CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 11, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013
of

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

2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
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Cumberland Pharmaceuticals Inc. Common Stock, no par value, shares are registered pursuant to Section 12(b) of the Act and are listed on the Nasdaq Global Select Market.

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates as of June 30, 2013 was $51,343,000. The number of shares of the registrant’s Common Stock, no par value, outstanding as of March 3, 2014 was 17,878,619.

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 2014 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 small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs. We market and sell our approved products through our hospital and field sales forces in the United States, which together comprised approximately 60 sales representatives and managers as of December 31, 2013.

Our product portfolio includes:

- Acetadote® (acetylcysteine) Injection, for the treatment of acetaminophen poisoning,
- Caldolor® (ibuprofen) Injection, for the treatment of pain and fever,
- Kristalose® (lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation,
- Omeclamox®-Pak, triple therapy combination medication for Helicobacter pylori (H. pylori) infection and duodenal ulcer disease,
- Hepatoren® (ifetroban) Injection, a Phase II candidate for the treatment of hepatorenal syndrome.

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

Our strategy includes maximizing the potential of our existing products and selectively expanding our portfolio of differentiated products. We market four products approved for sale in the United States. Through our international partners, we are working to bring our products to patients in countries outside the U.S. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to 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. During 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange. Our website address is www.cumberlandpharma.com. We make available through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all other press releases, filings and amendments to those reports as soon as reasonably practicable after their filing with the U.S. Securities and Exchange Commission, (“SEC”). These filings are also available to the public at www.sec.gov.

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PRODUCTS

Our key products include:

Products	Indication	Status
Acetadote®	Acetaminophen Poisoning	Marketed following FDA approval in 2004; new formulation FDA approved in 2011.
Caldolor®	Pain and Fever	Marketed following FDA approval in 2009.
Kristalose®	Chronic and Acute Constipation	Marketed by us since 2006.
Omeclamox®-Pak	H. pylori infection and duodenal ulcer disease	Marketed by us since January 1, 2014.
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 relieving and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency departments in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

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 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 the new formulation of Acetadote designed to replace our original formulation. The new formulation, which is the result of the aforementioned Phase IV commitment, contains no ethylene diamine tetracetic acid ("EDTA") or other stabilization agent, chelating agent or preservative. 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 United States Patent and Trademark Office (the “USPTO”) issued U.S. Patent number 8,148,356 (the “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompasses the Acetadote formulation and includes composition of matter claims. The 356 Acetadote Patent will expire in May 2026.

In March 2013, the USPTO issued U.S. Patent number 8,399,445 (the “445 Acetadote Patent”) which is also assigned to us. The claims of the 445 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. The 445 Acetadote Patent will expire in August 2025.

On February18, 2014, the USPTO issued U.S. Patent number 8,653,061 (the “061 Acetadote Patent”) which is assigned to us. The claims of the 061 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. Following its issuance, the 061 Acetadote Patent was listed in the FDA Orange Book. The 061 Acetadote Patent is scheduled to expire in August 2025. We are continuing to seek additional claims to protect our intellectual property associated with Acetadote.

On February 24, 2014, we received a Notice of Allowance from the USPTO for a patent relating to the use of the Acetadote formulation to treat patients with acetaminophen overdose. The new patent will include claims regarding the administration method of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection, and is scheduled to expire in April 2032.

On November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. That product, with the formulation containing EDTA, was subsequently introduced by APP, a division of Fresenius Kabi USA, around the end of 2012. On January 7, 2013, Perrigo announced initial distribution of our authorized generic acetylcysteine injection product. Both Acetadote and our authorized generic utilize the new, EDTA-free formulation which accounted for significant market share in 2013.

Acetadote Labeling Update

In June 2013, we announced that the FDA has approved updated labeling for Acetadote. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations. The new indication states, "Acetadote is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen." The product's previous indication included the qualifying phrase, "administered intravenously within 8 to 10 hours," which was originally intended to impress the urgency for early treatment. This phrase has been removed to avoid any potential confusion concerning efficacy when administration within that time period is not possible.

In addition, specific dosing guidance is now included for patients weighing over 100 kg. New language has also been added to alert health care providers that in certain clinical situations, therapy should be extended for some patients.

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 gathering additional data to determine whether we can address the FDA’s additional requirements.

Caldolor

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the United States for the treatment of both pain and fever. We conducted a series of clinical studies in over nine hundred adult patients to develop the data to support our submission for FDA approval. The FDA approved Caldolor for marketing in the United States 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 launched Caldolor and stocked the product at major wholesalers serving hospitals nationwide. We initially worked to establish a core group of medical facilities approving and purchasing the product. We then focused on building more sales volume and treating a broader range of patients within those stocked facilities.

We completed a series of Phase IV studies to gather additional data to support our Caldolor product. Those completed studies involved another 1,000 patients. The studies included evaluation of the product for the treatment of pediatric pain and pediatric fever in order to address our Phase IV commitment to the FDA for Caldolor. We are also evaluating improved packaging for the product.

We have worldwide commercial rights to Caldolor. We promote Caldolor in the United States through our dedicated hospital sales force. We have entered into several licensing agreements with experienced international partners to reach markets and 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 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 and internists.

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.

Omeclamox-Pak

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

Our involvement with Omeclamox-Pak was effective October 2013, through an agreement with Pernix Therapeutics ("Pernix"). Under the terms of the agreement, we promote the product to gastroenterologists across the United States through our field sales force that also promotes our Kristalose brand. Pernix continues to promote the product through its specialty sales force focusing on select primary care physicians. We are responsible for the marketing, sale and distribution of the product. We launched our promotion and distribution efforts to support Omeclamox-Pak in early 2014.

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. We would also seek orphan drug status and the associated seven years of marketing exclusivity for this indication.

Our acquisition of the rights to the ifetroban program includes an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property. Ifetroban was initially developed by a large pharmaceutical company for significant cardiovascular indications. They conducted extensive studies for their target indications and eventually donated the entire program to Vanderbilt University. Researchers at Vanderbilt identified ifetroban as a potentially valuable compound in treating patients for several niche indications. We acquired the rights to the ifetroban program from Vanderbilt through CET and intend to develop the product for several potential indications.

We have commenced manufacturing of an intravenous formulation of ifetroban and the FDA has cleared our Investigational New Drug ("IND") application for this product candidate. We have initiated a Phase II dose escalation clinical study to evaluate Hepatoren for the treatment of HRS and significantly progressed study enrollment in 2013. We have also filed patent applications to protect intellectual property related to the new indications for this product. 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 Caldolor and Acetadote through our dedicated hospital sales team. This team targets key hospitals across the U.S., and is comprised of sales professionals with substantial experience in the hospital market. 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. Our strategy has also involved increasing the focus of the hospital sales team on our Caldolor product and specifically our high priority accounts that already carry Caldolor. This strategy continues to contribute to Caldolor sales growth.

Gastroenterology market: We promote Kristalose and Omeclamox-Pak through a dedicated field sales team addressing a targeted group of physicians who are responsible for a majority of total retail prescriptions for both products. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe it provides product opportunities that can be penetrated with a modest sized sales force. By investing in our sales and marketing activities we believe that we can increase market share for both the products. Our focus on the gastroenterology market and our existing field sales infrastructure provided us with the rationale to add another gastroenterology product in 2013. We believe that our newest product, Omeclamox-Pak is an excellent fit for our field sales force. This force can feature both Kristalose and Omeclamox-Pak during most of their physician calls, expanding our presence in the gastroenterology market.

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 intellectual property or other protective features, and allow us to leverage our existing infrastructure. The addition of Omeclamox-Pak reflects our strategy as it meets our select criteria and our commitment to expanding our product portfolio. We will also continue to explore opportunities for label expansion to bring our products to new patient populations.

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 have established a network of select international partners to register our products and make them available to patients in their countries. We will continue to expand our network of international partners and continue to encourage our partners' commercialization efforts in their respective territories.

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

Caldolor Pediatric Fever Study

In August 2013, we announced top-line results from a clinical pediatric fever study evaluating the safety and efficacy of Caldolor compared to acetaminophen in treating fever (greater than or equal to 101.0ºF) in hospitalized patients ranging from birth to 16 years old. One hundred and three patients were enrolled in this multi-center, randomized, open-label active comparator study. The pediatric patients received either 10 mg/kg intravenous ibuprofen (not to exceed 400 mg per dose) or 10 mg/kg acetaminophen (not to exceed 650 mg per dose).

The primary endpoint of the study was to assess the area under the change in temperature versus time curve from baseline to two hours after the start of the initial dose of the study drug. In the two hours following dosing, pediatric patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen, p=0.012; therefore meeting the primary endpoint of the study.

After a single dose, significantly more patients receiving intravenous ibuprofen (93%) were no longer considered to be febrile (temperature less than 100.4ºF) compared to patients receiving acetaminophen (78%), p= 0.036.

Patients receiving intravenous ibuprofen experienced a greater temperature reduction compared to patients receiving acetaminophen at all temperature assessments during the four hours after dosing with reductions reaching statistical significance by ninety minutes post-dose.

No safety concerns were identified in the study and the incidence of adverse events was similar across treatment groups.

Caldolor Follow-Up Knee Arthroscopy Study

In February 2013, we announced favorable top-line results from a pilot clinical study evaluating the safety and analgesic efficacy of Caldolor compared to ketorolac injection in treating pain following knee arthroscopy procedures in adult patients. A follow-up, larger, multi-center study has been initiated to further study the safety and analgesic efficacy of Caldolor compared to ketorolac injection in treating pain following knee arthroscopy procedures in adult patients. One hundred patients are to be enrolled across four U.S. medical centers.

Caldolor Poster Presentations

Posters with data from three Caldolor studies were presented at the Annual Meeting of the American Society of Anesthesiologists in San Francisco in October 2013. The poster presentations were presented by Dr. Alberto Uribe, Post-Doctoral Researcher, Department of Anesthesiology, Wexner Medical Center at the Ohio State University.

A poster entitled "Multicenter, Open-label Surveillance Trials to Evaluate the Safety and Efficacy of a Shortened Infusion Time of Intravenous Ibuprofen" was presented. Two registry studies made up this presentation. In the first registry study eligible patients were enrolled to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from 13 clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

The second registry study was a Phase IV multi-center, open-label surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg of intravenous ibuprofen administered at induction of anesthesia and could continue Caldolor therapy for up to 24 hours. Three hundred patients from 21 clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

Another poster presentation was entitled "A Pilot Study to Determine the Efficacy of Intravenous Ibuprofen for Pain Control Following Arthroscopic Knee Surgery." This study was conducted at the Ohio State University Medical Center. The study enrolled fifty-one patients and the results indicate, compared to patients receiving ketorolac, patients receiving intravenous ibuprofen experienced less postoperative pain prior to discharge. Patients receiving Caldolor also

needed fewer narcotics and were less likely to require narcotics prior to discharge. This data supports the benefits of using Caldolor in a pre-emptive model of multimodal analgesia.

