# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# Form 10-K

**(Mark One)**

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

For the fiscal year ended December 31, 2012

**or**

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

For the transition period from_____to _____

**Commission file number 001-33637**

# CUMBERLAND PHARMACEUTICALS INC.

**(Exact Name of Registrant as Specified in Its Charter)**

| **Tennessee** | **62-1765329** |
|---|---|
| (State of Incorporation) | (I.R.S. Employer Identification No.) |

**2525 West End Avenue, Suite 950**
**Nashville, Tennessee 37203**
(Address of Principal Executive Offices) (Zip Code)

**(615) 255-0068**
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Name of each exchange on which registered |
|---|---|
| **Common stock, no par value** | **Nasdaq Global Select Market** |

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not 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. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| | | |
|---|---|---|
| Large accelerated filer ☐ | | Accelerated filer ☒ |
| Non-accelerated filer ☐ | (Do not check if smaller reporting company) | Smaller reporting company ☐ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.) Yes ☐ No ☒

The aggregate market value of common stock held by non-affiliates as of June 30, 2012 was $62,366,000. The number of shares of the registrant's Common Stock, no par value, outstanding as of March 1, 2013 was 18,717,786.

**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 2013 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 markets are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address poorly met medical needs.

Our product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, and Hepatoren®(*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome (HRS).We market and sell our approved products through our hospital and field sales forces in the United States, which together comprised more than 65 sales representatives and managers as of March 1, 2013.

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, manufacturing, sales, marketing, commercialization 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 of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our third party distribution partner to ensure availability and delivery of our products.

The following table sets forth our total net revenues, net income attributable to common shareholders and earnings per share (basic and diluted) for the years ended December 31:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| | (in millions, except per share data) | | |
| Total revenues, net | $ 48.9 | $ 51.1 | $ 45.9 |
| Net income attributable to common shareholders | 5.8 | 5.7 | 2.5 |
| Earnings per share - basic | $ 0.30 | $ 0.28 | $ 0.12 |
| Earnings per share - diluted | $ 0.30 | $ 0.28 | $ 0.12 |

We have been profitable since 2004, generating sufficient cash flows to fund our development and marketing programs. In 2009, we completed an initial public offering of our common stock to help facilitate our further growth. Our strategy includes maximizing the potential of our existing products and selectively expanding our portfolio of differentiated products. Our current products are approved for sale in the United States and other countries through our select international partners, and we are working with overseas partners to bring them to additional international markets. We also look for opportunities to expand into additional patient populations through new product indications, whether through our own clinical studies or by supporting investigator-initiated studies at reputable research institutions. We actively pursue opportunities to acquire additional late-stage development product candidates as well as marketed products in our target medical specialties. Further, we are supplementing these growth strategies with the early-stage drug development activities of Cumberland Emerging Technologies (CET), our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, which Cumberland has the opportunity to commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. 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, or 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: Approved by the FDA and launched in 2004; new formulation FDA approved in 2011. |
| Caldolor® | Pain and Fever | Marketed: Approved in 2009. |
| Kristalose® | Chronic and Acute Constipation | Marketed by us since 2006 |
| Hepatoren® | Hepatorenal Syndrome | In Phase II clinical development. |

***Acetadote***

Acetadote is an intravenous formulation of N-acetylcysteine, or NAC, indicated for the treatment of acetaminophen poisoning. Acetadote, which has been available in the United States since Cumberland's 2004 introduction of the product, is currently 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 relief and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

Originally approved in January 2004, 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. Our first Phase IV commitment (pediatric) was completed in 2004 and resulted in the FDA's 2006 approval of expanded labeling for Acetadote for use in pediatric patients. Our second Phase IV commitment (clinical) was completed in 2006 and resulted in further revised labeling for the product with FDA approval of additional safety data in 2008. We completed our third and final Phase IV commitment (manufacturing) for Acetadote in 2010, which has culminated in the approval and launch of a new, next generation formulation of the product.

In October 2010, we submitted a supplemental new drug application (sNDA) to the FDA for approval of a new formulation of Acetadote designed to replace the original formulation. The new formulation, which is the result of the aforementioned Phase IV commitment made to the FDA, addresses the FDA's safety concerns and contains no ethylene diamine tetracetic acid ("EDTA") or other stabilization and chelating agents and is preservative-free. In January 2011, we received FDA approval and commenced U.S. launch activities for this new Acetadote formulation. The original formulation has been removed from FDA reference materials and we no longer manufacture it. In April 2012, the USPTO issued a patent encompassing the Acetadote formulation and including composition of matter claims. The patent extends through May 2026.

In November 2012, the Company received a Notice of Allowance from the USPTO for a second patent relating to the formulation of Acetadote. The new patent will include claims regarding the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose and will expire in August 2025. We are continuing to seek additional claims to protect our intellectual property associated with Acetadote.

*Supplemental New Drug Application for Acetadote*

In the first quarter of 2010, we submitted an application to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. This sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that early-stage acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant and that these patients can also survive a significant number of days longer without transplant. In December 2010, the FDA issued a Complete Response Letter indicating that it had completed its review of the application and identified additional items that must be addressed prior to approval of the potential new indication. Since then, we have been addressing the additional requirements for that approval.

***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. The FDA approved Caldolor for marketing in the United States in June 2009 following a priority review. The product is indicated for use in adults for the management of mild to moderate pain, for the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever.

In September 2009, we implemented the U.S. launch of Caldolor and stocked the product at major wholesalers serving hospitals nationwide. We initially worked to establish a core group of medical facilities purchasing the product and then focused on building more sales volume and treating a broader range of patients within those stocked facilities.

We have worldwide commercial rights to Caldolor. We market Caldolor in the United States through our existing hospital sales force, and have entered into licensing agreements to reach patients outside the United States.

***Kristalose***

Kristalose is a prescription laxative administered orally for the treatment of constipation. An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient compliance and acceptance. We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a new 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, pediatricians, internists and colon and rectal surgeons.

In November 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. We also entered into a long-term supply agreement for the product. By entering into these transactions, we streamlined the supply chain for the product and are exploring opportunities to further develop the product.

***Hepatoren***

In April 2011, we entered into an agreement to acquire the rights to ifetroban, a new Phase II 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.

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, including as an Orphan Drug for HRS for which we will pursue seven years of marketing exclusivity.

The FDA has cleared our Investigational New Drug (IND) application for this product candidate and we have initiated a Phase II dose escalation clinical study to evaluate Hepatoren for the treatment of HRS. We have commenced manufacturing and have filed patent applications to protect intellectual property related to the new indication. We believe this product candidate is an excellent strategic fit given our established presence in the hospital acute care market.

## 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.

***Hospital market:*** We promote Acetadote and Caldolor 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. According to IMS Health, U.S. hospitals accounted for approximately $28 billion, or 9%, of U.S. pharmaceutical sales in 2011. However, IMS also reports that only 2% of approximately $23 billion total pharmaceutical industry promotional spending was focused on hospital-use drugs in 2011. The majority of 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 underserved and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity.

***Gastroenterology market:*** We promote Kristalose through a dedicated field sales force addressing a targeted group of physicians who are responsible for a majority of total retail Kristalose prescriptions nationally. By investing in our marketing program, we believe that we can increase market share for Kristalose and that we have the capability to promote additional gastroenterology products. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe it provides product opportunities but can be penetrated with a modest sized sales force.

***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 products. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that address poorly met medical needs, which we believe helps mitigate our exposure to risk, cost and time associated with drug discovery and research. We plan to continue to target products that are competitively differentiated, have valuable trademarks or other intellectual property, and allow us to leverage our existing infrastructure. We also plan to explore opportunities to seek approval for new uses of existing pharmaceutical products.

***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 also building a network of select international partners to register our products and make them available to patients in their countries.

***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 of CET, our majority-owned subsidiary. 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.

## CLINICAL DEVELOPMENT OVERVIEW

In 2012 we completed two registry studies with Caldolor designed to gather additional safety and efficacy data on a rapid infusion of the drug. We also completed a pilot study assessing the efficacy of Caldolor compared to ketorolac to treat pain associated with knee arthroscopy procedures were completed in 2012.

The first of two registry studies was a phase IV multi-center, open-label, single-dose surveillance clinical study to assess the safety and efficacy of ibuprofen administered intravenously over five to ten minutes to adult patients in the

hospital setting with fever (temperature >101ºF) and/or pain ( visual analog scale (VAS) assessment >3). Eligible patients were enrolled to receive one of two dose strengths (400mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen. 150 patients from 13 clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The second of two registry studies was a phase IV multi-center, open-label, single or multiple-dose 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 intravenous ibuprofen administered at induction of anesthesia. 300 patients from 21 clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

A pilot study to determine the efficacy of intravenous ibuprofen for pain control following arthroscopic knee surgery was also initiated and completed in 2012. A total of 51 patients were enrolled at a single site. Compared to patients receiving ketorolac, patients receiving intravenous ibuprofen experienced less postoperative pain prior to discharge, received less rescue narcotic and were less likely to require rescue narcotic prior to discharge.

***Phase IV Required Pediatric Assessment***

The required pediatric assessment for the Caldolor New Drug Application (NDA) was deferred for the treatment of fever and for the management of pain. The pediatric clinical study evaluating use to treat pain was completed and the one clinical study evaluating the treatment of fever is currently underway to address the Phase IV requirements.

The pediatric fever study currently underway is a multi-center, randomized, open-label, parallel, active comparator study in pediatric patients less than or equal to 16 years of age with fever greater than or equal to 101.0ºF (38.3ºC) to assess the efficacy, safety and pharmacokinetics of intravenous ibuprofen.

In 2012, we completed a pediatric pain study conducted in pediatric patients 6 to 17 years of age undergoing tonsillectomy to assess the safety and efficacy of intravenous ibuprofen. A total of 161 patients were enrolled in this study. Patients receiving intravenous ibuprofen demonstrated a significant decrease in the number of postoperative doses and total amount of fentanyl required after surgery. Further, there were significant decreases in the incidence of vomiting in the post-discharge period. There were no differences between treatment groups in the incidence of adverse events, surgical blood loss, postoperative bleeding or need for re-exploration.

No additional Phase IV commitments were required by the FDA.

***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 will continue to use and update the data as a part of our ongoing safety evaluation. In addition, this data will be used by our sales force and in our marketing materials to promote 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.

**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 our business development leads through our senior executives and our international network of pharmaceutical and medical industry insiders. These opportunities are reviewed and considered on a regular basis by a multi-disciplinary team of our managers against a

list of selection criteria. We have historically focused on product opportunities with relatively low acquisition, development and commercialization costs, employing a variety of transaction structures.

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.

Through CET, we are collaborating 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.

In August 2011, CET entered into a new collaboration agreement with Washington University in St. Louis to co-develop promising biomedical technologies. Washington University is a national leader in medical research and ranks among the top U.S. institutions in funding by the National Institutes of Health. This collaboration represents the fourth major university partnership for CET, which has similar arrangements with Vanderbilt University, the University of Tennessee and the University of Mississippi.

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

## 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 and 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;
- 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, Good Laboratory Practices, and Good Clinical Practices ("GCP"), 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. Prior to the launch of Caldolor, we expanded our medical affairs staff to support inquiries from medical professionals regarding the appropriate use of Caldolor as well as to support the efforts of our expanded hospital sales force. 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.

**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 more than 65 sales representatives and district managers, direct our national marketing campaigns and maintain key national account relationships. In January 2007, we converted our hospital sales force, which had previously been contracted to us by Cardinal Health Inc., to Cumberland employees through our wholly-owned subsidiary, Cumberland Pharma Sales Corp.

Our gastroenterology-focused team was formed in September 2006 with our re-launch of Kristalose and is a field sales force addressing high prescribers of laxatives. This gastroenterology sales force was previously contracted to us by Ventiv Commercial Services, LLC. In September 2010, we converted the field sales force to Cumberland employees as we had previously done with our hospital force.

Our sales and marketing executives conduct ongoing market analyses 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 influencers and health insurance companies.

**INTERNATIONAL PARTNERSHIPS**

We have licensed to third parties the right to distribute certain products outside the U.S. We have granted ***Alveda Pharmaceuticals Inc***., or Alveda, an exclusive license to distribute Caldolor in Canada subject to receipt of regulatory approval. Alveda is obligated to make payments to us upon Caldolor's achieving specified regulatory milestones in Canada and to pay us a royalty based on Canadian sales of Caldolor. This license terminates five years after regulatory approval is obtained in Canada for the later of the fever or pain indications.

The application for regulatory approval of Caldolor in Canada was approved in December 2011. Caldolor was launched in May 2012 by Alveda.

In October 2009, we announced that we entered into an exclusive partnership with ***Phebra Pty Ltd***., or Phebra, an Australian-based specialty pharmaceutical company, for the commercialization of Caldolor in Australia and New Zealand. Phebra has responsibility for obtaining any regulatory approval for the product, and for handling all ongoing regulatory requirements, product marketing, distribution and sales in the territories. We maintain responsibility for product formulation, development and manufacturing. Under the terms of the agreement, Cumberland received upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in those territories. The application for approval of Caldolor in Australia was approved in late 2012.

We also granted Phebra an exclusive license to market and distribute Acetadote in Australia, New Zealand, and Southeast Asia, subject to the receipt of regulatory approval. Phebra is obligated to make payments to us upon Phebra's achieving specified milestones as well as royalty payments. In April 2010, the Therapeutic Goods Administration granted approval for the commercialization of Acetadote in Australia and in October 2010, Phebra commenced with the Australian launch of the product. This introduction of Acetadote in Australia marked the introduction of Cumberland's products into international markets. In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country.

In December 2009, we announced that we entered into an exclusive partnership with ***DB Pharm Korea Co. Ltd.***, a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. Under the terms of the agreement, DB Pharm Korea is responsible for obtaining any regulatory approval for the product and handling ongoing regulatory requirements, product marketing, distribution and sales in Korea. We maintain responsibility for product formulation, development and manufacturing. Under the agreement, Cumberland will receive upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in South Korea.

In June 2011, we reached an agreement with ***Harvest & Health Co, Ltd*** in Taiwan and ***Insanbakti*** in Malaysia to market Caldolor and Acetadote. ***Al-Nabil International*** became our commercial partner of Caldolor and Acetadote in the U.A.E. in late 2011.

In February 2012, ***Harbin Gloria Pharmaceuticals Co. Ltd.***, became our commercial partner for Caldolor and Acetadote in China.

In December 2012, we also finalized agreements to commercialize Caldolor with ***SOHO Indistri Pharmas*** in Indonesia and ***Sandor Medicaids Pvt. Ltd.,*** in India. We are currently working to identify appropriate arrangements for the registration and commercialization of our products in other markets.

## MANUFACTURING AND DISTRIBUTION

We partner 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.

### *Manufacturing*

Our key manufacturing relationships include:

- In July 2000, we established an international manufacturing alliance with a predecessor to Hospira Australia Pty. Ltd., or Hospira. Hospira sources active pharmaceutical ingredients, or APIs, and manufactures Caldolor for us under an agreement that expires in June 2014, subject to early termination upon 45 days prior notice in the event of uncured material breach by us or Hospira. The agreement will automatically renew for successive three-year terms unless Hospira or we provide at least 12 months prior written notice of non-renewal. Under the agreement, we pay Hospira a transfer price per unit of Caldolor supplied. In addition, we reimburse Hospira for agreed-upon development, regulatory and inspection and audit costs.
- Mylan Inc. formerly Bioniche Teoranta sources APIs and manufactures our Acetadote product for sale in the U.S. at its FDA-approved manufacturing facility in Ireland. Our relationship with Bioniche began in

January 2002. Mylan manufactures and packages Acetadote for us, and we purchase Acetadote from Mylan pursuant to an agreement which expires in January 2014.

- We entered into an agreement with Bayer Healthcare, LLC, or Bayer, in February 2008 for the manufacture of Caldolor and Acetadote. The agreement expires in September 2013, subject to early termination upon 30 days prior written notice in the event of uncured material breach by us or Bayer. Under the agreement, we pay Bayer a transfer price per each unit of Caldolor or Acetadote supplied. In addition, we pay Bayer for agreed upon development costs.
- In November 2011, we entered into a non-exclusive agreement with Mylan Inc. to package Kristalose. Under the terms of the agreement, we provide Kristalose API to Mylan and they package it into 10 gram and 20 gram finished product units for which we pay a per unit packaging fee. The agreement expires in 2016 and automatically renews for one year unless either party provides 180 day notice prior to expiration.

***Distribution***

Like many other pharmaceutical companies, we employ an outside third-party logistics contractor to facilitate our distribution efforts. Since August 2002, Specialty Pharmaceutical Services, or SPS, has exclusively handled all aspects of our product logistics efforts, including warehousing, shipping, customer billing and collections. SPS is a division of Cardinal Health Inc. SPS's primary facility is located outside of Nashville, Tennessee, with more than 325,000 square feet of space and a well-established infrastructure. In 2008, SPS opened a second, distribution-only facility in Reno, Nevada, with an additional 88,000 square feet of space. We began utilizing this facility for distribution to certain locations in the second half of 2008. We maintain ownership of our finished products until sale to our customers.

**TRADEMARKS, PATENTS AND PROPRIETARY RIGHTS**

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 advisor's 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. The new Acetadote formulation does not contain EDTA or any other chelating or stabilization agent and is free of preservatives. The new formulation was listed in the FDA Orange Book following its FDA approval in January 2011. In April 2012, the USPTO issued U.S. Patent number 8,148,356 (the “Acetadote Patent”) which is assigned to us. The claims of the Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the Acetadote Patent was listed in the FDA Orange Book. The Acetadote Patent is scheduled to expire in May 2026 which time period includes a 270-day patent term adjustment granted by the USPTO. We also have additional patent applications relating to the uses of Acetadote which are pending with the USPTO.

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the 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 Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. 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 Laboratories, LLC (“Paddock”). By statute, where the Paragraph IV certification is to a patent timely listed before an 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 May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us.

On May 20, 2012, we received a fourth Paragraph IV certification notice from Sagent Agila LLC challenging the Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo Company. On August 9, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Perrigo Company (“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 Acetadote Patent. Under the Settlement Agreement, Paddock and Perrigo admit that the Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the first Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 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 (the “Authorized Generic”).

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 Acedadote 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 November 5, 2012, we received a Notice of Allowance from the USPTO for a second patent relating to its new formulation of Acetadote (the “Second Acetadote Patent”). The Second Acetadote Patent will include claims regarding the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose and will expire in August 2025.

On January 7, 2013, Perrigo announced initial distribution of our authorized generic acetylcysteine injection product.

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

***Caldolor***

We are the owner of U.S. Patent No. 6,727,286, which is directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which expires in 2021. This U.S. patent is associated with our completed international application No. PCT/US01/42894. We have filed for international patent protection in association with this PCT application in various countries, some of which have been allowed and some of which remain pending.

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty and other payment obligations related to Caldolor.

**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 and 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 the Acetadote containing EDTA. In late 2012, we entered into a settlement agreement with Paddock Laboratories and the Perrigo Company that included the right to distribute our authorized generic Acetadote injection product.

***Caldolor***

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

- Morphine, the most commonly used product for the treatment of acute, post-operative pain, is manufactured and distributed by several generic pharmaceutical companies.

- Other generic injectable opioids, including fentanyl, meperidine and hydromorphone, address this market.
- Ketorolac (brand name Toradol), an injectable NSAID, is also manufactured and distributed by several generic pharmaceutical companies.
- Ofirmev, an injectable acetaminophen product, was approved by the FDA in 2010 and is manufactured by Cadence Pharmaceuticals, Inc.

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 and liquid lactuloses. Amitiza is indicated for the treatment of chronic idiopathic constipation in adults and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. 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.

## 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, or 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, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

We and 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, 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. 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 identify, strength, quality, and identity.

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 biologics license application (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, or 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 was approved in 2004 by the FDA 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, and we intend to seek additional exclusivity for this product through new potential indications. This exclusivity would not prevent a product with a different formulation from competing with Acetadote.

***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 same manner and is comparable to '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.

***Recent 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. We do not anticipate this fee will have a material impact on our results of operations.

***Medicaid Rebate Rate:*** We currently provide rebates for Kristalose sold to Medicaid beneficiaries. Effective January 1, 2010, the rebate increased from eleven percent to thirteen percent of the average manufacturer price. Our sales of Kristalose under the Medicaid program have been increasing. The increased rebate percentage impacted our net revenue for Kristalose by less than $0.3 million for the year ended December 31, 2012.

***Federal grant funding***

The legislation established a 50% nonrefundable investment tax credit or grant for qualified investments in qualifying therapeutic discovery projects. The provision allocated $1 billion during the two-year period (2009-2010) for the program. The credit is available only to companies with 250 or fewer employees. The qualified investment for any tax year is the aggregate amount of the costs paid or incurred in that year for expenses necessary for and directly related to the conduct of the qualifying therapeutic discovery project. We submitted applications for four of our research projects prior to the deadline of July 21, 2010. In November 2010, we received a response from the Internal Revenue Service indicating approval for funding. We received grants of approximately $0.9 million based on actual 2009 and 2010 expenditures.

**Post approval activities**

Once a drug is on the U.S. market (following FDA approval of the NDA), 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 that of 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 it, the FDA reviews the events to assess which ones may indicate a drug problem. 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. Recently, several 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 regulation 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, 2012, we had approximately 106 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 sale personnel in particular.

In November 2012, we implemented a realignment of our national sales organization to more efficiently cover key targets in support of our three marketed products, Caldolor, Acetadote and Kristalose in the United States. As a result of this realignment on November 29, 2012, the Company's sales personnel moved from 95 individuals to 65 individuals, maintaining approximately two-thirds of its pre-realignment sales organization and consolidated its number of nationwide districts from 10 to 8. The Company does not expect to have further changes to its sales personnel as a result of the realignment.

**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 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 three products: Caldolor, Acetadote and Kristalose. 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.

In 2011, the FDA issued a press announcement asking 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 also is requiring manufacturers to update labels of 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 be administered primarily to hospitalized patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals' formulary lists by their P&T committees. A hospital's P&T committee generally

governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. Because Caldolor is a new drug, any mistakes made in the timely supply of Caldolor, education about how to properly administer Caldolor or any unexpected side effects that develop from use of the drug, may lead physicians to not accept Caldolor as a viable treatment alternative. The commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. We have set a price for Caldolor that we believe hospitals and other purchasers are willing to pay, but that will also generate sufficient profits. If we have set a price for Caldolor that hospitals consider too high, we may need to subsequently reduce the price for Caldolor. As with our other products, if the price for 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 is manufactured at Hospira Australia Pty. Ltd.'s facility in Australia and Bayer's facility in Kansas. Acetadote is manufactured primarily at Bayer's facility in Kansas and Mylan's manufacturing plant in Ireland is an alternative manufacturing source for Acetadote. The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy. If any one of these facilities is damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our products. 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.

In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practices, referred to as cGMP, 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 cGMP 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, other than our third-party 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 warehouses and ships our marketed products and
- Vanderbilt University 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 affecting 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. For example, in its June 2009 Caldolor approval letter, the FDA required us to conduct two additional Phase IV pediatric studies by 2011 and 2012, respectively. If the results of these Phase IV clinical studies are not favorable, we may not be able to expand the market for Caldolor to children ages 1-16. We may also experience delays associated with these required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling pediatric patients. Such delays could impact our ability to obtain an additional six months of FDA exclusivity.

In addition, we have only obtained regulatory approval to market our products in the United States. In 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 and successfully integrate them into our operations, our growth opportunities may be limited.***

We acquired rights to Caldolor, Acetadote, 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 Hepatoren product candidate has 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 product candidate. Hepatoren, which is injectable ifetroban, is a drug used to treat HRS. However, Hepatoren has not been approved by the FDA for marketing, and it is still subject to risks associated with its development.

The FDA has cleared our IND for this product candidate and we have initiated a Phase II dose escalation clinical study to evaluate Hepatoren for the treatment of HRS. We have commenced manufacturing and have filed patent applications to protect intellectual property related to the new indication. Delays in the completion of the clinical study could significantly

delay commercial launch and affect our product development costs. Moreover, results from the clinical study may not be favorable.

Even if Hepatoren is eventually successfully developed and approved by the FDA, it 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 Hepatoren 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 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, may have regulatory compliance issues and may not continue to be profitable.

***If governmental or third-party payors do not provide adequate reimbursement for our products, our revenue and prospects for continued 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 and enacted the PPACAt, as amended by the HCERA, or collectively the Healthcare Reform Act. Among other provisions, the Healthcare Reform Act 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 would 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 listed 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, thereby supplying, hospitals 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 affect 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 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 and scientific staff. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, 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 effect our day-to-day operations. We currently have a key man 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 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, 2012, we had 106 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 and 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 institute 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 or adverse events 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 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. 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, or the FTC, the Consumer Product Safety Commission, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency, or the 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, or 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 cGMP, 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, cGMP 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 cGMP, 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 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 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 adversely affect our operating results and our overall financial condition.

**RISKS RELATING TO INTELLECTUAL PROPERTY**

***Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited 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, in April 2012, the USPTO issued the Acetadote Patent which is assigned to us and is scheduled to expire in May 2026. Following the issuance of the Acetadote Patent, we received Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC, Mylan Institutional LLC, Sagent Agila LLC and Perrigo Company challenging the Acetadote Patent. We responded by filing five separate infringement lawsuits. Further, on November 13, 2012, we brought suit against the FDA alleging that the FDA's denial of our Citizen Petition, which requested that the FDA refrain from approving any applications for acetylcysteine injection containing EDTA, and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law. Although we have settled the litigation with Paddock Laboratories, LLC and Perrigo Company, the remaining lawsuits are still pending. In addition, on November 5, 2012, we received a Notice of Allowance from the USPTO for the Second Acetadote Patent, which is set to expire in August 2025. If we are unable to successfully defend the Acetadote patents and related intellectual property rights with respect to our Acetadote product, our financial condition and results of operations could be adversely affected.

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the 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 Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. in the United States District Court for the Northern District of Illinois, Eastern Division.

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

By statute, where the Paragraph IV certification to a patent timely listed before an 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 May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us with respect to the lawsuits.

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 ethylenediaminetetraacetic acid, or 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 the Company's request and stating that ANDAs referencing Acetadote that contain EDTA may be accepted and approved provided they meet all applicable requirements.

The Company believes this response contradicts the FDA's request to evaluate the reduction or removal of EDTA. On November 8, 2012, the Company learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. On November 13, 2012, the Company brought suit against the FDA in the United States District Court for the District of Columbia alleging that the FDA's denial of Cumberland's Citizen Petition and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law.

On November 5, 2012, the Company received a Notice of Allowance from the United States Patent and Trademark Office for a second patent relating to its new formulation of Acetadote. The new patent will include claims regarding the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose and will expire in August 2025.

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

The Company intends to continue to vigorously defend and protect its 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 our financial condition and results of operations.

We have a U.S. patent for Caldolor, and some related international patents, which are 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 if a competitor were to develop a sufficiently distinct formulation, it could develop and seek FDA approval for another ibuprofen product that competes with Caldolor. Upon receipt of FDA approval in June 2009, we received three years of marketing exclusivity for Caldolor. As our marketing exclusivity has now expired, a competitor with a generic form of injectable ibuprofen could enter the market.

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 under contractual obligations to us to diligently prosecute 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 an infringement or misappropriation legal action 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 expensive and time consuming.***

We have been involved in five lawsuits for infringement of the Acetadote Patent as previously described. Two of those suits have been settled. Because of their nature, these lawsuits may be expensive and time-consuming, and a court may decide that our Acetadote Patent is not valid or unenforceable, or may refuse to stop the remaining parties from selling their product at issue on the grounds that our patents do not cover the product in question. An adverse result in any such lawsuit could put the Acetadote Patent at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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 distract 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 securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

***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 cGMP 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 these employees or we 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 relatively new company seeking to capture significant growth. While our revenues and operating income have increased over time, 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 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, 2012, intangible assets relating to product and data acquisitions represented approximately 10% of our total assets. We may never realize the value of these assets. Generally accepted accounting principles 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 on acceptable terms or at all. In addition, the downgrade of the U.S. credit rating and the European debt situation have contributed to the instability in global credit markets. We are unable to predict the impact of these events, 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 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.***

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, or persons performing similar functions, 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 accounting principles generally accepted in the U.S., or 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 remediate any areas in need of improvement will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue our growth. 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, the U.S.-based Financial Accounting Standards Board, or FASB, continues to work together with the International Accounting Standards Board, or 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, or 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 recognizing revenue 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, 2013, the closing price of our common stock since our initial public offering has ranged from a low of $4.08 to a high of $17.05 per share. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

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

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

The economic downturn and market instability has made the business climate more volatile and more costly. 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 difficulties during challenging economic times, 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 requiring 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 procedure 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 significant material effect on our ability to operate and market out products.

