CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 11, 2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

(Mark One)

þ **Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2010

o **Transition Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File No. 001-33637
Cumberland Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Tennessee	**62-1765329**
State or other jurisdiction of Incorporation or organization	*(I.R.S. Employer Identification No.)*
2525 West End Avenue, Suite 950, Nashville, Tennessee	**37203**
(Address of principal executive offices)	*(Zip Code)*

(615) 255-0068
(Registrant s telephone number, Including area code)

Securities Registered Pursuant to Section 12(b) of the Act

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, no par value	Nasdaq Global Select Market

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this

Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

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

The number of shares of the registrant s Common Stock, no par value, outstanding as of March 1, 2011 was 20,411,484.

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 2011 annual meeting of shareholders.

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Item 1: Business

BUSINESS

Our Company

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

Our product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. We market and sell our products through our dedicated hospital and gastroenterology sales forces in the United States, which together comprised more than 100 sales representatives and managers as of March 1, 2011. We are also partnering our products to reach international markets. Net revenues for the years ended December 31, 2010, 2009 and 2008 were $45.9 million, $43.5 million and $35.1 million, respectively.

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, commercialization and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Our product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our quality and manufacturing professionals oversee the manufacture of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our third party distribution partner to ensure availability and delivery of our products.

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

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our website address is www.cumberlandpharma.com. We make available through our website, free of charge, our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments, as well as

other documents, as soon as reasonably practicable after

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their filing with the U.S. Securities and Exchange Commission, or SEC. These filings are also available to the public at www.sec.gov.

Our Strategy

Maximize sales of Acetadote and Kristalose
Since its launch in June 2004, we have consistently grown product sales for Acetadote, our injectable treatment for acetaminophen poisoning. Net revenue from Acetadote sales grew from $18.8 million in 2007 to $35.1 million in 2010, a compound annual growth rate of 23%. In 2009, we expanded our hospital sales force in preparation for the launch of Caldolor, and are also leveraging this expansion to support Acetadote sales. In early 2011, we received FDA approval for a new formulation of Acetadote and have subsequently launched that new product. We are working to secure patent protection for this new formulation, which we believe could provide us with long term protection for the product.

Kristalose competes in the high growth U.S. prescription laxatives market which, based on data from IMS Health, had sales of approximately $373 million in 2009. After acquiring exclusive U.S. rights to Kristalose in April 2006, we assembled an experienced, dedicated sales force and designed a new marketing program, re-launching the product in September 2006. We inherited this product on a downtrend and have been successful in halting that decline and moving toward growth by enhancing brand awareness and highlighting the product s many positive, competitive attributes.

Successfully commercialize Caldolor
We believe Caldolor, injectable ibuprofen, currently represents our most significant product opportunity based on the large potential markets for intravenous treatment of pain and fever, as well as clinical results for the product to date. In September 2009, we began marketing the product in the U.S. through our expanded hospital sales force. During 2010, we focused on obtaining formulary approval and stocking of the product at U.S. hospitals and other medical facilities. Beginning in the first quarter of 2011, we began working to increase that stocking as well as drive use of the product in those facilities. We hold international patent rights for Caldolor and, in connection with certain current and potential future international partners, are working to seek regulatory approval for and market Caldolor outside of the U.S.

Continue to build a high-performance sales organization to address our target markets
We believe that continuing to build our sales infrastructure will help drive prescription volume and product sales. We currently utilize two distinct sales teams to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the gastroenterology market.

Hospital market: We promote Acetadote and Caldolor through our dedicated hospital sales team of 72 representatives and managers. This team addresses 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 $31 billion, or 10%, of U.S. pharmaceutical sales in 2009. However, IMS also reports that only 2% of approximately $21 billion total pharmaceutical industry promotional spending was focused on hospital-use drugs in 2009. The majority of promotional spending is directed toward large, outpatient markets on drugs intended for chronic use rather than short-term, hospital use. We believe the hospital market is underserved and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity.

Gastroenterology market: We promote Kristalose through a dedicated field sales force addressing a targeted group of physicians who are responsible for a majority of total retail Kristalose prescriptions nationally. By investing in our marketing program, we believe that we will be able to increase market share for Kristalose and that we will be equipped to promote any further gastroenterology product

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additions as well. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe it provides product opportunities but can be penetrated with a modest sales force.

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

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 Pharmaceuticals has the opportunity to negotiate rights to further develop and commercialize them.

Our Products

Our key products include:

Product	Indication	Delivery	Status
Acetadote®	Acetaminophen Poisoning	Injectable	Marketed
Caldolor®	Pain and Fever	Injectable	Marketed
Kristalose®	Chronic and Acute Constipation	Oral Solution	Marketed

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 pain relief and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

Originally approved in January 2004, Acetadote received FDA approval as an orphan drug, which provided seven years of marketing exclusivity from date of approval. In connection with the FDA s approval of Acetadote, we committed to certain post-marketing activities for the product. Our first Phase IV commitment (pediatric) was completed in 2004 and resulted in the FDA s 2006 approval of expanded labeling for Acetadote for use in pediatric patients. Our second Phase IV commitment (clinical) was completed in 2006 and resulted in further revised labeling for the product with FDA approval of additional safety data in 2008. We completed our third and final Phase IV commitment (manufacturing) for Acetadote in 2010, which has culminated in the approval and launch of a new, next

generation formulation of the product.

In October 2010, we submitted a supplemental new drug application (sNDA) to the FDA for approval of a new formulation of Acetadote designed to replace the original formulation. The new formulation,

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which is the result of the aforementioned Phase IV commitment made to the FDA, addresses the FDA s safety concerns and contains no ethylene diamine tetracetic acid or other stabilization and chelating agents and is preservative-free. In January 2011, we received FDA approval and commenced U.S. launch activities for this new Acetadote product. The original formulation has been removed from FDA reference materials and we no longer manufacture it. We have filed a patent application with the U.S. Patent and Trademark Office to protect the proprietary new formulation.

In March 2010, we submitted another sNDA to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. The study showed that these patients can also survive a significant number of days longer without transplant, which would provide patients requiring transplant increased time for a donor organ to become available.

Acute liver failure is associated with a high mortality rate and frequent need for liver transplantation. Approximately half of acute liver failure cases are caused by acetaminophen poisoning while the other half result from a variety of causes including hepatitis and alcohol. Currently, transplantation of the liver is the only treatment for patients with liver failure not caused by acetaminophen overdose.

In May 2010, the FDA officially accepted the sNDA and granted a priority review with a response expected in September 2010. In August 2010, we announced that the FDA extended its review of the sNDA by three months, resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010. In December, we received a Complete Response Letter from the FDA indicating that the agency had completed its review of the application and had identified additional items that must be addressed prior to approving the new indication. We are in discussions with the FDA to gain clarity on a pathway to approval for this indication to treat a critically ill patient population with few treatment alternatives. In addition to expanded labeling for Acetadote, we have requested additional exclusivity for the product in association with the potential new indication.

We are also supporting a number of investigator-initiated studies to explore other potential indications for Acetadote.