Caldolor Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated intravenous ibuprofen safety database combining data from our clinical trials

as well as previously published study data. We used this data to support our NDA filing and continue to use and update the data as a part of our ongoing safety evaluation. 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.

Hepatoren Study

We are evaluating Hepatoren as a treatment for hepatorenal syndrome - a life threatening condition, with a high mortality rate and no approved treatment in this country. We have launched a sixty four patient study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study is designed to evaluate escalating dose levels of Hepatoren. Progression to higher dose levels is reviewed and approved by an independent safety committee. Enrollment is well underway at major medical centers across the U.S. Recently, several top tier research institutions have been added to the study as we evaluate enrollment rates at all the centers.

Kristalose Pilot Study

We obtained clearance from the FDA for an IND to evaluate the use of Kristalose in a new patient population. In June 2013, we initiated a pilot study and completed enrollment of forty patients at one site. The study is pending our final report to the FDA.

Acetadote Study

We initiated a study to evaluate the safety and efficacy of the new Acetadote formulation and dosing through a multi-center, double blind randomized controlled study. The study was terminated in 2013 due to lack of enrollment.

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. A multi-disciplinary internal management team reviews these opportunities on a regular basis using a list of selection criteria. We have historically focused on product opportunities that are a strategic fit with our commercial organization, development expertise and medical focus., employing a variety of transaction structures. Our addition of Omeclamox-Pak reflects our business development process and follows our selection criteria.

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

Through CET, we collaborate with a select group of academic research institutions located in the mid-south region of the U.S. Our business development team is responsible for identifying appropriate CET product candidates and

negotiating with our university partners to secure rights to these candidates. Although we believe that these collaborations may be important to our business in the future, they are not material to our business at this time.

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

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

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 ("GMPs", Good Laboratory Practices ("GLPs"), and Good Clinical Practices ("GCPs"), and performing periodic audits of such vendors; and
- maintaining systems for document control, product and process change control, customer complaint handling, product stability studies and annual drug product reviews.

PROFESSIONAL AND MEDICAL AFFAIRS

Our medical team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. 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 approximately 60 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, to coincide with our launch of Kristalose as a Cumberland product, 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.

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 health insurance companies.

INTERNATIONAL PARTNERSHIPS

We have focused our products commercial efforts and sales organization on the U.S. market. Our international strategy focuses on successfully entering into agreements with a network of select international partners for commercialization of our products in international territories. Our international partners register our products and make them available to patients in their countries. Our international partners, licensed product rights and territories include the following:

International Partner	Product(s)	Territory
Alveda Pharmaceuticals	Caldolor	Canada
Phebra Pty Ltd	Caldolor and Acetadote	Australia and New Zealand
DB Pharm Korea Co. Ltd	Caldolor	South Korea
Harbin Gloria Pharmaceuticals Co. Ltd	Caldolor and Acetadote	China, Hong Kong and Macau
Sandor Medicaids Pvt. Ltd.	Caldolor	India
GerminMED	Caldolor, Acetadote and Kristalose	Qatar and the greater Arabian Peninsula
PT. SOHO Industri Pharmasi	Caldolor	Pacific Rim
PT. ETHICA Industri Farmasi	Caldolor	Indonesia
Grifols	Caldolor	Spain, Portugal and the majority of South America
Valmorca	Caldolor	Venezuela
Al-Nabil International	Caldolor and Acetadote	U.A.E.

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

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

- Seeking regulatory approvals for the products,
- Launching the brand,
- Managing the ongoing marketing, sales and product distribution,
- Addressing the ongoing regulatory requirements in the international territories,

- Remitting any upfront, regulatory and sales milestone payments,
- Providing the transfer price for supplies of product,
- Calculating and paying any royalties, as applicable.

Our responsibilities include:

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

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

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. ("Mylan") 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 April 2014.
- We entered into an agreement with Bayer Healthcare, LLC, or Bayer, in February 2008 for the manufacture of Caldolor and Acetadote. The agreement expired in September 2013. Bayer completed its obligations under the agreement in January 2014. Under the agreement, we paid Bayer a transfer price per each unit of Caldolor or Acetadote supplied.
- In November 2011, we entered into an 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.
- We entered into agreements with three international manufacturers for the commercial supply of Caldolor. We are working to transfer the Caldolor manufacturing process to these three manufacturers under these new agreements.
- Under the agreement we signed with Pernix, they are responsible for providing Omeclamox-Pak inventory.

Distribution

Like many other pharmaceutical companies, we engage a third party contractor with appropriate facilities and logistical expertise to support our distribution efforts. Since August 2002, Cardinal Health ("Cardinal") has exclusively handled U.S. product logistics efforts, including warehousing, shipping, customer billing and collections. We extended our distribution relationship with Cardinal during May 2013, when we entered into the First Amendment ("First Amendment") to the Exclusive Distribution Agreement under which we have operated since August 2010. The Amendment primarily serves to extend the term of the Agreement through June 30, 2016 and revises the fee schedule under the Agreement. Combined, the Agreement and Amendment appoint Cardinal as the exclusive distribution agent for Acetadote, Caldolor and Kristalose in the United States and Puerto Rico. Under the Amendment,

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we have also engaged Cardinal to assist with our physician sample orders based on the Prescription Drug Marketing Act of 1987 (the “PDMA”) for samples shipping. After June 30, 2016, the contract is automatically renewed on a year-to-year basis that is terminable by either party with ninety days' notice. Under the Amendment and Agreement, Cardinal agrees to provide various services, including storage, distribution, returns, customer support, and system access support to us in connection with the distribution of our products under certain guidelines at established fees.

TRADEMARKS AND PATENTS

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

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

Acetadote and related litigation

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

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

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

Under the Settlement Agreement, Paddock and Perrigo admit that the 356 Acetadote Patent is valid and enforceable and that any Paddock or Perrigo generic Acetadote product (with or without EDTA) would infringe upon the 356 Acetadote Patent. In addition, Paddock and Perrigo will not challenge the validity, enforceability, ownership or patentability of the 356 Acetadote Patent through its expiration currently scheduled for May 2026. On November 12, 2012, in connection with the execution of the Settlement Agreement, we entered into a License and Supply Agreement with Paddock and Perrigo (the “License and Supply Agreement”). Under the terms of the License and Supply Agreement, once a third party receives final approval from the FDA for an ANDA to sell a generic Acetadote product and such third party made such generic version available for purchase in commercial quantities in the United States, we supply Perrigo with an authorized generic version of our Acetadote product (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 on November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. We brought suit against the FDA contesting the FDA's decision to

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approve the InnoPharma generic On November 13, 2012. On September 30, 2013, the United States District Court filed an opinion granting a summary judgment in favor of the FDA regarding this suit.

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

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

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

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

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

Caldolor

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

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

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 the Settlement agreement with Paddock and Perrigo that included the right to distribute our Authorized Generic Acetadote injection product. Our branded Acetadote now competes with both the EDTA free Authorized Generic Acetadote distributed by Paddock and Perrigo along with generic Acetadote that contains EDTA.

Caldolor

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

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

bowel syndrome with constipation and chronic idiopathic constipation. It is marketed by Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc. Liquid lactulose products are marketed by a number of pharmaceutical companies. There are several hundred OTC products used to treat constipation marketed by numerous pharmaceutical and consumer health companies. MiraLax (polyethylene glycol 3350), previously a prescription product, was indicated for the treatment of constipation and manufactured and marketed by Braintree Laboratories, Inc. Under an agreement with Braintree, Schering-Plough introduced MiraLax as an OTC product in February 2007.

Omeclamox-Pak

Omeclamox-Pak is a branded prescription product used for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. It combines three well-known and widely prescribed medications packaged together for patient convenience: omeprazole, clarithromycin, and amoxicillin. The three individual components of Omeclamox-Pak are also available through three separate prescriptions. The prescription combination products which we believe are our primary competitors are PrevPac (including a recently approved generic of PrevPac), Pylera and Helidax. All the competitor products are indicated for treatment of H. pylori. While there are several competitor products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the branded competing products, Omeclamox-Pak has the lowest pill burden, fewest days of therapy and the lowest cost.

GOVERNMENT REGULATION

Governmental authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacturing, distribution, marketing and sale of pharmaceutical products. In the U.S., the FDA under the Federal Food, Drug, and Cosmetic Act, ("FDCA"), the Public Health Service Act, and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or biologics license applications, ("BLAs"), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

We 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, promotional materials and patient brochures.

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

The FDCA and associated regulations detail the requirements at each step. The FDA uses a few special mechanisms to expedite drug development and the review process when a drug might address an unmet need or a serious disease

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or condition. Those mechanisms include accelerated approval, animal efficacy approval, fast track applications, and priority review.

The sponsor of the drug typically conducts human clinical trials in three sequential phases, but the phases may overlap. Phase I clinical trials are generally conducted in a small number of healthy volunteers, primarily to collect and assess pharmacokinetics and safety data at one or more dosages prior to proceeding into patients. In Phase II clinical trials, the sponsor evaluates the early efficacy of the product in short term trials on the targeted indication and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for patients in long term trials examining safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

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

The results of the nonclinical and clinical trials, together with detailed information on the manufacture and composition of the product and proposed labeling, are submitted to the FDA in the form of an NDA for marketing approval. The NDA undergoes a 60 day validation review period before it is accepted for filing. If the NDA is found to be incomplete it will not be accepted. Once the NDA is validated and accepted for filing, the FDA begins an in-depth review of the NDA. Under policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA (currently PDUFA V - effective October 1, 2012), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by two months to address deficiencies, or by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission at any time during the review clock period. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an approval letter. If not, a Complete Response letter will be sent informing applicants of changes that must be made before the application can be approved, with no implication regarding whether the application will ultimately be approved. An approval letter authorizes commercial marketing of the drug for the proposed indication(s) under study. The General Accounting Office ("GAO") reported that standard NDAs showed a steadier increase with the percentage of first-cycle approval letters rising from 43% for FY 2000 applications to 69% for FY 2010 applications. The percentage of priority NDAs receiving an approval letter at the end of the first review cycle fluctuated from FY 2000 through FY 2010, ranging between 47% and 80% during this time. The time and cost of completing these steps and obtaining FDA approval can vary dramatically depending on the drug. However, to complete these steps for a novel drug can take many years and cost millions of dollars.