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 and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, 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 or our independent registered public accounting firm identifies 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.

***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 or 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.

***Some provisions of our third amended and restated charter, bylaws, credit facility 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.

Under our bank credit agreement, it is an event of default if any person or entity obtains ownership or control, in one or a series of transactions, of more than 30% of our common stock or 30% of the voting power entitled to vote in the election of members of our board of directors.

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. Even if we become able to pay dividends in the future, we expect that we would retain such earnings to enhance capital and/or reduce long-term debt.

**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, without limitation:

- legislative, regulatory or other changes in the healthcare industry at the local, state or federal level which increase the costs of, or otherwise affect our operations;
- changes in reimbursement available to us by government or private payers, including changes in Medicare and Medicaid payment levels and availability of third-party insurance coverage;
- competition; and
- changes in national or regional economic conditions, including changes in interest rates and availability and cost of capital to us.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

As of December 31, 2012, we leased approximately 25,500 square feet of office space in Nashville, Tennessee for our corporate headquarters. The lease expires in October 2016. Of the 25,500 square feet of leased office space, we have subleased to others approximately 9,900 square feet. 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.**

See the discussion of legal proceedings contained in Part I, Item 1, *Business - Trademarks, Patents and Proprietary Rights*, of this Form 10-K, which is incorporated herein by reference.

**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." Prior to that time, there was no public market for our common stock. As of March 1, 2013, there were 209 shareholders of record, which excludes shareholders whose shares are held in nominee or street name by brokers. The closing price of our common stock on the Nasdaq Global Select Market on March 6, 2013 was $4.52 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 2011 and 2012:

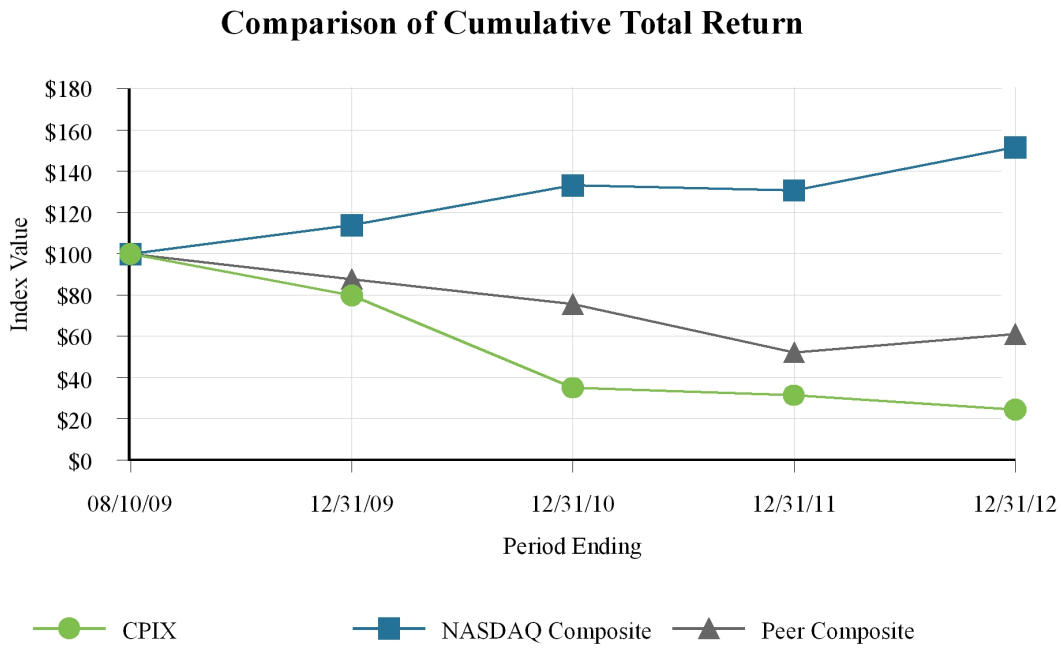
| | High | Low |
|---|---|---|
| **Fiscal year ended December 31, 2012:** | | |
| First quarter | $7.93 | $5.68 |
| Second quarter | 7.81 | 5.96 |
| Third quarter | 6.67 | 5.91 |
| Fourth quarter | 6.40 | 4.12 |
| **Fiscal year ended December 31, 2011:** | | |
| First quarter | 7.49 | 4.90 |
| Second quarter | 5.98 | 4.80 |
| Third quarter | 6.63 | 5.00 |
| Fourth quarter | 6.31 | 5.22 |

**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 August 10, 2009, which is the date of our initial public offering on the Nasdaq Global Select Market, 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 August 10, 2009, 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 and January 2013, our Board of Directors replaced the prior authorizations with $10 million authorizations for repurchases of our outstanding common stock.

The following table summarizes the activity, by month, during the fourth quarter of 2012:

| 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 | 68,487 | $6.21 | 68,487 | $6,691,588 |
| November | 121,531 (1) | 4.81 | 115,531 | 6,133,715 |
| December | 49,377 | 4.35 | 49,377 | 5,918,848 |
| Total | 239,395 | | | |

(1) Of this amount, 6,000 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:** | **2012** | **2011** | **2010** | **2009** | **2008** |
| | (in thousands, except per share data) | | | | |
| Net revenues | $ 48,851 | $ 51,143 | $ 45,876 | $ 43,537 | $ 35,075 |
| Costs and expenses | 40,033 | 41,293 | 39,375 | 37,761 | 27,793 |
| Operating income | 8,818 | 9,849 | 6,502 | 5,777 | 7,282 |
| Net income attributable to common shareholders | 5,842 | 5,658 | 2,457 | 3,091 | 4,766 |
| Earnings per share – basic | $ 0.30 | $ 0.28 | $ 0.12 | $ 0.22 | $ 0.47 |
| Earnings per share – diluted | $ 0.30 | $ 0.28 | $ 0.12 | $ 0.17 | $ 0.29 |

| Balance sheet data: | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2009 | 2008 |
| | (in thousands) | | | | |
| Cash and cash equivalents | $ 54,349 | $ 70,599 | $ 65,894 | $ 78,702 | $ 11,830 |
| Marketable securities | 16,686 | — | — | — | — |
| Working capital | 79,177 | 80,708 | 71,811 | 74,549 | 10,104 |
| Total assets | 98,594 | 95,518 | 92,054 | 103,724 | 31,119 |
| Total long-term debt and other long-term obligations (including current portion) | 5,042 | 5,485 | 7,802 | 20,155 | 7,666 |
| Convertible preferred stock | — | — | — | — | 2,604 |
| Retained earnings | 18,499 | 12,657 | 6,999 | 4,542 | 1,451 |
| Total equity | 85,566 | 82,835 | 77,715 | 72,221 | 17,555 |

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

Our product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, and Hepatoren (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from HRS. We market and sell our approved products through our hospital and field sales forces in the United States, which together comprised more than 65 sales representatives and managers as of March 1, 2013.

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, manufacturing, sales, marketing, commercialization 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 of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our third party distribution partners to ensure availability and delivery of our products.

We have been profitable since 2004, with annual revenues funding our development and marketing programs and generating positive cash flow. In 2009, we completed an initial public offering of our common stock, and listed on the NASDAQ exchange.

The following is a summary of our 2012 highlights and recent developments. For more information, please see Part I, Item I, *Business*, of this Form 10-K.

- In 2012, we entered into an exclusive licensing agreement for Acetadote and Caldolor with Harbin Gloria Pharmaceuticals Co., Ltd., a Chinese pharmaceutical company that has expertise in developing, registering, manufacturing and commercializing products in the China market.
- We extended our international reach of Caldolor into both Canada and Australia.
- Through CET, we expanded our collaborations on early-stage drug development activities. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland has the opportunity to negotiate rights to further develop and commercialize them. Including an expansion of our laboratory footprint.
- We recently completed a pediatric pain study of 161 patients. Patients receiving intravenous ibuprofen demonstrated a significant decrease in the number of postoperative doses and total amount of fentanyl required after surgery.
- We recently completed two Caldolor registry studies evaluating the safety and efficacy of Caldolor when administered over a shortened infusion time in treating pain and fever in adult patients. The studies involved 450 patients at 34 medical sites throughout the U.S.

- We continued our international expansion in late 2012 and finalized agreements to commercialize Caldolor with ***SOHO Indistri Pharmas*** in Indonesia and ***Sandor Medicaids Pvt. Ltd.,*** in India.
- The USPTO issued the Acetadote Patent which is assigned to us and is scheduled to expire in May 2026. Following the issuance of the Acetadote Patent, we received Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC, Mylan Institutional LLC, Sagent Agila LLC and Perrigo Company challenging the Acetadote Patent. We responded by filing five separate infringement lawsuits. Further, on November 13, 2012, we brought suit against the FDA alleging that the FDA's denial of our Citizen Petition, which requested that the FDA refrain from approving any applications for acetylcysteine injection containing EDTA, and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law. We have settled the litigation with Paddock Laboratories, LLC and Perrigo Company while the remaining lawsuits are still pending. On November 5, 2012, we received a Notice of Allowance from the USPTO for the Second Acetadote Patent, which is set to expire in August 2025.
- In November 2012, we implemented a realignment of our national sales organization to more efficiently cover key targets in support of our three marketed products.

## 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 stock-based compensation.

### 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, Caldolor 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 income, which is a component of net revenues, includes upfront payments under licensing agreements along with grant and rental income. Other income was less than two percent of net revenues in 2012, less than one percent in 2011, and less than three percent in 2010.

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 $0.2 million at both December 31, 2012 and 2011, for chargebacks, discounts and allowances for product damaged in shipment.

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

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Balance, January 1 | $ 3,216,622 | $ 2,626,313 | $ 1,863,012 |
| Current provision | 6,000,830 | 4,719,231 | 4,933,553 |
| Current provision for prior period sales | (367,060) | 380,235 | 306,706 |
| Actual product returns and credits issued | (5,478,529) | (4,509,157) | (4,476,958) |
| Balance, December 31 | $ 3,371,863 | $ 3,216,622 | $ 2,626,313 |

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 $3.4 million, $3.2 million and $2.6 million as of December 31, 2012, 2011 and 2010, respectively. Of these amounts, our estimated liability for fee for services represented $1.1 million, $1.0 million and $0.8 million, respectively, while our accrual for product returns totaled $1.8 million, $1.8 million and $1.4 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 $0.1 million in each of the three years ended December 31, 2012. A change in our product return estimate of one percentage point would have impacted net sales by $0.6 million, $0.6 million and $0.5 million for the years ended December 31, 2012, 2011 and 2010, respectively.

As a general rule, we do not allow customers to purchase additional product prior to a scheduled price increase. We occasionally make an exception to this policy when we offer odd-lot quantities at a slightly reduced price or when a customer opens a new facility and requests special terms on its initial purchase. To date, we believe these types of transactions have not been material. Moreover, when we offer special terms, we review the transaction against our revenue recognition policy for proper treatment. If we determine such transactions have become material, we will disclose the impact in the notes to our financial statements.

While we do not have regular access to our customers' inventory levels, we review each order from all of our customers. To the extent that an order reflects more than a normal purchasing pattern, management discusses the order with the customer prior to agreeing to process the order.

**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, 2012 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, 2012, we have unrecognized federal net operating loss carryforwards associated with the exercise of nonqualified options of $48.6 million.

**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, cancellation or repurchase of equity awards. The fair value of stock options and warrants are calculated using the Black-Scholes option-pricing model on the date of grant. We estimate volatility in accordance with SAB No. 107, as amended by SAB No. 110. As there was no public market for our common stock prior to our initial public offering and, therefore, a lack of company-specific historical or implied volatility data, we have determined the share-price volatility based on an analysis of certain publicly-traded companies that we consider to be our peers. The comparable peer companies used for our estimated volatility are publicly-traded companies with operations which we believe to be similar to ours. When identifying companies as peers, we consider such characteristics as the type of industry, size and/or type of product(s), research and/or product development capabilities, and stock-based transactions. We intend to continue to consistently estimate our volatility to value stock options in this manner until sufficient historical information regarding the volatility of our own shares becomes available, or circumstances change such that the identified entities are no longer similar to us. In

this latter case, we would utilize other similar entities whose share prices are publicly available. We estimate the expected life of employee share options based on the simplified method allowed by SAB No. 107, as amended by SAB No. 110. Under this approach, the expected term is presumed to be the average between the weighted-average vesting period and the contractual term. The expected term for options granted to non-employees is generally the contractual term of the option. The risk-free interest rate is based on the U.S. Treasury Note, Stripped Principal, on the date of grant with a term substantially equal to the corresponding option's expected term. We have never declared or paid any cash dividends nor do we plan to pay cash dividends in the foreseeable future.

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.

In the second quarter of 2012, we implemented an Option Exchange Program (the "Exchange Program") whereby certain outstanding stock options could be exchanged for shares of restricted stock. The Exchange Program was designed to provide a value-for-value exchange of equity instruments. The fair value of each exchanged option was determined on the date the Exchange Program commenced using the Black-Scholes option fair value model. The Company did not grant any stock options during 2012 and 2011. The following assumptions were used in calculating the fair value of employee and non-employee options granted during 2010 as well as the Exchange Program in 2012:

| | 2012 | 2010 | |
|---|---|---|---|
| | Exchange Program | Employee Options | Non-Employee Options |
| Dividend yield | — | — | — |
| Expected term (years) | 1.3 - 7.3 | 2.5 – 6.0 | 5.0 |
| Expected volatility | 37% - 78% | 49% – 53% | 52% – 53% |
| Risk-free interest rate | 0.23% - 1.50% | 0.8% – 2.8% | 2.2% – 2.4% |

**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 been within 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, 2012 compared to year ended December 31, 2011**

*Net product revenues.* Net product revenue decreased $2.9 million, or 6%, in 2012 as compared to 2011. The decrease was primarily due to a decrease in Acetadote revenue of $4.9 million, offset by the positive impact of both increased Kristalose revenue of $0.9 million and increased Caldolor revenue of $1.1 million.

The decrease in Acetadote revenue was primarily driven by lower volumes of Acetadote sales, especially in comparison to 2011 where we experienced a 13% increase over 2010 volumes. The increase in volumes during 2011 was due in part to our introduction of the new formulation of Acetadote. The formulation is free of EDTA and other stabilization and chelating agents and is also preservative-free. The new formulation of Acetadote has been well-received in the market, and continues to be the treatment of choice for acetaminophen overdose. Additionally, Acetadote revenue was positively impacted by the shortage of the oral form of n-acetylcysteine due to manufacturing delays. During 2012, the volume decline was partially offset by the impact of increases in the average selling price. During 2012, Acetadote product revenue was positively impacted by $0.3 million in sales under our product licensing agreement with Perrigo for our Authorized Generic product.

The increase in Kristalose net revenue was primarily due to an increase in the average selling price of the 10g and 20g packets, with a small increase in overall sales volumes.

The increase in Caldolor revenue was due to increased volume. Gross product revenue for Caldolor increased $1.1 million in 2012 as compared to 2011. The increase in revenue and gross revenue was primarily due to increased volume associated with continued success in penetrating our target market. We have continued to focus more of our sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product. In the fourth quarter of 2011, we notified our wholesalers that we discontinued the 400mg offering of Caldolor in the United States and concentrate our sales efforts on 800mg. As a result, during 2011, we recognized additional expense amounts for potential returns related to the 400mg product, of which a majority was related to sales in prior years.

*Other revenue.* Other revenue increased $0.7 million in 2012 as compared to 2011. The increase was primarily a result of an upfront payment we received in connection with an out-licensing agreement with our commercial partner in China, Harbin Gloria Pharmaceuticals.

*Cost of products sold.* Cost of products sold as a percentage of net revenues decreased from 10.5% in 2011 to 10.3% in 2012. The decrease is primarily due to a change in product mix.

*Selling and marketing.* Selling and marketing expense totaled $20.3 million in 2012, representing a decrease of $0.6 million, or 3%, as compared to 2011. The decrease was primarily due to decreases in royalty expenses and employee related expenses for recruitment, travel and training, partially offset by increased costs incurred as a result of the realignment of our sales force of $0.7 million.

*Research and development.* Research and development expense totaled $5.1 million in 2012, representing an increase of $0.1 million, or 1%, over 2011. The increase consisted of a $0.4 million increase in salaries and hiring expense due to the expansion of our research and development team, mostly offset by $0.3 million in decreased expenses for studies and lower consulting expenses.

*General and administrative.* General and administrative expense totaled $9.1 million in 2012, representing a decrease of $0.2 million, or 2%, over 2011. The decrease was primarily due to a decrease in charitable donations of inventory partially offset by increased legal and printing costs associated with our stock option exchange program during 2012.

*Interest income.* Interest income totaled $0.3 million in 2012 as compared to $0.2 million in 2011, representing an increase of $0.1 million due primarily to the investment of a portion of our cash balances in longer duration marketable securities beginning in the first quarter of 2012.

*Interest expense.* Interest expense totaled $0.1 million in 2012, representing a decrease of $0.3 million or 80% over 2011. This decrease was due to the early payoff of our term debt in 2011.

*Income tax expense.* As a percentage of income before income taxes, the effective tax rate decreased from 42% in 2011 to 36% in 2012. The decrease in effective tax rate was primarily due to the recognition of a deferred tax asset in 2012 related to the recognition of a deferred tax benefit associated with the option Exchange Program during the second quarter of 2012.

**Year ended December 31, 2011 compared to year ended December 31, 2010**

*Net product revenues.* Net product revenue increased $6.2 million, or 14%, in 2011 as compared to 2010. Net product revenue increased $7.4 million for Acetadote, which was partially offset by a decreases in Kristalose revenue of $1.0 million and Caldolor of $0.2 million.

An increase in volume of approximately 13% and an increase in the average selling price contributed to the increase in Acetadote revenue. In early 2011, we introduced the new formulation of Acetadote that is free of EDTA or other stabilization and chelating agents and is preservative-free. The new formulation of Acetadote has been well-received in the market, and continues to be the treatment of choice for acetaminophen overdose. Additionally, Acetadote revenue was positively impacted by the shortage of the oral form of n-acetylcysteine due to manufacturing delays.

The decrease in Kristalose net revenue was primarily due to a decrease in volume, partially offset by an increase in the average selling price. During 2011, we experienced manufacturing delays caused by a change in ownership of the plant that produces Kristalose. As previously noted, we acquired the full rights to Kristalose in 2011 and believe this will help alleviate some of the manufacturing delays we experienced in 2011.

Gross product revenue for Caldolor increased $0.2 million in 2011 as compared to 2010. The increase in gross revenue was primarily due to increased volume as we continue to penetrate our target market. Additionally, during the first quarter of 2011, we initiated a shift in focus and began transitioning part of our sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product. In the fourth quarter of 2011, we notified our wholesalers that we were discontinuing the 400mg offering of Caldolor and concentrating our sales efforts on 800mg. As a result, we recognized a reserve for potential returns related to the 400mg product, of which a majority was related to sales in prior years. The result of this reserve plus the normal sales allowances resulted in a decrease in net product revenue of $0.2 million.

*Other revenue.* Other revenue decreased $0.9 million in 2011 as compared to 2010. The decrease was primarily due to the recognition of $0.9 million of federal grant funding from the Qualifying Therapeutic Discovery Project, a component of the healthcare reform legislation enacted in 2010. This program was not available in 2011.

*Cost of products sold.* Cost of products sold as a percentage of net revenues increased from 7.8% in 2010 to 10.5% in 2011. The increase was primarily due to the recognition of $2.0 million of inventory write-downs during 2011 for potentially obsolete inventory. Excluding this charge, cost of products sold as a percentage of net revenues would have been 6.6%. This decrease was primarily due to the change in our sales mix in the periods.

*Selling and marketing.* Selling and marketing expense totaled approximately $20.9 million in 2011, representing a decrease of $1.7 million, or 8%, over 2010. The decrease was primarily due a decrease in royalty expense as a result of the Acetadote royalty agreement which expired in January 2011, decrease in sales force and related expenses and savings associated with bringing the field sales force in-house, rather than outsourcing. These decreases were partially offset by increased marketing and advertising expense due to significant investments made in marketing the new formulation of Acetadote and enhancing the brand message.

*Research and development.* Research and development expense totaled $5.0 million in 2011, representing an increase of $0.7 million, or 16%, over 2010. The increase was primarily due to increased personnel costs as we expanded our research and development team and increased annual product and establishment fees from the FDA for our products.

*General and administrative.* General and administrative expense totaled $9.3 million in 2011, representing an increase of $1.2 million, or 15%, over 2010. The increase was primarily due to increased charitable contributions as we donated inventory for humanitarian needs, increased travel expenses as we continued to expand our products world-wide and increased consulting and personnel costs.

*Interest expense.* Interest expense totaled $0.4 million in 2011, representing a decrease of $1.1 million, or 75%, over 2010. The decrease in interest expense was primarily due to the payoff of our term debt in July 2011 and lower interest rates as a result of modifying our line of credit agreement. In August 2011, we amended our debt agreement to provide up to $10 million of availability under our line of credit, with the option of increasing it to $20 million upon the satisfaction of certain conditions. As a result of amending our debt agreement, we were able to reduce the interest cost through the term of the line of credit facility (December 31, 2014).

*Income tax expense.* As a percentage of income before income taxes, the tax rate decreased from 54% in 2010 to 42% in 2011. The decrease was primarily due to an increase in pretax income without a corresponding increase in the nature and amount of permanent differences and the effects of the Therapeutic Discovery Tax Credit in 2010. As previously noted, we received $0.9 million of federal tax grants in 2010, which represented 50% of the eligible expenses. The full amount of the eligible expenses was not deductible for federal income purposes. The Therapeutic Discovery Tax Credit was not available in 2011.

**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, 2012, 2011 and 2010, we generated $7.1 million, $8.7 million and $0.3 million in cash flow from operations, respectively. We believe that our internally generated cash flows and amounts available under our line of credit will be adequate to service existing debt, finance internal growth and fund capital expenditures.

In 2012, we began investing a portion of our cash reserves 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). The variable rate demand notes, or 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, 2012, we had a total of approximately $16.7 million invested in marketable securities.

As of December 31, 2012 and 2011, our cash and cash equivalents, including marketable securities, totaled $71.0 million and $70.6 million, respectively. Our working capital (current assets minus current liabilities) was $79.2 million and $80.7 million, respectively, and our current ratio (current assets to current liabilities) was 10.8x and 13.2x, respectively. As of December 31, 2012, we also had approximately $5.6 million available on our line of credit.

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

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| | | (in thousands) | |
| Cash provided by (used in): | | | |
| Operating activities | $ 7,135 | $ 8,722 | $ 347 |
| Investing activities | (19,177) | (438) | (769) |
| Financing activities | (4,208) | (3,579) | (12,386) |
| Net (decrease) increase in cash and cash equivalents [(1)] | $ (16,250) | $ 4,705 | $ (12,808) |

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

The net decrease in cash and cash equivalents of $16.2 million for the year ended December 31, 2012 was primarily due to the previously noted investment of our cash reserves in government and government-backed securities which are reflected as a net use of cash in investing activities of $16.6 million. Our cash flows from operating activities were primarily due to the $5.8 million in net income for the year supplemented by cash inflows from our receivables. In

addition, our financing activities included the repurchase of common stock of $8.1 million in connection with our share repurchase program 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. During 2012, we recognized approximately $3.8 million of excess tax benefits. The excess tax benefit represents the income taxes that would have been paid if not for the tax deductions created upon the exercise of nonqualified stock options.

The net increase in cash and cash equivalents of $4.7 million for the year ended December 31, 2011 was primarily due to cash generated from our operating activities. Our net income increased from $2.4 million in 2010 to $5.7 million in 2011. The increase in cash and cash equivalents from operating activities was offset by increased purchases of fixed assets and intangibles of $0.4 million and cash used in financing activities of $3.6 million. During 2011, we paid in full our term debt facility of $5.3 million. In connection with the termination of the term debt facility, we increased our borrowings under our line of credit by $3.0 million. In addition, our financing activities included the repurchase of common stock of $4.4 million in connection with our share repurchase program discussed above. During 2011, we recognized approximately $2.4 million of excess tax benefits. The excess tax benefit represents the income taxes that would have been paid if not for the tax deductions created upon the exercise of nonqualified stock options.

The net decrease in cash and cash equivalents of $12.8 million for year ended December 31, 2010 was primarily due to cash used in financing activities, which included principal payments on our term debt of $12.7 million and the repurchase of common stock of approximately $4.8 million. These expenditures were offset by proceeds from the exercise of stock options of approximately $1.4 million and the excess tax benefit derived from the exercise of non-qualified options of approximately $3.9 million. Cash provided by operating activities for the year ended December 31, 2010 was primarily due to net income for the period and the collection of accounts receivable offset by the purchase of inventory.

In July 2011, we paid in full the outstanding term debt balance. In August 2011, we entered into a Fifth Amended and Restated Loan Agreement with our primary lender (the Agreement) to provide for an increase in the line of credit to $10 million. The credit facility may be increased up to $20 million upon the satisfaction of certain conditions. The interest rate is the BBA LIBOR Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement (2.21% at December 31, 2012). In addition, a commitment fee of 0.25% per annum is charged on the unused line of credit. The credit facility was extended to expire on December 31, 2014, at which time all principal amounts are due and payable. Interest is payable quarterly. Borrowings under the line of credit are collateralized by substantially all of our assets. We are no longer required to maintain minimum deposits with the lender The Amendment includes certain financial and restrictive covenants, all of which we are in compliance with.

Our manufacturing and supply agreement with one manufacturer, which expires in 2014, contains a minimum annual purchase obligation. We expect our normal inventory purchasing levels to be above the required minimum amounts. As of December 31, 2012, we had met our purchase obligations for 2012 under this agreement.

The following table summarizes our contractual cash obligations as of December 31, 2012:

| Contractual obligations[1] | Total [2] | Payments Due by Year | | | | |
|---|---|---|---|---|---|---|
| | | 2013 | 2014 | 2015 | 2016 | 2017 |
| | (in thousands) | | | | | |
| Amounts reflected in the balance sheet: | | | | | | |
| Line of credit | $ 4,360 | $ — | $ 4,360 | $ — | $ — | $ — |
| Estimated interest on debt [3] | 214 | 107 | 107 | — | — | — |
| Other cash obligations not reflected on the balance sheet: | | | | | | |
| Operating leases | 4,281 | 953 | 1,022 | 1,053 | 941 | 312 |
| Purchase obligations [4] | 1,584 | 975 | 609 | — | — | — |
| Total [1] | $ 10,439 | $ 2,035 | $ 6,098 | $ 1,053 | $ 941 | $ 312 |

(1) The table of contractual obligations excludes amounts due under the Kristalose purchase agreement as these amounts can not be determined until sales of the product 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.

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

(3) Represents the estimated interest payments on our line of credit based on the December 31, 2012 interest rate of LIBOR plus an applicable margin, or 2.21%. Interest payments are due and payable quarterly in arrears. The line of credit becomes due and payable in December 2014. Estimated interest for the line of credit is based on the assumption of a consistent outstanding balance.

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

## OFF-BALANCE SHEET ARRANGEMENTS

During 2012, 2011 and 2010, we did not engage in any off-balance sheet arrangements.

## RECENTLY ISSUED BUT NOT YET ADOPTED ACCOUNTING PRONOUNCEMENTS

There are no 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.

In the first quarter of 2012, we analyzed our return on our investments and determined investing 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), would yield a higher return with minimal additional risk. The variable rate demand notes, or VRDNs, are generally issued by municipal governments and are backed by a financial institution letter of credit. We hold a put right on the VRDN's, which allows us 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 risk related to interest rates for these accounts will produce less income than expected if market interest rates fall. Based on the $16.7 million in marketable securities a 1% decrease in the fair value of the securities would result in a reduction in pretax net income of $0.2 million.

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

The interest rate risk related to borrowings under our line of credit is a variable rate of LIBOR plus an applicable margin, as defined in the loan agreement (2.21% at December 31, 2012). As of December 31, 2012, we had outstanding borrowings of $4.4 million under our line of credit. If interest rates increased by 1.0%, the impact on interest expense in future periods would be less than $0.1 million. We have sufficient cash balances to pay down the line of credit to minimize our interest rate exposure.