Market for Acetadote

Acetaminophen is one of the most widely used drugs for oral treatment of pain and fever in the U.S. and can be found in many common over-the-counter products and prescription narcotics. Though safe at recommended doses, the drug can cause liver damage with excessive use. According to the American Association of Poison Control Centers National Poison Data System, acetaminophen poisoning was the leading cause of toxic drug ingestions reported to U.S. poison control centers in 2008. In a study published in 2005 that examined acute liver failure, researchers concluded that acetaminophen poisoning was responsible for acute liver failure in over half the patients examined in 2003, up from 28% in 1998. While an estimated 48% of cases were due to the accidental use over several days, causing chronic liver failure, an estimated 44% of the cases were intentional overdoses, causing acute liver failure. According to the FDA, four grams of acetaminophen is the daily maximum dosage recommended for adults. Ingesting just eight grams of acetaminophen a day can cause serious complications, especially in people, whose livers are stressed by virus, medication or alcohol. When used in conjunction with opiates, acetaminophen can offer effective pain relief after surgery or injury; however, patients taking acetaminophen/opiate combination drugs on a chronic basis often eventually require increasing amounts to achieve the same level of pain relief, which can also lead to liver failure. In January 2011, the FDA initiated a campaign to heighten awareness of the potential toxicity associated with

acetaminophen and announced that it is asking manufacturers of prescription

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acetaminophen combination products to limit the maximum amount of acetaminophen in these products to 325 mg per tablet in an effort to reduce adverse events.

NAC is widely accepted as the standard of care for acetaminophen overdose. According to *The Medical Letter on Drugs and Therapeutics,* NAC is virtually 100% effective in preventing severe liver damage, renal failure and death if administered within eight to ten hours of the overdose. Throughout Europe and much of the rest of the world, NAC has been available in an injectable formulation for over 25 years. Until the 2004 approval of Acetadote, however, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Many U.S. hospitals prepared an off-label, IV form of NAC from the oral solution to treat patients suffering from acetaminophen poisoning. For a number of these patients, an IV product is the only reasonable route of administration due to nausea and vomiting associated with oral administration. Given this market dynamic, we concluded that a medical need existed for an FDA-approved, injectable formulation of NAC for the U.S. market.

Competitive Advantages

We believe Acetadote offers clinical benefits relative to oral NAC including ease of administration, minimizing nausea and vomiting associated with oral NAC, accurate dosage control, shorter treatment protocol and reduction in overall cost of acetaminophen overdose management. Acetadote makes NAC administration easier to tolerate for patients and easier to administer for medical providers.

Acetadote also offers a significant cost benefit to both patient and hospital by reducing treatment regimen, usually from three days to one day. An independently conducted study of Acetadote as a cost-saving treatment for acetaminophen poisoning was published in the December 2009 issue of the peer-reviewed *Journal of Medical Economics*. The study concludes that Acetadote is a less costly treatment regimen than oral NAC in all evaluated scenarios. The cost differential between the use of oral NAC and Acetadote was shown to range between $881 and $2,259, and was primarily attributable to the time required to complete recommended treatment. Under approved therapeutic protocols, the oral product requires 72 hours to administer compared to 21 hours for Acetadote. Consequently, the use of Acetadote results in shorter hospital stays, resulting in substantial cost disparity between the treatments.

Caldolor®

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the United States for the treatment of both pain and fever. The FDA approved Caldolor for marketing in the United States in June 2009 following a priority review. The product is indicated for use in adults for the management of mild to moderate pain, for the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever.

In September 2009, we successfully implemented the U.S. launch of Caldolor, with more than 100 experienced sales professionals promoting the product across the country. Caldolor is stocked at the major wholesalers serving hospitals nationwide, and is available in 400mg and 800mg vials. We are focused on securing formulary approval and stocking nationally for Caldolor. Our sales group is highly focused on meeting with members of hospital pharmacy and therapeutic committees to secure placement on committee agendas to continue growing widespread formulary approval.

Beginning in 2011, we are reaching out to a wider audience within hospitals to drive pull-through sales of Caldolor in facilities that have added the product to formulary. Our sales professionals are equipped with marketing documents which highlight key differentiating factors including the product s ability to be safely dosed not only post-operatively

but also at induction of anesthesia. We supported the publication of Caldolor clinical data in 2010, with results from those trials appearing in peer-reviewed journals as well as being presented at appropriate medical meetings around the country.

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We have worldwide commercial rights to Caldolor. We market Caldolor in the United States through our existing hospital sales force, and are partnering with third parties to reach markets outside the United States.

The Market for Caldolor

Therapeutic agents used to treat pain are known as analgesics. Physicians prescribe injectable analgesics for hospitalized patients who have high levels of pain, require rapid pain relief or cannot take oral analgesics. According to IMS, the U.S. market for injectable analgesics exceeded $329 million, or 671 million units, in 2009. This market consists principally of generic opioids and the NSAID ketorolac.

Injectable opioids such as morphine, meperidine, hydromorphone and fentanyl accounted for approximately 622 million units sold in 2009. While opioids are widely used for acute pain management, they are associated with a variety of side effects including sedation, nausea, vomiting, constipation, headache, cognitive impairment, reduced GI motility and respiratory depression. Respiratory depression, if not monitored closely, can be deadly. Opioid-related side effects can warrant dosing limitations, which may reduce overall effectiveness of pain relief. Side effects from opioids can cause a need for further medication or treatment, and can increase lengths of stay in post-anesthesia care units as well as overall hospital stay, which can lead to increased costs for hospitals and patients.

Despite a poor safety profile, use of ketorolac, the only non-opioid injectable analgesic available in the U.S., has grown from approximately 38 million units in 2004, or 5% of the market, to approximately 48 million units in 2009, or 7% of the market, according to IMS Health. The FDA warns that ketorolac should not be used in various patient populations that are at-risk for bleeding, as a prophylactic analgesic prior to major surgery or for intra-operative administration when stoppage of bleeding is critical.

Caldolor is one of only two U.S.-approved injectable treatments for fever, with the other being an injectable acetaminophen product. Significant fever, generally defined as a temperature of greater than 102 degrees Fahrenheit, can cause hallucinations, confusion, convulsions and death. Hospitalized patients are subject to increased risk for developing fever, especially from exposure to infectious agents. Patients with endotracheal intubation, sedation, reduced gastric motility, nausea or recent surgery are frequently unable to ingest, digest, absorb, or tolerate oral products to reduce fever. Treatment for these patients ranges from rectal delivery of medication to physical cooling measures such as tepid baths, ice packs and cooling blankets.

Clinical Development Overview

We acquired from Vanderbilt University an exclusive, worldwide license to clinical trial data on the use of intravenous ibuprofen for treatment of hospitalized patients with severe sepsis syndrome, a complex inflammatory condition often resulting in high fever due to infection. Published in the *New England Journal of Medicine*, this data indicated that intravenous ibuprofen was effective in reducing high fever in critically ill patients who were largely unable to receive oral medication. Based upon data generated from this study, we met with the FDA to determine the requirements for gaining FDA approval of intravenous ibuprofen through a 505(b)(2) application. Following discussion with and recommendations by the FDA, we implemented a development program for Caldolor that was designed to obtain approval for a dual indication for the product management of pain and reduction of fever. We performed extensive formulation work resulting in a patented, proprietary product and conducted a number of clinical studies evaluating the safety and efficacy of Caldolor for treatment of pain and fever.

