third Party. In the event a Party brings or desires to bring an action in accordance with this Section 13.2, the other Party shall use its Commercially Reasonable Efforts to cooperate fully with the other Party. Except as expressly set forth in this Agreement, any recovery related to the Product which is realized by either Party as a result of such litigation, after reimbursement of any litigation expenses of GEL and CPI (including attorneys' fees), shall be shared equally by the Parties.

13.3. Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties or their Affiliates or subcontractor or sublicense in connection with the Development, Supply or Commercialization of the Product infringes the issued patent rights (or would infringe the claims, if issued, of a pending patent application) of any Third Party in the Territory ("Patent Claims"). In the event of litigation in accordance with this Section 13.3, the Party not controlling such litigation shall use its Commercially Reasonable Efforts to cooperate fully with the other Party. Neither Party shall enter

into any settlement of any litigation, without the prior written consent of the other, such consent not to be unreasonably withheld, delayed or conditioned.

SECTION 14. MISCELLANEOUS

14.1 Independent Contractor. Neither GEL nor CPI, together in each case with their respective employees or representatives, are under any circumstances to be considered as employees, Partners, joint venturers, agents or representatives of the other by virtue of this Agreement, and neither shall have the authority or power to bind the other or contract in the other's name.

14.2. Registration and Filing of this Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Regulatory Authority including, without limitation, the U.S. Securities and Exchange Commission or the U.S. Federal Trade Commission, in accordance with Applicable Law, such Party shall inform the other Party thereof. Should both Parties jointly agree in writing that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Applicable Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

14.3. Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given when so delivered in person, by overnight courier, by facsimile transmission (with receipt confirmed by automatic transmission report) or two (2) Business Days after being sent by registered or certified mail (postage prepaid, return receipt requested), as follows:

If to CPI: Cumberland Pharmaceuticals Inc.
2525 West End Avenue, Suite 950
Nashville, TN 37203
Attention: Chief Executive Officer
Telephone: (615) 255-0068
Facsimile: (615) 627-0629

If to GEL: GastroEntero-Logic, LLC,

Attention: Lewis Tepper
Facsimile: 302-778-9449
Telephone: 302-351-4077

Either Party may by notice given in accordance with this Section 14.3 to the other Party designate another address or person for receipt of notices hereunder.

14.4. Binding Effect; No Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns (other than pursuant to the foregoing Section 14.4(b)). Neither GEL nor CPI may assign any of its rights or delegate any of its liabilities or obligations hereunder, without the prior written consent of the other Party except that, without the prior consent of the other Party: (a) either Party may assign this Agreement, and GEL may transfer or assign the GEL IP, to any purchaser of all or a substantial part of its assets or business; and (b) either Party may assign this Agreement and/or its rights and obligations under this Agreement, in whole or in part, to any of its Affiliates and may assign any of its rights to payments of royalties or any other amounts due under this Agreement to any of its Affiliates or any Third Party provided that such Party remains obligated to the other Party, and the Third Party being assigned such rights, for the performance by such Party of its obligations under this Agreement. The assignment of a Party's rights under this Agreement in accordance with Section 14.4(b) shall not in any way create a contractual or business relationship and no privity of contract or otherwise shall exist between the non-assigning Party and the Third Party being assigned such rights and such Third Party shall not have any third-party beneficiary rights in this Agreement. Effective from the assignment of this entire Agreement in accordance with Section 14.4(a), the assigning Party shall be released from its obligations under this Agreement and all references in this Agreement to such Party shall be deemed to mean its assignee. The assignment or transfer of the GEL IP in accordance with Section 14.4(a) shall be subject to the licenses granted to CPI in this Agreement. Any purported assignment or transfer in violation of this Section will be void *ab initio* and of no force or effect.