**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 2012, 2011 and 2010. 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, 2012. Based on that evaluation, they have concluded that our disclosure controls and procedures were effective as of December 31, 2012 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 and the related attestation report of KPMG LLP, our independent registered public accounting firm, are included on page F-1 and F-3, respectively, of this annual report on Form 10-K, and incorporated herein by reference.

During our fourth quarter of 2012, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f)).

**Item 9B. Other Information.**

None.

**PART III**

The information called for by Part III of Form 10-K (Item 10 – Directors, Executive Officers and Corporate Governance, Item 11 – Executive Compensation, Item 12 – Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13 – Certain Relationships and Related Transactions, and Director Independence, Item 14 – Principal Accounting Fees and Services), is incorporated by reference from our proxy statement related to our 2013 annual meeting of shareholders, which is expected to be filed with the SEC on or around March 13, 2013.

**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. |
| 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. |
| 4.7# | Form of Non-Statutory Stock Option Agreement under the Amended and Restated 2007 Directors' Compensation Plan of Cumberland Pharmaceuticals Inc. |
| 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 |
| 10.8† | 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 8, 2013, effective as of January 1, 2013, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc. |
| 10 .12# | Employment Agreement dated March 8, 2013, effective as of January 1, 2013, by and between James L. Herman and Cumberland Pharmaceuticals Inc. |
| 10.13# | Employment Agreement dated March 8, 2013, effective as of January 1, 2013, by and between Leo Pavliv and Cumberland Pharmaceuticals Inc. |
| 10.16† | Fifth Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated August 2, 2011, 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, 2011 |
| 10.16.1 | First Amendment to Fifth Amended and Restated Loan Agreement, dated March 29, 2012, by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., originally dated August 2, 2011 |
| 10.16.2 | Waiver and Second Amendment to Fifth Amended and Restated Loan Agreement, dated March 7, 2013, by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., originally dated August 2, 2011 |

| 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 |
| 10.23† | Amended and Restated Lease Agreement, dated November 11, 2004, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007 |
| 10.24 | First Amendment to Amended and Restated Lease Agreement, dated August 23, 2005, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007 |
| 10.24.1 | Second Amendment to Amended and Restated Lease Agreement, dated January 9, 2006, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008 |
| 10.24.2† | Third Amendment to Amended and Restated Lease Agreement, dated July 3, 2012, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on August 9, 2012 |
| 10.25† | Manufacturing Agreement, dated February 6, 2008, by and between Bayer HealthCare, LLC, and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 12 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on June 20, 2008 |

| Exhibit Number | Description |
|---|---|
| 10.25.1 | First Amendment to the Manufacturing Agreement, effective January 19, 2009, between Bayer HealthCare, 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 August 9, 2012 |
| 10.25.2† | Second Amendment to the Manufacturing Agreement, effective June 30, 2012, 2009, between Bayer HealthCare, 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 August 9, 2012 |
| 10.26# | Employment Agreement dated March 8, 2013, effective as of January 1, 2013, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc. |
| 10.27# | Employment Agreement dated March 8, 2013, effective as of January 1, 2013, by and between Rick S. Greene and Cumberland Pharmaceuticals Inc. |
| 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. |
| 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 |
| 10.32†† | License and Supply Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company |
| 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 12, 2013.

**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*<br>A. J. Kazimi | Chairman and CEO<br>*(Principal Executive Officer and Director)* | March 12, 2013 |
| */s/ Rick S. Greene*<br>Rick S. Greene | Vice President and CFO<br>*(Principal Financial and Accounting Officer* | March 12, 2013 |
| */s/ Robert G. Edwards*<br>Robert G. Edwards | Director | March 12, 2013 |
| */s/ Thomas R. Lawrence*<br>Thomas R. Lawrence | Director | March 12, 2013 |
| */s/ Martin E. Cearnal*<br>Martin E. Cearnal | Director | March 12, 2013 |
| */s/ Gordon R. Bernard*<br>Gordon R. Bernard | Director | March 12, 2013 |
| */s/ Jonathan I. Griggs*<br>Jonathan I. Griggs | Director | March 12, 2013 |
| */s/ James R. Jones*<br>James R. Jones | Director | March 12, 2013 |
| */s/ Joey A. Jacobs*<br>Joey A. Jacobs | Director | March 12, 2013 |

## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Cumberland Pharmaceuticals Inc. 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, 2012. 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*.

Based on its assessment, management has concluded that, as of December 31, 2012, the Company's internal control over financial reporting was effective based on those criteria.

Cumberland Pharmaceuticals Inc.'s independent registered public accounting firm has issued an audit report on the effectiveness of Cumberland Pharmaceuticals Inc.'s internal control over financial reporting. This report appears on page F-3 of this annual report on Form 10-K.

*/s/ A. J. Kazimi*

A. J. Kazimi
Chief Executive Officer
March 12, 2013

*/s/ Rick S. Greene*

Rick S. Greene
Chief Financial Officer
March 12, 2013

## 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, 2012 and 2011, and the related consolidated statements of income and comprehensive income, equity, and cash flows for each of the years in the three year period ended December 31, 2012. In connection with our audits 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, 2012. 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, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 12, 2013 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

/s/ KPMG LLP
Nashville, Tennessee
March 12, 2013

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Cumberland Pharmaceuticals Inc.:

We have audited Cumberland Pharmaceuticals Inc.'s (the Company) internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, equity, and cash flows for each of the years in the three-year period ended December 31, 2012, and our report dated March 12, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP
Nashville, Tennessee
March 12, 2013

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

Consolidated Balance Sheets

December 31, 2012 and 2011

| | 2012 | 2011 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 54,349,381 | $ 70,599,146 |
| Marketable securities | 16,686,136 | — |
| Accounts receivable, net of allowances | 6,017,201 | 7,082,890 |
| Inventories | 6,218,355 | 5,774,694 |
| Prepaid and other current assets | 1,671,091 | 1,627,455 |
| Deferred tax assets | 2,290,078 | 2,223,882 |
| Total current assets | 87,232,242 | 87,308,067 |
| Property and equipment, net | 1,188,914 | 1,119,339 |
| Intangible assets, net | 9,476,798 | 7,023,064 |
| Deferred tax assets | 50,411 | — |
| Other assets | 645,366 | 67,846 |
| Total assets | $ 98,593,731 | $ 95,518,316 |
| **LIABILITIES AND EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,790,554 | $ 1,513,548 |
| Accrued liabilities | 5,264,806 | 5,086,400 |
| Total current liabilities | 8,055,360 | 6,599,948 |
| Revolving line of credit | 4,359,951 | 4,859,951 |
| Deferred tax liabilities | — | 645,029 |
| Other long-term liabilities | 611,933 | 578,119 |
| Total liabilities | 13,027,244 | 12,683,047 |
| Commitments and contingencies | | |
| Equity: | | |
| Shareholders' equity: | | |
| Common stock – no par value; 100,000,000 shares authorized; 18,937,107 and 20,020,535 shares issued and outstanding as of December 31, 2012 and 2011, respectively | 67,197,167 | 70,272,155 |
| Retained earnings | 18,499,154 | 12,656,662 |
| Total shareholders' equity | 85,696,321 | 82,928,817 |
| Noncontrolling interests | (129,834) | (93,548) |
| Total equity | 85,566,487 | 82,835,269 |
| Total liabilities and equity | $ 98,593,731 | $ 95,518,316 |

See accompanying notes to consolidated financial statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

Consolidated Statements of Income and Comprehensive Income

Years ended December 31, 2012, 2011 and 2010

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Revenues: | | | |
| Net product revenue | $ 47,944,031 | $ 50,893,794 | $ 44,704,570 |
| Other revenue | 907,206 | 248,982 | 1,171,801 |
| Net revenues | 48,851,237 | 51,142,776 | 45,876,371 |
| Costs and expenses: | | | |
| Cost of products sold | 5,046,179 | 5,362,554 | 3,586,646 |
| Selling and marketing | 20,329,493 | 20,940,060 | 22,674,505 |
| Research and development | 5,095,172 | 5,028,072 | 4,327,485 |
| General and administrative | 9,096,165 | 9,307,301 | 8,099,077 |
| Amortization | 466,126 | 655,302 | 686,911 |
| Total costs and expenses | 40,033,135 | 41,293,289 | 39,374,624 |
| Operating income | 8,818,102 | 9,849,487 | 6,501,747 |
| Interest income | 304,865 | 210,727 | 200,207 |
| Interest expense | (71,985) | (353,497) | (1,423,523) |
| Income before income taxes | 9,050,982 | 9,706,717 | 5,278,431 |
| Income tax expense | (3,244,776) | (4,080,204) | (2,851,420) |
| Net income | 5,806,206 | 5,626,513 | 2,427,011 |
| Net loss at subsidiary attributable to noncontrolling interests | 36,286 | 31,343 | 29,669 |
| Net income attributable to common shareholders | $ 5,842,492 | $ 5,657,856 | $ 2,456,680 |
| Earnings per share attributable to common shareholders: | | | |
| Basic | $ 0.30 | $ 0.28 | $ 0.12 |
| Diluted | $ 0.30 | $ 0.28 | $ 0.12 |
| Weighted-average common shares outstanding: | | | |
| Basic | 19,564,625 | 20,342,913 | 20,333,932 |
| Diluted | 19,787,537 | 20,572,132 | 21,058,577 |
| Comprehensive income | $ 5,806,206 | $ 5,626,513 | $ 2,427,011 |

See accompanying notes to consolidated financial statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

Consolidated Statements of Cash Flows

Years ended December 31, 2012, 2011 and 2010

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income | $ 5,806,206 | $ 5,626,513 | $ 2,427,011 |
| Adjustments to reconcile net income to net cash flows provided by operating activities: | | | |
| Depreciation and amortization expense | 901,649 | 1,040,407 | 978,398 |
| Deferred tax (benefit) expense | (829,846) | 1,665,110 | (332,349) |
| Share-based compensation | 636,528 | 779,305 | 768,630 |
| Excess tax benefit derived from exercise of stock options | (3,760,766) | (2,355,345) | (3,874,966) |
| Noncash interest expense | 24,075 | 137,487 | 352,484 |
| Noncash investment gains | (45,814) | — | — |
| Net changes in assets and liabilities affecting operating activities: | | | |
| Accounts receivable | 1,065,689 | (1,937,396) | 1,031,091 |
| Inventory | (443,661) | 1,909,148 | (2,860,969) |
| Prepaid, other current assets and other assets | (648,941) | (399,393) | 1,342,032 |
| Accounts payable and other accrued liabilities | 4,373,276 | 2,296,535 | 201,725 |
| Other long-term liabilities | 56,787 | (40,224) | 313,575 |
| Net cash provided by operating activities | 7,135,182 | 8,722,147 | 346,662 |
| Cash flows from investing activities: | | | |
| Additions to property and equipment | (464,893) | (257,502) | (577,159) |
| Additions to intangible assets | (2,071,926) | (180,269) | (191,483) |
| Proceeds from sale of marketable securities | 5,220,480 | — | — |
| Purchases of marketable securities | (21,860,802) | — | — |
| Net cash used in investing activities | (19,177,141) | (437,771) | (768,642) |
| Cash flows from financing activities: | | | |
| Net (repayments) borrowings on line of credit | (500,000) | 3,034,000 | — |
| Principal payments on note payable | — | (5,333,333) | (12,666,667) |
| Payments made in connection with repurchase of common shares | (8,086,594) | (4,247,440) | (4,846,791) |
| Costs of financing for long-term debt and credit facility | — | (17,637) | (110,000) |
| Proceeds from exercise of stock options | 618,022 | 629,865 | 1,362,760 |
| Excess tax benefit derived from exercise of stock options | 3,760,766 | 2,355,345 | 3,874,966 |
| Net cash used in financing activities | (4,207,806) | (3,579,200) | (12,385,732) |
| Net (decrease) increase in cash and cash equivalents | (16,249,765) | 4,705,176 | (12,807,712) |
| Cash and cash equivalents, beginning of year | 70,599,146 | 65,893,970 | 78,701,682 |
| Cash and cash equivalents, end of year | $ 54,349,381 | $ 70,599,146 | $ 65,893,970 |
| | | | |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the year for: | | | |
| Interest | $ 47,910 | $ 191,410 | $ 814,373 |
| Income taxes | 112,381 | 304,480 | 52,136 |
| Noncash investing and financing activities: | | | |
| Change in unpaid invoices for purchases of intangibles | 888,141 | 97,806 | — |
| Reclass of redeemable common stock to (from) equity | — | — | 1,930,000 |

See accompanying notes to consolidated financial statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

Consolidated Statements of Equity

Years ended December 31, 2012, 2011 and 2010

| | Cumberland Pharmaceuticals Inc. Shareholders | | | | |
|---|---|---|---|---|---|
| | Common stock | | | | |
| | Shares | Amount | Retained earnings | Non-controlling interest | Total equity |
| **Balance, December 31, 2009** | 20,180,486 | $ 67,711,746 | $ 4,542,126 | $ (32,536) | $ 72,221,336 |
| Net income | | | 2,456,680 | (29,669) | 2,427,011 |
| Share-based compensation | 5,636 | 786,649 | | | 786,649 |
| Exercise of options and related tax benefit | 767,794 | 5,237,726 | | | 5,237,726 |
| Repurchase of common shares | (615,455) | (4,887,247) | | | (4,887,247) |
| Reclass of redeemable common stock | | 1,930,000 | | | 1,930,000 |
| **Balance, December 31, 2010** | 20,338,461 | 70,778,874 | 6,998,806 | (62,205) | 77,715,475 |
| Net income | | | 5,657,856 | (31,343) | 5,626,513 |
| Share-based compensation | 10,144 | 755,511 | | | 755,511 |
| Exercise of options and related tax benefit | 415,003 | 2,985,210 | | | 2,985,210 |
| Repurchase of common shares | (743,073) | (4,247,440) | | | (4,247,440) |
| **Balance, December 31, 2011** | 20,020,535 | 70,272,155 | 12,656,662 | (93,548) | 82,835,269 |
| Net income | | | 5,842,492 | (36,286) | 5,806,206 |
| Share-based compensation | 20,199 | 632,818 | | | 632,818 |
| Exercise of options and related tax benefit | 165,182 | 4,378,788 | | | 4,378,788 |
| Repurchase of common shares | (1,268,809) | (8,086,594) | | | (8,086,594) |
| **Balance, December 31, 2012** | 18,937,107 | $ 67,197,167 | $ 18,499,154 | $ (129,834) | $ 85,566,487 |

See accompanying notes to consolidated financial statements.

## (1) Organization

Cumberland Pharmaceuticals Inc. and its subsidiaries (the Company or Cumberland) 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 markets are characterized by relatively concentrated prescriber bases that the Company believes can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address poorly met medical needs.

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

In order to create access to a pipeline 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 85%. The remaining interest is owned by Vanderbilt University and the Tennessee Technology Development Corporation. The operating results of CET allocated to the noncontrolling interests in the consolidated statements of income were approximately $36,000, $31,000 and $30,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

Effective January 1, 2007, the Company formed a wholly-owned subsidiary, Cumberland Pharma Sales Corp. (CPSC), for the purpose of employing the hospital sales forces that promote the Company’s products, Acetadote and Caldolor, in the acute care market. In September 2010, the Company converted its field sales force, which promotes Caldolor and Kristalose, to Cumberland employees. Previously, these sales forces were contracted through third-party sales organizations. In November 2012, the Company implemented a realignment of its national sales organization to more efficiently cover key targets in support of its three marketed products. Costs related to the realignment during 2012 totaled approximately $685,000 and were included as a component of selling and marketing expenses.

## (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. 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 $0.7 million, $0.1 million and $0.1 million for 2012, 2011 and 2010, 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, 2012 and 2011, 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, 2012, marketable securities was 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 income.

***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, takes title to finished goods at the time of shipment from the manufacturer and 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 income. 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.

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, related costs associated with the patent application is 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 on a straight-line basis over the following periods:

| | |
|---|---|
| Product rights | 15 years |
| 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. Assets to be disposed of, if any, are separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and no further depreciation or amortization is recorded on the asset upon classification as held-for-sale. The assets and liabilities of a disposal group classified as held-for-sale, if any, are presented separately in the appropriate asset and liability sections of the consolidated balance sheet. The Company recorded no impairment charges during 2012, 2011 and 2010.

***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, 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 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 expense 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 $0.9 million, $1.2 million and $1.2 million in 2012, 2011 and 2010, respectively, and are included as a component of selling and marketing expenses in the consolidated statements of income.

***Advertising Costs***

Advertising costs are expensed as incurred and totaled $1.8 million, $0.9 million and $0.8 million in 2012, 2011 and 2010, respectively, and are included as a component of selling and marketing expenses in the consolidated statements of income.

***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 and 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***

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

***Earnings 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. The cost of stock options is measured based on the grant-date fair value using the Black-Scholes option-pricing model, and the expense is recognized over the employee's requisite service period. 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 income. Funding received from private sector investments and grants are recorded as net revenues in the consolidated statements of income.

***Recent Accounting Guidance***

In June 2011, the FASB issued updated guidance in the form of a FASB Accounting Standards Update on "Comprehensive Income - Presentation of Comprehensive Income," to require an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The update eliminates the option to present the components of other comprehensive income as part of the statement of equity. The Company adopted this guidance effective January 1, 2012 and has applied it retrospectively. There was no significant impact to the Company's interim consolidated financial statements.

## (3) Revenues

*Product Revenues*

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

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Acetadote | $ 37,522,180 | $ 42,454,055 | $ 35,092,796 |
| Kristalose | 9,429,741 | 8,517,873 | 9,510,275 |
| Caldolor | 992,110 | (78,134) | 101,499 |
| Total net product revenues | $ 47,944,031 | $ 50,893,794 | $ 44,704,570 |

In December 2011, the Company discontinued sales of the 400mg Caldolor offering domestically and focused on the 800mg Caldolor offering. Gross product revenue for Caldolor was approximately $1.3 million, $0.3 million and $0.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. The Company recognized approximately $0.4 million of sales allowances in the fourth quarter of 2011 primarily for estimated return of the discontinued product.

As part of the November 12, 2012, Settlement Agreement with Paddock and Perrigo, the Company will supply Perrigo with an Authorized Generic version of the Company's Acetadote product, as discussed in Note 19, Commitments and Contingencies. Acetadote product revenue in 2012 includes $0.3 million in our share of the Authorized Generic distributed by Perrigo.

The allowances in accounts receivable for chargebacks, cash discounts and damaged goods were $0.2 million at December 31, 2012 and 2011, and the accruals for rebates, product returns and certain administrative and service fees included in other current liabilities were $3.4 million and $3.2 million, respectively, at December 31, 2012 and 2011.

*Other Revenues*

Other revenues during 2012, 2011 and 2010 are comprised of revenue generated by CET through grant funding from federal Small Business (SBIR/STTR) grant programs, and lease income generated by CET's Life Sciences Center and contract services. The Life Sciences Center is a research center that provides scientists with access to flexible lab space and other resources to develop biomedical products. Grant revenue from SBIR/STTR programs totaled approximately $0.1 million for each of the years ended December 31, 2012, 2011 and 2010, respectively. Other revenues in 2010 also included approximately $0.9 million of federal grants associated with the Therapeutic Discovery Project Credit, a component of the U.S. health care reform act enacted in March 2010. The Therapeutic Discovery Project Credit allowed entities to apply for funding based on qualified research activities. Funds were then granted to entities based on their qualified research expenses. Revenue was recognized after the application was approved and as qualified research expenses were incurred.

In 2012, the Company entered into an exclusive licensing agreement for Acetadote and Caldolor with Harbin Gloria Pharmaceuticals Co., Ltd., a Chinese pharmaceutical company that has expertise in developing, registering, manufacturing and commercializing products in the China market. In connection with the agreement, the Company has certain protective rights, including the right to review and approve all documents submitted to the Chinese State Drug Administration. The Company determined the agreement contains two units of accounting being the transfer of certain rights, including the product dossier, for Acetadote and Caldolor, separately. During 2012, the Company received nonrefundable, up-front payments totaling $0.7 million in exchange for the transfer of certain intellectual property, including its product dossiers, and recognized the

payments as other revenue in the consolidated statement of income when the intellectual property was provided to the licensee.

The licensing agreement provides for the Company to receive additional milestone payments of $0.7 million when the licensee receives notice from the regulatory authority granting approval to conduct clinical trials, or stating that no clinical trials are necessary. The Company is also entitled to receive milestone payments of $1.1 million upon receiving regulatory approval for each of Acetadote and Caldolor in China. The Company will recognize revenue for these substantive milestones using the milestone method. As of December 31, 2012, no revenue has been recognized related to milestones associated with Harbin Gloria.

## (4) Inventories

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

| | 2012 | 2011 |
|---|---|---|
| Raw materials | $ 1,310,670 | $ 774,637 |
| Finished goods | 4,907,685 | 5,000,057 |
| Total inventories | $ 6,218,355 | $ 5,774,694 |

Caldolor inventory represented the majority of net inventory on hand at December 31, 2012 and 2011 and has varying expiration dates that begin in the second quarter of 2014 and extend through January 2015. At December 31, 2012 and 2011, the Company has recognized amounts for potential obsolescence and discontinuance of approximately $2.6 million and $2.1 million, respectively, primarily for Caldolor. If actual sales in future periods are less than projected sales, the Company could incur additional obsolescence losses.

In the fourth quarter of 2010, the Company purchased certain packaging materials for the Caldolor product which is included in raw materials inventory and maintained at its third-party manufacturer.

In connection with the acquisition of certain product right assets related to the Kristalose brand as discussed in Note 6, the Company is responsible for purchasing the active pharmaceutical ingredient for Kristalose and maintains this raw material inventory at its third-party manufacturer. As the ingredients are consumed in production, the value of the ingredients is transferred from raw materials to finished goods.

## (5) Property and Equipment

Property and equipment consisted of the following at December 31:

| | Range of useful lives | 2012 | 2011 |
|---|---|---|---|
| Computer equipment | 3 – 5 years | $ 710,099 | $ 536,702 |
| Office equipment | 3 – 15 years | 123,937 | 116,502 |
| Furniture and fixtures | 5 – 15 years | 609,544 | 598,510 |
| Leasehold improvements | 3 – 15 years, or remaining lease term | 1,186,306 | 951,688 |
| Total property and equipment, gross | | 2,629,886 | 2,203,402 |
| Less: accumulated depreciation and amortization | | (1,440,972) | (1,084,063) |
| Total property and equipment, net | | $ 1,188,914 | $ 1,119,339 |

Depreciation expense, including amortization expense related to leasehold improvements, during 2012, 2011 and 2010 was approximately $0.4 million, $0.4 million and $0.3 million, respectively, and is included in general and administrative expense in the consolidated statements of income.

## (6) Intangible Assets

Intangible assets consisted of the following at December 31:

| | 2012 | 2011 |
|---|---|---|
| Product and license rights | $ 7,352,308 | $ 6,518,798 |
| Less: accumulated amortization | (520,385) | (54,259) |
| Total product and license rights | 6,831,923 | 6,464,539 |
| Patents | 2,735,117 | 608,561 |
| Less: accumulated amortization | (90,242) | (50,389) |
| Total patents | 2,644,875 | 558,172 |
| Trademarks | 9,020 | 9,020 |
| Less: accumulated amortization | (9,020) | (8,667) |
| Total trademarks | — | 353 |
| Total intangible assets | $ 9,476,798 | $ 7,023,064 |

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, generally 15 years.

During 2012, the Company recorded an additional $1.7 million in intangible assets for capitalized patent costs incurred in the protection of the Company's intellectual property.

Amortization expense related to product and license rights, trademarks and patents was $0.5 million, $0.7 million and $0.7 million in 2012, 2011 and 2010, and is expected to be approximately $0.7 million in each of the years 2013 through 2017.

## (7) Accrued Liabilities

Accrued liabilities consisted of the following at December 31:

| | 2012 | 2011 |
|---|---|---|
| Rebates, product returns, administrative fees and service fees | $ 3,371,863 | $ 3,216,622 |
| Employee wages and benefits | 1,473,983 | 1,071,691 |
| Other | 418,960 | 798,087 |
| Total accrued liabilities | $ 5,264,806 | $ 5,086,400 |

## (8) Debt

In July 2011, the outstanding term debt balance of $4.0 million was paid in full. The Company did not incur any prepayment penalties or other fees associated with the payoff. In connection with the repayment, approximately $0.1 million of unamortized deferred loan costs associated with the term debt was written off. These costs are included in interest expense in the consolidated statement of income for the year ended December 31, 2011.

In August 2011, the Company entered into a Fifth Amended and Restated Loan Agreement with its primary lender (the Agreement) to provide for an increase in the line of credit to $10 million. The credit facility may be increased up to $20 million upon the satisfaction of certain conditions. The interest rate is the BBA LIBOR Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement (2.21% at December 31, 2012). In addition, a commitment fee of 0.25% per annum is charged on the unused line of credit. The credit facility was extended to expire on December 31, 2014, at which time all principal amounts are due and payable. Interest is payable quarterly. Borrowings under the line of credit are collateralized by substantially all of the Company’s assets.

Under the Agreement, the Company is subject to certain financial covenants including, but not limited to, maintaining a Leverage Ratio and Interest Coverage Ratio, as those terms are defined in the Agreement, that are determined on a quarterly basis.

During March 2013, the Company and its primary lender amended certain provisions of the Agreement related to the repurchase of the Company's common stock. Previously, the Agreement allowed the Company to expend $10 million for share repurchases over the term of the Agreement. The amendment allows the Company $10 million for share repurchases from March 1, 2013 through the remaining term of the Agreement. The Company is in compliance with all covenants.

Furthermore, the lender may terminate the Agreement and require the Company to repay all outstanding amounts under certain conditions, as described in the Agreement, including, but not limited to: cross-default on any other credit agreement with an outstanding principal amount in excess of $500,000, material adverse

change in our business condition, operations or properties, violation of any covenant or a change in control of the Company.

## (9) 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, 2012 and 2011, there was no preferred stock outstanding.

### *(c) Common Stock*

During 2012, 2011 and 2010, the Company issued 20,199 shares, 10,144 shares and 5,636 shares of common stock, respectively, valued at $78,000, $59,000 and $56,000, respectively, as compensation for services, which is included in general and administrative expenses in the consolidated statements of income.

In the second quarter of 2012, the Company implemented an Option Exchange Program (the "Exchange Program") whereby certain outstanding stock options could be exchanged for shares of restricted stock. The Exchange Program expired on May 21, 2012, at which time 424,475 outstanding options were exchanged for 147,828 shares of restricted stock. The restriction period on the restricted stock lapse from one to four years after issuance. The Exchange Program was designed to provide a value-for-value exchange of equity instruments. The fair value of each exchanged option was determined on the date the Exchange Program commenced using the Black-Scholes option pricing model, and the following assumptions:

| | **Range of Assumptions** |
|---|---|
| Dividend yield | — |
| Expected term (years) | 1.3 - 7.3 |
| Expected volatility | 37% - 78% |
| Risk-free interest rate | 0.23% - 1.50% |

The Exchange Program resulted in no incremental compensation expense during 2012. The remaining unrecognized compensation costs for the exchanged options on the date of the exchange was approximately $0.3 million, and will be recognized over the restriction period.

The payment of dividends is restricted by the Agreement with the Company's primary lender.

***(d) Warrants***

In 2003, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of $6.00 per share as partial consideration for a modification to its line of credit. The warrants expire 10 years from the date of issuance. All of these warrants were outstanding and exercisable as of December 31, 2012 and 2011.

In connection with the issuance of shares of common stock to a related party in 2004, the Company issued warrants to purchase 40,000 shares of common stock at $6.00 per share at any time within 10 years of issuance. All of these warrants were outstanding and exercisable as of December 31, 2012 and 2011.

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, 2012 and 2011.

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, 2012 and 2011.

***(e) Share Repurchases***

In February and April 2010, the Company repurchased 163,022 shares of common stock totaling approximately $1.9 million for the settlement of tax liabilities associated with the exercise of certain stock options in 2009. The repurchase amount was based on the fair-market value of common stock on the date of settlement.

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 and January 2013, the Company's Board of Directors replaced the prior authorizations with new $10 million authorizations for repurchases of the Company's outstanding common stock. The Company repurchased 1,268,809 shares, 743,073 shares and 452,433 shares of common stock for approximately $8.1 million, $4.2 million and $3.0 million during the years ended December 31, 2012, 2011 and 2010, respectively.