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More than 1,400 subjects, including over 800 receiving IV Ibuprofen, were studied in seven clinical trials supporting our new drug application (NDA) filing. Below is a summary of the clinical trials that supported the NDA and that are currently described in our package insert:

Study name	Number of subjects	Setting	Study results
Pharmacokinetic Study	36	Healthy volunteers	Similar PK parameters between oral and Caldolor
Adult Safety Study	12	Healthy volunteers	Safe and well-tolerated IV infusion of Caldolor
Sepsis Study IND 32803(1)	455	Hospitalized patients with severe sepsis	Significant and sustained reduction of temperature in patients with high fever ($p<0.01$)(3)
Adult Malaria Fever Study	60	Hospitalized adult malaria patients	Significant reduction in temperature over 24 hours of treatment ($p=0.002$)
Phase III Adult Fever Study(2)	120	Hospitalized adult febrile patients	Significant, dose-dependent, reduction in temperature supporting 400mg dose ($p=0.0003$)
Phase III Adult Dose Ranging Pain Study(2)	406	Hospitalized adult abdominal and orthopedic post-operative patients	Dose-dependent, morphine sparing effect (22%) supporting 800mg dose Significant reduction in pain intensity scores (VAS)(4) over 24 hours of treatment ($p=0.001$)
Phase III Adult Abdominal Hysterectomy Pain Study(2)	319	Hospitalized adult abdominal hysterectomy patients	Significant, morphine-sparing effect (19%, $p<0.001$) Significant reduction in pain intensity scores (VAS) over 24 hours of treatment ($p=0.011$)
Total	1,408		

(1) Study data licensed from Vanderbilt University; Cumberland report filed 2003

(2) Pivotal Study

(3) P-value <0.05 represents statistical significance

(4) Visual Analog Scale

Additional Studies
Adult Orthopedic Pain Study: We initiated a Phase III pain study in post-operative adult patients who had undergone orthopedic surgical procedures. Patients, all with access to patient controlled analgesia (PCA) with morphine, were randomized to also receive either 800mg of Caldolor (multi-modal therapy) or placebo treatment (standard therapy) four times daily for up to five days. The first dose in this study

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was administered prior (pre-operatively) to the surgical procedure. The primary endpoint was reduction in patient pain intensity scores using VAS measured with movement.

We enrolled 185 patients in the safety population. There was a significant reduction in pain intensity scores using VAS. Patients receiving Caldolor reported a 26% greater reduction in pain intensity after 24 hours ($p<0.001$; with movement Area Under the Curve of VAS) compared to placebo. 24 hours after the first dose of Caldolor was administered patients receiving Caldolor reported a 32% greater reduction in pain at rest ($p<0.001$ at rest AUC-VAS) compared to placebo. In this study, we also investigated the efficacy of Caldolor in reducing morphine use by patients receiving the 800mg dose. There was a significant reduction in morphine use by those receiving 800mg of Caldolor after surgery and through hour 24.

Adult Burn Study: We conducted a multicenter, randomized, double-blind, placebo-controlled trial at five U.S. and international clinical sites, including hospital burn units and burn centers, to evaluate the safety and efficacy of Caldolor in treating fever and pain in hospitalized burn patients. Patients were administered 800mg of Caldolor every six hours for five consecutive days. The study raised no safety concerns and the medication was well tolerated. There was no difference in adverse effects between patients who received a placebo and those receiving Caldolor. The study evaluated 61 adult burn patients with second or third degree burns covering more than 10 percent total body surface area. Other participant criteria included an anticipated hospital stay of more than 72 hours and temperatures of 38.0 degrees Celsius (100.4 degrees Fahrenheit) or greater. Statistical significance was achieved for the primary endpoint of reducing fever in burn patients over the first 24 hours of treatment.

Adult Pharmacokinetics Study: We conducted a randomized, double-blind, placebo-controlled, single dose crossover study of the pharmacokinetics, safety and tolerability of Caldolor in healthy adult volunteers. Twelve subjects were randomized in equal proportions to receive a single dose of 800mg Caldolor, administered over five to seven minutes, and oral placebo administered concurrently, followed by a wash-out period of a single dose of 800mg oral ibuprofen and intravenous placebo given concurrently. There were no serious adverse events nor any adverse events classified as moderate or severe. The most common adverse event, which was classified as mild, was infusion site pain in three subjects. The results of the study indicate that the mean Cmax of Caldolor was approximately twice that of the oral dose and the median Tmax for Caldolor was 6.5 minutes compared to 1.5 hours for the oral product. The AUC was similar between the two products. Results from the trial demonstrate the effects of decreasing infusion time for Caldolor from the current package insert guideline of no less than 30 minutes to an infusion time of five to seven minutes.

Phase IV Required Pediatric Assessment

The required pediatric assessment for the Caldolor NDA was deferred until 2011 for the treatment of fever and until 2012 for the management of pain. Two clinical studies are currently underway to address the Phase IV requirements. By conducting pediatric clinical studies and supplying requested data to the FDA, Cumberland has the opportunity to obtain up to an additional six months of marketing exclusivity for Caldolor. If results of these trials are not favorable, we would not be eligible for additional pediatric exclusivity; however, unfavorable pediatric results would not impact marketing status for use in adults.

No additional Phase IV commitments were assigned by the FDA.

Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated IV ibuprofen safety database combining data from our clinical trials as well as previously published study data. We used this data to support our

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

In clinical trials supporting our proposed indications, no serious adverse events have been directly attributed to Caldolor. 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 NSAIDs, such as changes in renal function, bleeding events or gastrointestinal disorders.

Kristalose®
Kristalose is a prescription laxative administered orally for the treatment of constipation. An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient compliance and acceptance. We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a new dedicated field sales force and re-launched the product in September 2006 under the Cumberland brand. We direct our sales efforts to physicians who are the most prolific writers of prescription laxatives, including gastroenterologists, pediatricians, internists and colon and rectal surgeons.

Market for Kristalose
Constipation is a common condition in the U.S., affecting approximately 20% of the population each year. While many occurrences are non-recurring, a significant number are chronic in nature and require some treatment to control or resolve. Constipation treatments are sold in both the over-the-counter (OTC) and prescription segments. The prescription laxative market has historically consisted of a few highly promoted brands including MiraLax® (polyethylene glycol 3350), which is now being sold as an OTC product, and Amitiza®, as well as several generic forms of liquid lactulose. According to data from IMS Health, the prescription laxative market had sales of approximately $373 million in 2009.

Competitive Advantages
Kristalose is the only prescription-strength laxative available in pre-measured powder packets, making it very portable. The drug dissolves quickly in four ounces of water, offering patients a virtually tasteless, grit-free and calorie-free alternative to liquid lactulose treatments. We believe that Kristalose has competitive advantages over competing prescription laxatives, such as fewer potential side effects and contraindications as well as lower cost. There are no age limitations or length of use restrictions for Kristalose, and it is the only osmotic prescription laxative still sampled to physicians.