Section 505(b) (2) New Drug Applications

An NDA may be submitted under different methods, a 505(b)(1), 505(b)(2) or 505(j). Section 505(b) provides for the submission of an NDA to support the approval of a drug. Upon approval, a drug may be marketed only for the FDA-approved indication(s) in the approved dosage form. Further clinical trials may be necessary to gain approval for the use of the product for any additional indications or dosage forms. The FDA also requires post market safety surveillance reporting to monitor the side effects of the drug, which may result in withdrawal of approval after marketing begins.

Section 505(b)(1) or the 'full' NDA is used for new chemical entities ("NCEs") and requires full clinical and nonclinical development of a compound. Marketing exclusivity assigned to a 505(b)(1) approval is five years. A 505(b)(2) NDA permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant using previously reported safety and efficacy data, and for which the applicant has not obtained a right of reference. Generally new studies are required to provide data on the proposed change. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs which have a new dosage form, strength, route of administration, formulation or indication or combination drugs. Marketing exclusivity for a 505(b)(2) submission is three years. Any marketing exclusivity is independent of patent

exclusivity.

We successfully secured FDA approvals for Acetadote in January 2004 and for Caldolor in June 2009 pursuant to the 505(b)(2) pathway.

Special protocol assessment process

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

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

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

Orphan drug designation

The Orphan Drug Act of 1983, ("Orphan Drug Act"), encourages manufacturers to seek approval of products intended to treat “rare diseases and conditions” with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval. Acetadote received Orphan Drug designation in October 2001 and in 2004 the FDA approved the product to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetadote was entitled to marketing exclusivity until January 2011 for the treatment of this approved indication.

Section 505(j) abbreviated new drug applications

An ANDA is a type of NDA where approval of a generic drug is based on demonstrating comparability to an innovator drug product (the RLD or Reference Listed Drug). Applications are "abbreviated" because they generally don't include preclinical and clinical data to establish safety and effectiveness. Generics must demonstrate that the product is bioequivalent (i.e., performs in the same manner and is comparable to the 'innovator' product in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended

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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. This fee has not had a material impact and is not expected to have a material impact on our results of operations.

Physician Payments Sunshine Act: The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, or Sunshine Act, which require manufacturers of pharmaceuticals and medical devices covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services, or CMS for aggregation and subsequent public disclosure. Under the Sunshine Act, beginning August 1, 2013, we have been required to collect data regarding reportable transfers of value and will report such data to CMS by March 31, 2014. Failure to report appropriate data may result in civil or criminal fines and/or penalties. In addition to the Federal Sunshine Act, similar reporting requirements have also been enacted on the state level requiring transparency of interactions with health care professionals.

Medicaid Rebate Rate: We currently provide rebates for 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.

Post approval activities

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

If we amend the NDA for an FDA approved product, such as adding safety or efficacy labeling claims, promoting those new claims, making certain manufacturing changes or product enhancements we will need FDA review and

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approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications, product enhancements, and manufacturing and labeling changes may require us to conduct additional clinical trials under FDA's IND regulations. Even if such studies are conducted, they are still subject to the same requirements and timelines as an original NDA.

The FDA continuously gathers information about possible adverse reactions to the products it has approved for use. The FDA requires all manufacturers to report adverse events. It also provides a procedure for consumers and physicians to voluntarily report their concerns about drugs. The agency collects those reports through MedWatch and uses its Adverse Event Reporting System (AERS) to store and analyze them. Because some events may occur after the use of a drug for reasons unrelated to 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 regulations and we believe that our operations comply with such regulations. We anticipate that the effects of compliance with federal, state and local laws and regulations relating to the discharge of materials into the environment will not have any material effect on our capital expenditures, earnings or competitive position.

SEASONALITY

There are no significant seasonal aspects to our business.

BACKLOG

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

EMPLOYEES

As of December 31, 2013, we had 96 full-time employees. We believe that our future will depend in part on our continued ability to attract, hire, and retain qualified personnel, including hospital and field sales personnel in particular.

Item 1A. Risk Factors.

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

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

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 by January 2014. The FDA requested this action to protect consumers from the risk of severe liver damage which can result from excess acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures.

The FDA also 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

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relatively new compared to some of its competitors, 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 has historically been manufactured at Hospira Australia Pty. Ltd.'s facility in Australia and Bayer's facility in Kansas. We entered into agreements with three international manufacturers for the commercial supply of Caldolor and we are working to transfer the Caldolor manufacturing process to each of these manufacturers. Commercial units have not yet been supplied by these manufacturers. If the new international manufacturers of Caldolor are unable to begin producing inventory in the agreed upon time period,we could suffer an inability to meet demand for our products. Acetadote was previously manufactured at Bayer's facility in Kansas and Bayer completed its obligations under the agreement in January 2014. Acetadote is currently manufactured and packaged in Ireland by Mylan pursuant to an agreement which expires in April 2014. If new manufacturer(s) of Acetadote are unable to begin producing inventory and Mylan is unable to continue to produce inventory after April 2014,we could suffer an inability to meet demand for our products. 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, ("GMPs"), enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with GMP requirements and with other FDA, state and foreign regulatory requirements. We have no control over our manufacturers' compliance with these regulations and standards. If our third-party manufacturers do not comply with these requirements, we could be subject to:

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

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

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

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

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- 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 impacting us.

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

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

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

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

Expansion of the market for our products may be subject to certain limitations. In the past, these limitations have included FDA required Phase IV commitments. We may also experience delays associated with future required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling patients. Such delays could impact our ability to explore opportunities for label expansion and limit our ability to bring our products to new patient populations.

In addition, we have only obtained regulatory approval to market our products in the United States. 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, our growth opportunities may be limited.

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

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

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

We recently acquired rights to Omeclamox-Pak and under the terms of the agreement, we promote the product to gastroenterologists across the United States through our field sales force that also promotes our Kristalose brand. We are responsible for the marketing, sale and distribution of the product. We launched our promotion and distribution

efforts to support Omeclamox-Pak in early 2014. If we are unable to successfully integrate the marketing, sale and distribution of Omeclamox-Pak or any other potential product candidates into our current infrastructure or if they require significantly

greater resources and investments than originally anticipated, we may face financial and operational risks and uncertainties. If we are unable to successfully integrate any acquired product rights, both current and future, these product rights acquisitions may not be beneficial to us in the long term.

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 hepatorenal syndrome ("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 as we evaluate Hepatoren as a treatment for HRS, a life threatening condition with no approved treatment in this country. We have launched a 64 patient study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study is designed to evaluate escalating dose levels of Hepatoren. Enrollment is underway at major medical centers across the U.S. We have commenced manufacturing and have filed patent applications to protect intellectual property related to the new indication. Delays in the enrollment and 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 and may have regulatory compliance issues.

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

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

In March 2010, the U.S. government passed into law the Patient Protection and Affordable Care Act, ("PPACA") along with the Health Care and Education Reconciliation Act of 2010, ("HCERA"), which modified the revenue provisions of the PPACA. The PPACA, as amended by the HCERA, constitutes the healthcare reform legislation. The legislation calls for an increase in certain Medicare drug rebates paid by pharmaceutical manufacturers and an industry fee imposed on pharmaceutical manufacturers according to the individual manufacturer’s relative percentage of total industry sales to specified government programs. At this time no assurances can be given that these measures, or any other measures included in the Healthcare Reform Act, will not have an adverse effect on our revenues in the future. Furthermore, future cost control initiatives, legislation and regulations could decrease the price that we 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 included on their formulary lists. Having products listed on these formulary lists creates competition among pharmaceutical companies which, in turn, has created a trend of downward pricing pressure in our industry. In addition, many managed care organizations are pursuing various ways to reduce pharmaceutical costs and are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. Our products might not be included on the formulary lists of managed care organizations, and downward pricing pressure in our industry generally could negatively impact our operations.

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

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

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

Our CET joint initiative with Vanderbilt University 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 impact 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.

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

As of December 31, 2013, we had 96 full-time employees. We may need to continue to expand our managerial, operational, financial and other resources in order to increase our marketing efforts with regard to our currently marketed products, continue our business development and product development activities and commercialize our product candidates. We have experienced, and may continue to experience, growth and increased expenses in the scope of our operations in connection with the continued marketing and development of our products. Our financial performance will depend, in part, on our ability to manage any such growth and expenses of the current organization effectively.

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

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

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

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

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

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

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

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

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to

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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, ("FTC"), the Consumer Product Safety Commission, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency, ("EPA"), as well as by comparable agencies in foreign countries. These activities are also regulated by various agencies of the states and localities in which our products are sold. For more information, see “Business—Government Regulation".

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

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

Under the FDCA, the federal government has extensive enforcement powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to, the authority to initiate court action to seize unapproved or non-complying products, to enjoin non-complying activities, to halt manufacturing operations that are not in compliance with GMP, and to seek civil monetary and criminal penalties. The initiation of any of these enforcement activities, including the restriction or prohibition on sales of our products, could materially 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, during April 2012, the United States Patent and Trademark Office (the “USPTO”) issued U.S. Patent number 8,148,356 (the “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

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

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

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

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

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

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

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

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

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

On September 30, 2013, the United States District Court for the District of Columbia filed an opinion granting a Summary Judgment in favor of the FDA regarding Cumberland’s November 13, 2012 suit. On November 1, 2013, the United States District Court for the District of Delaware filed opinions granting Sagent’s and InnoPharma’s motions to dismiss our May 2012 and June 2012 suits. We are considering our legal options and intend to continue to vigorously defend and protect our Acetadote product and related intellectual property.

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

On February 24, 2014, we received a Notice of Allowance from the USPTO for a patent relating to the use of the Acetadote formulation to treat patients with acetaminophen overdose. The new patent will include claims regarding the administration method of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection, and is scheduled to expire in April 2032.

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

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We have a U.S. patent and related international patents which include composition of matter claims that emcompass the Caldolor formulation and claims directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor, ibuprofen, is in the public domain, and a competitor could try to develop, test and seek FDA approval for a sufficiently distinct formulation for another ibuprofen product that competes with Caldolor. The U.S. patent is listed in the FDA Orange Book and expires in November of 2021.

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 pursue its patent applications and allow us the opportunity to consult, review and comment on patent office communications, we cannot be sure that it will perform as required. If a licensor does not perform and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights.