**(10) 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:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Numerator: | | | |
| Net income attributable to common shareholders | $ 5,842,492 | $ 5,657,856 | $ 2,456,680 |
| Denominator: | | | |
| Weighted-average shares outstanding – basic | 19,564,625 | 20,342,913 | 20,333,932 |
| Dilutive effect of restricted stock and stock options | 222,912 | 229,219 | 724,645 |
| Weighted-average shares outstanding – diluted | 19,787,537 | 20,572,132 | 21,058,577 |

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

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Anti-dilutive shares | 687,430 | 1,079,904 | 640,718 |

## (11) Income Taxes

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

| | 2012 | 2011 |
|---|---|---|
| **Deferred Tax Assets** | | |
| Net operating loss and tax credits | $ 1,159,865 | $ 1,025,621 |
| Property and equipment and intangibles | 153,361 | 92,470 |
| Allowance for accounts receivable | 74,362 | 92,977 |
| Reserve for expired product | 706,960 | 735,992 |
| Inventory | 1,185,419 | 1,079,541 |
| Deferred charges | 582,480 | 563,141 |
| Cumulative compensation costs incurred on deductible equity awards | 1,251,382 | 584,212 |
| Total deferred tax assets | 5,113,829 | 4,173,954 |
| **Deferred Tax Liabilities** | | |
| Intangible assets | (2,665,022) | (2,500,642) |
| Net deferred tax assets, before valuation allowance | 2,448,807 | 1,673,312 |
| Less: deferred tax asset valuation allowance | (108,318) | (94,459) |
| Net deferred tax assets | $ 2,340,489 | $ 1,578,853 |

As a result of the Exchange Program, discussed in Note 9, Shareholder's Equity, the Company recognized a deferred tax asset in 2012 related to the expected tax benefit of previously recognized compensation expense for incentive stock options that were exchanged. The deferred tax asset will be realized when the restrictions lapse on the restricted stock.

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, 2012:

| Years of expiration | Federal | State |
|---|---|---|
| 2014 | $ — | $ 2,249,078 |
| 2015 - 2017 | — | 504,822 |
| 2018 - 2024 | — | 51,629,844 |
| 2029 | 48,566,499 | — |
| Total federal and state net operating loss carryforwards | $ 48,566,499 | $ 54,383,744 |

The Company has unrecognized federal net operating loss carryforwards as a result of the exercise of nonqualified options of approximately $48.6 million. These benefits will be recognized in the year in which they are able to reduce current income taxes payable. The usage of these net operating losses carryforwards resulted in the Company paying minimal income taxes in 2009 through 2012, and the Company expects to pay minimal income taxes in 2013. The Company has $54.4 million of state net operating loss carryforwards. This amount includes $51.8 million from the exercise of nonqualified options during 2009. The state net

operating loss carryforwards above include approximately $2.4 million that is subject to a full valuation allowance at December 31, 2012.

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

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Current: | | | |
| Federal | $ (3,185,743) | $ (1,992,804) | $ (2,665,404) |
| State and other | (820,669) | (422,290) | (518,365) |
| Total current income tax expense | (4,006,412) | (2,415,094) | (3,183,769) |
| Deferred: | | | |
| Federal | 677,190 | (1,543,261) | 268,563 |
| State | 84,446 | (121,849) | 63,786 |
| Total deferred income tax benefit (expense) | 761,636 | (1,665,110) | 332,349 |
| Total income tax expense | $ (3,244,776) | $ (4,080,204) | $ (2,851,420) |

The Company's deferred tax benefit in 2012 was primarily a result of the income tax benefit arising from the Exchange Program. The Company’s deferred tax expense in 2011 was primarily due to the write-off for tax purposes of the Kristalose license rights but maintained as a component of products rights for book purposes, and due to inventory write-downs. The deferred tax benefit for 2010 was primarily due to rent and expired product expenses recognized for book purposes in 2010 that will not be deductible for tax purposes until the future.

Deferred income tax benefit (expense) is comprised of the following components for the years ended December 31:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Deferred tax (expense) benefit, excluding items below | $ (39,870) | $ 439,744 | $ 459,575 |
| Inventory write-downs | 179,755 | 817,840 | 31,228 |
| Creation of operating loss carryforwards | 25,552 | 11,348 | 9,567 |
| Creation (utilization) of tax credit carryforwards | 108,699 | 56,395 | (3,115) |
| Change in valuation allowance due to changes in net deferred tax asset balances | (15,291) | (13,597) | (10,750) |
| Deductible equity awards | 667,171 | (330,329) | (132,193) |
| Intangible assets | (164,380) | (2,646,511) | (21,963) |
| Deferred income tax benefit (expense) | $ 761,636 | $ (1,665,110) | $ 332,349 |

The valuation allowance at December 31, 2012 and 2011 is primarily related to state tax benefits at CET that will likely not be realized.

The Company's effective income tax rate for 2012, 2011 and 2010 reconciles with the federal statutory tax rate as follows:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Federal tax expense at statutory rate | 34 % | 35 % | 34% |
| State income tax expense (net of federal income tax benefit) | 4 % | 4 % | 6% |
| Permanent differences associated with tax grants | — % | — % | 5% |
| Permanent differences associated with stock options | (5)% | 2 % | 4% |
| Other permanent differences | 3 % | 2 % | 4% |
| Other | — % | (1)% | 1% |
| Net income tax expense | 36 % | 42 % | 54% |

During 2010, the Company applied for and received tax-free grants under the Therapeutic Discovery Project. Qualifying expenses certified under this program are nondeductible for federal income tax purposes. Approximately $0.4 million of qualifying expenses related to 2009 for which the Company filed an amended tax return in 2011.

The Company's 2009 federal tax return was selected for examination during 2012, and this examination was completed during the year with no significant findings or adjustments. Federal tax years that remain open to examination are 2010 through 2012. 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 2007 to 2012.

Excluding the alternative minimum tax (AMT) tax credits, the Company will need to generate future taxable income of approximately $5.7 million in order to fully realize the deferred tax assets. Taxable income, excluding tax deductions generated by the exercise of nonqualified options, for 2012, 2011 and 2010 was approximately $9.4 million, $5.7 million and $7.3 million, respectively. 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, 2012. The amount of the deferred tax assets considered realizable, however, could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

## (12) Stock-Based Compensation Plans

The Company has grants outstanding under three equity compensation plans, with two 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 income. Stock compensation expense recorded as a component of equity consisted of the following for the years ended December 31:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Share-based compensation - employees | $ 555,898 | $ 627,353 | $ 688,408 |
| Share-based compensation - nonemployees | 76,920 | 128,158 | 98,241 |
| Total share-based compensation | $ 632,818 | $ 755,511 | $ 786,649 |

At December 31, 2012, there was approximately $1.4 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted-average period of 3.0 years. This amount relates primarily to unrecognized compensation cost for employees.

*Stock Options*

Stock option activity for 2012 and 2011 was as follows:

| | Number of shares | Weighted-average exercise price per share | Weighted-average remaining contractual term (years) | Aggregate intrinsic value |
|---|---|---|---|---|
| Outstanding, December 31, 2010 | 1,905,470 | $ 6.45 | 3.3 | $ 2,853,707 |
| Options granted | — | — | | |
| Options exercised | (503,411) | 2.19 | | |
| Options forfeited or expired | (125,901) | 10.24 | | |
| Outstanding, December 31, 2011 | 1,276,158 | 7.75 | 2.9 | 700,294 |
| Options granted | — | — | | |
| Options exercised | (173,688) | 3.55 | | |
| Options forfeited or expired | (435,599) | 12.22 | | |
| Outstanding, December 31, 2012 | 666,871 | 5.93 | 1.4 | $ 132,348 |
| Exercisable at December 31, 2012 | 660,023 | $ 5.88 | 1.4 | $ 132,348 |

Information related to the stock option plans during 2012, 2011 and 2010 was as follows:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Intrinsic value of options exercised | $ 495,480 | $ 1,742,103 | $ 5,519,588 |
| Weighted-average fair value of options exercised | $ 1.00 | $ 2.06 | $ 4.13 |

The Company did not grant any stock options during 2012 and 2011. The fair value of employee and nonemployee options granted during 2010 was estimated using the Black-Scholes option-pricing model and consisted of the following assumptions:

| | Range of Assumptions | |
|---|---|---|
| | Employee Options | Non-Employee Options |
| Dividend yield | — | — |
| Expected term (years) | 2.5 – 6.0 | 5.0 |
| Expected volatility | 49% – 53% | 52% – 53% |
| Risk-free interest rate | 0.8% – 2.8% | 2.2% – 2.4% |

The Company determined the expected life of employee share options based on the simplified method allowed by SEC Staff Accounting Bulletin (SAB) No. 107, as amended by SAB No. 110. Under this approach, the expected term is presumed to be the average between the weighted-average vesting period and the contractual term. The expected term for options granted to nonemployees is generally the contractual term of the option. The expected volatility over the term of the respective option was based on the volatility of similar publicly-traded entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, size, and financial leverage. The risk-free interest rate is based on the U.S. Treasury Note, Stripped Principal, on the date of grant with a term substantially equal to the corresponding option’s expected term. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

The Company agreed to repurchase up to $1.9 million in common stock during the first quarter of 2010 to provide for the settlement of the remaining tax liabilities associated with the exercise of stock options in 2009. The repurchase of these shares was completed in 2010.

*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 activity was as follows:

| | Number of shares | Weighted-average grant-date fair value |
|---|---|---|
| Nonvested, December 31, 2010 | — | $ — |
| Shares granted | 149,320 | 5.40 |
| Shares vested | (1,000) | 5.28 |
| Shares forfeited | (12,150) | 5.28 |
| Nonvested, December 31, 2011 | 136,170 | 5.41 |
| Shares granted | 286,453 | 4.87 |
| Shares vested | (7,000) | 5.28 |
| Shares forfeited | (32,093) | 5.68 |
| Nonvested, December 31, 2012 | 383,530 | 4.99 |

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.

## (13) 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 2012, 2011 and 2010, the Company contributed approximately $50,000 in each year to the Plan as an employer match of participant contributions.

In 2012, the Company established a non-qualified unfunded deferred compensation plan that allows participants to defer receipt of a portion of their compensation. The liability under the plan was $0.1 million as of December 31, 2012. The Company had assets of $0.6 million, consisting of company-owned life insurance contracts as of December 31, 2012, generally designated to pay benefits of the deferred compensation plan.

## (14) Leases

The Company is obligated under long-term real estate leases for corporate office space expiring in October 2016. 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 2012, 2011 and 2010 was approximately $0.9 million, $0.8 million and $0.6 million, respectively, and sublease income was approximately $0.5 million,

$0.4 million and $0.3 million. Future minimum sublease income under noncancelable operating subleases is approximately $0.6 million through 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: | | |
| 2013 | $ | 953,440 |
| 2014 | | 1,022,019 |
| 2015 | | 1,052,662 |
| 2016 | | 941,247 |
| 2017 and thereafter | | 311,816 |
| Total future minimum lease payments | $ | 4,281,184 |

## (15) Fair Value of Financial Instruments

In 2012, the Company began purchasing marketable securities that are solely classified as trading securities. The following table summarizes the fair value of these marketable securities, by level within the fair value hierarchy, as of December 31, 2012:

| | Level 1 | Level 2 | Total |
|---|---|---|---|
| U.S. Treasury notes and bonds | $ 2,473,596 | $ — | $ 2,473,596 |
| U.S. Agency issued mortgage-backed securities - variable rate | — | 3,708,920 | 3,708,920 |
| U.S. Agency notes and bonds - fixed rate | — | 1,505,177 | 1,505,177 |
| SBA loan pools - variable rate | — | 1,988,443 | 1,988,443 |
| Municipal bonds - VRDN | 7,010,000 | — | 7,010,000 |
| Total fair value of marketable securities | $ 9,483,596 | $ 7,202,540 | $ 16,686,136 |

We had no marketable securities outstanding as of December 31, 2011. The fair values of all other financial instruments outstanding as of December 31, 2012 approximate their carrying values.

## (16) 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 Federal Deposit Insurance Corporation insurance limits.

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:

| | 2012 | 2011 | 2010 |
|---|---|---|---|
| Customer 1 | 35% | 36% | 35% |
| Customer 2 | 30% | 28% | 31% |
| Customer 3 | 28% | 31% | 26% |

The Company's accounts receivable, net of allowances, due from these three customers at December 31, 2012 and 2011 was 81% and 95%, respectively.

## (17) Manufacturing and Supply Agreements

The Company utilizes one primary supplier to manufacture each of its products and product candidates. The Company has an agreement with a second supplier of Acetadote that expires in February 2014. 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.

## (18) Employment Agreements

The Company has entered into employment agreements with all its full-time and part-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.

## (19) 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, generally 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.

*Legal Matters*

The Company developed a new formulation of Acetadote (acetylcysteine) Injection as part of a Phase IV commitment in response to a request by the Food and Drug Administration ("FDA"). In April 2012, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent number 8,148,356 (the "Acetadote Patent"), which is assigned to the Company and scheduled to expire in May 2026.

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

On November 12, 2012, the Company entered into a settlement agreement with Paddock Laboratories, LLC and Perrigo Company to resolve the challenges and the pending litigation with those two companies. The remaining infringement suits are currently pending.

On November 13, 2012, the Company brought suit against the FDA contesting the FDA's decision to approve the Innopharma Inc. generic. The Company intends to continue to vigorously defend and protect its Acetadote product and related intellectual property rights.

In November 2012, the Company also received a Notice of Allowance for a second Acetadote patent with a term that expires in August 2025. If the Company is unable to successfully defend the Acetadote patents and related intellectual property rights associated with its Acetadote product, its financial condition and results of operations could be adversely affected in the event of a loss of patent and lower sales volumes due to competition.

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 Acetadote patent issue discussed above, will not have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

**(20) Quarterly Financial Information (Unaudited)**

The following table sets forth the unaudited operating results for each fiscal quarter of 2012 and 2011:

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Total |
|---|---|---|---|---|---|
| 2012: | | | | | |
| Net revenues | $ 10,256,212 | $ 12,366,940 | $ 12,531,719 | $ 13,696,366 | $ 48,851,237 |
| Operating income | 646,015 | 1,939,931 | 2,979,163 | 3,252,993 | 8,818,102 |
| Net income attributable to common shareholders | 423,208 | 1,744,290 | 1,869,494 | 1,805,500 | 5,842,492 |
| Earnings per share attributable to common shareholders [(1)] | | | | | |
| Basic | $ 0.02 | $ 0.09 | $ 0.10 | $ 0.09 | $ 0.30 |
| Diluted | $ 0.02 | $ 0.09 | $ 0.10 | $ 0.09 | $ 0.30 |
| 2011: | | | | | |
| Net revenues | $ 10,666,927 | $ 14,389,741 | $ 13,054,278 | $ 13,031,830 | $ 51,142,776 |
| Operating income | 1,408,001 | 3,631,857 | 3,098,360 | 1,711,269 | 9,849,487 |
| Net income attributable to common shareholders | 721,160 | 2,177,619 | 1,847,412 | 911,665 | 5,657,856 |
| Earnings per share attributable to common shareholders [(1)] | | | | | |
| Basic | $ 0.04 | $ 0.11 | $ 0.09 | $ 0.05 | $ 0.28 |
| Diluted | $ 0.03 | $ 0.11 | $ 0.09 | $ 0.04 | $ 0.28 |

(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, 2012, 2011 and 2010

| 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: | | | | | |
| 2010 | $ 235,280 | $ 1,494,834 | $ — | $ (1,566,366) [1] | $ 163,748 |
| 2011 | 163,748 | 2,151,890 | — | (2,080,058) [1] | 235,580 |
| 2012 | 235,580 | 2,069,470 | — | (2,116,463) [1] | 188,587 |
| Valuation allowance for deferred tax assets: | | | | | |
| For the years ended December 31: | | | | | |
| 2010 | $ 70,112 | $ 10,750 | $ — | $ — | $ 80,862 |
| 2011 | 80,862 | 13,597 | — | — | 94,459 |
| 2012 | 94,459 | 13,859 | — | — | 108,318 |

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

EXHIBIT 4.7

**CUMBERLAND PHARMACEUTICALS INC.**
**AMENDED AND RESTATED 2007 DIRECTORS' INCENTIVE PLAN**
**NON-STATUTORY STOCK OPTION AGREEMENT**

1. Grant of Option. Cumberland Pharmaceuticals Inc. (the "Company"), a Tennessee corporation, hereby grants to the Participant an option (the "Option") to purchase from the Company up to the number of shares of common stock in the Company (the "Shares") described in the attached Notice of Stock Option Grant (the "Notice"). This grant is made subject to the terms of the Cumberland Pharmaceuticals Inc. Amended and Restated 2007 Directors' Incentive Plan (the "Plan") and the number of shares granted is subject to adjustment as described in the Plan. Unless otherwise defined in this Non-Statutory Stock Option Agreement (the "Option Agreement"), capitalized terms used in this Option Agreement shall have the same meaning as those capitalized terms in the Plan. This Option is *not* intended to qualify as an incentive stock option within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended.

2. Exercise Price. If the Option is exercised, the purchase price per Share shall be as shown in the attached Notice.

3. Method of Exercise. The Option shall be exercisable from time to time, in whole or in part, by written notice as described in Section 9 hereof, accompanied by payment of the purchase price for the Shares which the Participant elects to purchase by cash, check, or such other instrument as the Company may accept under the terms of the Plan. The Company shall make prompt delivery of such Shares, and in no event shall delivery of such shares be made more than thirty (30) days after cash, check or other instrument is accepted by the Company in payment for the Shares, except that if any law or regulation requires the Company to take any action with respect to the Shares specified in such notice before issuance thereof, then the date of delivery of such Shares shall be extended for the period necessary for the Company to take such action.

4. Vesting.

(a) The Option shall vest in accordance with the schedule set forth in the Notice. Service as a member of the Company's Board of Directors (a "Director") for only a portion of the vesting period, even if a substantial portion, will not entitle the Participant to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a termination of service as Director.

(b) Upon termination of Participant's service as Director, the Option, to the extent unvested, shall lapse and be cancelled, and be of no further force and effect, as of midnight of such date.

(c) Upon a Change of Control Event, the Option will vest to the extent provided in Section 9.2 of the Plan.

5. Termination of Option; Restrictions on Exercise. Except as otherwise stated in this Agreement, this Option, to the extent not previously exercised, shall expire on the expiration date set forth in the attached Notice (the "Expiration Date"). The following additional provisions shall apply to the exercise of this Option:

(a) *Termination of Service as Director.* If Participant's service as Director is terminated for any reason, the right to exercise this Option (to the extent that it is vested in accordance with the applicable provisions of Section 4 hereof) shall end on the earlier of the following dates: (i) two (2) years after the date of such termination or (ii) the Expiration Date. Except as expressly set forth otherwise herein, this Option shall terminate in all other respects upon such termination of Participant's service as Director.

(b) *Death of Participant.* If the Participant's service as Director is terminated due to his/her death during the term of this Option, the Participant's legal representative, or the person so entitled under the Participant's last will and testament, or under applicable intestate laws, shall have the right to exercise this Option for the number of Shares vested under Section 4 hereof as of the time of Participant's death, and such right shall expire and this Option shall terminate on the Expiration Date.

6. Provisions of Plan. The terms and provisions of the Plan (including any written amendments made to the Plan from time to time) are hereby incorporated herein by reference. In the event of a conflict between the terms or provisions contained herein and the terms or provisions of the Plan, the applicable terms and provisions of the Plan will govern and prevail; however, in the event of a conflict regarding specific terms and provisions addressing the duration of this Option after termination of Participant's service as Director, the terms and provisions of this Option will govern. Participant is advised to consult his or her tax adviser concerning tax issues regarding the Option.

7. Tax Treatment of Option. The Participant is responsible for any federal, state, local, or foreign tax, including income tax, social security tax, payroll tax, payment on account, or other tax-related withholding with respect to this Option (including the grant, vesting and exercise of the Option and the receipt of Shares and sale of Shares). The Company does not guarantee any

particular tax treatment or results in connection with the grant, vesting or exercise of the Option.

8. Code Section 409A. This Option Agreement is intended to be exempt from the requirements of Internal Revenue Code Section 409A ("Section 409A") and regulations or other authority under Section 409A, and not intended to provide for any deferral of compensation that fails to satisfy the requirements of Section 409A. Notwithstanding any other provision of Option Agreement to the contrary, it is intended that any payment or benefit provided for in this Option Agreement that constitutes "nonqualified deferred compensation," as that term is defined in Code Section 409A, shall be provided and issued in a manner, and at such time and in such form, as complies with the applicable requirements of Section 409A. Any provision in this Option Agreement that would result in the imposition of excise taxes or any other taxes upon Participant under Section 409A shall be void and without effect. To the extent permitted under Section 409A, the parties shall reform the provision, provided such reformation shall not subject Participant to additional tax or interest and shall not require the Company to incur any additional compensation costs as a result of the reformation. In addition, any provision that is required to appear in this Option Agreement for purposes of Section 409A compliance and that is not expressly set forth shall be deemed to be set forth herein, and this Option Agreement shall be administered in all respects as if such provision were expressly set forth. References in this Option Agreement to Section 409A include rules, regulations, and guidance of general application issued by the Department of the Treasury under Section 409A.

9. Notices. Any notice, request, instruction or other document given under this Option Agreement shall be in writing and shall be addressed and delivered in the case of the Company, to the Secretary of the Company at the principal office of the Company and, in the case of the Participant, at the Participant's address as set forth in the attached Notice or to such other address as the Participant may provide in a written notice to the Company, a copy of which shall be on file with the Secretary of the Company.

10. Governing Law. This Option Agreement shall be construed in accordance with and governed by the law of the State of Tennessee, without giving effect to the conflict of law provisions thereof.

11. Miscellaneous. The grant of this Option does not create any contractual or other right to receive future grants of Options, or benefits in lieu of Options, even if the Participant has a history of receiving Options or other stock awards. The granting of this Option and the vesting schedule set forth in the Notice do not constitute a promise, either express or implied, of continued engagement as a Director and shall not interfere with the Company's right or the Participant's right to terminate Participant's directorship at any time, with or without cause.

12. Headings. The headings of the Sections hereof are provided for convenience only and are not to serve as a basis for interpretation or construction, and shall not constitute a part of this Option Agreement.

13. Signature. This Option Agreement shall be deemed executed by the Company and the Participant upon execution by such parties of the attached Notice.

FOR FUTURE USE

**NOTICE OF EXERCISE**

Cumberland Pharmaceuticals Inc.:

The undersigned hereby elects to exercise the purchase rights granted in the attached Option Agreement # ___ and associated Notice of Stock Option Grant. In accordance with the terms thereof, the undersigned elects to purchase _____ shares of common stock of Cumberland Pharmaceuticals Inc. and tenders herewith payment of the purchase price for such shares in full.

Please issue said shares of common stock in the name of the undersigned.

Date: _____

PARTICIPANT:

Signature: _____

Print Name: _____

Social Security No. _____

Phone Number: _____

Delivery Information:

Address: _____

City, State, Zip: _____

$ _____
Payment Attached

**CUMBERLAND PHARMACEUTICALS INC.**
**AMENDED AND RESTATED 2007 LONG-TERM INCENTIVE COMPENSATION PLAN**
**INCENTIVE STOCK OPTION AGREEMENT**

1. Grant of Option. Cumberland Pharmaceuticals Inc. (the "Company"), a Tennessee corporation, hereby grants to the Participant an option (the "Option") to purchase from the Company up to the number of shares of common stock (the "Shares") described in the attached Notice of Stock Option Grant (the "Notice"). This grant is made subject to the terms of the Cumberland Pharmaceuticals Inc. Amended and Restated 2007 Long-Term Incentive Compensation Plan (the "Plan") and the number of shares granted is subject to adjustment as described in the Plan. Unless otherwise defined in this Incentive Stock Option Agreement (the "Option Agreement"), capitalized terms used in this Option Agreement shall have the same meaning as those capitalized terms in the Plan.

2. Exercise Price. If the Option is exercised, the purchase price per Share shall be as shown in the attached Notice.

3. Method of Exercise. The Option granted under this Option Agreement shall be exercisable from time to time, in whole or in part, by written notice as described in Section 9 hereof, accompanied by payment of the purchase price for the Shares which the Participant elects to purchase by cash, check, or such other instrument as the Company may accept. The Company shall make prompt delivery of such Shares, and in no event shall delivery of such shares be made more than thirty (30) days after cash, check or other instrument is accepted by the Company in payment for the Shares, except that if any law or regulation requires the Company to take any action with respect to the Shares specified in such notice before issuance thereof, then the date of delivery of such Shares shall be extended for the period necessary for the Company to take such action.

4. Vesting.

(a) The Option shall vest in accordance with the schedule set forth in the Notice. Employment for only a portion of the vesting period, even if a substantial portion, will not entitle the Participant to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a termination of employment.

(b) Upon the Participant's Employment Termination, the Option, to the extent unvested, shall lapse and be cancelled, and be of no further force and effect, as of midnight of such date, unless the Board resolves (under Section 4(b) of the Plan) to cancel or cause the forfeiture of the Option at an earlier time.

(c) Upon an Acquisition Event and/or a Change in Control Event, the Option will vest to the extent provided in the Plan.

5. Termination of Option; Restrictions on Exercise. Except as otherwise stated in this Agreement, this Option, to the extent not previously exercised, shall expire on the expiration date set forth in the attached Notice (the "Expiration Date"). The following additional provisions shall apply to the exercise of this Option:

(a) *Termination of Employment.* Except as otherwise provided in this Option Agreement or in the Plan, if Participant's employment with the Company and its Related Entities is terminated by the Participant or the Company, the right to exercise this Option (to the extent that it is vested in accordance with the applicable provisions of Section 4 hereof) shall end on the earlier of the following dates: (i) ninety (90) days after such termination or (ii) the expiration date of this Option shown in the Notice. Except as expressly set forth otherwise herein, this Option shall terminate in all other respects upon such termination of employment.

(b) *Death of Participant.* If the Participant's employment with the Company is terminated due to his/her death during the term of this Option, the Participant's legal representative, or the person so entitled under the Participant's last will and testament, or under applicable intestate laws, shall have the right to exercise this Option for the number of Shares vested under Section 4 hereof as of the time of Participant's death, and such right shall expire and this Option shall terminate on the Expiration Date.

6. Provisions of Plan. The terms and provisions of the Plan (including any written amendments made to the Plan from time to time) are hereby incorporated herein by reference. In the event of a conflict between the terms or provisions contained herein and the terms or provisions of the Plan, the applicable terms and provisions of the Plan will govern and prevail; however, in the event of a conflict regarding specific terms and provisions addressing the duration of this Option after termination of employment, the terms and provisions of this Option will govern.

7. Tax Treatment of Option. The Participant is responsible for any federal, state, local, or foreign tax, including income tax, social security tax, payroll tax, payment on account, or other tax-related withholding with respect to this Option (including the grant, vesting and exercise of the Option and the receipt of Shares and sale of Shares). The Company does not guarantee any

particular tax treatment or results in connection with the grant, vesting or exercise of the Option.

8. Code Section 409A. This Option Agreement is intended to be exempt from the requirements of Internal Revenue Code Section 409A ("Section 409A") and regulations or other authority under Section 409A, and not intended to provide for any deferral of compensation that fails to satisfy the requirements of Section 409A. Notwithstanding any other provision of Option Agreement to the contrary, it is intended that any payment or benefit provided for in this Option Agreement that constitutes "nonqualified deferred compensation," as that term is defined in Code Section 409A, shall be provided and issued in a manner, and at such time and in such form, as complies with the applicable requirements of Section 409A. Any provision in this Option Agreement that would result in the imposition of excise taxes or any other taxes upon Participant under Section 409A shall be void and without effect. To the extent permitted under Section 409A, the parties shall reform the provision, provided such reformation shall not subject Participant to additional tax or interest and shall not require the Company to incur any additional compensation costs as a result of the reformation. In addition, any provision that is required to appear in this Option Agreement for purposes of Section 409A compliance and that is not expressly set forth shall be deemed to be set forth herein, and this Option Agreement shall be administered in all respects as if such provision were expressly set forth. References in this Option Agreement to Section 409A include rules, regulations, and guidance of general application issued by the Department of the Treasury under Section 409A.