14.5. No Implied Waivers; Rights Cumulative. No failure on the part of GEL or CPI to exercise and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, including the right or power to terminate this Agreement, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or Partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

14.6. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

14.7. Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance (except for any obligation for the payment of money), in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 14.7, to the extent that such delay in delivery or nonperformance is caused by any event reasonably beyond the control of such Party and without the fault or negligence of the such Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Regulatory Authority (a

"Force Majeure"); provided, however, that the Party affected by such a condition shall, within ten (10) days of its occurrence, give written notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its Commercially Reasonable Efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for a period of one hundred eighty (180) consecutive calendar days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the other Party.

14.8. Amendment. This Agreement may not be amended except by an instrument signed by each of the Parties hereto.

14.9. Rules of Construction. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or ruling of construction providing that ambiguities in an agreement or other document shall be construed against the Party drafting such agreement or document.

14.10. Publication. The Parties acknowledge that each of CPI and GEL intends to issue press releases and other public statement disclosing the existence of or relating to this Agreement, and each agrees to provide the other Party a copy of such release and statement and to obtain the express written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law, including securities laws applicable to a public company.

14.11. Expenses. Except as expressly set forth herein, each Party shall bear all fees and expenses incurred by such Party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, including attorneys', accountants' and other professional fees and expenses.

14.12. Governing Law; Submission to Jurisdiction; Waiver. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware without regarding to its conflict of laws principles. In the event any action shall be brought to enforce or interpret the terms of this Agreement, the Parties agree that such action will be brought in the State or Federal courts located in New York, New York. Each of GEL and CPI hereby irrevocably submits with regard to any action or proceeding for itself and in respect to its property, generally and unconditionally, to the nonexclusive jurisdiction of the aforesaid courts. Each of GEL and CPI hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement: (a) any claim that it is not personally subject to the jurisdiction of the above-named courts for any reason other than the failure to lawfully serve process; (b) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise); and (c) to the fullest extent permitted by Applicable Law, that (i) the suit, action or

proceeding in any such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper, and (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

14.13. Entire Agreement. This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, between the Parties.

14.14. Third Party Beneficiaries. None of the provisions of this Agreement, express or implied, is intended to be or shall be for the benefit of or enforceable by any Person (including, without limitation, any creditor of either Party hereto) other than CPI and GEL and their respective successors and permitted assigns. No such Person shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

14.16. Rights in Bankruptcy. The Parties acknowledge that all rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar foreign laws (collectively, the "Bankruptcy Code"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Code or such foreign laws. If a case is commenced during the Term by or against GEL or its Affiliates under a Bankruptcy Code then, unless and until this Agreement is rejected as provided in such Bankruptcy Code, GEL (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a Bankruptcy Code case is commenced during the Term by or against GEL, this Agreement is rejected as provided in the Bankruptcy Code and CPI elects to retain its rights hereunder as provided in the Bankruptcy Code, then GEL, subject to the Bankruptcy Code case (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee), shall provide to CPI copies of all information necessary for CPI to prosecute, maintain and enjoy its license under the GEL IP under the terms of this Agreement held by GEL and such successors and assigns promptly upon CPI's written request therefor. All rights, powers and remedies of CPI, as a licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, the Bankruptcy Code) in the event of the commencement of a Bankruptcy Code case by or against GEL.

14.17. Counterparts; Signatures. This Agreement may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile or e-mail transmission shall be deemed to be original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

CUMBERLAND PHARMACEUTICALS INC.

Signature: /s/ A.J. Kazimi
Print: A.J. Kazimi

Title: Chief Executive Officer

GASTRO-ENTERO LOGIC, LLC,

Signature: /s/ Lewis Tepper
Print: Lewis Tepper

Title: Member

[Signature Page to License and Supply Agreement]

Exhibit "A"

GEL Trademark(s)

Serial/ Registration No.	Trademark	Type of Trademark: Intent-to-Use/ In-use Mark
Serial No. 85466921 Reg. No. 4203719	OMECLAMOX®	In-use Mark
Serial No. 86170802 Reg. No. 4588520	OMECLAMOX-PAK®	In-use Mark

Exhibit "B"