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

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

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

We have been involved in lawsuits for infringement of the Acetadote Patents as previously described. Because of their nature, these lawsuits can be costly and time-consuming, and we only experience limited benefits and patent protection. A significant adverse ruling in any such lawsuit could put the Acetadote Patents at risk of being invalidated or interpreted narrowly and could put our existing 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 we breach any of the agreements under which we license rights to our products and product candidates from others, we could lose the ability to continue commercialization of our products and development and commercialization of our product candidates.

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

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

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are a relatively new company seeking to capture significant growth. As we execute our business strategy of adding new products like Omeclamox-Pak, increasing market share in Caldolor and striving to maintain market share in our Acetadote product, we anticipate that there may be fluctuations in our future operating results. We may not be able to maintain or improve our current levels of revenue or income. Potential causes of future fluctuations in our operating results may include:

- New product launches, which could increase revenues but also increase sales and marketing expenses;
- Acquisition activity and other charges (such as for inventory expiration);
- Increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional studies and development;
- Changes in the competitive, regulatory or reimbursement environment, which could drive down revenues or drive up sales and marketing or compliance costs; and
- Unexpected product liability or intellectual property claims and lawsuits.

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

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

Our total assets include intangible assets related to our acquisitions. As of December 31, 2013, intangible assets relating to product and data acquisitions represented approximately 18% of our total assets. We may never realize the value of these assets. U.S. Generally Accepted Accounting Principles ("GAAP") require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any determination requiring the write-off of a significant portion of unamortized intangible assets would adversely affect our results of operations.

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

We may need to raise additional funds in order to meet the capital requirements of running our business and acquiring and developing new pharmaceutical products. If we require additional funding, we may seek to sell common stock or other equity or equity-linked securities, which could result in dilution to our shareholders. We may also seek to raise capital through a debt financing, which would result in ongoing debt-service payments and increased interest expense. Any financings would also likely involve operational and financial restrictions being imposed on us. We might also seek to sell assets or rights in one or more commercial products or product development programs. Additional capital might not be available to us when we need it. In addition, if recent trends in the stability in global credit markets continue or grow we could be adversely impacted. We are unable to predict the impact of these trends, and if economic conditions deteriorate, our business, results of operations and ability to raise needed capital could be materially and adversely affected. If we are unable to raise additional capital when needed due to the reasons listed above and lack of creditworthiness, bank failures, or price decline in market investments, we could be forced to scale back our operations to conserve cash.

If we are unable to 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 GAAP.

We cannot assure you that we will not, in the future, identify areas requiring improvement in our internal control over financial reporting. We cannot assure you that the measures we will take to improve these controls will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue to expand. If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm

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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, ("FASB"), continues to work together with the International Accounting Standards Board, ("IASB"), on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards, ("IFRS"), outside of the U.S. These efforts by the FASB and IASB may result in different accounting principles under GAAP that may result in materially different financial results for us in areas including, but not limited to principles for 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 3, 2014, the closing price of our common stock since our initial public offering has ranged from a low of $4.03 to a high of $17.05 per share. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

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

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

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

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,” “esti “should,” “seek,” “anticipate” and other comparable terms or the negative thereof. In addition, we, through our senior management, from time to time make forward-looking oral and written public statements concerning our expected future operations and other developments. While forward-looking statements reflect our good-faith beliefs and best judgment based upon current information, they are not guarantees of future performance and are subject to known and unknown risks and uncertainties, including those mentioned in Item 1A, “Risk Factors,” Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Form 10-K. 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, 2013, 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 3, 2014, there were 81 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 3, 2014 was $4.67 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 2012 and 2013:

	High	Low
Fiscal year ended December 31, 2013:		
First quarter	$5.10	$4.03
Second quarter	5.37	4.52
Third quarter	5.85	4.33
Fourth quarter	5.41	4.53
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

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 2013:

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	52,607	$4.76	52,607	$6,234,591
November	72,673 (1)	4.91	72,673	5,877,852
December	54,274	5.08	54,274	5,602,293
Total	179,554			

(1) Of this amount, 19,291 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:	2013	2012	2011	2010	2009
	(in thousands, except per share data)				
Net revenues	$32,027	$48,851	$51,143	$45,876	$43,537
Costs and expenses	35,829	40,033	41,293	39,375	37,761
Operating (loss) income	(3,801)	8,818	9,849	6,502	5,777
Net (loss) income attributable to common shareholders	(2,105)	5,842	5,658	2,457	3,091
Earnings (loss) per share – basic	$(0.11)	$0.30	$0.28	$0.12	$0.22
Earnings (loss) per share – diluted	$(0.11)	$0.30	$0.28	$0.12	$0.17

Balance sheet data:	As of December 31, 2013	2012	2011	2010	2009
	(in thousands)				
Cash and cash equivalents	$40,869	$54,349	$70,599	$65,894	$78,702
Marketable securities	14,020	16,686	—	—	—
Working capital	61,134	79,177	80,708	71,811	74,549
Total assets	87,614	98,594	95,518	92,054	103,724
Total long-term debt and other long-term obligations (including current portion)	869	5,042	5,485	7,802	20,155
Retained earnings	16,395	18,499	12,657	6,999	4,542
Total equity	79,292	85,566	82,835	77,715	72,221

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

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

EXECUTIVE SUMMARY

We are a growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology. These markets are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs

Our product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever, Kristalose® (lactulose) for Oral Solution, a prescription laxative, Omeclamox®-Pak, triple therapy combination medication for Helicobacter pylori (H. pylori) infection and duodenal ulcer disease, 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 approximately 60 sales representatives and managers as of December 31, 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, regulatory, manufacturing, sales, marketing and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Our product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our quality and manufacturing professionals oversee the manufacture and release of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our distribution partners to ensure availability and delivery of our products.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. During 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange.

The following is a summary of our 2013 highlights and recent developments. For more information, please see Part I, Item I, Business, of this Form 10-K.

- In 2013, we added Omeclamox-Pak, a branded prescription product used for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. This innovative product combines three well-known and widely prescribed medications: omeprazole, clarithromycin, and amoxicillin. Our involvement with Omeclamox-Pak was effective October 2013, including recognition of $1.0 million in product revenue during the fourth quarter of 2013, through an agreement with Pernix. We launched our promotion and distribution efforts to support Omeclamox-Pak in early 2014 and we are responsible for the marketing, sale and distribution of the product.
- In June 2013, we announced that the FDA has approved updated labeling for Acetadote. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations.
- We continued our international expansion throughout 2013 by finalizing agreements to commercialize Caldolor in several new large markets including: India, Indonesia, the Pacific Rim, the Arabian Peninsula, Spain, Portugal and the majority of South America.
- A poster with data from two Caldolor studies involving four hundred fifty patients was presented at the Annual Meeting of the American Society of Anesthesiologists in San Francisco in October 2013. The poster presentation included the safety and efficacy of a shortened infusion time of intravenous ibuprofen.

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- We obtained our second U.S. patent for Acetadote in March 2013. The claims of the 445 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acetaminophen overdose. The 445 Acetadote Patent will expire in August 2025. We are continuing to seek additional claims to protect our intellectual property associated with Acetadote.
- We extended our relationship with our long-serving, third party distribution contractor, Cardinal Health through June 30, 2016. Since August 2002 they have exclusively handled U.S. product logistics efforts, including warehousing, shipping, customer billing and collections.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Accounting Estimates and Judgments

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. We base our estimates on past experience and on other factors we deem reasonable given the circumstances. Past results help form the basis of our judgments about the carrying value of assets and liabilities that are not determined from other sources. Actual results could differ from these estimates. These estimates, judgments and assumptions are most critical with respect to our accounting for revenue recognition, marketable securities, inventory, intangible assets, research and development accounting, provision for income taxes and share-based payment.

Revenue Recognition

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

Our revenue is derived primarily from the product sales of Acetadote, Caldolor, Omeclamox-Pak and Kristalose. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our wholesalers for a particular product. Other revenue, which is a component of net revenues, includes upfront payments under licensing agreements along with grant and rental income. Other income was less than 3 percent of net revenues in 2013, less than two percent in 2012, and less than one percent in 2011.

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 $0.6 million and $0.2 million at December 31, 2013 and 2012, respectively for chargebacks, discounts and allowances for product damaged in shipment.

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

	2013	2012	2011
Balance, January 1	$3,371,863	$3,216,622	$2,626,313
Current provision	4,181,403	6,000,830	4,719,231
Current provision for prior period sales	—	(367,060)	380,235
Actual product returns and credits issued	(5,116,126)	(5,478,529)	(4,509,157)
Balance, December 31	$2,437,140	$3,371,863	$3,216,622

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 $2.4 million, $3.4 million and $3.2 million as of December 31, 2013, 2012 and 2011, respectively. Of these amounts, our estimated liability for fee for services represented $0.5 million, $1.1 million and $1.0 million, respectively, while our accrual for product returns totaled $1.6 million, $1.8 million and $1.8 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, 2013. A change in our product return estimate of one percentage point would have impacted net sales by $0.3 million, $0.6 million and $0.6 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Fair Value of Marketable Securities

We invest in variable rate demand notes and a portfolio of government-backed securities (including U.S. Treasuries, government-sponsored enterprise debentures and government-sponsored adjustable rate mortgage-backed securities), in order to maximize our return on cash. We classify these investments as trading securities, and mark the investments to fair value at the end of each reporting period, with the adjustment being recognized in the statement of income as a component of interest income. These investments are generally valued using observable market prices by third-party pricing services, or are derived from such services' pricing models. The level of management judgment required in establishing fair value of financial instruments for which there is a quoted price in an active market is minimal. Similarly there is little subjectivity or judgment required for instruments valued using valuation models that are standard across the industry and where all parameter inputs are quoted in active markets. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security.

Inventories

We record amounts for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market value based upon assumptions about remaining shelf life, future demand and market conditions. The estimated inventory obsolescence amounts are calculated based upon specific review of the inventory expiration dates and the quantity on-hand at December 31, 2013 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, 2013, we have unrecognized federal net operating loss carryforwards associated with the exercise of nonqualified options of $43.4 million. In addition to these unrecognized federal net operating loss carryforwards, as of December 31, 2013, we have recognized federal Orphan Drug and Research and Development tax credits of $1.0 million that expire between 2021 and 2033.

Share-Based Payments

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

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

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. If we need to evaluate volatility in the future to value stock options, we intend to use our own historical volatility to the extent it is sufficient. We would supplement the estimate of our volatility using peer companies in the above manner until historical information regarding the volatility of our own shares is sufficient. 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.

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 following assumptions were used in calculating the fair value of options exchanged in 2012 as part of the Exchange Program.