9. Notices. Any notice, request, instruction or other document given under this Option Agreement shall be in writing and shall be addressed and delivered in the case of the Company, to the Secretary of the Company at the principal office of the Company and, in the case of the Participant, at the Participant's address as set forth in the attached Notice or to such other address as the Participant may provide in a written notice to the Company, a copy of which shall be on file with the Secretary of the Company.

10. Governing Law. This Option Agreement shall be construed in accordance with and governed by the law of the State of Tennessee, without giving effect to the conflict of law provisions thereof.

11. Relation to Other Benefits. Unless otherwise provided, the benefits received by the Participant under this Option Agreement will not be taken into account or treated as normal salary or compensation in determining any benefits to which the Participant may be entitled under any profit sharing, retirement, bonus, long service, or other benefit or compensation plan maintained by the Company, including the amount of any life insurance coverage available to any beneficiary of the Participant under any life insurance plan covering employees of the Company, or as part of the calculation of any severance, resignation, termination, redundancy or end of service payments.

12. Miscellaneous. The grant of this Option does not create any contractual or other right to receive future grants of Options, or benefits in lieu of Options, even if the Participant has a history of receiving Options or other stock awards.

13. Headings. The headings of the Sections hereof are provided for convenience only and are not to serve as a basis for interpretation or construction, and shall not constitute a part of this Option Agreement.

14. Signature. This Option Agreement shall be deemed executed by the Company and the Participant upon execution by such parties of the attached Notice.

FOR FUTURE USE

**NOTICE OF EXERCISE**

Cumberland Pharmaceuticals Inc.:

The undersigned hereby elects to exercise the purchase rights granted in the attached Option Agreement # ___ and associated Notice of Stock Option Grant. In accordance with the terms thereof, the undersigned elects to purchase _____ shares of Common Stock of Cumberland Pharmaceuticals Inc. and tenders herewith payment of the purchase price for such shares in full.

Please issue said shares of Common Stock in the name of the undersigned.

Date: _____

PARTICIPANT

Signature:

Print Name:

Address:

City, State,
Zip:

Social Security
Number:

Phone
Number:

$ _____
Payment Attached

**CUMBERLAND PHARMACEUTICALS INC.**
**AMENDED AND RESTATED 2007 LONG-TERM INCENTIVE COMPENSATION PLAN**
**NON-STATUTORY STOCK OPTION AGREEMENT**

1. Grant of Option. Cumberland Pharmaceuticals Inc. (the "Company"), a Tennessee corporation, hereby grants to the Participant an option (the "Option") to purchase from the Company up to the number of shares of common stock (the "Shares") described in the attached Notice of Stock Option Grant (the "Notice"). This grant is made subject to the terms of the Cumberland Pharmaceuticals Inc. Amended and Restated 2007 Long-Term Incentive Compensation Plan (the "Plan") and the number of shares granted is subject to adjustment as described in the Plan. Unless otherwise defined in this Non-Statutory Stock Option Agreement (the "Option Agreement"), capitalized terms used in this Option Agreement shall have the same meaning as those capitalized terms in the Plan. This Option is *not* intended to qualify as an incentive stock option within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended.

2. Exercise Price. If the Option is exercised, the purchase price per Share shall be as shown in the attached Notice.

3. Method of Exercise. The Option granted under this Option Agreement shall be exercisable from time to time, in whole or in part, by written notice as described in Section 9 hereof, accompanied by payment of the purchase price for the Shares which the Participant elects to purchase by cash, check, or such other instrument as the Company may accept. The Company shall make prompt delivery of such Shares, and in no event shall delivery of such shares be made more than thirty (30) days after cash, check or other instrument is accepted by the Company in payment for the Shares, except that if any law or regulation requires the Company to take any action with respect to the Shares specified in such notice before issuance thereof, then the date of delivery of such Shares shall be extended for the period necessary for the Company to take such action.

4. Vesting.

(a) The Option shall vest in accordance with the schedule set forth in the attached Notice. Employment (or consulting) for only a portion of the vesting period, even if a substantial portion, will not entitle the Participant to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a termination of employment (or consulting engagement).

(b) Upon the Participant's Employment Termination (or termination of the consulting engagement), the Option, to the extent unvested, shall lapse and be cancelled, and be of no further force and effect, as of midnight of such date, unless the Board resolves (under Section 4(b) of the Plan) to cancel or cause the forfeiture of the Option at an earlier time.

(c) Upon an Acquisition Event and/or a Change in Control Event, the Option will vest to the extent provided in the Plan.

5. Termination of Option; Restrictions on Exercise. Except as otherwise stated in this Agreement, this Option, to the extent not previously exercised, shall expire on the expiration date set forth in the attached Notice (the "Expiration Date"). The following additional provisions shall apply to the exercise of this Option:

(a) *Termination of Employment (or Consulting Engagement).* Except as otherwise provided in this Option Agreement or in the Plan, if Participant's employment with the Company and its Related Entities is terminated by the Participant or the Company (or if the Participant's consulting engagement is terminated), the right to exercise this Option (to the extent that it is vested in accordance with the applicable provisions of Section 4 hereof) shall end on the earlier of the following dates: (i) ninety (90) days after such termination or (ii) the expiration date of this Option shown in the attached Notice. Except as expressly set forth otherwise herein, this Option shall terminate in all other respects upon such termination of employment (or consulting engagement).

(b) *Death of Participant.* If the Participant's employment (or consulting engagement) with the Company is terminated due to his/her death during the term of this Option, the Participant's legal representative, or the person so entitled under the Participant's last will and testament, or under applicable intestate laws, shall have the right to exercise this Option for the number of Shares vested under Section 4 hereof as of the time of Participant's death, and such right shall expire and this Option shall terminate on the Expiration Date.

6. Provisions of Plan. The terms and provisions of the Plan (including any written amendments made to the Plan from time to time) are hereby incorporated herein by reference. In the event of a conflict between the terms or provisions contained herein and the terms or provisions of the Plan, the applicable terms and provisions of the Plan will govern and prevail; however, in the event of a conflict regarding specific terms and provisions addressing the duration of this Option after termination of employment (or consulting engagement), the terms and provisions of this Option will govern.

7. Tax Treatment of Option. The Participant is responsible for any federal, state, local, or foreign tax, including income tax, social security tax, payroll tax, payment on account, or other tax-related withholding with respect to this Option (including the grant, vesting and exercise of the Option and the receipt of Shares and sale of Shares). The Company does not guarantee any particular tax treatment or results in connection with the grant, vesting or exercise of the Option.

8. Code Section 409A. This Option Agreement is intended to be exempt from the requirements of Internal Revenue Code Section 409A ("Section 409A") and regulations or other authority under Section 409A, and not intended to provide for any deferral of compensation that fails to satisfy the requirements of Section 409A. Notwithstanding any other provision of Option Agreement to the contrary, it is intended that any payment or benefit provided for in this Option Agreement that constitutes "nonqualified deferred compensation," as that term is defined in Code Section 409A, shall be provided and issued in a manner, and at such time and in such form, as complies with the applicable requirements of Section 409A. Any provision in this Option Agreement that would result in the imposition of excise taxes or any other taxes upon Participant under Section 409A shall be void and without effect. To the extent permitted under Section 409A, the parties shall reform the provision, provided such reformation shall not subject Participant to additional tax or interest and shall not require the Company to incur any additional compensation costs as a result of the reformation. In addition, any provision that is required to appear in this Option Agreement for purposes of Section 409A compliance and that is not expressly set forth shall be deemed to be set forth herein, and this Option Agreement shall be administered in all respects as if such provision were expressly set forth. References in this Option Agreement to Section 409A include rules, regulations, and guidance of general application issued by the Department of the Treasury under Section 409A.

9. Notices. Any notice, request, instruction or other document given under this Option Agreement shall be in writing and shall be addressed and delivered in the case of the Company, to the Secretary of the Company at the principal office of the Company and, in the case of the Participant, at the Participant's address as set forth in the attached Notice or to such other address as the Participant may provide in a written notice to the Company, a copy of which shall be on file with the Secretary of the Company.

10. Governing Law. This Option Agreement shall be construed in accordance with and governed by the law of the State of Tennessee, without giving effect to the conflict of law provisions thereof.

11. Relation to Other Benefits. Unless otherwise provided, the benefits received by the Participant under this Option Agreement will not be taken into account or treated as normal salary or compensation in determining any benefits to which the Participant may be entitled under any profit sharing, retirement, bonus, long service, or other benefit or compensation plan maintained by the Company, including the amount of any life insurance coverage available to any beneficiary of the Participant under any life insurance plan covering employees of the Company, or as part of the calculation of any severance, resignation, termination, redundancy or end of service payments.

12. Miscellaneous. The grant of this Option does not create any contractual or other right to receive future grants of Options, or benefits in lieu of Options, even if the Participant has a history of receiving Options or other stock awards.

13. Headings. The headings of the Sections hereof are provided for convenience only and are not to serve as a basis for interpretation or construction, and shall not constitute a part of this Option Agreement.

14. Signature. This Option Agreement shall be deemed executed by the Company and the Participant upon execution by such parties of the attached Notice.

FOR FUTURE USE

**NOTICE OF EXERCISE**

Cumberland Pharmaceuticals Inc.:

The undersigned hereby elects to exercise the purchase rights granted in the attached Option Agreement # ___ and associated Notice of Stock Option Grant (Non-Statutory Stock Option). In accordance with the terms thereof, the undersigned elects to purchase _____ shares of Common Stock of Cumberland Pharmaceuticals Inc. and tenders herewith payment of the purchase price for such shares in full.

Please issue said shares of Common Stock in the name of the undersigned.

Date: _____

PARTICIPANT

Signature:

Print Name:

Address:

City, State, Zip:

Social Security Number:

Phone Number:

$ _____
Payment Attached

Exhibit 10.11

March 8, 2013

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 1st, 2013, 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 thirty-five thousand dollars ($435,000.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2013. 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. For a period of one year 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 in competition with, or reasonably likely to become in competition with, the Company.

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. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 8th of March, 2013:

/s/ A.J. Kazimi

A.J. Kazimi

Exhibit 10.12

March 8, 2013

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 1st, 2013, 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 one hundred ninety-two thousand five hundred dollars ($192,500.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2013. 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.

1. 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. For a period of one year 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 in competition with, or reasonably likely to become in competition with, the Company.

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. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

By: A.J. Kazimi
Chief Executive Officer

Accepted as to all terms and conditions
as of the 8th of March, 2013:

/s/ James L. Herman

James L. Herman

Exhibit 10.13

March 8, 2013

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 1st, 2013, 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 seventeen thousand two hundred fifty dollars ($317,250.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2013. 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. For a period of one year 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 in competition with, or reasonably likely to become in competition with, the Company.

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. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 8th of March, 2013:

/s/ Leo Pavliv

Leo Pavliv

Exhibit 10.26

March 8, 2013

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

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

Dear Marty:

Effective January 1, 2013, 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 and 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 forty-two thousand one hundred dollars ($242,100.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2013. 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. For a period of one year 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 in competition with, or reasonably likely to become in competition with, the Company.

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. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 8th of March, 2013:

/s/ Martin E. Cearnal

Martin E. Cearnal

Exhibit 10.27

March 8, 2013

Rick S. Greene
2525 West End Ave, Suite 950
Nashville, TN 37203

Re: Employment of Rick S. Greene as Vice President, Finance & Accounting and Chief Financial Officer by Cumberland Pharmaceuticals Inc.

Dear Rick,

Effective January 1, 2013, 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, Finance & Accounting and 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 two hundred thirty-seven thousand dollars ($237,000.00), payable in arrears in equal monthly installments on the last day of each calendar month of 2013. 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.

(a) 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.

(b) Assuming you maintain an active license, the Company agrees to pay the following expenses which are professional costs associated with your CPA: Tennessee Department of Revenue Professional Privilege Tax, Continuing Professional Education (the Company will reimburse 32 hours of the 40 hours required per year), Tennessee Society of CPAs Annual Membership (excludes elective fees), and the Tennessee State Board of Accounting License Fee.

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. For a period of one year 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 in competition with, or reasonably likely to become in competition with, the Company.

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. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 8th of March, 2013:

/s/ Rick S. Greene

Rick S. Greene

**EXHIBIT 10.31**

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

# SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this 9th day of November, 2012 ("Effective Date") by and between Cumberland Pharmaceuticals Inc., a Tennessee corporation having its principal place of business at 2525 West End Ave., Suite 950, Nashville, Tennessee 37023 ("Cumberland"), Paddock Laboratories, LLC, a Delaware limited liability company having its principal place of business at 3940 Quebec Avenue N, Minneapolis, Minnesota 55427 ("Paddock") and Perrigo Company, a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allergan, Michigan 49010 ("Perrigo"). Each of Cumberland, Paddock and Perrigo may be referred to herein individually as a "Party" and collectively as the "Parties", and each of Perrigo and Paddock may be referred to herein as a "Defendant" and together as the "Defendants".

## RECITALS

WHEREAS, Cumberland sells an N-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form, free of EDTA (edetate disodium), pursuant to supplemental New Drug Application 21-539 (the "Acetadote® EDTA-Free NDA") under the trademark Acetadote® (or any replacement trademark) (the "Acetadote® EDTA-Free Product"), and Cumberland previously sold an N-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form containing EDTA under the trademark Acetadote® (the "Acetadote® EDTA Product"), which Acetadote® EDTA Product Cumberland has withdrawn from the market due to safety concerns and which Cumberland has delisted from the U.S. Food and Drug Administration's Orange Book;

WHEREAS, Cumberland owns the following U.S. Patent relating to the Acetadote® products: 8,148,356 (the "'356 Patent");

WHEREAS, Paddock filed with the FDA (as defined below) ANDA (as defined below) [***] (the "Paddock ANDA") requesting approval from the FDA to market a generic product containing N-acetylcysteine as its active ingredient in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form and [***] (the "Paddock Generic Product");

WHEREAS, Perrigo, the parent company of Paddock, filed with the FDA ANDA [***] (the "Perrigo ANDA") requesting approval from the FDA to market a generic product containing N-acetylcysteine as its active ingredient in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form [***] (the "Perrigo Generic Product");

WHEREAS, Cumberland filed Civil Action No. 12-CV-00619 (LPS) in the United States District Court for the District of Delaware (the "Delaware Court"), in which Cumberland alleges that Defendants, by filing of the Paddock ANDA, infringed the '356 Patent as specified therein (the "First Action");

WHEREAS, Cumberland filed Civil Action No. 12-CV-06327 in the United States District Court for the Northern District of Illinois Eastern Division (the "Illinois Court"), in which Cumberland alleges that Perrigo, by filing of the Perrigo ANDA, infringed the '356 Patent as specified therein (the "Second Action", and with the First Action, the "Actions"); and

WHEREAS, each Party desires to resolve, compromise and settle the Actions on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the covenants exchanged herein and other good and valuable consideration, the sufficiency and receipt of all of which are hereby acknowledged, Defendants and Cumberland intending to be legally bound hereby agree as follows:

I. DEFINITIONS

"'356 Patent" has the meaning set forth in the Recitals.

"Acetadote® EDTA-Free NDA" has the meaning set forth in the Recitals.

"Acetadote® EDTA-Free Product" has the meaning set forth in the Recitals.

"Acetadote® EDTA Product" has the meaning set forth in the Recitals.

"Actions" has the meaning set forth in the Recitals.

"Affiliate(s)" shall mean, with respect to any entity, any corporation, association, company, organization or other entity which directly or indirectly controls, is controlled by or under common control with Paddock, Perrigo or Cumberland, as the case may be. For purposes of this definition, "control" means the ability, directly or indirectly, through ownership of securities, by agreement, or by any other method, to direct more than fifty (50%) of the outstanding equity votes of any entity, whether or not represented by securities, or to otherwise control the management decisions of any entity.

"Agreement" has the meaning set forth in the introductory paragraph hereof.

"ANDA" shall mean Abbreviated New Drug Application as defined in 21 CFR § 355(j) et seq., as amended from time to time

"Commercially Reasonable Efforts" shall mean that degree of effort, expertise and resources which a person of ordinary skill, ability and experience in the matters addressed herein would typically utilize and otherwise apply with respect to fulfilling the obligations assumed hereunder.

"Cumberland" has the meaning set forth in the introductory paragraph hereof.

"Defendant" and "Defendants" have the meaning set forth in the introductory paragraph hereof.

"Defendants' Releasees" has the meaning set forth in Section 4.1.

"Delaware Court" has the meaning set forth in the Recitals.

"Dismissal Effective Date" has the meaning set forth in Section 2.1.

"Effective Date" has the meaning set forth in the introductory paragraph hereof.

"FDA" shall mean the Food and Drug Administration of the United States of America.

"Illinois Court" has the meaning set forth in the Recitals.

"Law" shall mean any local, state or federal rule, regulation, statute or law.

"License and Supply Agreement" has the meaning set forth in Section 2.1.

"Licensed Patents" shall mean the '356 Patent, and all continuations, divisionals and extensions thereof, and all reexaminations and reissues thereof..

"Losses" has the meaning set forth in Section 4.1.

"NDA" means a New Drug Application (as more fully described in 21 C.F.R. 314.50 et seq. or its successor regulation) and all amendments and supplements thereto submitted to the FDA.

"Other Acetadote® Patent Litigations" has the meaning set forth in Section 6.3.

"Paddock" has the meaning set forth in the introductory paragraph hereof.

"Paddock ANDA" has the meaning set forth in the Recitals.

"Paddock Generic Product" has the meaning set forth in the Recitals.

"Parties" shall have the meaning set forth in the introductory paragraph hereof.

"Perrigo" has the meaning set forth in the introductory paragraph hereof.

"Perrigo ANDA" has the meaning set forth in the Recitals.

"Perrigo Generic Product" has the meaning set forth in the Recitals.

"Plaintiff's Releasees" has the meaning set forth in Section 4.1.

"Stipulations of Dismissal" has the meaning set forth in Section 2.1.

"Term" has the meaning set forth in Section 8.1.

"Territory" shall mean the United States of America, its territories, commonwealths and possessions.

"Third Party" shall mean any person, entity or other organization (other than the Parties and their respective Affiliates).

Any other capitalized terms used but not defined in this Article I shall have the meanings assigned to such terms in the body of this Agreement.

## II. DISMISSAL OF LITIGATION

2.1. On the Effective Date, the Parties shall execute and deliver to each other the License and Supply Agreement attached as Exhibit 2 hereto (the "License and Supply Agreement"). Within three (3) business days of the Effective Date, the respective Parties will execute and file with the Delaware Court and Illinois Court, all necessary papers, including the Stipulations of Dismissal attached as Exhibit 1, required to dismiss without prejudice all claims and counterclaims, motions, and petitions asserted in the Actions (the "Stipulations of Dismissal"). The date upon which the Actions are dismissed against all Parties pursuant to the Stipulations of Dismissal shall be referred to herein as the "Dismissal Effective Date". If for any reason the courts in the Actions do not approve the Stipulations of Dismissal and enter them as orders of the courts, the Parties agree to confer promptly in good faith in an effort to modify the Stipulations of Dismissal and this Agreement or take such other action as is required to overcome the objections of the courts.

2.2. Nothing herein or in the License and Supply Agreement shall be deemed to be Cumberland's consent to or approval of any ANDA in the United States or any similar application or filing in any foreign jurisdiction by Defendants or any of their Affiliates, or to permit Defendants or any of their Affiliates the right to reference or cross-reference any New Drug Application, regulatory filing or other proprietary materials or information.

## III. WITHDRAWAL OF ANDA; PATENT MATTERS

3.1. Paddock acknowledges, agrees and admits, on behalf of itself and its Affiliates, that (a) the Paddock Generic Products infringe the '356 Patent, (b) the '356 Patent is valid and (c) the '356 Patent is enforceable. Perrigo acknowledges, agrees and admits, on behalf of itself and its Affiliates, that (i) the Perrigo Generic Products infringe the '356 Patent, (ii) the '356 Patent is valid and (iii) the '356 Patent is enforceable.

3.2. No later than three (3) business days after the Effective Date, Paddock shall take all steps necessary to withdraw and cancel the Paddock ANDA filed with the FDA. During the term of the License and Supply Agreement, Paddock agrees that neither it nor any of its Affiliates shall refile the Paddock ANDA with the FDA or file any ANDA that references the Acetadote® EDTA Product or Acetadote® EDTA-Free Product, provided that the foregoing shall not preclude Perrigo from seeking the approval of or maintaining the Perrigo ANDA with the FDA.

3.3. From and after the Effective Date and continuing for the terms of this Agreement and the License and Supply Agreement (whichever is longer), each Defendant agrees, on behalf of itself and its Affiliates and its and their respective successors and assigns, not to challenge the validity, enforceability, ownership or patentability of any of the Licensed Patents, or the infringement of any of the Licensed Patents by the manufacture, use and sale of the Perrigo Generic Product and the Paddock Generic Product, including by suing, directly or indirectly, Cumberland or any of its Affiliates in any action in any forum seeking an order or decision that any of the Licensed Patents is invalid or unenforceable, is not exclusively owned by Cumberland and/or its Affiliates, or that the manufacture, use or sale of the Perrigo Generic Product or Paddock Generic Product does not infringe any of the Licensed Patents. Further, each Defendant agrees, on behalf of itself and its Affiliates and its and their respective successors and assigns, not to seek reexamination of any of the Licensed Patents in any court or administrative agency having jurisdiction to consider the issue. Further, Defendants will not, and will cause their Affiliates to not, directly or indirectly participate in, support or assist any such challenges by any person.

3.4. From and after the Effective Date and continuing for the terms of this Agreement and the License and Supply Agreement (whichever is longer), neither of the Defendants nor any of their respective Affiliates, nor any of their respective officers, or employees, will assist, encourage, or provide any information or support to, any entity attacking the validity or enforceability or defending against the alleged infringement of any of the Licensed Patents, except as compelled by Law. Neither of the Defendants nor any of their respective Affiliates, nor any of their respective officers, or employees, will encourage any expert witnesses who are under their control to assist, encourage, or provide any information or support to any entity attacking the validity or enforceability or defending against the alleged infringement of the any of the Licensed Patents or consent to any of the foregoing, except as compelled by Law.

3.5. In return for the rights, releases, and other consideration set forth in this Agreement and the License and Supply Agreement, except as permitted under the License and Supply Agreement, the Defendants agree that neither the Defendants nor any of their Affiliates will market, offer for sale, sell or distribute any Perrigo ANDA Product or Paddock ANDA Product or any other generic N-acetylcysteine product that references a product covered by any Cumberland NDA as the reference listed drug, or encourage, assist or participate in the profits from the marketing, offer for sale, for sale or distribution of a generic N-acetylcysteine that references a product covered by any Cumberland NDA as the reference listed drug, other than pursuant to the License and Supply Agreement.

3.6. Notwithstanding this Article III, nothing herein shall prevent Perrigo from maintaining the paragraph IV certification under Section 505(j)(2)(A)(vii)(IV) of the FFDCA (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) that is contained in the Perrigo ANDA.

## IV. **RELEASE OF CLAIMS**

4.1. Effective on the Dismissal Effective Date, Defendants, their Affiliates and each of their respective predecessors, successors, assigns, officers, directors, managers, employees and trustees (collectively, the "Defendants' Releasees") fully, finally and forever release, relinquish,

acquit and discharge Cumberland, its Affiliates and each of their respective predecessors, successors, assigns, officers, directors, managers, employees and trustees (collectively, the "Plaintiff's Releasees") of and from, and covenant not to sue, not to assign to any other entity or person a right to sue and not to authorize any other entity or person to sue any Plaintiff's Releasee for any and all claims, counterclaims, actions, causes of action, suits, defenses, judgments, debts, offsets, accounts, torts, damages, demands and liabilities whatsoever, including costs, expenses, and attorneys' fees (collectively, "Losses") of every name and nature, both at law and in equity, for acts, transactions, facts, matters or omissions whether known or unknown, foreseen or unforeseen, accrued as of the Dismissal Date, relating to (i) any and all claims, liabilities, defenses or counterclaims in the Actions with respect to any cause of action asserted therein arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product; (ii) any and all claims, liabilities, defenses or counterclaims relating to the issues in the Actions and arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product that could have been asserted in the Actions; (iii) any claim or liability that has arisen between Cumberland and Defendants relating to the issues in the Actions and arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product, including but not limited to any antitrust or unfair competition claims relating to the '356 Patent or the Actions; and (iv) any damages or other remedies flowing from (i)–(iii) above. Notwithstanding this release, nothing herein shall preclude Defendants' Releasees from asserting Losses arising from any activities occurring after the Dismissal Effective Date, including breach of this Agreement or the License and Supply Agreement, and all such claims are reserved.

4.2. Effective on the Dismissal Effective Date, Cumberland and each of the other Plaintiff's Releasees fully, finally and forever release, relinquish, acquit and discharge Defendants and each of the other Defendants' Releasees of and from, and covenant not to sue, not to assign to any other entity or person a right to sue and not to authorize any other entity or person to sue any Defendants' Releasees for any and all Losses of every name and nature, both at law and in equity, for acts, transactions, facts, matters or omissions whether known or unknown, foreseen or unforeseen, accrued as of the Dismissal Date, relating to (i) any and all claims, liabilities, defenses or counterclaims in the Actions with respect to any cause of action asserted therein arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product; (ii) any and all claims, liabilities, defenses or counterclaims relating to the issues in the Actions and arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product that could have been asserted in the Actions; (iii) any claim or liability that has arisen between Cumberland and Defendants relating to the issues in the Actions and arising out of or relating to the Perrigo ANDA or the Paddock ANDA or their filing or the Perrigo Generic Product or Paddock Generic Product; and (iv) any damages or other remedies flowing from (i)–(iii) above. Notwithstanding this release, nothing herein shall preclude Plaintiff's Releasees from asserting Losses arising from any activities occurring after the Dismissal Effective Date, including breach of this Agreement or the License and Supply Agreement, and all such claims are reserved.

4.3. Each Party hereby expressly waives any and all provisions, rights and benefits conferred by §1542 of the California Civil Code, or by any law of the United States or principle of common law that is similar, comparable or equivalent to §1542 of the California Civil Code, with respect to the matters released in Sections 4.1 and 4.2. Each Party represents, warrants and covenants that it has not heretofore assigned or transferred, and will not assign or otherwise transfer, to any person or entity any matters released by such Party in Sections 4.1 and 4.2, as the case may be, and such Party agrees to indemnify and hold harmless the other Parties from and against all such released matters arising from any such alleged or actual assignment or transfer.

4.4. Nothing in this Agreement shall preclude by release, contract, claim or issue preclusion or otherwise, Cumberland from raising any infringement assertion or Defendants from raising a non-infringement defense of any of the Licensed Patents or their foreign equivalents in connection with any product that was not the subject of the Actions.

4.5. Nothing in this Agreement releases or shall be deemed to release any Party from any violation of any provision of this Agreement or the License and Supply Agreement, and each Party is entitled to enforce the obligations hereunder and thereunder.

## V. REGULATORY MATTERS

5.1. Within ten (10) business days following the execution of this Agreement, the Parties shall submit this Agreement and the License and Supply Agreement to the Federal Trade Commission of the United States ("FTC") and the Department of Justice of the United States ("DOJ" and, together with FTC, the "Agencies") for review pursuant to Section 1112 of the Medicare Prescription Drug Improvement and Modernization Act of 2003. The Parties shall promptly in good faith coordinate the foregoing filings and respond promptly in good faith to any requests for additional information made by either of such Agencies. Each Party reserves the right to communicate with the FTC and/or DOJ regarding such filings as it believes appropriate. Each Party will keep the other Parties informed of such responses and communications and shall not disclose any confidential information of the other Parties without such other Party's consent, which will not be unreasonably withheld or delayed. In the event that the FTC or DOJ threatens to institute a judicial or administrative proceeding raising material objections against any Party related to this Agreement or the License and Supply Agreement, or any subpart thereof, the Parties shall use Commercially Reasonable efforts to modify this Agreement and/or the License and Supply Agreement to address the objections raised by the FTC or DOJ while maintaining the material terms of the transaction.