CPI Trademark(s)

Serial/ Registration No.	Trademark	Type of Trademark: Intent-to-Use/ In-use Mark
2965809	Cumberland Pharmaceuticals®	In-Use Mark
3274306	Cumberland Pharmaceuticals®	In-Use Mark
2965810		In-Use Mark

Exhibit C

Reserved

Exhibit D

Reserved

Exhibit E

Reserved

Exhibit F

Reserved

Exhibit G

Reserved

Exhibit "H"

Agency Letter to FDA

Via Facsimile
240-276-9327

Food and Drug Administration
Center for Drug Evaluation and Research
Metro Park North 4
7519 Standish Place
Rockville, MD 20855

[Insert Date]

RE: NDA 50-824, Omeprazole delayed-release capsules, 20 mg,
Clarithromycin tablets, 500 mg and Amoxicillin capsules, 500 mg
NDA Holder: GastroEntero-Logic, LLC

SUBJECT: APPOINTMENT OF REGULATORY AGENT

Dear [Director at time]:

This letter will serve to advise your office that effective immediately, we have appointed the following named company as our agent for all regulatory matters. Any and all correspondence or discussions with FDA relative to the above referenced application should be made with:

Cumberland Pharmaceuticals Inc.
2525 West End Avenue, Suite 950
Nashville, TN 37203
Attention: _____
Title: Senior Director, Scientific and Regulatory Affairs
Telephone: _____
Facsimile: _____

Cumberland Pharmaceuticals Inc. is authorized and delegated by our company to submit and receive all correspondence, and to represent us in any discussion or meeting, on scientific or administrative matters pertaining to the referenced application.

Please alert your document room of this change and make sure all appropriate fax numbers and contact names and addresses within your systems are updated accordingly to reflect this change.

Sincerely,

Name
Title

Enc. Form FDA 356h

cc: Desk copies to Regulatory Support Branch:

Exhibit "I"

Pharmacovigilance Agreement
between
GastroEntero-Logic, LLC and Cumberland Pharmaceuticals Inc.

I. Purpose

This agreement between GastroEntero-Logic, LLC ("GEL") and Cumberland Pharmaceuticals Inc. ("Cumberland") is established to facilitate accurate, timely exchange of adverse events and company compliance with regulatory reporting requirements. This agreement implements Section 12.3.2 of the License and Supply Agreement (the "Supply Agreement") between GEL and CUMBERLAND dated November 16, 2015.

II. Scope

This document describes safety data exchange procedures between GEL and CUMBERLAND for the Omeclamox-Pak®, which is being marketed in the United States under approved New Drug Application number 50-824 (the "Product"). This includes spontaneous and literature safety data. Each company will follow this agreement.

III. Definitions

A. Adverse Event

An adverse event ("AE") shall have the meaning attributed to "Adverse drug experience" as set forth in Title 21 Section 314.80 in the Code of Federal Regulations (the "Code").

B. Serious AE

A serious adverse event (SAE) shall have the meaning attributed to "Serious adverse drug experience" as set forth in the Code.

For clinical studies, any AEs meeting the regulatory criteria for "serious" that occur after the signing of the study-specific informed consent and prior to the initial dose of study product are to be collected and communicated as SAEs. Any SAEs occurring after the end of the monitoring period should be collected if voluntarily reported by the investigator to the sponsor.

C. Nonserious AE

Any AE not meeting the criteria for serious as defined in Section III.B is considered nonserious.

D. Unexpected Report

Unexpected Report shall have the meaning attributed to "Unexpected adverse drug experience" as set forth in the Code.

E. Expedited Report (15-day Alerts)

An expedited report is required for an SAE that meets a regulatory definition of serious as defined above and which requires prompt reporting to the FDA pursuant to the Code. Each company's regulatory clock start for an expedited report begins on the date of receipt from the originating company.