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	2012 Exchange Program
Dividend yield	—
Expected term (years)	1.3 - 7.3
Expected volatility	37% - 78%
Risk-free interest rate	0.23% - 1.50%

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, 2013 compared to year ended December 31, 2012

Net revenues. Net revenues in 2013 decreased approximately $16.8 million compared to 2012. The decline in net revenues was primarily attributable to decreases in Acetadote product revenue of $18.7 million. This decrease was partially offset by an increase in Caldolor product revenue of $1.1 million and revenue of $1.0 million generated from our new product, Omeclamox-Pak.

The increase in Caldolor 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.

The decrease in Acetadote net revenue was a result of decreased sales volume of the branded Acetadote product largely as a result of generic competition during 2013. Our Acetadote product revenue also included $9.2 million in sales of our authorized generic in 2013 and $0.3 million in 2012.

Other revenue. We recognized $0.9 million of other revenue in both 2013 and 2012, primarily as the result of upfront payments we received in connection with out-licensing agreements with international commercial partners.

Cost of products sold. As a percentage of net revenues, cost of products sold increased to 17.0% in 2013 compared to 10.3% in 2012. The increase in costs of sales as a percentage of revenue was attributable to a change in the sales mix along with the recognition of $0.9 million of inventory write-downs during 2013 for potentially obsolete inventory.

Selling and marketing. Selling and marketing expense for 2013 totaled $14.4 million, compared to $20.3 million for 2012. The $5.9 million decrease was driven primarily by decreased salaries, benefits and other selling expenses of $4.4 million along with $1.1 million in decreased travel, convention and promotion expense. These reductions were primarily a result of our new commercial strategy and sales force realignment that went into effect during the fourth quarter of 2012.

Research and development. Research and development costs for 2013 was $5.6 million, compared to $5.1 million in 2012, representing an increase of $0.5 million, or 10.2%. The increase was a result of increased product development and study costs in 2013 compared to 2012.

General and administrative. General and administrative expense totaled $9.5 million in 2013, representing an increase of $0.4 million, or 4.8%, over 2012. The increase was primarily due to several small cost increases including CET rent, stock-based compensation and retirement expense.

Amortization. Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for 2013 totaled $0.9 million, representing an increase of approximately $0.4 million compared to 2012. The increase was primarily due to increased capitalized patents and capitalized patent defense costs.

Income taxes. Income tax benefit for 2013 was $1.5 million, representing a decrease in tax expense of $4.8 million from the $3.2 million of income tax expense in 2012. As a percentage of loss before income taxes, the income tax benefit was 41.4% for 2013 compared to expense of 35.8% of income before income taxes for 2012. The tax rate for 2013 was positively impacted by the reinstatement of the U.S. research and development tax credit during 2013. The tax rate percentage in 2012 was primarily due to the recognition of a deferred tax benefit associated with the exchange of certain incentive stock options.

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 $0.3 million, or 3%, 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.

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, 2013, 2012 and 2011, we generated $0.7 million, $7.1 million and $8.7 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, 2013 and 2012, we had approximately $14.0 million and $16.7 million invested in marketable securities, respectively.

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

	2013	2012
Cash and cash equivalents	$40,869,457	$54,349,381
Marketable securities	14,019,761	16,686,136
Total cash, cash equivalents and marketable securities	$54,889,218	$71,035,517
Working capital (current assets less current liabilities)	$61,133,945	$79,176,882
Current ratio (multiple of current assets to current liabilities)	9.1	10.8
Revolving line of credit availability	$10,000,000	$5,640,049

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

	2013	2012	2011
Cash provided by (used in):			
Operating activities	$746,126	$7,135,182	$8,722,147
Investing activities	(5,071,939)	(19,177,141)	(437,771)
Financing activities	(9,154,111)	(4,207,806)	(3,579,200)
Net (decrease) increase in cash and cash equivalents	$(13,479,924)	$(16,249,765)	$4,705,176

The net use of cash and cash equivalents for the year ended December 31, 2013 was partly attributable to net investing and repayment of financing activities during the year. Net investing activities which used cash included $0.1 million in purchases of equipment and investment in intangible assets of $7.5 million. The investment in intangible assets includes our $4.0 million investment in Omeclamox-Pak. The cash used in investing activities was offset by our decrease of $2.5 million in net investment in marketable securities, with the decrease primarily in our VRDN's. In addition, we continue to repurchase shares of our common stock, totaling $4.8 million during the period, 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. We also repaid the outstanding balance of our revolving line of credit of $4.4 million

during the year. While net cash provided by operating activities was $0.7 million, the net loss of $2.2 million contributed to the net decrease in cash equivalents.

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. 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 $5.6 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 $4.2 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.

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 (2.17% at December 31, 2013). 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, and we currently do not have any outstanding principal amounts on this credit facility. Interest and the unused line fee are 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. During March 2014, we amended certain provisions of the Agreement with our primary lender related to the aggregate ownership of the Company's common stock over 30% as well as amending certain covenants in which we were not in compliance with as a result of the net loss during 2013. As a result of the amendment, the Company is in compliance with all covenants.

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, 2013, we had met our purchase obligations under this agreement.

The following table summarizes our contractual cash obligations as of December 31 2013:

		Payments Due by Year				
Contractual obligations[1]	Total [2]	2014	2015	2016	2017	2018
Amounts reflected in the balance sheet:						
Line of credit	$—	$—	$—	$—	$—	$—
Estimated interest on debt [3]	21,000	21,000	—	—	—	—
Other cash obligations not reflected on the balance sheet:						
Operating leases	3,327,744	1,022,019	1,052,662	941,247	232,964	78,852
Purchase obligations [4]	609,375	609,375	—	—	—	—
Total [1]	$3,958,119	$1,652,394	$1,052,662	$941,247	$232,964	$78,852

(1) The table of contractual obligations excludes amounts due under the Kristalose purchase agreement as these amounts cannot 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 and unused line of credit payments on our line of credit based on the December 31, 2013 interest rate of LIBOR plus an applicable margin, or 2.17%. Interest and unused line of credit payments are due and payable quarterly in arrears. Any outstanding amounts due on 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 zero outstanding balance.

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

OFF-BALANCE SHEET ARRANGEMENTS

During 2013, 2012 and 2011, 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 $14.0 million in

marketable securities outstanding at December 31, 2013, a 1% decrease in the fair value of the securities would result in a reduction in pretax net income of $0.1 million.

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

The interest rate risk related to borrowings under our line of credit is a variable rate of LIBOR plus an applicable margin, as defined in the loan agreement (2.17% at December 31, 2013). As of December 31, 2013, no borrowings were outstanding under our line of credit.

Exchange Rate Risk

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

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange losses were immaterial for 2013, 2012 and 2011. 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, 2013. Based on that evaluation, they have concluded that our disclosure controls and procedures were effective as of December 31, 2013 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 2013, 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 2014 annual meeting of shareholders, which is expected to be filed with the SEC on or around March 12, 2014.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report:

(1) Financial Statements

(2) Financial Statement Schedule

(b) Exhibits

Exhibit Number	Description
3.1	Third Amended and Restated Charter of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
3.2	Second Amended and Restated Bylaws of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
4.1	Specimen Common Stock Certificate of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 5 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on August 6, 2007
4.2	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on October 21, 2003, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
4.3	Stock Purchase Warrant, issued to S.C.O.U.T. Healthcare Fund L.P. on April 15, 2004, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on June 22, 2007
4.4	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on April 6, 2006, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
4.5#	Form of Option Agreement under 1999 Stock Option Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
4.6.1#	Form of Incentive Stock Option Agreement under the Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.6.2#	Form of Non-Statutory Stock Option Agreement under the Amended and Restated 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.7#	Form of Non-Statutory Stock Option Agreement under the Amended and Restated 2007 Directors' Compensation Plan of Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
4.8	

	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on July 22, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 19, 2010
4.9	Form of Senior Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-184091) as filed with the SEC on September 25, 2012.
4.10	Form of Subordinated Indenture, incorporated herein by reference to the corresponding exhibit to Registrant's Registration Statement Form S-3 (File No. 333-184091) as filed with the SEC on September 25, 2012

Exhibit Number	Description
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
10.2	Novation Agreement, dated January 27, 2006, by and among Bioniche Life Sciences, Inc., Bioniche Pharma Group Ltd., and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.3†	First Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated November 16, 2006, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.3.1†	Second Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated March 25, 2008, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.3.2†	Third Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, effective April 25, 2011, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on June 24, 2011
10.7†	Exclusive Distribution Agreement, effective as of July 1, 2010, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on August 13, 2010
10.7.1†	First Amendment to Exclusive Distribution Agreement, dated March 31, 2013, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report of Form 8-K (File No. 001-33637) as filed with the SEC on June 3, 2013
10.8†	Strategic Alliance Agreement, dated July 21, 2000, by and between F.H. Faulding & Co. Limited and Cumberland Pharmaceuticals Inc., including notification of assignment from F.H. Faulding & Co. Limited to Mayne Pharma Pty Ltd., dated April 16, 2002, incorporated herein by reference to the corresponding exhibit to Amendment No. 4 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 23, 2007
10.10†	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007

10.11#	Employment Agreement dated March 7, 2014, effective as of January 1, 2014, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10 .12#	Employment Agreement dated March 7, 2014, effective as of January 1, 2014, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement dated March 7, 2014, effective as of January 1, 2014, by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.

10.14#	Employment Agreement dated March 7, 2014, effective as of January 1, 2014, by and between Rick S. Greene and Cumberland Pharmaceuticals Inc.
10.15#	Employment Agreement dated March 7, 2014, effective as of January 1, 2014, by and between James L. Herman 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 incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.16.2	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, incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.16.3	Waiver to Fifth Amended and Restated Loan Agreement, dated March 6, 2014, 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

Exhibit Number	Description
10.25††	Omeclamox-Pak® Promotion Agreement, dated October 1, 2013, by and between Cumberland Pharmaceuticals Inc. and Pernix Therapeutics, LLC
10.28†	Asset Purchase and Royalty Agreement for Kristalose dated November 15, 2011 by and between Mylan Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on November 22, 2011
10.29†	Packaging Agreement effective November 1, 2011 by and among Mylan Institutional Inc., Mylan Pharmaceuticals Inc. and Cumberland Pharmaceuticals Inc. incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 7, 2012
10.30#	Supplemental Executive Retirement and Savings Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on May 24, 2012
10.31†	Settlement Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
10.32†	License and Supply Agreement, dated November 9, 2012, by and between Cumberland Pharmaceuticals Inc., Paddock Laboratories, LLC and Perrigo Company incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33637) as filed with the SEC on March 12, 2013
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 11, 2014.