In 2009, we completed a multicenter, randomized, open label, crossover patient preference study evaluating Kristalose compared to similar products in liquid forms. Over a 14-day period, 50 patients with a recent diagnosis of chronic constipation were administered both Kristalose and liquid lactulose in a crossover study. Patient preference was measured through survey responses collected at the end of the study. Overall, more patients preferred Kristalose, noting portability as a key differentiating feature. More patients also preferred the taste of Kristalose as well as the consistency compared to the syrup formulations. There was no significant difference in adverse effects between patients who took Kristalose and those taking liquid lactulose. We are also exploring opportunities to expand into new indications with Kristalose.

Early-stage product candidates

Our pre-clinical product candidates are being developed through CET, our 85%-owned subsidiary. Cumberland Pharmaceuticals negotiates rights to develop and commercialize CET product candidates, and in conjunction with research institutions has obtained nearly $1 million in grant funding from the National Institutes of Health to support the development of these programs.

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Four of the more advanced CET development programs are:

Ø In collaboration with Vanderbilt University, we are currently developing a new palliative treatment for fluid buildup in the lungs of cancer patients. The product candidate is a protein therapeutic being designed to treat pleural effusion, a condition which occurs when cancer spreads to the surface of the lung and chest cavity, causing fluid to accumulate and patients to suffer shortness of breath and chest pain. An estimated 100,000 patients are affected by this condition each year. Vanderbilt University researchers believe they have found a method of treating this condition which may involve less pain, a higher success rate and faster healing time, resulting in significantly shorter hospital stays.

Ø In collaboration with the University of Mississippi, we are developing a highly purified, injectable anti-infective used to treat fungal infections in immuno-compromised patients. This product candidate s active ingredient is currently FDA-approved in a different formulation, and while it is the therapeutic of choice for infectious disease specialists in treating such fungal infections, it can produce serious side effects related to renal toxicity, often resulting in dosage limitations or discontinued use. University of Mississippi researchers have developed what they believe is a purer and safer form of the anti-infective.

Ø In collaboration with the University of Tennessee, we are currently developing a novel asthma therapeutic designed to prevent remodeling of airway smooth muscle to reduce asthmatic reaction in pediatric patients. Airway remodeling occurs when the cells or muscles that line the airway become inflamed and can result in decreased lung function. University of Tennessee researchers believe they have found a treatment that can reduce, or even prevent, asthma attacks in children.

Ø CET previously entered into an agreement with Vanderbilt University to develop a novel treatment to improve renal function in patients with hepatorenal syndrome, a condition where kidneys fail suddenly due to cirrhosis of the liver. The product candidate may reduce renal blood flow in association with acute kidney failure. In the third quarter of 2010, Cumberland Pharmaceuticals entered into an option agreement with CET to assume the rights and responsibilities associated with the product candidate. We have commenced product manufacturing and submitted an investigational new drug application for the clinical evaluation of this product candidate.

BUSINESS DEVELOPMENT

Since inception, we have had an active business development program focused on acquiring rights to marketed products and product candidates that fit our strategy and target markets. We source our business development leads through our senior executives and our international network of pharmaceutical and medical industry insiders. These opportunities are reviewed and considered on a regular basis by a multi-disciplinary team of our managers against a list of selection criteria. We have historically focused on product opportunities with relatively low acquisition, development and commercialization costs, employing a variety of deal structures.

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

Through CET, we are collaborating with a growing list of reputable research institutions. 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.

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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 and monitoring our clinical trials;
- creating case report forms and other study-related documents;
- overseeing clinical work contracted to third parties; and
- overseeing CET grant funding proposals.

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- maintaining investigational and marketing applications through the submission of appropriate reports;
- submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;
- monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices, 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 clinical and regulatory team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. Prior to the launch of Caldolor, we expanded our medical affairs staff to support inquiries from medical professionals regarding the appropriate use of Caldolor as well as to support the efforts of our expanded hospital sales force. In addition to coordinating the call center, our clinical/regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including more than 100 sales representatives and district managers, direct our national marketing

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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., or Cardinal, to Cumberland employees through our wholly-owned subsidiary, Cumberland Pharma Sales Corp.

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

Our sales and marketing executives conduct ongoing market analyses to evaluate marketing campaigns and promotional programs. The evaluations include development of product profiles, testing of the profiles against the needs of the market, determining what additional product information or development work is needed to effectively market the products and preparing financial forecasts. We utilize professional branding and packaging as well as promotional items to support our products, including direct mail, sales brochures, journal advertising, educational and reminder leave-behinds, patient educational pieces and product sampling. We also regularly attend targeted trade shows to promote broad awareness of our products. Our National Accounts group is responsible for key large buyers and related marketing programs. This group supports sales and marketing efforts by maintaining relationships with our wholesaler customers as well as with third-party payors such as Group Purchasing Organizations, Pharmacy Benefit Managers, Hospital Buying Groups, state and federal government purchasers and influencers and health insurance companies.

International sales and marketing

We have licensed to third parties the right to distribute certain products outside the U.S. We have granted Alveda Pharmaceuticals Inc., or Alveda, an exclusive license to distribute Caldolor in Canada subject to receipt of regulatory approval. Alveda is obligated to make payments to us of up to $1,000,000 Canadian upon Caldolor s achieving specified regulatory milestones in Canada and to pay us a royalty based on Canadian sales of Caldolor. This license terminates five years after regulatory approval is obtained in Canada for the later of the fever or pain indications.

In December 2009, we announced that we entered into an exclusive partnership with DB Pharm Korea Co. Ltd., a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. Under the terms of the agreement, DB Pharm Korea is responsible for obtaining any regulatory approval for the product and handling ongoing regulatory requirements, product marketing, distribution and sales in Korea. We maintain responsibility for product formulation, development and manufacturing. Under the agreement, Cumberland will receive up to $500,000 in upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in South Korea.

In October 2009, we announced that we entered into an exclusive partnership with Phebra Pty Ltd., or Phebra, an Australian-based specialty pharmaceutical company, for the commercialization of Caldolor in Australia and New Zealand. Phebra has responsibility for obtaining any regulatory approval for the product, and for handling all ongoing regulatory requirements, product marketing, distribution and sales in the territories. We will maintain responsibility for product formulation, development and manufacturing. Under the terms of the agreement, Cumberland will receive up to $500,000 in upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in those territories.

We also granted Phebra an exclusive license to market and distribute Acetadote in Australia, New Zealand, and Southeast Asia, subject to the receipt of regulatory approval. Phebra is obligated to make payments to us of up to $325,000 upon Phebra s achieving specified milestones as well as royalty

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payments. In April 2010, the Therapeutic Goods Administration granted approval for the commercialization of Acetadote in Australia and in October 2010, Phebra commenced with the Australian launch of the product. This introduction of Acetadote in Australia marked the introduction of Cumberland s products into international markets. In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country.

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:

Ø 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.