F. Initial Awareness Date (IAD)

The initial awareness date of a report that contains the minimum information to have a valid report, as described in Section III G, is the first date any employee of either company or its affiliate or agent becomes aware of the event. Awareness date for follow-up information will be the date of first receipt of that information.

G. Valid Report

Valid Reports are reports of AEs that contain the following minimum basic information about the applicable AE: an identifiable patient, a product, a reporting source, and an AE. No reports will be exchanged nor will any of the AE timelines for AE data exchange begin until the minimum information necessary to constitute a Valid Report has been collected.

H. Periodic Adverse Event Reports

CUMBERLAND shall prepare summary reports containing AEs that meet the regulatory criteria for reporting and are reported according to a non-expedited schedule, based upon the (i) ICH guideline E2B, (ii) *Guideline for Postmarketing Reporting of Adverse Drug Experiences* (published by the FDA on March 1992), and (iii) *Guidance for Industry Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products:Clarification of What to Report finalized* (published by the FDA on August 1997).

Periodic reports shall contain previously reported expedited reports as well as non-expedited reports.

IV. General

A. All communication between GEL and CUMBERLAND will be in English. Translations will be the responsibility of the originating company, if necessary.

B. All exchange of AEs and related source information will be via electronic means. Any documents for which original copies are necessary will be exchanged via overnight mail.

C. If any company retains a consultant for review of clinical trial or postmarketing safety data, any resulting report will be provided to the other company.

D. GEL will be responsible for maintaining a worldwide safety database, if necessary.

V. Regulatory Reporting

GEL will have sole responsibility for communicating expedited reports and for submitting expedited and periodic reports to the regulatory agencies.

VI. Clinical Trial Adverse Events.

Should either Party decide to initiate any clinical trial, this agreement will be amended to establish a process to exchange clinical safety data.

VII. Post marketed Adverse Events

1. <u>Adverse Events Collected by GEL</u>

a. <u>Transmission to CUMBERLAND</u>

In the event a GEL company representative collects information regarding an AE, GEL will provide the source information to CUMBERLAND within one (1) business day. The information should include initially, at a minimum, patient identifier, patient demographics, a brief description of the actual event, including date of onset, and outcome, and be as complete as possible. CUMBERLAND shall then comply with its obligations described below in Section VII.2.

b. <u>Follow-up Information</u>

CUMBERLAND shall have responsibility for and control over obtaining all follow-up information.

2. <u>Adverse Events Collected by CUMBERLAND</u>

a. <u>Transmission to GEL</u>

AE's collected by CUMBERLAND and the related MedWatch form FDA3500A prepared by CUMBERLAND or any MedWatch form FDA3500A based on information provided by GEL will be forwarded to GEL within (i) 24 hours or the next working day of receipt by e-mail, in the case of a SAE and (ii) five (5) business days, by e-mail, in the case of a nonserious AE.

b. <u>Serious Adverse Events</u>

i. SAE Content

SAE reports should include initially, at a minimum, patient initials, patient demographics, a brief description of the actual event, including date of onset, and outcome, and be as complete as possible.

ii. SAE Exchange Time Lines

CUMBERLAND will prepare SAEs MedWatch form FDA3500A, and GEL will prepare the 15-day alert cover letter and the report will be submitted by GEL. GEL will provide CUMBERLAND with a copy to the 15-day alert filed with the regulatory authority.

3. Literature reports

CUMBERLAND will have the primary responsibility for reviewing domestic medical literature for potential AEs related to any of the components of the Product. Should the search result in an AE, CUMBERLAND will prepare the MedWatch form FDA3500A, and, in the case of an SAE, GEL will prepare the 15-day alert cover letter ready for submission by GEL within five (5) business days of CUMBERLAND's Initial Awareness Date of the literature based SAE.

4. **Periodic Adverse Event Reports**

Any information needed by GEL for the approval and submission of periodic reports (including but not limited to regulatory actions/status, clinical studies, etc) will be requested by GEL and provided by CUMBERLAND in a timely manner that enables compliance with report submission. GEL will provide CUMBERLAND a copy of the required periodic report within one week following submission to the FDA.