Cumberland Pharmaceuticals, Inc.

/s/ A. J. Kazimi

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

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

Signature	Title	Date
/s/ A. J. Kazimi A. J. Kazimi	Chairman and CEO (Principal Executive Officer and Director)	March 11, 2014
/s/ Rick S. Greene Rick S. Greene	Vice President and CFO (Principal Financial and Accounting Officer	March 11, 2014
/s/ Robert G. Edwards Robert G. Edwards	Director	March 11, 2014
/s/ Thomas R. Lawrence Thomas R. Lawrence	Director	March 11, 2014
/s/ Martin E. Cearnal Martin E. Cearnal	Director	March 11, 2014
/s/ Gordon R. Bernard Gordon R. Bernard	Director	March 11, 2014
/s/ Jonathan I. Griggs Jonathan I. Griggs	Director	March 11, 2014
/s/ James R. Jones James R. Jones	Director	March 11, 2014
/s/ Joey A. Jacobs Joey A. Jacobs	Director	March 11, 2014

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, 2013. 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 (1992). Based on its assessment, management has concluded that, as of December 31, 2013, 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 11, 2014

/s/ Rick S. Greene
Rick S. Greene
Chief Financial Officer
March 11, 2014

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, 2013 and 2012, and the related consolidated statements of operations and comprehensive (loss) income, equity, and cash flows for each of the years in the three-year period ended December 31, 2013. 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, 2013. 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, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 11, 2014 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

/s/ KPMG LLP
Nashville, Tennessee
March 11, 2014

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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) 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's 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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) 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, 2013 and 2012, and the related consolidated statements of operations and comprehensive (loss) income, equity, and cash flows for each of the years in the three-year period ended December 31, 2013, and our report dated March 11, 2014 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP
Nashville, Tennessee
March 11, 2014

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2013 and 2012

	2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$40,869,457	$54,349,381
Marketable securities	14,019,761	16,686,136
Accounts receivable, net of allowances	4,530,424	6,017,201
Inventories	5,722,882	6,218,355
Prepaid and other current assets	825,675	1,671,091
Deferred tax assets	2,711,516	2,290,078
Total current assets	68,679,715	87,232,242
Property and equipment, net	880,647	1,188,914
Intangible assets, net	15,498,819	9,476,798
Deferred tax assets	1,208,891	50,411
Other assets	1,345,666	645,366
Total assets	$87,613,738	$98,593,731
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$2,035,853	$2,790,554
Other current liabilities	5,509,917	5,264,806
Total current liabilities	7,545,770	8,055,360
Revolving line of credit	—	4,359,951
Other long-term liabilities	776,125	611,933
Total liabilities	8,321,895	13,027,244
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock – no par value; 100,000,000 shares authorized; 17,985,503 and 18,937,107 shares issued and outstanding as of December 31, 2013 and 2012, respectively	63,073,941	67,197,167
Retained earnings	16,394,540	18,499,154
Total shareholders' equity	79,468,481	85,696,321
Noncontrolling interests	(176,638)	(129,834)
Total equity	79,291,843	85,566,487
Total liabilities and equity	$87,613,738	$98,593,731

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive (Loss) Income
Years ended December 31, 2013, 2012 and 2011

	2013	2012	2011
Revenues:			
Net product revenue	$31,100,698	$47,944,031	$50,893,794
Other revenue	926,764	907,206	248,982
Net revenues	32,027,462	48,851,237	51,142,776
Costs and expenses:			
Cost of products sold	5,439,422	5,046,179	5,362,554
Selling and marketing	14,387,745	20,329,493	20,940,060
Research and development	5,615,501	5,095,172	5,028,072
General and administrative	9,489,976	9,055,959	9,307,301
Amortization	896,156	506,332	655,302
Total costs and expenses	35,828,800	40,033,135	41,293,289
Operating (loss) income	(3,801,338)	8,818,102	9,849,487
Interest income	230,291	304,865	210,727
Interest expense	(103,422)	(71,985)	(353,497)
(Loss) income before income taxes	(3,674,469)	9,050,982	9,706,717
Income tax benefit (expense)	1,523,051	(3,244,776)	(4,080,204)
Net (loss) income	(2,151,418)	5,806,206	5,626,513
Net loss at subsidiary attributable to noncontrolling interests	46,804	36,286	31,343
Net (loss) income attributable to common shareholders	$(2,104,614)	$5,842,492	$5,657,856
Earnings (loss) per share attributable to common shareholders:			
Basic	$(0.11)	$0.30	$0.28
Diluted	$(0.11)	$0.30	$0.28
Weighted-average common shares outstanding:			
Basic	18,332,997	19,564,625	20,342,913
Diluted	18,332,997	19,787,537	20,572,132
Comprehensive (loss) income	$(2,151,418)	$5,806,206	$5,626,513

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
Years ended December 31, 2013, 2012 and 2011

	2013	2012	2011
Cash flows from operating activities:			
Net (loss) income	$(2,151,418)	$5,806,206	$5,626,513
Adjustments to reconcile net (loss) income to net cash flows provided by operating activities:			
Depreciation and amortization expense	1,301,835	901,649	1,040,407
Deferred tax (benefit) expense	(1,579,918)	(829,846)	1,665,110
Share-based compensation	674,955	636,528	779,305
Excess tax benefit derived from exercise of stock options	(48,024)	(3,760,766)	(2,355,345)
Noncash interest expense	24,075	24,075	137,487
Noncash investment losses (gains)	178,822	(45,814)	—
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	1,486,777	1,065,689	(1,937,396)
Inventories	495,473	(443,661)	1,909,148
Prepaid, other current assets and other assets	117,021	(648,941)	(399,393)
Accounts payable and other accrued liabilities	58,855	4,373,276	2,296,535
Other long-term liabilities	187,673	56,787	(40,224)
Net cash provided by operating activities	746,126	7,135,182	8,722,147
Cash flows from investing activities:			
Additions to property and equipment	(97,412)	(464,893)	(257,502)
Additions to intangible assets	(7,462,080)	(2,071,926)	(180,269)
Proceeds from sale of marketable securities	6,859,061	5,220,480	—
Purchases of marketable securities	(4,371,508)	(21,860,802)	—
Net cash used in investing activities	(5,071,939)	(19,177,141)	(437,771)
Cash flows from financing activities:			
Net (repayments) borrowings on line of credit	(4,359,951)	(500,000)	3,034,000
Principal payments on note payable	—	—	(5,333,333)
Repurchase of common shares	(4,800,908)	(8,086,594)	(4,247,440)
Costs of financing for long-term debt and credit facility	—	—	(17,637)
Exercise of stock options	(41,276)	618,022	629,865
Excess tax benefit derived from exercise of stock options	48,024	3,760,766	2,355,345
Net cash used in financing activities	(9,154,111)	(4,207,806)	(3,579,200)
Net (decrease) increase in cash and cash equivalents	(13,479,924)	(16,249,765)	4,705,176
Cash and cash equivalents, beginning of year	54,349,381	70,599,146	65,893,970
Cash and cash equivalents, end of year	$40,869,457	$54,349,381	$70,599,146
Supplemental disclosure of cash flow information:			
Net cash paid (refunded) during the year for:			
Interest	$79,347	$47,910	$191,410
Income taxes	(129,509)	112,381	304,480
Noncash investing and financing activities:			
Change in unpaid invoices for purchases of intangibles	543,905	888,141	97,806

See accompanying notes to consolidated financial statements.

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Statements of Equity
Years ended December 31, 2013, 2012 and 2011

	Cumberland Pharmaceuticals Inc. Shareholders				
	Common stock Shares	Amount	Retained earnings	Non-controlling interest	Total equity
Balance, December 31, 2010	20,338,461	$70,778,874	$6,998,806	$(62,205)	$77,715,475
Net income (loss)			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 (loss)			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
Net loss			(2,104,614)	(46,804)	(2,151,418)
Share-based compensation	19,743	670,934			670,934
Exercise of options and related tax benefit	36,758	6,748			6,748
Repurchase of common shares	(1,008,105)	(4,800,908)			(4,800,908)
Balance, December 31, 2013	17,985,503	$63,073,941	$16,394,540	$(176,638)	$79,291,843

See accompanying notes to consolidated financial statements.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
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 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 operations were approximately $46,804, $36,286 and $31,343 for the years ended December 31, 2013, 2012 and 2011, respectively.

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

(2) Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

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

Segment Reporting

The Company has one operating segment which is specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. 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 $0.8 million, $0.7 million and $0.1 million for 2013, 2012 and 2011, respectively.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

Reclassifications

In 2013, the Company began reflecting all amortization expense of intangible assets in Amortization in the consolidated statements of operations and comprehensive (loss) income. A portion of these amounts were previously included as a component of General and Administrative. The prior year consolidated financial statements have been reclassified to conform to the presentation in 2013.

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, 2013 and 2012, cash equivalents consist primarily of money market funds.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

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, 2013 and 2012, marketable securities were comprised solely of trading securities. Trading securities are carried at fair value with unrealized gains and losses recognized as a component of interest income in the consolidated statements of operations.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount. The Company records allowances for amounts that could become uncollectible in the future based on historical experience, including amounts related to chargebacks, cash discounts and credits for damaged product. The Company reviews each customer balance to assess collectibility. The majority of the Company's products are distributed through independent pharmaceutical wholesalers. Net product revenues and accounts receivable take into account the sale of the product at the wholesale acquisition cost, and an accrual is recorded to reflect the difference between the wholesale acquisition cost and the estimated average end-user contract price. This accrual is calculated on a product-specific basis and is based on the estimated number of outstanding units sold to wholesalers that will ultimately be sold in end-user contracts. When the wholesaler sells the product to the end-user at the agreed upon end-user contract price, the wholesaler charges the Company for the difference between the wholesale acquisition price and the end-user contract price and this chargeback is offset against the initial accrual balance.