5.2. If at any time this Agreement is rendered null and void with respect to the Territory, or any portion thereof by the actions of a Third Party or government entity, or if the Parties cannot fulfill their respective obligations with respect to this Agreement, it is the intent of the Parties that no Party will be in any way prejudiced with respect to its claims, causes of action, defenses and counterclaims in the Actions, and no consent judgment, order or dismissal entered by a Party pursuant to this Agreement in the Territory or portion thereof, as applicable, will be deemed an admission on the part of such Party, and the Parties would be free to assert any and all claims and defenses with respect to the reinstated portion of the Actions in any future litigation. In particular, if this Agreement is terminated for any reason: (a) Cumberland will have the right

to recommence or refile the First Action before the Delaware Court and the Second Action before the Illinois Court; (b) each Party consents, with respect to any such refiled Action or declaratory judgment action, to (i) the jurisdiction of the Delaware Court with respect to the subject matter of the First Action and the jurisdiction of the Illinois Court with respect to the subject matter of the Second Action, and irrevocably and unconditionally waives any objection to the laying of venue in such courts or that the Actions or declaratory judgment action have been brought in an inconvenient forum, (ii) waive any statute of limitations defenses in connection with such recommenced or refiled Actions or declaratory judgment action, (iii) the License and Supply Agreement will immediately terminate; (iv) Perrigo and Paddock will have the right to defend themselves on any basis, including challenging the infringement, validity and enforceability of the Licensed Patents; and (v) the Agreement will not be available as evidence in any proceeding. Termination of this Agreement shall not release any Party from liability (in an action at law or otherwise) for any obligations, liabilities or damages incurred prior to such termination and arising out of a breach of any of its representations, warranties, covenants or agreements set forth in this Agreement. In addition, Article VI shall survive any termination of this Agreement.

## VI. **CONFIDENTIALITY**

6.1. The Parties hereby agree that, except to enforce this Agreement or unless otherwise agreed to by the Parties in writing or required by law, including as required by a court, government or other regulatory agency, that the Parties, their Affiliates and their respective employees, officers, directors and other representatives shall not publish or otherwise disclose the contents of this Agreement and/or any exhibits attached hereto. The Parties may state publicly that the Actions have been settled on terms that are confidential, but no public announcement concerning the terms or subject matter of this Agreement shall be made, either directly or indirectly, by any Party, except as set forth in Section 6.2.

6.2. If either Party determines that a release of information concerning this Agreement is required by applicable Law, legal process (including without limitation any subpoena or discovery ordered by any court of competent jurisdiction) or by stock exchange rules, it shall notify the other in writing at least ten (10) days (or such shorter period where legally required) before the time of the proposed release; it being understood and agreed that each such Party that proposes to make any such release of information shall use its Commercially Reasonable Efforts to ensure that any such release shall not include more information regarding the existence or terms of this Agreement than is required by Law, legal process or by stock exchange rule and shall seek the highest level of confidentiality then available for such information proposed to be released. Such notice shall include the exact text of the proposed release and the time and manner of the release. At the other Party’s request, and before the release, the Party desiring to release further information shall consult with the other Party on the necessity for the disclosure and the text of the proposed further disclosure. Perrigo and Cumberland recognize that in addition to the other exceptions set forth herein, disclosure of this Agreement to IRS and other tax authorities may be required, and Perrigo and Cumberland each waives the requirements of this subsection with respect to disclosure to such entities.

6.3. Defendants acknowledge that Cumberland is currently engaged in ANDA-related patent litigations with Third Parties concerning infringement of the '356 Patent on the basis of marketing and selling of generic versions of Cumberland's Acetadote® product in the United States, and may become engaged in future patent litigations concerning infringement of the '356 Patent on the basis of marketing and selling of generic versions of Cumberland's Acetadote® product in the United States (collectively, "Other Acetadote® Patent Litigations"). Defendants recognize that parties to the Other Acetadote® Patent Litigations may request a copy of this Agreement and the License and Supply Agreement in connection with discovery and that Cumberland may be compelled to provide such copies. Defendants further acknowledge that Cumberland may be required to provide a copy of this Agreement and the License and Supply Agreement under the terms of other settlement agreements. In either instance, Cumberland agrees to use Commercially Reasonable Efforts to notify Defendants at least two (2) weeks in advance of any proposed production of the terms of this Agreement to parties in any such litigation. Cumberland may disclose such terms to a third party litigant with whom Cumberland is engaged in an Other Acetadote® Patent Litigations to the extent reasonably necessary to settle, or to comply with settlement of, any such Other Acetadote® Patent Litigations, subject to any such third party litigant agreeing to keep any terms so disclosed confidential. Defendants hereby consent to Cumberland's disclosure of the terms of this Agreement and the License and Supply Agreement to any such third party litigant subject to appropriate confidentiality limitations no less stringent than those set forth herein.

## VII. REPRESENTATIONS AND WARRANTIES

7.1. Mutual Representations and Warranties. Cumberland represents and warrants to Defendants, as of the date of this Agreement, and each of the Defendants represents and warrants to Cumberland, as of the date of this Agreement, that:

7.1.1. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

7.1.2. Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

7.1.3. This Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

7.1.4. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

7.1.5. Such Party has been advised by its counsel of its rights and obligations under this Agreement and enters into this Agreement freely, voluntarily, and without duress; and

7.1.6. Such Party is not relying on any promises, inducements, or representations other than those provided herein.

7.2. Cumberland Representations and Warranties. Cumberland represents and warrants to Defendants that, as of the date of this Agreement, Cumberland is the owner of the '356 Patent.

7.3. No Other Warranties. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTIONS 7.1 AND 7.2 OF THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

## VIII. **MISCELLANEOUS**

8.1. Waiver. A waiver by any Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of any Party.

8.2. No Admission of Liability. Except as provided in Article III, nothing in this Agreement shall be construed as or deemed to be an admission by the Parties hereto, or any of them, of any unlawful, improper, or actionable conduct or omission by any of them, and each Party hereto expressly denies liability of any kind whatsoever.

8.3. Choice of Law and Remedies. This Agreement shall be governed and interpreted in accordance with the laws of the State of Delaware without regard to conflicts of law principles. The Delaware Court (and any appropriate appellate court) shall have exclusive jurisdiction in all matters arising under this Agreement, and the Parties hereto expressly consent and submit to the personal and subject matter jurisdiction of such courts. This Agreement does not limit or restrict the remedies available to any Party for the breach by another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this Agreement, including claims for patent infringement.

8.4. Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and assigns. This Agreement and the rights granted herein may not be assigned or transferred (whether by contract, operation of law or otherwise) by Perrigo or Paddock without the prior written consent of Cumberland, provided that each of Perrigo and Paddock may assign or transfer its rights and obligations hereunder to any Affiliate or to a successor or assignee of all or substantially all of its relevant prescription pharmaceutical business or assets, without Cumberland's prior consent, but only if such Affiliate, successor or assignee is not at such time involved in a litigation or other legal proceeding with Cumberland. Cumberland may assign or transfer its rights and obligations hereunder to any Affiliate or to a successor or assignee of all or substantially all of its relevant prescription pharmaceutical business or assets, without Perrigo's or Paddock's prior consent.

8.5. Costs. Each Party shall each bear its own costs and legal fees associated with the Actions and the negotiation and preparation of, and completion of tasks contemplated under, this Agreement and the License and Supply Agreement.

8.6. Severability. If any of the terms or provisions of this Agreement are in or come into conflict with any applicable Law within the Territory then such term or provision shall be deemed inoperative to the extent it may conflict therewith and shall be deemed to be modified to conform with such Law unless such modification would render the affected provision inconsistent with or contrary to the intent of the Parties. However, in the event the terms and conditions of this Agreement are materially altered as a result of this subsection, the Parties shall in good faith attempt to renegotiate said terms and conditions to resolve any disputes related thereto.

8.7. Integration. This Agreement, the Stipulations of Dismissal and the License and Supply Agreement shall constitute the entire agreement among the Parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both oral and written, among the Parties with respect to such subject matter.

8.8. Territory. The Parties acknowledge and agree that this Agreement and the License and Supply Agreement, and the fact that the Parties have entered into this Agreement and the License and Supply Agreement and consummated the transactions contemplated hereby, shall not have any effect outside the United States and its territories and possessions. The Parties hereby agree that neither this Agreement nor the License and Supply Agreement nor those facts may be proffered, or be referred to in any testimonial or other evidence, by any Party or any of their Affiliates at any trial, action or other proceeding regarding any foreign equivalents of the Perrigo Generic Product, Paddock Generic Product or foreign counterparts of the ‘356 Patent or any other Licensed Patent. Nothing herein shall be construed as an admission or waiver as to any factual or legal matter by any Party or their Affiliates with respect to any jurisdiction outside of the United States.

8.9. Amendments. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

8.10. Descriptive Headings. The captions and descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

8.11. Third Party Benefit. Except as otherwise expressly set forth herein, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party.

8.12. Notice. Any notices or reports required or permitted under this Agreement shall be in writing and shall be deemed to have been given for all purposes if mailed by first class certified or registered mail or transmitted electronically be facsimile with mailed confirmation copy to the following address of each Party:

| | |
|---|---|
| For Perrigo: | Perrigo Company<br>515 Eastern Avenue<br>Allegan, MI 49010<br>Attn: General Counsel |
| For Paddock: | Paddock Laboratories, LLC<br>c/o Perrigo Company<br>515 Eastern Avenue<br>Allegan, MI 49010<br>Attn: General Counsel |
| For Cumberland: | Cumberland Pharmaceuticals Inc.<br>2525 West End Ave., Suite 950,<br>Nashville, Tennessee 37023<br>Attn: Chief Executive Officer |

or to such other addresses as shall have been subsequently furnished by written notice to the other Parties.

8.13. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

8.14. Counterparts. This Agreement may be executed in any number of signature page counterparts transmitted via facsimile, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same Agreement.

8.15. Interpretation.

8.15.1. The singular form of any noun or pronoun shall include the plural when the context in which such a word is used is such that it is apparent the singular is intended to include the plural or vice versa. Neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The word “any” shall mean “any and all” unless otherwise clearly indicated by context. “$” as used in this Agreement means the lawful currency of the United States of America. Where a Party’s consent is required hereunder, except as otherwise specified herein, such Party’s consent may be granted

or withheld in such Party's sole discretion. Derivative forms of any capitalized term defined herein shall have meanings correlative to the meaning specified herein.

8.15.2. Unless the context requires otherwise: (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (iii) any reference herein to any Person shall be construed to include the Person's successors and permitted assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Appendices or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Appendices or Exhibits of this Agreement.

SIGNATURES FOLLOW ON NEXT PAGE

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in duplicate by their duly authorized representatives in the places provided below.

Perrigo Company

By /s/ Andrew Solomon

Title Assistant Secretary

Date November 10, 2012

Cumberland Pharmaceuticals Inc.

By /s/ A.J. Kazimi

Title Chief Executive Officer

Date November 12, 2012

Paddock Laboratories, LLC

By /s/ Andrew Solomon

Title Assistant Secretary

Date November 10, 2012

**EXHIBIT 1: STIPULATIONS OF DISMISSAL**

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

| | | |
|---|---|---|
| CUMBERLAND PHARMACEUTICALS INC. | ) | |
| | ) | |
| Plaintiff, | ) | No. 12-CV-00619 |
| | ) | |
| v. | ) | |
| | ) | |
| PERRIGO COMPANY | ) | Hon. [____] |
| PADDOCK LABORATORIES, LLC ) | | |
| Defendants | ) | |
| | ) | |
| | ) | |

**JOINT STIPULATION OF DISMISSAL**

Pursuant to Federal Rule of Civil Procedure 41(a)(1), Plaintiff Cumberland Pharmaceuticals Inc. and Defendants Perrigo Company and Paddock Laboratories, LLC hereby stipulate and agree that the above action, including all claims, counterclaims, and affirmative defenses, is hereby dismissed without prejudice, and without costs, disbursements or attorneys' fees to any party.

Dated: _____

**[_____]**

_____

**[_____]**

*Attorneys for Plaintiff Cumberland Pharmaceuticals Inc.*

Dated: _____

**[_____]**

_____

**[_____]**

*Attorneys for Defendants Perrigo Company and Paddock Laboratories, LLC*

SO ORDERED this ____ day of _____, 2012.

_____

United States District Judge

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

| | | |
|---|---|---|
| CUMBERLAND PHARMACEUTICALS INC. | ) | |
| | ) | |
| Plaintiff, | ) | No. 12-CV-06327 |
| | ) | |
| v. | ) | |
| | ) | |
| PERRIGO COMPANY | ) | Hon. [____] |
| | ) | |
| Defendants | ) | |
| | ) | |
| | ) | |

**JOINT STIPULATION OF DISMISSAL**

Pursuant to Federal Rule of Civil Procedure 41(a)(1), Plaintiff Cumberland Pharmaceuticals Inc. and Defendant Perrigo Company hereby stipulate and agree that the above action, including all claims, counterclaims, and affirmative defenses, is hereby dismissed without prejudice, and without costs, disbursements or attorneys' fees to any party.

Dated: _____

**[_____]**

_____

**[_____]**

*Attorneys for Plaintiff Cumberland Pharmaceuticals Inc.*

Dated: _____

**[_____]**

_____

**[_____]**

*Attorneys for Defendant Perrigo Company*

SO ORDERED this ____ day of _____, 2012.

_____

United States District Judge

**EXHIBIT 2: LICENSE AND SUPPLY AGREEMENT**

(To come)

**EXHIBIT 10.32**

*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

This License and Supply Agreement ("Agreement") is entered into this 9th day of November, 2012 ("Effective Date") by and between Cumberland Pharmaceuticals Inc., a Tennessee corporation having its principal place of business at 2525 West End Ave., Suite 950, Nashville, Tennessee 37023 ("Cumberland"), Paddock Laboratories, LLC, a Delaware limited liability company having its principal place of business at 3940 Quebec Avenue N, Minneapolis, Minnesota 55427 ("Paddock") and Perrigo Company, a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allergan, Michigan 49010 ("Perrigo"). Each of Cumberland, Paddock and Perrigo may be referred to herein individually as a "Party" and collectively as the "Parties", and each of Perrigo and Paddock may be referred to herein as a "Defendant" and together as the "Defendants".

## RECITALS

WHEREAS, Cumberland sells an N-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form, free of EDTA (edetate disodium), pursuant to supplemental New Drug Application 21-539 (the "Acetadote® EDTA-Free NDA") under the trademark Acetadote® (or any replacement trademark) (the "Acetadote® EDTA-Free Product"), and Cumberland previously sold an N-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form containing EDTA under the trademark Acetadote® (the "Acetadote® EDTA Product"), which Acetadote® EDTA Product Cumberland has withdrawn from the market due to safety concerns and which Cumberland has delisted from the U.S. Food and Drug Administration's Orange Book;

WHEREAS, Cumberland owns the following U.S. Patent relating to the Acetadote® products: 8,148,356 (the "'356 Patent");

WHEREAS, Paddock filed with the FDA (as defined below) ANDA (as defined below) [***] (the "Paddock ANDA") requesting approval from the FDA to market a generic product containing N-acetylcysteine as its active ingredient in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form [***];

WHEREAS, Perrigo, the parent company of Paddock, filed with the FDA ANDA [***] (the "Perrigo ANDA") requesting approval from the FDA to market a generic product containing N-acetylcysteine in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form as its active ingredient ; [***]

WHEREAS, Cumberland filed Civil Action No. 12-CV-00619 (LPS) in the United States District Court for the District of Delaware (the "First Action"), in which Cumberland alleges that Defendants, by filing of the Paddock ANDA, infringed the '356 Patent as specified therein;

WHEREAS, Cumberland filed Civil Action No. 12-CV-06327 in the United States District Court for the Northern District of Illinois Eastern Division, in which Cumberland alleges

that Perrigo, by filing of the Perrigo ANDA, infringed the ’356 Patent as specified therein (the “Second Action”, and with the First Action, the “Actions”); and

WHEREAS, Cumberland and Defendants have settled the Actions pursuant to the terms of the Settlement Agreement (the “Settlement Agreement”) between the Parties, dated as of the date hereof, and pursuant to the Settlement Agreement have agreed to enter into this Agreement, pursuant to which Cumberland will agree to supply Perrigo, [***], with an authorized generic version of the Acetadote® [***] Product and license Perrigo to sell such authorized generic versions, in each case on the terms and conditions contained herein.

NOW, THEREFORE, in consideration of the foregoing premises and the covenants exchanged herein and other good and valuable consideration, the sufficiency and receipt of all of which are hereby acknowledged, Defendants and Cumberland intending to be legally bound hereby agree as follows:

## I. DEFINITIONS

“’356 Patent” has the meaning set forth in the Recitals.

“Acetadote® EDTA-Free NDA” has the meaning set forth in the Recitals.

“Acetadote® EDTA-Free Product” has the meaning set forth in the Recitals.

“Acetadote® EDTA Product” has the meaning set forth in the Recitals.

“Actions” has the meaning set forth in the Recitals.

“Affiliate(s)” shall mean, with respect to any entity, any corporation, association, company, organization or other entity which directly or indirectly controls, is controlled by or under common control with Paddock, Perrigo or Cumberland, as the case may be. For purposes of this definition, “control” means the ability, directly or indirectly, through ownership of securities, by agreement, or by any other method, to direct more than fifty (50%) of the outstanding equity votes of any entity, whether or not represented by securities, or to otherwise control the management decisions of any entity.

“Agreement” has the meaning set forth in the introductory paragraph hereof.

“ANDA” shall mean Abbreviated New Drug Application as defined in 21 C.F.R. § 355(j) et seq., as amended from time to time

[***].

[***].

"Bundled Sale" shall mean, as defined in 42 C.F.R. § 447.502, an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code ("NDC") level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those that would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

"cGMPs" shall mean Current Good Manufacturing Practices as defined in 21 C.F.R. § 210 et seq., as amended time to time.

"Commencement Date" shall mean:

(a) [***].

(b) [***].

"Commercially Reasonable Efforts" shall mean that degree of effort, expertise and resources which a person of ordinary skill, ability and experience in the matters addressed herein would typically utilize and otherwise apply with respect to fulfilling the obligations assumed hereunder.

"Cumberland" has the meaning set forth in the introductory paragraph hereof.

"Defendant" and "Defendants" have the meaning set forth in the introductory paragraph hereof.

"Effective Date" has the meaning set forth in the introductory paragraph hereof.

"FDA" shall mean the Food and Drug Administration of the United States of America.

"FFDCA" shall mean the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. §301 et seq., and any related federal and/or state law or regulation in the Territory pertaining to the safety, effectiveness, adulteration, misbranding, mishandling, packaging, labeling or storage of pharmaceutical ingredients, finished pharmaceutical products, and/or medical devices that may be applicable to the Products during the Term.

"Follow-On Product" has the meaning set forth in Section 2.5.

[***].

[***].

"Intellectual Property" shall mean all intellectual property owned or licensed to a party including, without limitation, provisional patent applications, utility patent applications, patents, and reissues, reexaminations, extensions and substitutions thereof, trade secrets, know-how, copyrights, trade names, trademarks, and trade dress.

"Law" shall mean any local, state or federal rule, regulation, statute or law.

"Licensed Patents" shall mean the '356 Patent, and all continuations, divisionals and extensions thereof, and all reexaminations and reissues thereof.

"Losses" shall mean any liabilities, damages, costs or expenses, including reasonable attorneys' fees, incurred by either Party which arise from any claim, lawsuit or other action by a Third Party.

"Manufacturing Cost" with respect to a Product shall mean the aggregate cost to manufacture, label and package the Product, calculated as follows:

(a) [***].

(b) [***].

All costs included in Manufacturing Costs shall be shall be determined in accordance with United States generally accepted accounting principles ("GAAP"), as consistently applied by Cumberland in accordance with its past practice and in the ordinary course of its business.

"NDA" means a New Drug Application (as more fully described in 21 C.F.R. 314.50 et seq. or its successor regulation) and all amendments and supplements thereto submitted to the FDA.

"Net Sales" shall mean the gross amounts invoiced from the sale of Products and Perrigo ANDA Products by Perrigo and its Affiliates to independent Third Parties in an arms-length transaction, in each case after subtracting the following to the extent specifically and solely allocated to the Product or the Perrigo ANDA Product, as the case may be, and actually taken, paid, accrued, allowed, included or allocated in the gross sales prices with respect to such sales (and consistently applied as set forth below) (the "Deductions"):

(a) [***].

(b) [***].

(c) [***].

Notwithstanding the foregoing, Net Sales shall be determined in accordance with GAAP in the Territory, consistently applied by Perrigo in accordance with its past practice and in the ordinary course of its business and on a basis consistent with Perrigo's annual audited financial statements. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to the Products or Perrigo ANDA Product, as the case may be, and other generic products of Perrigo and its Affiliates such that the Products or Perrigo ANDA Product, as the case may be, does not bear a disproportionate portion of such deductions. In no event shall the Profit Share payable to Cumberland be taken as a deduction from Net Sales.

"Paddock" has the meaning set forth in the introductory paragraph hereof.

"Paddock ANDA" has the meaning set forth in the Recitals.

"Parties" shall have the meaning set forth in the introductory paragraph hereof.

"Perrigo" has the meaning set forth in the introductory paragraph hereof.

"Perrigo ANDA" has the meaning set forth in the Recitals.

"Perrigo ANDA Product" means an N-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form sold pursuant to the Perrigo ANDA.

"Perrigo Fiscal Quarter" shall mean those consecutive periods for which Perrigo is obligated to submit SEC Form 10-Q filings, which generally approximate three (3) calendar month periods beginning on or about January 1, April 1, July 1, and October 1, respectively.

"Product" or "Products" shall mean (a) Cumberland's Acetadote® [***] For avoidance of doubt, the Products shall not include any product containing (i) any active pharmaceutical ingredient other than N-acetylcysteine in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form, or (ii) any pharmaceutical product marketed under the mark Acetadote® or any similar marks.

"Profit Share" shall have the meaning set forth in Section 4.2.

"Settlement Agreement" has the meaning set forth in the Recitals.

"Significant Market Change" shall mean an increase or decrease in the number of companies marketing an n-acetylcysteine product in an amount of 6gm/30ml (200mg/ml) and in an intravenous injectable dosage form as compared to the number of companies in the immediately preceding quarter, provided that such increase or decrease results in a material change to level of Perrigo's sales of the Product (based on sales of units of Product). Such change can be caused by either: (a) new FDA approvals and launches of Generic Acetadote® Products; (b) a decision by a party distributing a Generic Acetadote® product to cease marketing such Product; or (c) an inability by a party distributing a Generic Acetadote® product to supply such Product.

"Specifications" shall mean all Product, regulatory, manufacturing, quality control, and quality assurance procedures, processes, practices, standards, instructions and specifications comprising Cumberland's FFDCA approval applicable to the manufacture and packaging of Products, and such other FDA and/or other regulatory requirements as may be applicable.

"Supply Price" shall mean, with respect to a Product [***].

"Term" has the meaning set forth in Section 8.1.

"Territory" shall mean [***].

"Third Party" shall mean any person, entity or other organization (other than the Parties and their respective Affiliates).

Any other capitalized terms used but not defined in this Article I shall have the meanings assigned to such terms in the body of this Agreement.

## II. SCOPE OF AGREEMENT

2.1 Authorized Generic Appointment. Subject to the terms and conditions of this Agreement and effective as of the applicable Commencement Date, Cumberland hereby appoints Perrigo, and Perrigo hereby accepts its appointment, as Cumberland's [***] authorized generic distributor of each of the Products in the Territory during the Term. Such appointment grants to Perrigo the [***] right and license, under the Licensed Patents, to market, sell, promote and distribute each of the Products in the Territory after the applicable Commencement Date for such Product during the Term. Perrigo may not sublicense, assign, transfer or delegate any of the foregoing appointment or rights, other than to Paddock and its other Affiliates, but only for so long as such Affiliates remain Affiliates of Perrigo. The foregoing does not grant to Perrigo any right to manufacture or have manufactured any Product, or to market, sell, promote or distribute any Product in a combined form with any other pharmaceutical product. For avoidance of doubt, the foregoing shall not be construed to prohibit or limit in any manner Cumberland's right to (a) market, sell, promote or distribute any Product in the Territory, or Cumberland's Acetadote® EDTA-Free Product in the Territory, or (b) grant to any Third Party the right to do any of the same. Pursuant to the terms and conditions of this Agreement, commencing on the Commencement Date, and except as otherwise permitted pursuant to this Agreement, Perrigo shall acquire exclusively from Cumberland such total quantities of Products as Perrigo may require to market, sell, promote and/or distribute the Products in the Territory.

2.2 Restrictions. Perrigo and its Affiliates shall not market, sell, promote or distribute the Products (a) prior to the Commencement Date, (b) outside the Territory, (c) to any purchaser or distributee that Perrigo or its Affiliates knows, or reasonably should know, intends to utilize, resell or redistribute the Products outside the Territory, or (d) for any use, within or outside of the Territory, that is not a use for which Cumberland has received approval from the FDA. In the event that Perrigo or any of its Affiliates becomes aware of, or Cumberland notifies Perrigo that, a Third Party is utilizing, reselling or redistributing any Products sold or distributed by or on behalf of Perrigo hereunder in violation of this Section 2.2, Perrigo and its Affiliates shall immediately cease all sale and distribution of the Products to such Third Party and Perrigo and its Affiliates shall use its Commercially Reasonable Efforts to cause such Third Party to cease such violation. Without limiting the foregoing, Perrigo shall be responsible for compliance with the terms and conditions of this Agreement by all of its Affiliates and its

and their respective distributors, sales agents, resellers and other Third Parties used to market, promote, distribute and sell the Products.

2.3 Pricing; Bundled Sales. Perrigo will have the right in its sole discretion to establish the price at which the Products will be sold to Third Parties. Neither Perrigo nor any of its Affiliates shall sell, distribute or dispose of any Product in any manner that would constitute a Bundled Sale.

2.4 Supply Exceptions. Notwithstanding anything to the contrary in this Agreement, Cumberland shall not be obligated to supply Products to Perrigo and Perrigo and its Affiliates shall not be permitted to sell Products during any time period in which there is in effect an injunction or similar court order prohibiting the manufacture, marketing, distribution, sale or use of the Products or Cumberland's Acetadote® product in the Territory.

2.5 Follow-On Products. If Cumberland obtains approval from the FDA to market and sell a product containing N-acetylcysteine for prevention or mitigation of hepatic injury due to acetaminophen that differs from the Products in pharmaceutical form and/or strength (a "Follow-On Product"), Perrigo shall have the right to request that Cumberland enter into good faith negotiations regarding an arrangement in which Perrigo would be granted the right to sell an authorized generic version of such Follow-On Product following any patent expiration or expiration of FDA exclusivity. Perrigo may request such right to negotiations by providing Cumberland with a written request no later than thirty (30) days after the FDA's approval of the Follow-On Product. If Perrigo provides Cumberland with such written request within such thirty (30) day period, Cumberland agrees to engage in such good faith, non-exclusive negotiations with Perrigo for a period of sixty (60) days from its receipt of such written request. For avoidance of doubt, neither Perrigo nor Cumberland shall be obligated to enter into any arrangement with respect to an authorized generic version of a Follow-On Product.

2.6 No Implied Rights. Except for the rights expressly granted to Perrigo pursuant to this Agreement, Cumberland does not grant to Perrigo or Paddock, whether by implication, estoppel or otherwise, any rights or interests in or to the Products or any Intellectual Property therein or relating thereto, or any right to reference any NDA owned or controlled by Cumberland or its Affiliates. Nothing in the Agreement shall be deemed to (a) constitute any agreement, acquiescence or admission on the part of Cumberland as to the propriety of the Perrigo ANDA or Paddock ANDA or (b) prohibit Cumberland from challenging such application in any proceeding brought before the FDA or any court or other governmental or regulatory body.

## III. FORECASTS AND SUPPLY

3.1 Obligation to Supply. Subject to the terms and conditions of this Agreement, Cumberland shall use its Commercially Reasonable Efforts to maintain quantities of the Products that are sufficient for Perrigo to commence the introduction and sale of the Products in the Territory after the occurrence of the applicable Commencement Date. The Products supplied to Perrigo shall have a different National Drug Code than Cumberland's Acetadote® products, which National Drug Code shall be obtained by Perrigo at its sole expense.