VIII. Regulatory Inquiries/ *Ad Hoc* Issues

A. Serious Safety Issue

GEL will be sole contact for safety issues arising with the FDA.

IX. Company Contact Information

For company contact information, refer to Appendix 1, which shall be amended by written notice from time to time by the relevant party as necessary to update such information. Each company is responsible for notifying the other company regarding changes in contact information within 3 business days of the change.

X. Terms of the Agreement

This agreement is effective upon signatures by authorized representatives of both companies. It is in effect until both companies agree to terminate this agreement or until the Supply Agreement is terminated. In the event this agreement conflicts with the Supply Agreement, the terms of the Supply Agreement shall prevail.

This exchange of safety data outlined in this agreement may be reviewed at the request of either company and amended at any time by mutual consent. If there is disagreement regarding interpretation of any aspect of this agreement, the procedures in this document will be adhered to by both companies during any discussions. Renegotiation will be considered complete when both companies have mutually agreed to a written agreement or addendum.

Any amendment to the agreement, except changes to Appendix 1, requires signatures from GEL and CUMBERLAND.

The preceding is agreed to in full by the undersigned.

_____
Lewis Tepper Date:
GastroEntero-Logic, LLC

_____
Amy Rock Date:
Senior Director, Regulatory & Scientific Affairs
Cumberland Pharmaceuticals Inc.

Appendix 1
Contact Information

GEL	CUMBERLAND
Individual Case-Related Inquiries/AE Communication	
Name: Lewis Tepper	Name: Alex Peng, PharmD
Title: Member	Title: Medical Information Specialist
Phone: 201-947-5453	Phone: 615-255-0068
Fax: 201-947-7964	Fax: 615-627-0630
E-mail: ltepper@gelllc.com	E-mail: apeng@cumberlandpharma.com
General Safety Data Exchange Agreement Questions	
Name: Lewis Tepper	Name: Amy D. Rock, PhD
Title: Member	Title: Sr. Director of Regulatory & Scientific Affairs
Phone: 201-947-5453	Phone: 615-255-0068
Fax: 201-947-7964	Fax: 615-627-0630
E-mail: ltepper@gelllc.com	E-mail: arock@cumberlandpharma.com
General Safety-Related Issues	
Name: Lewis Tepper	Name: Amy D. Rock
Title: Member	Title: Sr. Director of Regulatory & Scientific Affairs
Phone: 201-947-5453	Phone: 615-255-0068
Fax: 201-947-7964	Fax:
E-mail: ltepper@gelllc.com	E-mail: arock@cumberlandpharma.com

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Cumberland Pharmaceuticals Inc.:

We consent to the incorporation by reference in the registration statement No. 333-164376 on Form S-8 and No. 333-184091 on Form S-3 of Cumberland Pharmaceuticals Inc. of our reports dated March 14, 2016, with respect to the consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for each of the years in the three-year period ended December 31, 2015, and all related financial statement schedule, which report appears in the December 31, 2015 annual report on Form 10-K of Cumberland Pharmaceuticals Inc.

/s/ KPMG LLP

Nashville, Tennessee
March 14, 2016

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, A.J. Kazimi, certify that:

1. I have reviewed this Form 10-K of Cumberland Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 14, 2016

By: /s/ A.J. Kazimi

A.J. Kazimi
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Michael Bonner, certify that:

1. I have reviewed this Form 10-K of Cumberland Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 14, 2016

By: /s/ Michael Bonner

Michael Bonner

Senior Director and Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Cumberland Pharmaceuticals Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, A.J. Kazimi, Chief Executive Officer, and Michael Bonner, Senior Director and Chief Financial Officer, of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. section 1350), that, based on my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ A.J. Kazimi

A.J. Kazimi
Chief Executive Officer
March 14, 2016

/s/ Michael Bonner

Michael Bonner
Senior Director and Chief Financial Officer
March 14, 2016