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

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

Inventories

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

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

Prepaid and Other Current Assets

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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

Property and Equipment

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

Intangible Assets

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

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

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

Impairment of Long-Lived Assets

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

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 2013, 2012 and 2011.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

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 in both 2013 and 2012, and $1.2 million in 2011. They are included as a component of selling and marketing expenses in the consolidated statements of operations.
Advertising Costs
Advertising costs are expensed as incurred and totaled $2.1 million, $3.0 million and $0.9 million in 2013, 2012 and 2011, respectively, and are included as a component of selling and marketing expenses in the consolidated statements of operations.
Research and Development
Research and development costs are expensed in the period incurred. Research and development costs are comprised mainly of clinical trial expenses, salaries 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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

Comprehensive (Loss) Income
Total comprehensive (loss) income was comprised solely of net (loss) 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 operations. Funding received from private sector investments and grants are recorded as net revenues in the consolidated statements of operations.
Recent Accounting Guidance
In July 2013, the FASB issued updated guidance in the form of a FASB Accounting Standards Update on "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists". This update requires, unless certain conditions exists, an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. The Accounting Guidance is effective prospectively for reporting periods beginning after December 15, 2013, with early adoption permitted. Retrospective application is permitted. The Company is currently evaluating the impact of ASU 2013-11 on its consolidated financial statements and related disclosures.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(3) Revenues

Product Revenues

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

	2013	2012	2011
Acetadote	$18,846,753	$37,522,180	$42,454,055
Omeclamox-Pak	1,045,815	—	—
Kristalose	9,118,475	9,429,741	8,517,873
Caldolor	2,089,655	992,110	(78,134)
Total net product revenues	$31,100,698	$47,944,031	$50,893,794

As part of the October 28, 2013 agreement further discussed in Note 6, the Company entered into an agreement with Pernix Therapeutics to promote Omeclamox-Pak. Under the terms of the agreement, effective October 1, 2013, the Company began to share in the revenue of this product including $1.0 million during 2013. Effective January 2014 the Company began promoting Omeclamox-Pak to gastroenterologists across the United States through its field sales force.

As part of the November 12, 2012, Settlement Agreement with Paddock and Perrigo, the Company supplies Perrigo with an Authorized Generic version of the Company's Acetadote product. Acetadote product revenue in 2013 includes $9.2 million in the Company's share of the Authorized Generic distributed by Perrigo, and 2012 includes $0.3 million.

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 $2.9 million, $1.3 million and $0.3 million for the years ended December 31, 2013, 2012 and 2011, 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.

The allowances in accounts receivable for chargebacks, cash discounts and damaged goods were $0.6 million at December 31, 2013 and $0.2 million at 2012, and the accruals for rebates, product returns and certain administrative and service fees included in other current liabilities were $2.4 million and $3.4 million, respectively, at December 31, 2013 and 2012.

Other Revenues

During 2013, the Company entered into six new agreements with international partners for commercialization of certain of the Company's products into additional international territories and amended its agreement with Harbin Gloria Pharmaceuticals Co., Ltd ("Harbin Gloria"), a Chinese pharmaceutical company, to extend its territory. As a result of the new and amended agreements, the Company recognized approximately $0.6 million of non-refundable up-front payments as other revenue in the consolidated statement of operations during 2013.

The agreements entered into during 2013 provide that each of the partners are responsible for seeking regulatory approvals for the products, and following approvals, will handle ongoing distribution and sales in the respective international territories. The Company maintains responsibility for the intellectual property and product formulations. Under the licensing agreements, the Company is entitled to receive additional milestone payments upon the partners' achievement of defined regulatory approvals and sales milestones. The Company will recognize revenue for these substantive milestones using the milestone method. The agreements

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

provide for up to $0.6 million in milestone payments related to regulatory approvals and up to $4.0 million in milestone payments related to total and annual product sales. As of December 31, 2013, the Company has not recognized any revenues related to milestones associated with the new agreements. The Company is also entitled to receive royalties on future sales of the products under the agreements.

In 2012, the Company entered into an exclusive licensing agreement for Acetadote and Caldolor with Harbin Gloria. 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. During 2012, the Company received nonrefundable, up-front payments totaling approximately $0.7 million in exchange for the transfer of certain intellectual property, including its product dossiers, and recognized these payments as other revenue in the consolidated statement of operations 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, 2013, no revenue has been recognized related to milestones associated with Harbin Gloria.

Other revenues during 2013, 2012 and 2011 also includes revenue generated by CET through grant funding from federal Small Business grant programs, and lease income generated by CET's Life Sciences Center and contract services. The Life Sciences Center is a research center that provides scientists with access to flexible lab space and other resources to develop biomedical products. Grant revenue from SBIR/STTR programs totaled approximately $0.1 million for each of the years ended December 31, 2013, 2012 and 2011.

(4) Inventories

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

	2013	2012
Raw materials and work in process	$2,025,020	$1,310,670
Finished goods	3,697,862	4,907,685
Total inventories	$5,722,882	$6,218,355

Caldolor inventory represented the majority of net inventory on hand at December 31, 2013 and December 31, 2012, and had varying original expiration dates that began in the second quarter of 2014 and extended through January 2015. During 2013, the Company provided stability data to the FDA supporting that the Caldolor product expiration dates may be extended by up to a year. In January 2014, the FDA notified the Company that it had approved its request to extend the original shelf life of the Caldolor 800mg vials from five to six years.

At December 31, 2013 and 2012, the Company has recognized amounts for potential obsolescence and discontinuance of approximately $3.5 million and $2.6 million, respectively, primarily for Caldolor. If actual sales in future periods are less than projected sales, the Company could incur additional obsolescence losses.

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.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(5) Property and Equipment

Property and equipment consisted of the following at December 31:

	Range of useful lives	2013	2012
Computer equipment	3 – 5 years	$754,088	$710,099
Office equipment	3 – 15 years	132,999	123,937
Furniture and fixtures	5 – 15 years	616,759	609,544
Leasehold improvements	3 – 15 years, or remaining lease term	1,223,453	1,186,306
Total property and equipment, gross		2,727,299	2,629,886
Less: accumulated depreciation and amortization		(1,846,652)	(1,440,972)
Total property and equipment, net		$880,647	$1,188,914

Depreciation expense, including amortization expense related to leasehold improvements, was $0.4 million during 2013, 2012 and 2011, and is included in general and administrative expense in the consolidated statements of operations.

(6) Intangible Assets

Intangible assets consisted of the following at December 31:

	2013	2012
Product and license rights	$12,139,031	$7,352,308
Less: accumulated amortization	(1,096,238)	(520,385)
Total product and license rights	11,042,793	6,831,923
Patents	4,866,570	2,735,117
Less: accumulated amortization	(410,544)	(90,242)
Total patents	4,456,026	2,644,875
Trademarks	9,020	9,020
Less: accumulated amortization	(9,020)	(9,020)
Total trademarks	—	—
Total intangible assets	$15,498,819	$9,476,798

On October 28, 2013, the Company entered into an agreement with Pernix Therapeutics to promote Omeclamox-Pak. Omeclamox-Pak is a branded prescription product that combines omeprazole, amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. It is the first FDA approved triple combination medication to contain omeprazole as the proton pump inhibitor and is prescribed over a shortened treatment period of ten days. Under the terms of the agreement, the Company

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

will promote the product to gastroenterologists across the United States through its field sales force which also promotes its Kristalose brand. Pernix will promote the product through its specialty sales force focusing on select primary care physicians. The companies will cooperate in the marketing and other activities needed to support the commercialization of the brand. The Company paid an upfront payment of $4.0 million to Pernix Therapeutics on October 29, 2013. There are also additional milestones at the first and second anniversary dates of the execution of the agreement totaling $4.0 million in the aggregate. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits will be paid by Cumberland to Pernix Therapeutics monthly.

The $4.0 million upfront payment the Company paid to Pernix Therapeutics on October 29, 2013 is included in product and license rights and will be amortized over the remaining expected useful life of the acquired asset, currently the life of the agreement, which ends in June 2032.

In 2011, the Company acquired the Kristalose trademark and FDA registration from Mylan Inc. The agreement requires the Company to make future quarterly payments over a seven-year period equal to a percentage of Kristalose net sales. The payments are being treated as consideration for the assets acquired, and are being capitalized and amortized over the remaining expected useful life of the acquired asset, currently the term of the agreement, 15 years. During 2013, the Company paid $0.8 million to Mylan in quarterly Kristalose payments.

During 2013, the Company recorded an additional $2.1 million in intangible assets for capitalized patent costs, including amounts incurred in the protection of the Company's intellectual property.

Amortization expense related to product and license rights, trademarks and patents was $0.9 million, $0.5 million and $0.7 million in 2013, 2012 and 2011, and is expected to be approximately $1.2 million in each of the years 2014 through 2018.

(7) Other Current Liabilities

Other current liabilities consisted of the following at December 31:

	2013	2012
Rebates, product returns, administrative fees and service fees	$2,437,140	$3,371,863
Employee wages and benefits	1,110,726	1,473,983
Accrued inventory purchases	1,236,000	—
Other	726,051	418,960
Total other current liabilities	$5,509,917	$5,264,806

(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 and these costs are included in interest expense in the consolidated statement of operations 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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
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Daily Floating Rate plus an Applicable Margin, as those terms are defined in the Agreement (2.17% at December 31, 2013). 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, and the Company does not have any outstanding principal amounts on the credit facility. Interest and the unused line fee are payable quarterly. Borrowings under the line of credit are collateralized by substantially all of the Company's assets.

Under the 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.

During March 2014, the Company and its primary lender amended certain provisions of the Agreement related to the aggregate ownership of the Company's common stock over 30% as well as amending certain covenants in which the Company was not in compliance with as a result of the net loss during 2013. As a result of the amendment, 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, 2013 and 2012, there was no preferred stock outstanding.

(c) Common Stock

During 2013, 2012 and 2011, the Company issued 19,743 shares, 20,199 shares and 10,144 shares of common stock, respectively, valued at $56,000, $78,000 and $59,000, respectively, as compensation for services, which is included in general and administrative expenses in the consolidated statements of operations.

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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
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stock lapses 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 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, 2013 and 2012.

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, 2013 and 2012.

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, 2013 and 2012.