3.2 Forecasts. Within thirty (30) days following the Commencement Date, Perrigo shall prepare and deliver to Cumberland a forecast of estimated quarterly Product orders, based on a reasonable, good faith estimate of actual demand, for each of the Perrigo Fiscal Quarters remaining in the Perrigo fiscal year in which the Commencement Date occurs. Thereafter, thirty (30) days before the first day of each Perrigo Fiscal Quarter, Perrigo will provide Cumberland rolling quarterly forecasts, each forecast covering a one (1) year period. The first Perrigo Fiscal Quarter of each forecast will be considered firm and Cumberland shall not be obligated to provide more than the forecasted amount during the applicable Perrigo Fiscal Quarter. The forecast for the first Perrigo Fiscal Quarter covered by the forecast may not increase by more than [***] from the most recent previous forecast for that Perrigo Fiscal Quarter. Perrigo shall not be bound to the previous obligation for any Perrigo Fiscal Quarter in which there has been a Significant Market Change, provided that Cumberland shall not be required in any case to fulfill any quantity of Product ordered pursuant to Perrigo's Product order that exceeds more than [***] of the amount of Products included in the then applicable first Perrigo Fiscal Quarter of the current forecast.

3.3 Product Orders. All Product orders shall be in writing and shall be consistent with the amounts forecast pursuant to Section 3.2, in batch size (or multiples thereof) quantities, shall be based on a reasonable, good faith estimate of actual demand, and shall be submitted at least ninety (90) days in advance of requested delivery. The delivery date specified in a Product order shall not be less than ninety (90) days after the date on which the Product order is received by Cumberland. Within ten (10) days after receipt of a Product order from Perrigo, Cumberland shall notify Perrigo in writing of its acceptance of the Product order and requested delivery date (subject to availability of sufficient

labeling and packaging materials) or rejection of the Product order for failure to comply with the requirements of this Agreement. Except as may be agreed by Cumberland, Cumberland shall not be required in any case to fulfill any quantity of Product ordered pursuant to Perrigo's Product order that exceeds more than [***] of the amount of Products included in the then applicable first Perrigo Fiscal Quarter of the current forecast. Each acquisition by Perrigo of Products shall be governed only by the terms of this Agreement and none of the terms or conditions in Perrigo's forms (whether contained in a Product order, invoice, acknowledgement or other) shall be applicable.

3.4 Product Specifications. Cumberland will manufacture, package, label, store, and ship the Products in accordance with Perrigo's reasonable directions, but in all cases subject to the Specifications set forth in the applicable NDA for such Products, as any such NDA may be amended from time to time. The Parties shall work in good faith to agree upon the labeling and packaging for the Products. In the event that Cumberland cannot reasonably manufacture any Product in accordance with the Specifications, Cumberland shall promptly so advise Perrigo.

3.5 Product Returns. Returns by customers or others to Perrigo of Products shall be the responsibility and obligation of Perrigo alone, except as set forth in Section 6.2.

3.6 [***].

## IV. PAYMENTS AND REPORTS

4.1 Supply Price for Products. [***].

4.2 Profit Share. (a) In consideration of the rights granted to Defendants hereunder, Perrigo shall pay to Cumberland a percentage of aggregate Net Sales of Products and Perrigo ANDA Products in the Territory (the "Profit Share") according to the following:

(i) [***].

(ii) [***].

(iii) [***].

(b) [***].

(c) [***].

(d) [***].

4.3 Records; Audit Rights. Perrigo agrees to keep, and shall cause its Affiliates to keep, accurate books of account and records in sufficient detail to enable the Profit Share payable hereunder to be determined, and not more frequently than once per year, duly authorized independent auditors selected by Cumberland and acceptable to Perrigo, the acceptance of which shall not be unreasonably withheld or delayed, shall have the right at all reasonable business hours on reasonable advance notice to Perrigo, but subject to a non-use and nondisclosure agreement reasonably acceptable to Perrigo, to perform an inspection of such books of account and records. Such books of account and records shall be kept available for at least three (3) years after the relevant Product is sold. Profit Share found to be due as a result of Cumberland's examination of Perrigo's books of

accounts shall be paid immediately. If such underpayment exceeds five percent (5%) of the total amount owed to Cumberland for the period then being audited, Perrigo shall reimburse Cumberland for the reasonable fees and expenses of such independent auditor performing the audit.

4.4 Method of Payment. All payments required to be made to Cumberland under this Agreement shall be made in United States dollars by wire transfer to the account of Cumberland Pharmaceuticals Inc., [***], Nashville, Tennessee or such other account as may be specified by Cumberland in writing to Perrigo.

4.5 Late Payments. Any amount owing to Cumberland and not paid when due shall bear interest at the U.S. Prime Rate as published by Citibank, NA that is applicable to the date on which the payment was first due.

## V. SHIPPING; STORAGE

5.1 All shipments of Products from Cumberland to Perrigo will be shipped to Perrigo's designated United States facility, and will be in accordance with the reasonable instructions for shipping and packing set forth in the relevant Perrigo Product order. Delivery shall be made F.O.B., Cumberland's shipping dock. Each order will be shipped to a single destination. Title and risk of loss or damage to the Products shall pass to Perrigo upon delivery to the designated carrier at Cumberland's shipping dock. Any and all transportation and insurance costs for the Products shall be paid by Perrigo.

5.2 Perrigo shall store and distribute the Products in accordance with the Specifications.

## VI. PRODUCTS TESTING/INSPECTION

6.1 Quality. Cumberland shall perform quality assurance testing with respect to the Products supplied hereunder, including stability testing. Cumberland shall provide the results thereof to Perrigo in the form of a Certificate of Analysis (hereinafter "COA"). Cumberland shall also provide Perrigo with Material Safety Data Sheets as required for the Products, and updates of same as necessary. Perrigo will permit Cumberland's personnel, upon reasonable notice, to visit at reasonable intervals, and for reasonable durations during regular business hours, any Perrigo facility used for the storage and distribution of the Products and will allow such personnel to review and make copies of any relevant records in connection therewith. The Parties shall utilize their best efforts to enter into a Quality Agreement within sixty (60) days of the Effective Date.

6.2 Inspection. Perrigo shall have a period of fifteen (15) days from the later of (a) the date of Perrigo's receipt of the Products at the Perrigo facility designated in the Product order, or (b) the date of Perrigo's receipt of the COA's applicable to such Products, to inspect any shipment of Products to determine whether such shipment conforms to the Specifications. If Perrigo determines that the Products do not conform in all material respects to the Specifications, it shall immediately notify Cumberland. Perrigo's failure to notify Cumberland within the stipulated period shall be deemed, for purposes of this

Agreement, as Perrigo's acceptance of such shipment and shall constitute a waiver of any claims Perrigo may have against Cumberland with respect to such shipment subject, however, to Perrigo's right to reject Products for latent defects discovered by Perrigo after such stipulated period has expired, provided that such notice is provided by Perrigo to Cumberland within five (5) business days following the discovery of such latent defects. If Cumberland agrees that the Products do not conform to the Specifications, Perrigo shall return the non-conforming Products to Cumberland, at a location designated by Cumberland and at Cumberland's expense. Cumberland shall use Commercially Reasonable Efforts to replace any non-conforming Products thereafter.

6.3 Disagreement Regarding Compliance. In the event Cumberland does not agree with Perrigo's determination that the Products fail to meet the Specifications, the Parties shall, in good faith, attempt to resolve such dispute. In the event the Parties cannot resolve said dispute among themselves they may submit the matter to an independent Third Party testing laboratory agreeable to both Perrigo and Cumberland for a binding opinion. The expenses of obtaining the advisory opinion shall be borne by the Party against whom the dispute is decided by such laboratory.

## VII. REGULATORY AND RECALLS

7.1 Cumberland Regulatory Responsibility. Cumberland shall remain responsible for maintaining and fulfilling all regulatory requirements in the Territory with respect to the Products that are imposed by Law upon Cumberland as the manufacturer of the Products and the holder of the NDA in connection therewith. Perrigo shall be responsible for obtaining, maintaining and fulfilling all regulatory requirements in the Territory with respect to the Products that are imposed by Law upon Perrigo in connection with Perrigo's marketing, distribution and sale of the Products. Each Party will, on a timely basis, provide the other Party with all information that such Party has that the other Party does not have that is reasonably necessary and relevant to either Party's obligations in fulfilling such requirements. Perrigo and Cumberland shall cooperate in the reporting of adverse drug experience information and other post marketing reports as are required to be filed with the FDA or its equivalent. Perrigo shall submit to Cumberland all complaints, adverse drug experience reports and other medical inquiries associated with the Products within forty-eight (48) hours of Perrigo's receipt of such reports. Cumberland will be responsible for fulfilling any regulatory requirements with respect to such events, including but not limited to the filing of all Form FD 2253's, and will make any necessary contact with the FDA regarding the subject matter of same. The Parties will cooperate in good faith to develop a procedure for handling adverse drug experience reports.

7.2 Perrigo Regulatory Responsibility. Perrigo shall be responsible for filing and maintaining all documentation and other information as required by each and every state and locality (hereinafter "State") for the purpose of listing the Products on each such State's formulary or other similar authority, and for obtaining such other approvals as may be necessary to market, promote, sell and distribute the Products in the Territory.

Cumberland shall provide Perrigo, at Perrigo's expense, with such assistance as reasonably necessary to obtain such listings. Perrigo will pay Medicaid and other applicable rebates required by Law or contract with respect to the Products sold by it. If for any reason Perrigo does not obtain the requisite regulatory approvals and formulary listings and as a result is not able to distribute and sell the Products in the Territory, Perrigo shall reimburse Cumberland for all expenditures made or commitments given by Cumberland in obtaining the production materials required to be procured to manufacture the Products and the production and delivery of the Products pursuant to this Agreement.

7.3 Recalls. In the event Perrigo or Cumberland shall be required or requested by any governmental authority (or shall voluntarily decide) to recall any Products because such Products may violate any Laws or for any other reason, the Parties shall cooperate fully with one another in connection with any recall. To the extent a recall is due to Cumberland's gross negligence, willful misconduct or material breach of this Agreement, Cumberland shall reimburse Perrigo for all of the reasonable costs and expenses actually incurred by Perrigo in connection with the recall including, but not limited to, costs of retrieving Products already delivered to customers, costs and expenses Perrigo is required to pay for notification, shipping and handling charges, and such other costs as may be reasonably related to the recall. To the extent a recall is due to Perrigo's gross negligence, willful misconduct or material breach of this Agreement, Perrigo shall remain responsible for the Supply Price for such recalled Products and shall reimburse Cumberland for all the reasonable costs and expenses described above in the immediately preceding sentence actually incurred by Cumberland in connection with such recall, including without limitation administration of the recall and such other actual costs as may be reasonably related to the recall. To the extent a recall results from a cause other than the gross negligence, willful misconduct or material breach of this Agreement of or by Perrigo or Cumberland, the Parties shall share equally in the costs of the recall. Prior to any reimbursements pursuant to this Section, the Party claiming any reimbursement shall provide the other Party with reasonably acceptable documentation of all reimbursable costs and expenses. Notwithstanding anything herein to the contrary, neither Party will be liable to the other under this Section 7.2 for consequential damages or lost profits of any kind.

7.4 Regulatory Action. In the event either Party receives notice of an inspection or other notification by a governmental entity, including the FDA, directly relating to the Products, promotional materials or other matters within the scope of this Agreement, such Party shall notify the other Party as soon as practicable, and provide to such other Party, within ten (10) days, copies of all relevant documents as such other Party may reasonably request. Perrigo and Cumberland agree to cooperate with each other during any inspection, investigation or other inquiry by the FDA or any other governmental entity relating to the Products, including providing information and/or documentation, as requested by the FDA or other governmental entity.

7.5 Perrigo Marketing Activities. Notwithstanding anything to the contrary set forth elsewhere herein, Perrigo shall have the right, without Cumberland's prior approval, to

promote and publicize the Products in its customary fashion, and may publicize such information about the Products as it usually and customarily provides for its own products utilizing its usual and customary channels of communication, and its standard forms, which may be revised from time to time, provided that such promotion and publicizing of the Products conforms with all applicable Laws and is consistent with the Specifications and NDA. Perrigo shall use its own branding in connection with its marketing, promotion, sale and distribution of the Products, and may not use the Cumberland name or any Cumberland trademark, including without limitation Acetadote®, or any confusingly similar variation thereof, in connection with such branding, the Products or otherwise without Cumberland's prior written consent.

7.6 No Alterations. Perrigo agrees not to repackage or otherwise alter the form of the finished packaged Products delivered to Perrigo from Cumberland without the prior written permission of Cumberland.

## VIII. TERM AND TERMINATION

8.1 Term. The term of this Agreement shall begin on the Effective Date and, unless terminated earlier pursuant to Section 8.2, shall end on [***] (the "Term").

8.2 Early Termination.

(a) If either Party shall at any time fail to abide by or fail to perform in any material respect in accordance with any of the terms and conditions of this Agreement, the other Party shall have the right to terminate this Agreement upon thirty (30) days' written notice to the defaulting Party specifying the default complained of, setting forth the underlying reasons for its belief that a default has occurred and the remedy sought, provided that such notice of termination shall not be effective if the defaulting Party has cured such breach within such thirty (30) day period.

(b) If either Party (i) institutes or has instituted against it any insolvency, receivership, bankruptcy or other proceedings for the settlement of that Party's debts, and such proceedings are not dismissed within sixty (60) days, (ii) makes a general assignment for the benefit of creditors, or (iii) dissolves, the other Party may terminate this Agreement upon written notice effective immediately.

(c) Cumberland may terminate this Agreement upon written notice effective immediately in the event that Perrigo or any of its Affiliates challenges in any lawsuit, action or other legal or administrative proceeding (including by the filing of a Paragraph IV certification) in support of a generic N-acetylcysteine product that references a product covered by any Cumberland NDA as the reference listed drug, or challenges in any reexamination or similar proceeding, the ownership, validity or enforceability of any of the Licensed Patents, or otherwise breaches any provision of Article III of the Settlement Agreement, provided that the foregoing shall not apply to Perrigo's maintaining the paragraph IV

certification under Section 505(j)(2)(A)(vii)(IV) of the FFDCA (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) that is contained in the Perrigo ANDA.

(d) Cumberland may terminate this Agreement on written notice effective immediately if (i) except as permitted under Section 3.6, Perrigo or any of its Affiliates makes, has made, uses, offers for sale, sells or imports in the Territory, directly or indirectly, any Generic Acetadote® EDTA Product or Generic Acetadote® EDTA-Free Product or assists or authorizes any Third Party to do any of the foregoing, or (ii) Perrigo or any of its Affiliates files with the FDA an ANDA that references Cumberland's Acetadote® product.

(e) Notwithstanding anything else contained herein, if Perrigo fails to pay when due any amount owing to Cumberland hereunder and fails to cure such default within thirty (30) days of notice thereof, then Cumberland shall have the right to terminate this Agreement by written notice effective immediately.

(f) Cumberland may terminate this Agreement upon ninety (90) days' written notice if it has decided to cease all of its commercialization activities relating to the production of N-acetylcysteine-based pharmaceutical products.

(g) Cumberland may terminate this Agreement upon thirty (30) days' written notice if, after the Commencement Date, Perrigo either (i) has discontinued sale of the Products or (ii) has not acquired any Product from Cumberland in two (2) consecutive calendar quarters provided that Perrigo's failure to acquire Product is not due to Cumberland's inability to supply the Product or a Significant Market Change.

(h) This Agreement shall be automatically and immediately terminated if the Settlement Agreement is terminated pursuant to Section 5.2 thereof.

(i) In the event that all of the asserted claims of the Licensed Patents are held invalid or unenforceable by the United States Court of Appeals for the Federal Circuit (or a United States District Court if such decision is not appealed), either Party may terminate this Agreement as of the date of the decision. For purposes of this Section 8.2(i), "asserted claims of the Licensed Patents" means all claims of the Licensed Patents asserted against Defendants or their Affiliates or any Third Party in any current or future litigations.

8.3 Effect of Termination. If this Agreement expires or is terminated for any reason:

(a) all rights and licenses granted to Perrigo hereunder automatically and immediately shall terminate;

(b) Perrigo shall pay, within thirty (30) days of such expiration or termination, all payments due to Cumberland as of the effective date of such expiration or termination, if any;

(c) subject to Section 8.4, unless this Agreement has been terminated pursuant to Sections 8.2(a), 8.2(c) or 8.2(d), Perrigo shall have the right to sell the Products remaining in its inventory for a period of ninety (90) days following such expiration or termination, subject to the terms and conditions of this Agreement (including the obligation to pay Profit Share in respect of such Products);

(d) any and all obligations under Articles IX and X shall survive;

(e) any liabilities or obligations accrued as of the date of expiration or termination shall survive; and

(f) in the event of termination based upon Sections 8.2(f) or (i), Perrigo may thereafter market Perrigo ANDA Product free from any further obligation to Cumberland under this Agreement, provided that, other than with respect to the Licensed Patents as necessary to market the Perrigo ANDA Product, this Section 8.3(f) does not and shall not be construed to grant any license, covenant not to sue or other right to Perrigo under any of Cumberland's or its Affiliates' patents (including the Licensed Patents), any other intellectual property rights or any regulatory rights or exclusivities.

8.4 Product Sell-Off. Following the expiration of the ninety (90) day period immediately following the effective date of expiration or termination of this Agreement, notwithstanding Section 8.3(c), Perrigo shall no longer be permitted to sell the Products, and Perrigo promptly shall destroy any Products remaining in its inventory at such time. Promptly thereafter, an officer of Perrigo shall certify in writing to Cumberland that Perrigo has fully complied with the provisions of this Section 8.4.

## IX. INDEMNIFICATION AND INSURANCE

**9.1 Perrigo Indemnification Obligation. Perrigo agrees to indemnify, defend and hold Cumberland harmless from and against any Losses resulting from or arising out of (a) Perrigo's storage, handling, marketing, promotion, distribution, sale and/or delivery of the Products and Perrigo ANDA Products; (b) the breach by Perrigo of its representations, warranties or obligations under this Agreement; or (c) the gross negligence or willful misconduct of Perrigo, its employees or its agents (collectively "Perrigo Activities"), except to the extent such Losses result from or arise out of Cumberland Activities.**

**9.2 Cumberland Indemnification Obligation. Cumberland agrees to indemnify, defend and hold Perrigo harmless from and against any Losses resulting from or arising out of (a) Cumberland's manufacturing of the Products to the extent such manufacturing does not conform to the Specifications; (b) the breach by Cumberland of its representations, warranties or obligations under this Agreement; or (c) the gross negligence or willful misconduct of Cumberland, its employees or its**

**agents (collectively "Cumberland Activities"), except to the extent such Losses result from or arise out of Perrigo Activities.**

**9.3 Indemnification Procedure. A Party seeking indemnification ("Indemnified Party") under Section 9.1 or Section 9.2 shall notify, in writing, the other Party ("Indemnifying Party") within ten (10) days of the assertion of any claim or discovery of any fact upon which the Indemnified Party intends to base a claim for indemnification. An Indemnified Party's failure to so notify the Indemnifying Party shall not, however, relieve such Indemnifying Party from any liability under this Agreement to the Indemnified Party with respect to such claim except to the extent that such** Indemnifying Party is actually denied, during the period of delay in notice, the opportunity to remedy or otherwise mitigate the event or activity(ies) giving rise to the claim for indemnification and thereby suffers or otherwise incurs additional liquidated or other readily quantifiable damages as a result of such failure. The Indemnifying Party, while reserving the right to contest its obligations to indemnify hereunder, shall be responsible for the defense of any claim, demand, lawsuit or other proceeding in which the allegations, if proved, would trigger the Indemnifying Party's obligations under Section 9.1 or 9.2, (a) that solely seek monetary damages and (b) as to which the Indemnifying Party expressly agrees in writing that, as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the claim in full (the matters described in (a) and (b), the "Litigation Conditions"). At its option, the Indemnified Party may assume responsibility for such defense if the Litigation Conditions are not satisfied, by written notice to the Indemnifying Party. The Indemnified Party shall have the right at its own expense to participate jointly with the Indemnifying Party in the defense of any such claim, demand, lawsuit or other proceeding, but the Indemnifying Party shall have the right, subject to the Litigation Conditions being satisfied, to settle, try or otherwise dispose of or handle such claim, demand, lawsuit or other proceeding on such terms as the Indemnifying Party shall deem appropriate, subject to any reasonable objection of the Indemnified Party. Any settlement agreed to by the Indemnifying Party over the objection of the Indemnified Party may only provide a monetary relief and may not include any admission of liability or injunctive relief or other action restricting the Indemnified Party.

**9.4 Insurance. During the Term, each Party shall** maintain comprehensive general liability insurance, including products liability coverage, with limits of not less than two million dollars ($2,000,000) per occurrence and ten million dollars ($10,000,000) in the aggregate. **Each Party will provide to the other Party, no later than thirty (30) days after the Effective Date, with evidence of insurance reflecting the comprehensive general liability and products liability programs it has in effect.**

## X. CONFIDENTIAL INFORMATION

10.1 Confidentiality Obligations. "Confidential Information" is any information relating to the business or business plans of a Party, including know-how, formulas, trade secrets, clinical or non-clinical data, processes, specifications, suppliers and customers. Except as provided below, during the Term and for five (5) years thereafter, neither Party shall release to any Third Party any Confidential Information of the other Party or any information with respect to the existence and terms of this Agreement without the prior written consent of the other (other than to its employees, consultants, independent contractors, agents, Affiliates, and actual or potential acquirers, provided that such employees, consultants, independent contractors, agents, Affiliates, and actual or potential acquirers are bound by terms and conditions of confidentiality no less protective than the terms and conditions hereunder), and neither Party shall use the Confidential Information of the other Party for any purpose not contemplated by this Agreement. Neither Perrigo nor Cumberland shall issue any press release or public announcement or disclosure with respect to the Agreement without the prior consent of the other as to the form and content of such release, except as such release or announcement may be required by Law or by applicable stock exchange rules, but subject to Section 10.3.

10.2 Exceptions. The obligations of confidentiality and non-use of each Party under this Article X shall not apply to information to the extent the receiving Party can demonstrate that such information: (a) is or has become generally available to the public, without any breach by the receiving Party of the provisions of this Agreement or any other applicable agreement between the Parties; (b) was rightfully in the possession of the receiving Party, without confidentiality restrictions, prior to such Party's receipt pursuant to this Agreement; (c) was rightfully acquired by the receiving Party from a Third Party who was entitled to disclose such information, without confidentiality or proprietary restrictions; or (d) was independently developed by the receiving Party without using or referring to the disclosing Party's Confidential Information.

10.3 Required Disclosures. If either Party determines that a release of information concerning this Agreement is required by applicable Law, legal process (including without limitation any subpoena or discovery ordered by any court of competent jurisdiction) or by stock exchange rules, it shall notify the other in writing at least ten (10) days (or such shorter period where legally required) before the time of the proposed release; it being understood and agreed that each such Party that proposes to make any such release of information shall use its Commercially Reasonable Efforts to ensure that any such release shall not include more information regarding the existence or terms of this Agreement than is required by Law, legal process or by stock exchange rule and shall seek the highest level of confidentiality then available for such information proposed to be released. Such notice shall include the exact text of the proposed release and the time and manner of the release. At the other Party's request, and before the release, the Party desiring to release further information shall consult with the other Party on the necessity for the disclosure and the text of the proposed further disclosure. Perrigo and Cumberland recognize that in addition to the other exceptions set forth herein, disclosure of this

Agreement to IRS and other tax authorities may be required, and Perrigo and Cumberland each waives the requirements of this subsection with respect to disclosure to such entities.

## XI. REPRESENTATIONS AND WARRANTIES

11.1 Representations, Warranties and Covenants by Cumberland. Cumberland hereby represents and warrants and covenants to Perrigo and Paddock, as of the Effective Date, as follows:

(a) Cumberland is a corporation duly organized and validly existing under the laws of the State of Tennessee;

(b) Cumberland has the requisite corporate authority to execute and deliver this agreement and to perform its obligations hereunder;

(c) Any Products delivered by Cumberland to Perrigo shall, have been manufactured, packaged, stored and shipped by Cumberland in all material respects with CGMPs, Specifications, and any other applicable Laws, and shall not be adulterated, misbranded or otherwise violative of the FFDCA or other applicable Laws in any material respect; and

(d) Cumberland has and will maintain throughout the Term all permits, licenses, registrations and other forms of governmental authorization and approval as required by Law in order for Cumberland to execute and deliver this Agreement and to perform its obligations hereunder in accordance with all applicable Laws.

11.2 Representation, Warranties and Covenants by Perrigo and Paddock. Each of Perrigo and Paddock hereby represents and warrants and covenants to Cumberland, as of the Effective Date, as follows:

(a) Perrigo is a corporation duly organized and in good standing under the laws of Michigan, and Paddock is a limited liability company duly organized and in good standing under the laws of Delaware;

(b) Perrigo and Paddock each have the requisite corporate authority to execute and deliver this Agreement and to perform its obligations hereunder;

(c) Perrigo and Paddock each have and will maintain throughout the Term all federal, state and local permits, licenses, registrations and other forms of governmental authorization and approval as required by Law in order for it to execute and deliver this Agreement and to perform its obligations hereunder; and

(d) Perrigo will perform its obligations hereunder in accordance with all applicable Laws, and shall test, store, handle, market, promote, sell and distribute the Products in accordance with all applicable Laws and the Specifications.

11.3 Disclaimer. Except as set forth in Section 11.1, CUMBERLAND MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED OR OTHERWISE, OF ANY KIND WITH RESPECT TO THE PRODUCTS OR THE MANUFACTURE, SALE, DISTRIBUTION OR USE THEREOF, AND CUMBERLAND HEREBY DISCLAIMS AND SHALL NOT BE RESPONSIBLE FOR ANY OR ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OR REPRESENTATIONS OF WORKMANSHIP, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

11.4 Limitation of Liability. UNLESS THE CONDUCT OF CUMBERLAND IS DETERMINED BY A COURT OF COMPETENT JURISDICTION TO HAVE BEEN WILLFUL MISCONDUCT OR FRAUDULENT, CUMBERLAND AND ITS AFFILIATES, EMPLOYEES, AGENTS, OFFICERS AND DIRECTORS SHALL NOT BE LIABLE IN ANY WAY WHATSOEVER FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES SUFFERED BY PERRIGO, PADDOCK OR ANY OTHER PERSON, INCLUDING WITHOUT LIMITATION LOST PROFITS OR BUSINESS REVENUE OR OTHER ECONOMIC LOSS OF ANY KIND WHATSOEVER, WHETHER OR NOT SUCH DAMAGES ARE FORESEEABLE OR CUMBERLAND, ITS AFFILIATES, EMPLOYEES, AGENTS, OFFICERS OR DIRECTORS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL THE TOTAL COLLECTIVE LIABILITY OF CUMBERLAND AND ITS AFFILIATES, EMPLOYEES, AGENTS, OFFICERS AND DIRECTORS FOR A PARTICULAR CLAIM, REGARDLESS OF VALUE OR NATURE, EXCEED THE AMOUNTS PAID UNDER THIS AGREEMENT FOR THE PORTION OF THE PRODUCTS THAT ARE THE SUBJECT MATTER OF THAT PARTICULAR CLAIM. IN NO EVENT SHALL THE COLLECTIVE LIABILITY OF CUMBERLAND AND ITS AFFILIATES, EMPLOYEES, AGENTS, OFFICERS AND DIRECTORS FOR ALL CLAIMS IN CONNECTION WITH THIS AGREEMENT EXCEED THE TOTAL AMOUNT PAID BY PERRIGO TO CUMBERLAND HEREUNDER. THE ABOVE LIMITATION SHALL NOT APPLY TO THIRD PARTY PRODUCT LIABILITY INDEMNIFICATION CLAIMS.

## XII. NOTICES

12.1 Notices. Any notices or reports required or permitted under this Agreement shall be in writing and shall be deemed to have been given for all purposes if mailed by first class certified or registered mail or transmitted electronically be facsimile with mailed confirmation copy to the following address of each Party:

For Perrigo:

Perrigo Company
515 Eastern Avenue
Allegan, MI 49010
Attn: General Counsel

| | |
|---|---|
| For Paddock: | Paddock Laboratories, LLC<br>c/o Perrigo Company<br>515 Eastern Avenue<br>Allegan, MI 49010<br>Attn: General Counsel |
| For Cumberland: | Cumberland Pharmaceuticals Inc.<br>2525 West End Ave., Suite 950,<br>Nashville, Tennessee 37023<br>Attn: Chief Executive Officer |

or to such other addresses as shall have been subsequently furnished by written notice to the other Parties.