Ø Bioniche Teoranta, or Bioniche, sources APIs and has manufactured 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. Bioniche manufactures and packages Acetadote for us, and we purchase Acetadote from Bioniche pursuant to an agreement that we are currently renegotiating.

Ø Inalco S.p.A. and Inalco Biochemicals, Inc., or collectively Inalco, from which we licensed exclusive U.S. commercialization rights to Kristalose in April 2006, source APIs and supply us with the product under an agreement that expires in 2021. The agreement renews automatically for successive three-year terms unless we or Inalco provide written notice of intent not to renew at least 12 months prior to expiration of a term. Either we or Inalco may terminate this agreement upon at least 45 days prior written notice in the event of uncured material breach. Under the agreement, we are required to pay Inalco a transfer price per unit of Kristalose supplied and a percentage royalty in the low to mid single-digits throughout the term of the agreement based on our net sales of Kristalose. We are required to purchase minimum quantities of Kristalose. In 2010, Inalco sold its facility that manufactured the API for Kristalose, resulting in shipping delays and possible increases in supply prices. We are currently in discussions with Inalco regarding these price increases, as well as an amendment to the Inalco agreement.

Ø We entered into an agreement with Bayer Healthcare, LLC, or Bayer, in February 2008 for the manufacture of Caldolor and Acetadote. The agreement expires in February 2013, subject to early termination upon 30 days prior written notice in the event of uncured material breach by us or Bayer. The agreement will automatically renew for successive one-year terms unless Bayer or we provide at least six months prior written notice of non-renewal. Under the agreement, we pay Bayer a transfer price per each unit of Caldolor or Acetadote supplied. In addition,

we pay Bayer for agreed upon development costs.

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Distribution

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

INTELLECTUAL PROPERTY

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

Acetadote was approved by the FDA in January 2004 as an orphan drug for the intravenous treatment of acetaminophen overdose. As an orphan drug, we were entitled to seven years of marketing exclusivity for the treatment of this approved indication, which expired in January 2011. In January 2011, we received FDA approval for our next generation, new formulation of Acetadote, for which we have applied for patent protection through U.S. patent application No. 11/209,804, as well as through international application No. PCT/US06/20691, both of which are directed to acetylcysteine compositions, methods of making the same and methods of using the same. In addition, we have an exclusive, worldwide license to NAC clinical data from Newcastle Master Misercordiae Hospital in Australia. We have no expected outstanding payment obligations pursuant to this contract.

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.

In 2009, we also filed the first of several new patent applications for Caldolor. Part of an ongoing initiative to protect the value of our intellectual property, the new applications address our proprietary method of dosing intravenous ibuprofen.

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

In addition, we received three years marketing exclusivity upon receipt of FDA approval for Caldolor. We intend to seek further exclusivity from the FDA upon completion of successful pediatric clinical trials for the product.

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Kristalose

We are the exclusive licensee of U.S. Patent No. 5,480,491 owned by Inalco relating to Kristalose, directed to a process for preparation of crystalline lactulose. Related license rights include an exclusive license to use related Inalco know-how and the Kristalose trademark to manufacture, market and distribute Kristalose in the U.S. Under our agreement with Inalco, Inalco is solely responsible for prosecuting and maintaining both the patents and know-how that we license from them. Our license expires in 2021 and is subject to earlier termination for material breach. Our payment obligations under this agreement are described under Manufacturing and Distribution Manufacturing.

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:

- Ø product attributes such as efficacy, safety, ease-of-use and cost-effectiveness;
- Ø brand awareness and recognition driven by sales and marketing and distribution capabilities;
- Ø intellectual property and other exclusivity rights;
- Ø availability of resources to build and maintain developmental and commercial capabilities;
- Ø successful business development activities;
- Ø extent of third-party reimbursements; and
- Ø 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. Despite the availability of injectable NAC outside the United States, Acetadote, to our knowledge, is the only injectable NAC product approved in the U.S. to treat 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. and Hospira Inc.

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:

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

Ø DepoDur® is an extended release injectable formulation of morphine that is marketed by EKR Therapeutics, Inc.

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

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 OTC products. The prescription products which we believe are our primary competitors are Amitiza® and liquid lactuloses. Amitiza is indicated for the treatment of chronic idiopathic constipation in adults and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. Liquid lactulose products are marketed by a number of pharmaceutical companies.

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

GOVERNMENT REGULATION

Pharmaceutical companies are subject to extensive regulation by national, state, and local agencies in countries in which they do business. The manufacture, distribution, marketing and sale of pharmaceutical products is subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products and we may be criminally prosecuted. 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.

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FDA Approval Process

The steps required to be taken before a new prescription drug may be marketed in the U.S. include:

Ø completion of pre-clinical laboratory and animal testing;

Ø the submission to the FDA of an investigational new drug application, or IND, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;

Ø performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and

Ø submission and approval of an NDA.

The sponsor of the drug typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more dosages. In Phase II clinical trials, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

The FDA requires that clinical trials be conducted in accordance with the FDA s good clinical practices (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 pre-clinical and clinical trials, together with, among other things, 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 FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten 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 three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. The FDA may also issue an approvable letter setting forth further conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug for certain indications. According to the FDA, the median total approval time for NDAs approved during calendar year 2004 was approximately 13 months for standard applications. If the FDA s evaluations of the NDA submission and the clinical and manufacturing procedures and facilities are not favorable, it may refuse to approve the NDA and issue a not-approvable letter. 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.

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Section 505(b)(2) New Drug Applications

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a stand-alone or full NDA. Section 505(b)(2) of the FDC Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) 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 and for which the applicant has not obtained a right of reference. 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.

We successfully secured FDA approvals for Acetadote in January 2004 and for Caldolor in June 2009 pursuant to the 505(b)(2) pathway. Upon approval of a full or 505(b)(2) NDA, a drug may be marketed only for the FDA-approved indications in the approved dosage forms. Further clinical trials are necessary to gain approval for the use of the product for any additional indications or dosage forms. The FDA may also require post-market reporting and may require surveillance programs to monitor the side effects of the drug, which may result in withdrawal of approval after marketing begins.

Special Protocol Assessment Process

The special protocol assessment, or SPA, process generally involves FDA evaluation of a proposed Phase III clinical trial protocol and a commitment from the FDA that the design and analysis of the trial are adequate to support approval of an NDA, if the trial is performed according to the SPA and meets its endpoints. The FDA s guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA s evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases.

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. 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.

Orphan Drug Designation

The Orphan Drug Act of 1983, or Orphan Drug Act, encourages manufacturers to seek approval of products intended to treat rare diseases and conditions with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval. Acetadote received Orphan Drug designation in October 2001 and was approved by the FDA for the intravenous treatment of moderate to severe acetaminophen overdose in January 2004. As an orphan drug, Acetadote was entitled to marketing exclusivity until

January 2011 for the treatment of this approved indication, and we intend to seek additional exclusivity for this product through new potential indications. This exclusivity would not prevent a product with a different formulation from competing with Acetadote, however.

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The Hatch-Waxman Act

The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. It is under this provision that we received three years marketing exclusivity for Caldolor upon receipt of FDA approval in June 2009.