(e) Share Repurchases

On May 13, 2010, the Company announced a share repurchase program to purchase up to $10 million of its common stock pursuant to Rule 10b-18 of the Securities Act. In January 2011, April 2012 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 1,008,105 shares, 1,268,809 shares and 743,073 shares of common stock for approximately $4.8 million, $8.1 million and $4.2 million during the years ended December 31, 2013, 2012 and 2011, respectively.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(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:

	2013	2012	2011
Numerator:			
Net (loss) income attributable to common shareholders	$(2,104,614)	$5,842,492	$5,657,856
Denominator:			
Weighted-average shares outstanding – basic	18,332,997	19,564,625	20,342,913
Dilutive effect of restricted stock and stock options	—	222,912	229,219
Weighted-average shares outstanding – diluted	18,332,997	19,787,537	20,572,132

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

	2013	2012	2011
Anti-dilutive shares	407,954	687,430	1,079,904

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(11) Income Taxes

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

	2013	2012
Deferred Tax Assets		
Net operating loss and tax credits	$2,144,460	$1,159,865
Property and equipment and intangibles	214,478	153,361
Allowance for accounts receivable	235,446	74,362
Reserve for expired product	600,406	706,960
Inventory	1,495,895	1,185,419
Deferred charges	666,236	582,480
Cumulative compensation costs incurred on deductible equity awards	1,378,690	1,251,382
Total deferred tax assets	6,735,611	5,113,829
Deferred Tax Liabilities		
Intangible assets	(2,683,587)	(2,665,022)
Net deferred tax assets, before valuation allowance	4,052,024	2,448,807
Less: deferred tax asset valuation allowance	(131,617)	(108,318)
Net deferred tax assets	$3,920,407	$2,340,489

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, 2013:

Years of expiration	Federal	State
2014	$—	$2,249,078
2015 - 2017	—	504,822
2018 - 2024	—	51,629,844
2029	43,398,774	—
2033	$1,975,521	$2,032,527
Total federal and state net operating loss carryforwards	$45,374,295	$56,416,271

The Company has total recognized carryforward tax assets of $0.3 million for charitable contribution carryforwards, foreign tax credits and AMT carryforwards. In addition, the Company has recognized as of December 31, 2013 federal Orphan Drug and Research and Development tax credits of $1.0 million that expire between 2021 and 2033.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

The Company has unrecognized federal net operating loss carryforwards as a result of the exercise of nonqualified options of approximately $43.4 million. These benefits occurred as a result of the actual tax benefit realized upon an employee's exercise exceeding the cumulative book compensation charge associated with the awards and will be recognized in the year in which they are able to reduce current income taxes payable. Accordingly, deferred tax assets are not recognized for these net operating loss carryforwards or credit carryforwards resulting from the exercise of nonqualified options. The 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 2014. The Company has $56.4 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 $2.8 million that is subject to a full valuation allowance at December 31, 2013.

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

	2013	2012	2011
Current:			
Federal	$(45,287)	$(3,185,743)	$(1,992,804)
State and other	(11,580)	(820,669)	(422,290)
Total current income tax expense	(56,867)	(4,006,412)	(2,415,094)
Deferred:			
Federal	1,426,701	677,190	(1,543,261)
State	153,217	84,446	(121,849)
Total deferred income tax benefit (expense)	1,579,918	761,636	(1,665,110)
Total income tax expense	$1,523,051	$(3,244,776)	$(4,080,204)

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.

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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

	2013	2012	2011
Deferred tax (expense) benefit, excluding items below	$37,940	$(39,870)	$439,744
Inventory write-downs	310,477	179,755	817,840
Creation of operating loss carryforwards	788,342	25,552	11,348
Creation (utilization) of tax credit carryforwards	196,631	108,699	56,395
Change in valuation allowance due to changes in net deferred tax asset balances	(23,299)	(15,291)	(13,597)
Deductible equity awards	127,308	667,171	(330,329)
Allowance for accounts receivable	161,084	—	—
Intangible assets	(18,565)	(164,380)	(2,646,511)
Deferred income tax benefit (expense)	$1,579,918	$761,636	$(1,665,110)

The valuation allowance at December 31, 2013 and 2012 is primarily related to state tax benefits at CET that will likely not be realized.

The Company's effective income tax rate for 2013, 2012 and 2011 reconciles with the federal statutory tax rate as follows:

	2013	2012	2011
Federal tax expense at statutory rate	34%	34%	35%
State income tax expense (net of federal income tax benefit)	4%	4%	4%
Permanent differences associated with general business credits	5%	—%	(1)%
Permanent differences associated with stock options	—%	(5)%	2%
Other permanent differences	—%	3%	2%
Other	(1)%	—%	—%
Net income tax expense	42%	36%	42%

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 2013. Due to a 2009 net operating loss carryback, federal tax years 2006 through 2008 remain open to the extent of net operating losses utilized in those years. State tax years that remain open to examination are 2008 to 2013. The Company has no unrecognized tax benefits in 2013, 2012 or 2011.

Excluding the alternative minimum tax (AMT) tax credits, the Company will need to generate future taxable income of approximately $11.3 million in order to fully realize the deferred tax assets. Taxable income (loss), excluding tax deductions generated by the exercise of nonqualified options, for 2013, 2012 and 2011 was a loss of approximately $(2.0) million, income of $9.4 million and income of $5.7 million, respectively. Based upon the level of taxable income over the last three years and projections for future taxable income

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

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, 2013. 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 operations. Stock compensation expense recorded as a component of equity consisted of the following for the years ended December 31:

	2013	2012	2011
Share-based compensation - employees	$614,818	$555,898	$627,353
Share-based compensation - nonemployees	56,116	76,920	128,158
Total share-based compensation	$670,934	$632,818	$755,511

At December 31, 2013, there was approximately $1.5 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted-average period of 2.6 years. This amount relates primarily to unrecognized compensation cost for employees.

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Stock Options
Stock option activity for 2013 and 2012 was as follows:

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
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
Options granted	—	—		
Options exercised	(171,100)	3.50		
Options forfeited or expired	(139,275)	6.25		
Outstanding, December 31, 2013	356,496	6.96	1.0	$360
Exercisable at December 31, 2013	356,496	$6.96	1.0	$360

Information related to the stock option plans during 2013, 2012 and 2011 was as follows:

	2013	2012	2011
Intrinsic value of options exercised	$212,444	$495,480	$1,742,103
Weighted-average fair value of options exercised	$0.12	$1.00	$2.06

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

The Company did not grant any stock options during 2013, 2012 or 2011.

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, 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
Shares granted	195,925	4.78
Shares vested	(17,193)	3.58
Shares forfeited	(41,678)	3.97
Nonvested, December 31, 2013	520,584	5.05

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 2013, 2012 and 2011, the Company contributed approximately $50,000 in each year to the Plan as an employer match of participant contributions.

In 2012 and 2013, the Company established non-qualified unfunded deferred compensation plans that allow participants to defer receipt of a portion of their compensation. The liability under the plans was $0.3 million as of December 31, 2013. The Company had assets of $1.3 million, consisting of company-owned life insurance contracts as of December 31, 2012, generally designated to pay benefits of the deferred compensation plans.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(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 2013, 2012 and 2011 was approximately $0.9 million, $0.9 million and $0.8 million, respectively, and sublease income was approximately $0.5 million, $0.5 million and $0.4 million. Cumulative future minimum sublease income under noncancelable operating subleases totals approximately $0.5 million and will be paid through the lease ending in October 2016. Future minimum lease payments under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are as follows:

Year ending December 31:	
2014	$1,022,019
2015	1,052,662
2016	941,247
2017	232,964
2018 and thereafter	78,852
Total future minimum lease payments	$3,327,744

(15) Fair Value of Financial Instruments

In 2012, the Company began purchasing marketable securities that are solely classified as trading securities. There were no transfers of assets between levels within the fair value hierarchy. The following table summarizes the fair value of these marketable securities, by level within the fair value hierarchy:

	December 31, 2013			December 31, 2012		
	Level 1	Level 2	Total	Level 1	Level 2	Total
U.S. Treasury notes and bonds	$2,829,809	$—	$2,829,809	$2,473,596	$—	$2,473,596
U.S. Agency issued mortgage-backed securities - variable rate	—	3,049,754	3,049,754	—	3,708,920	3,708,920
U.S. Agency notes and bonds - fixed rate	—	1,496,700	1,496,700	—	1,505,177	1,505,177
SBA loan pools - variable rate	—	1,748,498	1,748,498	—	1,988,443	1,988,443
Municipal bonds - VRDN	4,895,000	—	4,895,000	7,010,000	—	7,010,000
Total fair value of marketable securities	$7,724,809	$6,294,952	$14,019,761	$9,483,596	$7,202,540	$16,686,136

The fair values of all other financial instruments outstanding as of December 31, 2013 and 2012 approximate their carrying values.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements — (Continued)

(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:

	2013	2012	2011
Customer 1	19%	35%	36%
Customer 2	23%	30%	28%
Customer 3	23%	28%	31%
Customer 4	24%	1%	—%

The Company's accounts receivable, net of allowances, due from these four customers at December 31, 2013 and 2012 was 85.3% and 81%, respectively.

(17) Manufacturing and Supply Agreements

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

(18) Employment Agreements

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

(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, currently the term of the agreement, 15 years.

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

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
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As discussed in Note 6, in connection with the agreement with Pernix to promote Omeclamox-Pak, the Company will make monthly royalty payments based on tiered levels of gross profits. These costs will be period expenses of the Company. There are also additional milestones at the first and second anniversary dates of the execution of the agreement totaling $4.0 million in the aggregate that the Company will capitalize and amortize over the remaining expected useful life of the acquired asset, currently the life of the agreement, which ends in June 2032.

Legal Matters

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

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

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

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

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

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(20) Quarterly Financial Information (Unaudited)

The following table sets forth the unaudited operating results for each fiscal quarter of 2013 and 2012:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2013:					
Net revenues	$10,258,132	$7,081,088	$6,528,575	$8,159,667	$32,027,462
Operating income (loss)	1,326,051	(1,140,544)	(1,514,768)	(2,472,077)	(3,801,338)
Net income (loss) attributable to common shareholders	854,709	(639,018)	(819,942)	(1,500,363)	(2,104,614)
Earnings (loss) per share attributable to common shareholders [1]					
Basic	$0.05	$(0.03)	$(0.04)	$(0.08)	$(0.11)
Diluted	$0.05	$(0.03)	$(0.04)	$(0.08)	$(0.11)
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

(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.

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21) Subsequent event

On February 28, 2014, the Company entered into an agreement with Astellas Pharma US, Inc. ("Astellas") to acquire certain product rights, intellectual property and related assets of Vaprisol®. Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia. The Company paid an upfront payment of $2.0 million to Astellas at closing. There is an additional milestone at the first anniversary date of the execution of the agreement of $2.0 million, dependent upon first year sales of Vaprisol achieving certain levels.

Schedule II
CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Valuation and Qualifying Accounts
Years ended December 31, 2013, 2012 and 2011

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:					
2011	$163,748	$2,151,890	$—	$(2,080,058)[1]	$235,580
2012	235,580	2,069,470	—	(2,116,463)[1]	188,587
2013	188,587	2,498,170	—	(2,093,641)[1]	593,116
Valuation allowance for deferred tax assets:					
For the years ended December 31:					
2011	$80,862	$13,597	$—	$—	$94,459
2012	94,459	13,859	—	—	108,318
2013	108,318	23,299	—	—	131,617

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