**XII. GOVERNING LAW AND PARTIES BOUND**

13.1 Governing Law. The validity and interpretation of this Agreement and the legal relations of the Parties to it shall be governed exclusively by the internal laws, and not the law of conflicts, of the State of Delaware. The Parties each hereby submit to the non-exclusive jurisdictions of federal and state courts in the State of Delaware for the purposes of any suit, action or other proceeding relating to this Agreement. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or state courts of the State of Delaware, and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

13.2 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and assigns. This Agreement and the rights granted herein may not be assigned or transferred (whether by contract, operation of law or otherwise) by Perrigo or Paddock without the prior written consent of Cumberland, provided that each of Perrigo and Paddock may assign or transfer its rights and obligations hereunder to any Affiliate or to a successor or assignee of all or substantially all of its relevant prescription pharmaceutical business or assets, without Cumberland's prior consent, but only if such Affiliate, successor or assignee is not at such time involved in a litigation or other legal proceeding with Cumberland. Cumberland may assign or transfer its rights and obligations hereunder to any Affiliate or to a successor or assignee of all or substantially

all of its relevant prescription pharmaceutical business or assets, without Perrigo's or Paddock's prior consent. Notwithstanding anything to the contrary contained herein, Cumberland shall be free to delegate any and all of its obligations under this Agreement to an Affiliate or Third Party, including without limitation to use any one or more contract manufacturers to produce and package the Products (including without limitation any active pharmaceutical ingredient and/or finished tablets).

## XIV. FORCE MAJEURE

14.1 If either Party is prevented from complying, either totally or in part, with any of the terms or provisions set forth herein (other than for any payment obligations hereunder), by reason of force majeure, including, by way of example and not of limitation, fire, flood, explosion, storm, strike, lockout or other labor dispute, riot, war, rebellion, accidents, acts of God, acts of governmental agencies or instrumentalities (including, but not limited to, lack of a sufficient governmentally mandated quota of the Products) or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing contingencies or not, said Party shall provide written notice of same to the other Party. Said notice shall be provided within ten (10) working days of the occurrence of such event and shall identify the requirements of this Agreement or such of its obligations as may be affected and to the extent so affected, said obligations shall be suspended during the period of such disability. The Party prevented from performing hereunder shall use Commercially Reasonable Efforts to remove such disability, and shall continue performance whenever such causes are removed. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the force majeure condition and the duration of the affected Party's nonperformance. If the period of any previous actual nonperformance of Cumberland because of Cumberland force majeure conditions plus the anticipated future period of Cumberland nonperformance because of such conditions will exceed an aggregate of one hundred eighty (180) days within any twenty-four (24) month period, Perrigo may terminate this Agreement by notice to Cumberland. If the period of any previous actual nonperformance of Perrigo because of Perrigo force majeure conditions plus the anticipated future period of Perrigo nonperformance because of such conditions will exceed an aggregate of one hundred eighty (180) days within any twenty-four (24) month period, Cumberland may terminate this Agreement by notice to Perrigo. The provisions of Sections 8.3 and 8.4 and Article XXI shall apply in the event of any such termination. When such circumstances as those contemplated herein arise, the Parties shall discuss in good faith, what, if any, modification of the terms set forth herein may be required in order to arrive at an equitable solution.

## XV. AMENDMENTS

15.1 No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

## XVI. INDEPENDENT CONTRACTORS

16.1 This Agreement shall not constitute or give rise to any employer-employee, agency, partnership or joint venture relationship among or between the Parties, and each Party's performance hereunder is that of a separate, independent entity.

## XVII. NO IMPLIED RIGHTS

17.1 Nothing in this Agreement shall be deemed or implied to be the grant by one Party to the other of any right, title or interest in the Products, Intellectual Property or any other proprietary right of the other, except as is expressly provided for herein.

## XVIII. SEVERABILITY

18.1 To the extent any provision or term set forth herein is or becomes unenforceable by operation of Law, such unenforceability shall not affect the remaining provisions of this Agreement. The Parties agree to renegotiate in good faith any provision or term held to unenforceable and to be bound by the mutually agreed substitute provision.

## XIX. MODIFICATION BY OPERATION OF LAW

19.1 If any of the terms or provisions of this Agreement are in or come into conflict with any applicable Law within the Territory then such term or provision shall be deemed inoperative to the extent it may conflict therewith and shall be deemed to be modified to conform with such Law unless such modification would render the affected provision inconsistent with or contrary to the intent of the Parties. However, in the event the terms and conditions of this Agreement are materially altered as a result of this subsection, the Parties shall in good faith attempt to renegotiate said terms and conditions to resolve any disputes related thereto.

## XX. DESCRIPTIVE HEADINGS

20.1 The captions and descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

## XXI. SURVIVAL

21.1 The provisions of Sections 3.5, 8.3, 8.4, 11.3 and 11.4, and Articles IV, VII, IX, X, XII, XIII, and XV through XXVI shall survive any expiration or termination of this Agreement.

## XXII. ENTIRE AGREEMENT

22.1 This Agreement, including the Exhibits attached hereto, together with the Settlement Agreement, contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior drafts or understandings.

## XXIII. WAIVER

23.1 A waiver by any Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of any Party.

## XXIV. SINGULAR AND PLURAL

24.1 The singular form of any noun or pronoun shall include the plural when the context in which such a word is used is such that it is apparent the singular is intended to include the plural or vice versa. Neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The word “any” shall mean “any and all” unless otherwise clearly indicated by context. “$” as used in this Agreement means the lawful currency of the United States of America. Where a Party’s consent is required hereunder, except as otherwise specified herein, such Party’s consent may be granted or withheld in such Party’s sole discretion. Derivative forms of any capitalized term defined herein shall have meanings correlative to the meaning specified herein.

24.2 Unless the context requires otherwise: (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (iii) any reference herein to any Person shall be construed to include the Person’s successors and permitted assigns, (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Appendices or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Appendices or Exhibits of this Agreement.

## XXV. COUNTERPARTS

25.1 This Agreement may be executed in any number of signature page counterparts transmitted via facsimile, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same Agreement.

## XXVI. DOCUMENT PREPARATION

26.1 Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

SIGNATURES FOLLOW ON NEXT PAGE

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in duplicate by their duly authorized representatives in the places provided below.

Perrigo Company

| | |
|---|---|
| By | /s/ Andrew Solomon |
| Title | Assistant Secretary |
| Date | November 10, 2012 |

Cumberland Pharmaceuticals Inc.

| | |
|---|---|
| By | /s/ A.J Kazimi |
| Title | Chief Executive Officer |
| Date | November 12, 2012 |

Paddock Laboratories, LLC

| | |
|---|---|
| By | /s/ Andrew Solomon |
| Title | Assistant Secretary |
| Date | November 10, 2012 |

**FIRST AMENDMENT TO**
**FIFTH AMENDED AND RESTATED LOAN AGREEMENT**

**THIS FIRST AMENDMENT TO FIFTH AMENDED AND RESTATED LOAN AGREEMENT** (this "Amendment"), dated as of March 29, 2012, is made and entered into on the terms and conditions hereinafter set forth, by and between CUMBERLAND PHARMACEUTICALS, INC., a Tennessee corporation (the "Borrower"), and BANK OF AMERICA, N.A., a national banking association (the "Bank").

**RECITALS:**

1. The Borrower and the Bank are parties to a Fifth Amended and Restated Loan Agreement dated as of August 2, 2011 (as the same heretofore may have been or hereafter may be further amended, restated, supplemented, extended, renewed, replaced or otherwise modified from time to time, the "Loan Agreement"), pursuant to which the Bank has agreed to extend credit to the Borrower subject to and upon the terms and conditions set forth in the Loan Agreement.

2. The parties hereto desire to amend the Loan Agreement in certain respects as more particularly hereinafter set forth.

3. Capitalized terms used but not otherwise defined in this Amendment shall have the same meanings as in the Loan Agreement.

**AGREEMENTS:**

**NOW, THEREFORE,** in consideration of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of all of which are hereby acknowledged, the parties hereto agree as follows:

1. **Amendment of Section 8.8.** Section 8.8 of the Loan Agreement is hereby amended as follows:

(a) Clause (d)(ii) is hereby amended by inserting "(as hereinafter defined)" immediately after "Cash Equivalents" in the second line.

(b) The literary paragraph following clause (d), which begins, "As used herein, "Cash Equivalents" means . . ." is hereby deleted in its entirety.

2. **Amendment of Section 8.13.** Section 8.13 of the Loan Agreement is hereby amended by adding the following new subsection (d) and related definitions:

(d) Other Permitted Investments, but only if and for so long as Borrower's Cash Equivalents exceed $10,000,000.

As used herein:

"Cash Equivalents" means investments permitted by the Investment Policy and having maturities of not more than twelve months from the date of acquisition, but excluding investments described in paragraph 3 of Part III of the Investment Policy.

"Investment Policy" means the Borrower 's Investment Policy Effective January 2012, a copy of which is attached hereto as Exhibit B.

"Other Permitted Investments" means (i) investments permitted by the Investment Policy other than Cash Equivalents, and (ii) equity investments in connection with payments to entities engaged in

researching and developing pharmaceutical products if the Borrower's primary purpose is to derive rights to such pharmaceutical products.

1. **Addition of Exhibit B.** The Loan Agreement is hereby amended by adding thereto the Exhibit B that is attached to this Amendment.

2. **Conditions to Effectiveness.** This Amendment shall be effective only upon the satisfaction of the following conditions:

(a) the Borrower, the Bank and the other parties whose names appear on the signature page(s) hereof shall have executed and delivered a counterpart of this Amendment;

(b) each of the representations and warranties of the Borrower contained in Section 5 shall be true and correct as of the date as of which all of the other conditions contained in this Section 4 shall have been satisfied;

(c) the Borrower shall have paid all cost and expenses, including attorney's fees, reasonably incurred by the Bank in connection with the preparation, execution, delivery and any recording or filing of this Amendment or any instrument, document or agreement contemplated hereby; and

(d) the Bank shall have received such other documents, instruments, certificates, opinions and approvals as it reasonably may have requested.

3. **Representations and Warranties of the Borrower.** As an inducement to the Bank to enter into this Amendment, the Borrower hereby represents and warrants that on and as of the date hereof, and taking into account the provisions hereof, the representations and warranties contained in the Loan Agreement and the other Loan Documents are true and correct in all material respects, except for representations and warranties that expressly relate to an earlier date, which remain true and correct as of said earlier date.

4. **Effect of Amendment; Continuing Effectiveness of Loan Agreement and Loan Documents.**

(a) Neither this Amendment nor any other indulgences that may have been granted to the Borrower by the Bank shall constitute a course of dealing or otherwise obligate the Bank to modify, expand or extend the agreements contained herein, to agree to any other amendments to the Loan Agreement or to grant any consent to, waiver of or indulgence with respect to any other noncompliance with any provision of the Loan Documents.

(b) Upon and after the effectiveness of this Amendment, each reference in the Loan Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Loan Agreement, and each reference in the other Loan Documents to "the Loan Agreement", "thereunder", "thereof" or words of like import referring to the Loan Agreement, shall mean and be a reference to the Loan Agreement as modified hereby. This Amendment shall constitute a Loan Document for all purposes of the Loan Agreement and the other Loan Documents.

(c) Except to the extent amended or modified hereby, the Loan Agreement, the other Loan Documents and all terms, conditions and provisions thereof shall continue in full force and effect in all respects and shall be construed in accordance with the modification of the Loan Agreement effected hereby.

5. **Release and Waiver.** The Borrower hereby acknowledges and stipulates that it has no claims or causes of action of any kind whatsoever against the Bank, its affiliates, officers, directors, employees or agents. The Borrower represents that it is entering this Amendment freely, and with the advice of counsel as to its legal alternatives. The Borrower hereby releases the Bank, its affiliates, officers, directors, employees and agents, from any and all claims, causes of action, demands and liabilities of any kind whatsoever whether direct or indirect, fixed or contingent, liquidated or unliquidated, disputed or undisputed, known or unknown, that the Borrower has or may acquire in the future relating in any way to

any event, circumstance, action or failure to act to the date of this Amendment, excluding, however, claims or causes of actions resulting solely from the Bank's own gross negligence or willful misconduct. The release by the Borrower herein, together with the other terms and provisions of this Amendment, are executed by the Borrower advisedly and without coercion or duress from the Bank, the Borrower having determined that the execution of this Amendment, and all of its terms, conditions and provisions are in the Borrower's economic best interest.

6. **Further Actions.** Each of the parties to this Amendment agrees that at any time and from time to time upon written request of the other party, it will execute and deliver such further documents and do such further acts and things as such other party reasonably may request in order to effect the intents and purposes of this Amendment.

7. **Counterparts.** This Amendment may be executed in multiple counterparts or copies, each of which shall be deemed an original hereof for all purposes. One or more counterparts or copies of this Amendment may be executed by one or more of the parties hereto, and some different counterparts or copies executed by one or more of the other parties. Each counterpart or copy hereof executed by any party hereto shall be binding upon the party executing same even though other parties may execute one or more different counterparts or copies, and all counterparts or copies hereof so executed shall constitute but one and the same agreement. Each party hereto, by execution of one or more counterparts or copies hereof, expressly authorizes and directs any other party hereto to detach the signature pages and any corresponding acknowledgment, attestation, witness or similar pages relating thereto from any such counterpart or copy hereof executed by the authorizing party and affix same to one or more other identical counterparts or copies hereof so that upon execution of multiple counterparts or copies hereof by all parties hereto, there shall be one or more counterparts or copies hereof to which is(are) attached signature pages containing signatures of all parties hereto and any corresponding acknowledgment, attestation, witness or similar pages relating thereto.

8. **Miscellaneous.**

(a) This Amendment shall be governed by, construed and enforced in accordance with the laws of the State of Tennessee, without reference to the conflicts or choice of law principles thereof.

(b) The headings in this Amendment and the usage herein of defined terms are for convenience of reference only, and shall not be construed as amplifying, limiting or otherwise affecting the substantive provisions hereof.

(c) All references herein to the preamble, the recitals or sections, paragraphs, subparagraphs, annexes or exhibits are to the preamble, recitals, sections, paragraphs, subparagraphs, annexes and exhibits of or to this Amendment unless otherwise specified. The words "hereof", "herein" and "hereunder" and words of similar import, when used in this Amendment, refer to this Amendment as a whole and not to any particular provision of this Amendment.

(d) Any reference herein to any instrument, document or agreement, by whatever terminology used, shall be deemed to include any and all amendments, modifications, supplements, extensions, renewals, substitutions and/or replacements thereof as the context may require.

(e) When used herein, (1) the singular shall include the plural, and vice versa, and the use of the masculine, feminine or neuter gender shall include all other genders, as appropriate, (2) "include", "includes" and "including" shall be deemed to be followed by "without limitation" regardless of whether such words or words of like import in fact follow same, and (3) unless the context clearly indicates otherwise, the disjunctive "or" shall include the conjunctive "and".

**IN WITNESS WHEREOF,** the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

**[Remainder of Page Intentionally Left Blank;**
**Signature Pages Follow]**

[Signature Page to First Amendment to Fifth Amended and Restated Loan Agreement
(Cumberland Pharmaceuticals, Inc.) dated as of March 29, 2012]

**BORROWER:**

CUMBERLAND PHARMACEUTICALS INC.

By: /s/ A.J. Kazimi
Name: A.J. Kazimi
Title: Chief Executive Officer

**CONSENTED TO AND APPROVED:**

CUMBERLAND PHARMA SALES CORP.

By: /s/ A.J. Kazimi
Name: A.J. Kazimi
Title: Chief Executive Officer

**ACKNOWLEDGED:**

CUMBERLAND EMERGING TECHNOLOGIES, INC.

By: /s/ A.J. Kazimi
Name: A.J. Kazimi
Title: Chief Executive Officer

[Signature Page to First Amendment to Fifth Amended and Restated Loan Agreement
(Cumberland Pharmaceuticals, Inc.) dated as of March 29, 2012]

**Bank:**

BANK OF AMERICA, NA

By: /s/ Suzanne B. Smith

Name: Suzanne B. Smith

Title: Senior Vice President

**EXHIBIT B**


# INVESTMENT POLICY

**Effective January 2012**

## I. Purpose of the Policy

The purpose of the policy is to provide liquidity to fund the firm's ongoing operating needs, and act as a repository for both the accumulation of cash reserves needed to cushion economic down cycles and cash earmarked for the firm's strategic needs.

## II. Investment Objectives

The policy objectives, listed in order of importance, are as follows:

1. Preserve principal;
2. Maintain sufficient liquidity to meet forecasted cash needs;
3. Maintain a diversified portfolio in order to minimize credit risk; and
4. Maximize yield subject to the above criteria.

## III. Authorized Investments

**Pursuant to the objectives above the Company's portfolio may be invested in certain authorized investments outlined below. The portfolio may not be invested in any investment vehicle or security not specified below, including, for example, auction rate securities.**

1. *US Treasury Securities* - US Treasury notes, bills and bonds. There is no upper limit restriction as to the maximum dollar amount or percent of the portfolio that may be invested in the US Treasury securities.

2. *United States Government Obligations* - Any obligation issued or backed (federal agencies). Obligations backed by the full faith and credit of the United States Government are preferred but not required. No more than 25% may be invested in obligations of any one federal agency.

3. *Funds* - Any open end money market fund regulated by the U.S. government under Investment Company Act rule 2a-7. Any investment fund regulated advised by a Registered Investment Advisor under rule 3c7. Such fund investment guidelines must state that “the fund will seek to maintain a $1 per share net asset value.” The company's investment in any one fund may not exceed 10% of the assets of the fund into which it is invested.

4. *Bank Obligations* - Any certificate of deposit, time deposit, eurodollar CD issued by a foreign branch of a US bank, bankers' acceptance, bank note or letter of credit issued by a US bank may not exceed the FDIC insured level unless the issuing bank has at least the second highest long term debt rating from at least one recognized rating agency or minimum assets of $5 Billion. Bank Obligations shall not represent more than 30% of the Company's portfolio.

5. *Repurchase Agreements* - Any Repurchase Agreement purchased from one of the top 50 US banks **(based on assets)** or one of the primary dealers regulated by the Federal Reserve that is at least 102% collateralized by US Government obligations. Repurchase Agreements may not represent more than 50% of the Company's portfolio.

6. *Commercial Paper* - Any directly held commercial paper issued by a domestic corporation with a maturity of 270 days or less that carries a rating not less than A-1 or P-1, or F-1 by a nationally recognized statistical rating organization (for example, *Standard & Poor's, Moody's or Fitch*). Commercial paper shall not represent more than 50% of the Company's portfolio.

## IV. Investment Authorization

Prior to making an investment, the transaction must be approved by the CEO. Upon approval, the Chief Financial Officer is responsible for completing the transaction. Quarterly, the Chief Financial Officer shall submit to the CEO a summary document listing open investments in order to review asset allocation, investment selection, portfolio performance and overall adherence to the investment policy guidelines.

**WAIVER AND SECOND AMENDMENT TO**
**FIFTH AMENDED AND RESTATED LOAN AGREEMENT**

**THIS WAIVER AND SECOND AMENDMENT TO FIFTH AMENDED AND RESTATED LOAN AGREEMENT** (this "Amendment"), dated as of March 7, 2013, is made and entered into on the terms and conditions hereinafter set forth, by and between CUMBERLAND PHARMACEUTICALS INC., a Tennessee corporation (the "Borrower"), and BANK OF AMERICA, N.A., a national banking association (the "Bank").

**RECITALS:**

1. The Borrower and the Bank are parties to a Fifth Amended and Restated Loan Agreement dated as of August 2, 2011, as amended by a First Amendment to Fifth Amended and Restated Loan Agreement dated March 29, 2012 (as the same heretofore may have been or hereafter may be further amended, restated, supplemented, extended, renewed, replaced or otherwise modified from time to time, the "Loan Agreement"), pursuant to which the Bank has agreed to extend credit to the Borrower subject to and upon the terms and conditions set forth in the Loan Agreement.

2. The Borrower has repurchased shares of its capital stock in excess of the amount permitted by Section 8.8(d) of the Loan Agreement and has requested that the Bank waive the Borrower's noncompliance with that Section.

3. The parties hereto desire to amend the Loan Agreement in certain respects as more particularly hereinafter set forth.

4. Capitalized terms used but not otherwise defined in this Amendment shall have the same meanings as in the Loan Agreement.

**AGREEMENTS:**

**NOW, THEREFORE,** in consideration of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of all of which are hereby acknowledged, the parties hereto agree as follows:

1. **Waiver Regarding Section 8.8(d).** Prior to the date hereof, the Borrower has expended $10,654,445 in respect of repurchases of its capital stock, which exceeds the $10,000,000 amount permitted by Section 8.8(d). The Bank hereby waives this noncompliance with that section, and acknowledges and agrees that the same shall not constitute an event of default under the Loan Agreement.

2. **Amendment of Section 8.8(d).** Section 8.8(d) of the Loan Agreement is hereby amended by deleting "the date of this Agreement" from the second line and substituting in lieu thereof "March 1, 2013".

3. **Conditions to Effectiveness.** This Amendment shall be effective only upon the satisfaction of the following conditions:

(a) the Borrower, the Bank and the other parties whose names appear on the signature page(s) hereof shall have executed and delivered a counterpart of this Amendment;

(b) each of the representations and warranties of the Borrower contained in Section 4 shall be true and correct as of the date as of which all of the other conditions contained in this Section 3 shall have been satisfied;

(c) the Borrower shall have paid all cost and expenses, including attorney's fees, reasonably incurred by the Bank in connection with the preparation, execution, delivery and any recording or filing of this Amendment or any instrument, document or agreement contemplated hereby; and

(d) the Bank shall have received such other documents, instruments, certificates, opinions and approvals as it reasonably may have requested.

1. **Representations and Warranties of the Borrower.** As an inducement to the Bank to enter into this Amendment, the Borrower hereby represents and warrants that on and as of the date hereof, and taking into account the provisions hereof, the representations and warranties contained in the Loan Agreement and the other Loan Documents are true and correct in all material respects, except for representations and warranties that expressly relate to an earlier date, which remain true and correct as of said earlier date.

2. **Effect of Amendment; Continuing Effectiveness of Loan Agreement and Loan Documents.**

(a) Neither this Amendment nor any other indulgences that may have been granted to the Borrower by the Bank shall constitute a course of dealing or otherwise obligate the Bank to modify, expand or extend the agreements contained herein, to agree to any other amendments to the Loan Agreement or to grant any consent to, waiver of or indulgence with respect to any other noncompliance with any provision of the Loan Documents.

(b) Upon and after the effectiveness of this Amendment, each reference in the Loan Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Loan Agreement, and each reference in the other Loan Documents to "the Loan Agreement", "thereunder", "thereof" or words of like import referring to the Loan Agreement, shall mean and be a reference to the Loan Agreement as modified hereby. This Amendment shall constitute a Loan Document for all purposes of the Loan Agreement and the other Loan Documents.

(c) Except to the extent amended or modified hereby, the Loan Agreement, the other Loan Documents and all terms, conditions and provisions thereof shall continue in full force and effect in all respects and shall be construed in accordance with the modification of the Loan Agreement effected hereby and the waiver contained herein.

3. **Release and Waiver.** The Borrower hereby acknowledges and stipulates that it has no claims or causes of action of any kind whatsoever against the Bank, its affiliates, officers, directors, employees or agents. The Borrower represents that it is entering this Amendment freely, and with the advice of counsel as to its legal alternatives. The Borrower hereby releases the Bank, its affiliates, officers, directors, employees and agents, from any and all claims, causes of action, demands and liabilities of any kind whatsoever whether direct or indirect, fixed or contingent, liquidated or unliquidated, disputed or undisputed, known or unknown, that the Borrower has or may acquire in the future relating in any way to any event, circumstance, action or failure to act to the date of this Amendment, excluding, however, claims or causes of actions resulting solely from the Bank's own gross negligence or willful misconduct. The release by the Borrower herein, together with the other terms and provisions of this Amendment, are executed by the Borrower advisedly and without coercion or duress from the Bank, the Borrower having determined that the execution of this Amendment, and all of its terms, conditions and provisions are in the Borrower's economic best interest.

4. **Further Actions.** Each of the parties to this Amendment agrees that at any time and from time to time upon written request of the other party, it will execute and deliver such further documents and do such further acts and things as such other party reasonably may request in order to effect the intents and purposes of this Amendment.

5. **Counterparts.** This Amendment may be executed in multiple counterparts or copies, each of which shall be deemed an original hereof for all purposes. One or more counterparts or copies of this Amendment may be executed by one or more of the parties hereto, and some different counterparts or copies executed by one or more of the other parties. Each counterpart or copy hereof executed by any

party hereto shall be binding upon the party executing same even though other parties may execute one or more different counterparts or copies, and all counterparts or copies hereof so executed shall constitute but one and the same agreement. Each party hereto, by execution of one or more counterparts or copies hereof, expressly authorizes and directs any other party hereto to detach the signature pages and any corresponding acknowledgment, attestation, witness or similar pages relating thereto from any such counterpart or copy hereof executed by the authorizing party and affix same to one or more other identical counterparts or copies hereof so that upon execution of multiple counterparts or copies hereof by all parties hereto, there shall be one or more counterparts or copies hereof to which is(are) attached signature pages containing signatures of all parties hereto and any corresponding acknowledgment, attestation, witness or similar pages relating thereto.

6. **Miscellaneous.**

(a) This Amendment shall be governed by, construed and enforced in accordance with the laws of the State of Tennessee, without reference to the conflicts or choice of law principles thereof.

(b) The headings in this Amendment and the usage herein of defined terms are for convenience of reference only, and shall not be construed as amplifying, limiting or otherwise affecting the substantive provisions hereof.

(c) All references herein to the preamble, the recitals or sections, paragraphs, subparagraphs, annexes or exhibits are to the preamble, recitals, sections, paragraphs, subparagraphs, annexes and exhibits of or to this Amendment unless otherwise specified. The words "hereof", "herein" and "hereunder" and words of similar import, when used in this Amendment, refer to this Amendment as a whole and not to any particular provision of this Amendment.

(d) Any reference herein to any instrument, document or agreement, by whatever terminology used, shall be deemed to include any and all amendments, modifications, supplements, extensions, renewals, substitutions and/or replacements thereof as the context may require.

(e) When used herein, (1) the singular shall include the plural, and vice versa, and the use of the masculine, feminine or neuter gender shall include all other genders, as appropriate, (2) "include", "includes" and "including" shall be deemed to be followed by "without limitation" regardless of whether such words or words of like import in fact follow same, and (3) unless the context clearly indicates otherwise, the disjunctive "or" shall include the conjunctive "and".

**IN WITNESS WHEREOF,** the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

**[Remainder of Page Intentionally Left Blank;**
**Signature Pages Follow]**

[Signature Page to Second Amendment to Fifth Amended and Restated Loan Agreement
(Cumberland Pharmaceuticals Inc.) dated as of March 7, 2013]

**BORROWER:**

CUMBERLAND PHARMACEUTICALS INC.

By: /s/ Rick S. Greene
Name: Rick S. Greene
Title: Vice President and Chief Financial Officer

**CONSENTED TO AND APPROVED:**

CUMBERLAND PHARMA SALES CORP.

By: /s/ Rick S. Greene
Name: Rick S. Greene
Title: Vice Presiden and Chief Financial Officer

**ACKNOWLEDGED:**

CUMBERLAND EMERGING TECHNOLOGIES, INC.

By: /s/ Rick S. Greene
Name: Rick S. Greene
Title: Vice President and Chief Financial Officer

[Signature Page to Second Amendment to Fifth Amended and Restated Loan Agreement
(Cumberland Pharmaceuticals Inc.) dated as of March 7, 2013]

**Bank:**

BANK OF AMERICA, NA

By: /s/ Suzanne B. Smith

Name: Suzanne B. Smith

Title: Senior Vice President

**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 11, 2013, with respect to the consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, equity, and cash flows for each of the years in the three-year period ended December 31, 2012, the related financial statement schedule, and the effectiveness of internal control over financial reporting as of December 31, 2012, which reports appear in the December 31, 2012 annual report on Form 10-K of Cumberland Pharmaceuticals Inc.

/s/ KPMG LLP

Nashville, Tennessee

March 12, 2013

**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 12, 2013

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, Rick S. Greene, 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 12, 2013

By: /s/ Rick S. Greene
Rick S. Greene
Vice President 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, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, A.J. Kazimi, Chief Executive Officer, and Rick S. Greene, Vice President 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 12, 2013

*/s/ Rick S. Greene*

Rick S. Greene
Vice President and Chief Financial Officer
March 12, 2013