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 will be 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 will be 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 would subject us to this fee, our sales volume in such programs is less than $10 million, with the first $5 million of sales being exempt from the fee. We do not anticipate this fee will have a material impact on our results of operations.

Medicaid Rebate Rate

We currently provide rebates for Kristalose sold to Medicaid beneficiaries. Effective January 1, 2010, the rebate increased from eleven percent to thirteen percent of the average manufacturer price. Our sales of Kristalose under the Medicaid program have been increasing. We expect the increased rebate percentage will impact our net revenue for Kristalose by less than $0.1 million for the year ended December 31, 2011.

Federal Grant Funding

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

Other Regulatory Requirements

Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved

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products or place conditions on any approvals that could restrict the commercial applications of these products.

If we seek to make certain changes to an FDA-approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA s IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products. 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 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.

Outside of the U.S., our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval process described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

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.

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EMPLOYEES

As of March 1, 2011, we had 131 full-time employees. In addition, we believe that utilizing experienced, independent contractors and consultants is a cost-efficient and effective way to accomplish our goals and a number of individuals have provided or are currently providing services to us pursuant to agreements between the individuals or their employers and us. None of our employees are represented by a collective bargaining unit. We believe that we have positive relationships with our employees.

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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:

Ø The prices of our products relative to other drugs or competing treatments;

Ø Any unfavorable publicity concerning us, our products, or the markets for these products such as information concerning product contamination or other safety issues in either of our product markets, whether or not directly involving our products;

Ø Perception by physicians and other members of the healthcare community of the safety or efficacy of our products or competing products;

Ø Regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products;

Ø Changes in intellectual property protection available for our products or competing treatments;

Ø The availability and level of third-party reimbursement for sales of our products; and

Ø 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.

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

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difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected.

Caldolor is manufactured at Hospira Australia Pty. Ltd. s facility in Australia and Bayer s facility in Kansas. Beginning in early 2011, Acetadote is manufactured primarily at Bayer s facility in Kansas and Bioniche s manufacturing plant in Ireland is an alternative manufacturing source for Acetadote. The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy. If any one of these facilities is damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our products. Kristalose is manufactured through a complex process involving trade secrets of the manufacturer; therefore, it would be particularly difficult to find a new manufacturer of Kristalose on an expedited basis. As a result of these factors, our ability to manufacture Kristalose may be substantially impaired if the manufacturer is unable or unwilling to supply sufficient quantities of the product.

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

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

- Ø fines and civil penalties;
- Ø suspension of production or distribution;
- Ø suspension or delay in product approval;
- Ø product seizure or recall; and
- Ø withdrawal of product approval.

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

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

- Ø Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which warehouses and ships our marketed products; and
- Ø Vanderbilt University and the Tennessee Technology Development Corporation, co-owners with us of CET, and the universities that collaborate with us in connection with CET s research and development programs.

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

Competitive pressures could reduce our revenues and profits.

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

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Our competitors may sell or develop drugs that are more effective and useful and 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 health care payors have recently emphasized 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 branded pharmaceuticals. While there are no generic equivalents competing with our products at this time, in the future we could face generic competition.

The commercial launch of Caldolor is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.

Caldolor represents a substantial portion of our future growth. Caldolor was approved by the FDA in June 2009, and we started commercializing Caldolor in the United States in September 2009. The commercial success of Caldolor is dependent on many third-parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P&T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to be administered primarily to hospitalized patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals formulary lists by their P&T committees. A hospital s P&T committee generally governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. Because Caldolor is a new drug with little track record, 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.

In addition to the extensive external efforts required, the commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. Internally, the successful commercialization of Caldolor depends on our ability to maintain a well-trained, qualified sales force, to equip our sales force with effective supportive materials, to target appropriate markets and to accurately price Caldolor. In addition, as Caldolor is a newly marketed drug, our sales force will need to be credible and persuasive in order to convince physicians and pharmacists in target markets to use Caldolor. If we are unable to provide our sales force with convincing supportive materials, such as clinical papers, sales literature and formulary kits, they may not be able to sell Caldolor in sufficient quantities. We must also target the right hospitals across the United States. Any failure in sales force coverage could limit our ability to generate market acceptance for Caldolor. We also 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. If we have set

the initial price for Caldolor too low, we may not generate adequate profits and may not be able to raise the price of the drug in the future.

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Any attempt by us to expand the potential market for Caldolor is subject to limitations.

In its June 2009 Caldolor approval letter, the FDA required us to conduct two additional Phase IV pediatric studies by 2011 and 2012, respectively. If the results of these Phase IV clinical studies are not favorable, we may not be able to expand the market for Caldolor to children ages 1-16. We may also experience delays associated with these required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling pediatric patients. Such delays could impact our ability to obtain an additional six months of FDA exclusivity.

In addition, we have only obtained regulatory approval to market Caldolor in the United States. In foreign jurisdictions such as Canada, New Zealand, South Korea, Southeast Asia and Australia we have licensed the right to market Caldolor to third parties. These third parties are responsible for seeking regulatory approval for Caldolor in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for Caldolor will be obtained outside the United States.

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

We acquired rights to Caldolor, Acetadote and Kristalose. 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.

If we are unable to maintain 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 or 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. If we are unable to establish and maintain adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses and may not continue to be profitable.

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

Our financial success depends, in part, on the availability of adequate reimbursement from third-party healthcare payors. Such third-party payors include governmental health programs such as Medicare and Medicaid, managed care providers and private health insurers. Third-party payors are increasingly challenging the pricing of medical products

and services, while governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

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For example, in March 2010, the U.S. government passed into law and enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, Health Care Reform Act). Among other provisions, the Health Care Reform Act calls for an increase in certain Medicare drug rebates paid by pharmaceutical manufacturers and an industry fee imposed on pharmaceutical manufacturers according to the individual manufacturer s relative percentage of total industry sales to specified government programs. At this time no assurances can be given that these measures, or any other measures included in the Health Care 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.

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

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

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

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

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

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

Ø CET investigates early-stage products, which have the greatest risk of failure prior to FDA approval and commercialization;

Ø 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;

Ø 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;

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- 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. 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.

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;

Ø loss of revenue; and

Ø 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

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from the use or misuse of our products or any similar products sold by other companies could have a material adverse impact on our results of operations.

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

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

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

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

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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, and 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

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

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

Any change in the FDA s enforcement policy could have a material adverse effect on our business, financial condition and results of operations.

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

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

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, 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.

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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. 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. Although a patent application and other applications relating to uses of Acetadote are in prosecution, they have not yet been issued. Barriers to competitive market entry include the time and cost associated with the development, regulatory approval and manufacturing of a similar formulation.

We do not have composition of matter or use patents for our marketed products. We do have a U.S. patent, No. 6,727,286 for Caldolor, and some related international patents, which are directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor ibuprofen is in the public domain, and if a competitor were to develop a sufficiently distinct formulation, it could develop and seek FDA approval for another ibuprofen product that competes with Caldolor. Upon receipt of FDA approval in June 2009, we received three years of marketing exclusivity for Caldolor.

Kristalose is manufactured under a contract with Inalco, which owns U.S. Patent No. 5,480,491, related to the manufacture of Kristalose. This patent is not directed to the composition or use of Kristalose and does not prevent a competitor from developing a formulation and developing and seeking FDA approval for a product that competes with Kristalose.

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 U.S. Patent and Trademark Office 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,

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and we might not have adequate remedies for any breach. Also, others could acquire or independently develop similar technology.

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

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

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

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

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

Competitors may infringe our 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 U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed during this type of litigation. In addition, there

could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are a relatively new company seeking to capture significant growth. While our revenues and operating income have increased over time, we anticipate that there may be fluctuations in our future operating results. We may not be able to maintain or improve our current levels of revenue or income. Potential causes of future fluctuations in our operating results may include:

Ø new product launches, which could increase revenues but also increase sales and marketing expenses;

Ø acquisition activity and other charges (such as for inventory expiration);

Ø increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional development;

Ø changes in the competitive, regulatory or reimbursement environment, which could drive down revenues or drive up sales and marketing or compliance costs; and

Ø 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 a large amount of 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, 2010, intangible assets relating to product and data acquisitions represented approximately 8% of our total assets. We may never realize the value of these assets. Generally accepted accounting principles require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any

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determination requiring the write-off of a significant portion of unamortized intangible assets would adversely affect our results of operations.

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

We may need to raise additional funds in order to meet the capital requirements of running our business and acquiring and developing new pharmaceutical products. If we require additional funding, we may seek to sell common stock or other equity or equity-linked securities, which could result in dilution to our shareholders. We may also seek to raise capital through a debt financing, which would result in ongoing debt-service payments and increased interest expense. Any financings would also likely involve operational and financial restrictions being imposed on us. We might also seek to sell assets or rights in one or more commercial products or product development programs. Additional capital might not be available to us when we need it on acceptable terms or at all. If we are unable to raise additional capital when needed, we could be forced to scale back our operations to conserve cash.

RISKS RELATED TO OWNING OUR STOCK

The market price of our common stock may fluctuate substantially.

The price for the shares of our common stock sold in our initial public offering was determined by negotiation between the representatives of the underwriters and us. This price may not have reflected the market price of our common stock following our initial public offering. Through March 1, 2011, the closing price of our common stock has ranged from a low of $4.70 to a high of $17.05 per share. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

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

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

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

which would directly affect our ability to attain our operating goals on schedule and on budget.

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We are experiencing increased costs 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 (Sarbanes-Oxley Act), Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and other rules 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.

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, beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2010, as required by Section 404 of the Sarbanes-Oxley Act. 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 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 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.

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:

Ø the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval;

Ø advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders;

Ø limitations on persons authorized to call a special meeting of shareholders;

Ø a staggered board of directors;

Ø 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

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over then current prices, and may limit the ability of shareholders to remove our current management or approve transactions that our shareholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

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

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

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

We have never paid cash dividends on our capital stock. We do not anticipate paying cash dividends to our shareholders in the foreseeable future. The availability of funds for distributions to shareholders will depend substantially on our earnings. Even if we become able to pay dividends in the future, we expect that we would retain such earnings to enhance capital and/or reduce long-term debt.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K that are not historical factual statements are forward-looking statements. Forward-looking statements include, among other things, statements regarding our intent, belief or expectations, and can be identified by the use of terminology such as may, will, expect, believe, intend, plan, 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 Risk factors, 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:

Ø 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;

Ø 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;

Ø competition; and

Ø changes in national or regional economic conditions, including changes in interest rates and availability and cost of capital to us.

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Item 1B: Unresolved Staff Comments

None

Item 2: Properties

As of December 31, 2010, 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 expiring in July 2011, CET leases approximately 6,900 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. In January 2011, we notified the landlord of our intent to renew CET s lease for five years.

Item 3: Legal Proceedings

We are not currently engaged in any legal proceedings.

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

MARKET INFORMATION

Our common stock, no par value, has been traded on the Nasdaq Global Select Market since August 11, 2009 under the symbol CPIX. Prior to that time, there was no public market for our common stock. As of March 1, 2011, there were 134 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 1, 2011 was $5.75 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 since the completion of our initial public offering and through December 31, 2010:

	High	Low
Fiscal year ended December 31, 2009:		
Fourth quarter	$ 16.77	$ 11.78
Fiscal year ended December 31, 2010:		
First quarter	14.52	10.26
Second quarter	11.11	6.16
Third quarter	6.90	4.70
Fourth quarter	8.18	5.63

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 with Bank of America. Any future decision to declare or pay dividends will be at the sole discretion of our Board of Directors.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The information required by this section is incorporated by reference to Note 10 to the consolidated financial statements for the year ended December 31, 2010 beginning on page F-22 of this Annual Report on Form 10-K.

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PERFORMANCE GRAPH

The following stock performance graph 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 Nasdaq Pharmaceutical Stocks. The graph assumes an initial investment of $100 on August 10, 2009, and that all dividends were reinvested.

Comparison of Cumulative Total Return

USE OF PROCEEDS FROM INITIAL PUBLIC OFFERING OF COMMON STOCK

On August 10, 2009, our Registration Statement on Form S-1 (File No. 333-142535) was declared effective for our initial public offering. The use of our proceeds from our initial public offering since December 31, 2009 has been reflected in the periodic reports filed during the year ending December 31, 2010. The remaining funds are expected to be used for general corporate purposes and acquisitions of product candidates, new products and intellectual property rights to products or companies that complement our business.

PURCHASES OF EQUITY SECURITIES

The following table summarizes the activity, by month, during the fourth quarter of 2010:

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 1 October 31	39,751	$ 6.38	381,796	$ 7,531,094(1)
November 1 November 30	18,035	6.69	399,831	7,410,516
December 1 December 31	52,602	6.87	452,433	7,049,308
Total	110,388			

(1)

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, our Board of Directors modified the existing repurchase program to provide for the repurchase of $10 million of our outstanding common stock, in addition to the amount repurchased in 2010.

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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 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:	**2010**	**2009**	**2008**	**2007**	**2006**
		(in thousands, except per share data)			
Net revenues	$ 45,876	$ 43,537	$ 35,075	$ 28,064	$ 17,815
Cost of products sold	3,587	4,137	3,046	2,670	2,399
Selling and marketing	22,675	20,194	14,387	10,053	7,349
Research and development	4,327	4,993	4,429	3,694	2,233
General and administrative	7,990	7,643	5,140	4,138	2,999
Other operating expenses	796	794	791	783	612
Operating income	6,502	5,777	7,282	6,725	2,224
Earnings per share basic	$ 0.12	$ 0.22	$ 0.47	$ 0.40	$ 0.45
Earnings per share diluted	$ 0.12	$ 0.17	$ 0.29	$ 0.24	$ 0.27

	As of December 31,				
Balance sheet data:	**2010**	**2009**	**2008**	**2007**	**2006**
		(in thousands)			
Cash and cash equivalents	$ 65,894	$ 78,702	$ 11,830	$ 10,815	$ 6,255
Working capital	71,811	74,549	10,104	6,669	3,945
Total assets	92,054	103,724	31,119	28,919	26,481
Total long-term debt and other long-term obligations (including current portion)	7,802	20,155	7,666	7,623	10,543
Convertible preferred stock			2,604	2,743	2,743
Retained earnings (accumulated deficit)	6,999	4,542	1,451	(3,316)	(7,360)
Total equity	77,715	72,221	17,555	16,746	11,126

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. 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.

OVERVIEW

We are a profitable and growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Cumberland is dedicated to providing innovative products which improve quality of care for patients. Our primary target markets are hospital acute care and gastroenterology, which are characterized by relatively concentrated

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physician prescriber bases that we believe can be penetrated effectively with relatively small, targeted sales forces.

Our product portfolio includes Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. We market our products through our dedicated hospital and gastroenterology sales forces in the United States, and work to partner our products to reach international markets.

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, clinical and regulatory affairs, and sales and marketing. Our internal product development and regulatory executives develop proprietary product formulations, design and manage our clinical trials, prepare all regulatory submissions and manage our medical call center. Our products are manufactured by third parties, which are overseen and managed by Cumberland s quality control and manufacturing group. All aspects of commercialization are handled by our sales and marketing professionals, and we work closely with our distribution partner to make our products available across the United States.

Our strategy to grow our company includes maximizing the potential of our existing products and continuing to build a portfolio of new, differentiated products. All of our current products are approved for sale in the United States, and Acetadote is approved for sale in Australia. We are expanding our partner base outside of the U.S. to bring our products to select international markets. We also look for opportunities to expand into additional patient populations through new product indications, whether through proprietary clinical studies or by supporting investigator-initiated studies at reputable research institutions. We are actively pursuing opportunities to acquire additional late-stage development product candidates as well as marketed products in our target medical specialties. Further, we are supplementing the aforementioned growth strategies with the early-stage drug development activities of CET, our majority-owned subsidiary. CET partners with universities and other research organizations to cost-effectively develop promising, early-stage product candidates, which Cumberland has the opportunity to commercialize.

Our operating results have fluctuated in the past and are likely to fluctuate in the future. These fluctuations can result from competitive factors, new product acquisitions or introductions, the nature, scope and result of our research and development programs, execution of our growth strategy and other factors. As a result of these fluctuations, our historical financial results are not necessarily indicative of future results.

2010 HIGHLIGHTS AND RECENT DEVELOPMENTS

Acetadote®

Submission of Application for New Formulation of Acetadote
In October 2010, we submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for approval of a new formulation of Acetadote, which was the result of a Phase IV commitment Cumberland made to the FDA upon receipt of initial marketing approval of the product. In January 2011, the FDA approved the new formulation, which does not contain ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. We have commenced U.S. launch activities for this next generation product, which will replace the currently marketed product. We will no longer manufacture the previously approved formulation for the U.S. market and the original formulation has been delisted. We have provided a request

to the FDA that they not approve a generic to the previous formulation and documented that the new formulation was developed based on their Phase IV requirement. We have also filed a patent application with the U.S. Patent and Trademark Office to protect the proprietary new formulation.

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Supplemental New Drug Application for Acetadote
In March 2010, we submitted a sNDA to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA includes data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. The study showed that these patients can also survive a significant number of days longer without transplant, which would provide patients requiring transplant increased time for a donor organ to become available.

In May 2010, the FDA officially accepted the sNDA and granted a priority review with a response expected in September 2010. In August 2010, we announced that the FDA extended its review of the sNDA by three months, resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010. In December, the FDA issued a Complete Response Letter indicating that it had completed its review of the application and had identified additional work required or items that must be addressed prior to approval of the potential new indication. We are currently in discussion with the FDA to gain clarity on the pathway to approval for this important indication.

Launch of Acetadote in Australia
In April 2010, the Therapeutic Goods Administration granted approval to our partner Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, for the commercialization of Acetadote in Australia. In October 2010, Phebra commenced with the Australian launch of Acetadote and began promoting wide distribution of the product. This introduction of Acetadote in Australia marked Cumberland s entry into international markets. In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country. Phebra is also our marketing partner for Acetadote in certain Asia Pacific markets, and continues to work toward obtaining approval for the product in those areas.

Caldolor®
In June 2009, the FDA approved Caldolor, our intravenous formulation of ibuprofen, for marketing in the United States through a priority review. In September 2009, we implemented the U.S. launch of Caldolor with our experienced sales professionals promoting the product across the country. Caldolor is fully stocked at the wholesalers serving hospitals nationwide, available in both 400mg and 800mg vials.

In 2010, we focused our sales and marketing efforts primarily on securing formulary approval nationally for Caldolor, and the product is now stocked at a growing number of U.S. medical facilities. In early 2011, we began transitioning some of our sales and marketing resources to also drive pull-through sales for the product. We expect those activities to generate greater use of the product in 2011.

Submission of Marketing Application in South Korea
In December 2009, we entered into an exclusive partnership with DB Pharm Korea Co. Ltd., a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. Under the terms of the agreement, DB Pharm Korea is responsible for obtaining any regulatory approval for the product and handling ongoing regulatory requirements, product marketing, distribution and sales in Korea. We maintain responsibility for product formulation, development and manufacturing. DB Pharm Korea has submitted its application for regulatory approval of Caldolor in South Korea, and is preparing for the launch of the product in that territory.

License Agreement for Canada

In April 2010, we entered into an exclusive agreement with Alveda Pharmaceuticals Inc., a Toronto-based specialty pharmaceutical company, for the commercialization of Caldolor in Canada. Under the agreement, Alveda will seek Canadian regulatory approval for Caldolor and, upon approval, will handle ongoing regulatory requirements as well as product marketing, distribution and sales throughout Canada. Cumberland will maintain responsibility for product formulation, development and

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manufacturing. In exchange for the license to the product, Cumberland will receive royalties on future sales of Caldolor in addition to upfront and milestone payments as well as a transfer price.

Compassionate Use in Australia
In December 2009, we entered into an exclusive agreement with Phebra Pty Ltd. for distribution of Caldolor in Australia and New Zealand. In April 2010, Phebra made the product available in Australia on a limited, compassionate use basis. The TGA, which regulates drugs and medical devices in Australia, operates compassionate use programs that allow patients with critical clinical needs to access products not yet approved through their medical practitioner. Phebra is also pursuing full regulatory approval of Caldolor for these territories.

Other Developments

New Board of Directors Appointments
In April 2010, we added three new members to our Board of Directors when Cumberland shareholders elected Gordon R. Bernard, M.D., Jonathan Griggs and James Jones at our annual meeting. In January 2011, Joey Jacobs also joined our Board of Directors. We believe each new director brings significant experience in an area critical to our company s continued growth and success.

Amendment of Senior Credit Facility
In September 2010, we amended our senior credit facility with Bank of America. With this amendment, we reduced the outstanding balance on our term loan from $12 million to $6 million on an original term loan of $18 million. We also expanded our line of credit to $6 million, which increases our access to funding for future growth. We expect to achieve a net interest savings by retiring debt with cash that would have earned a much lower yield. The debt repayment, which was funded with excess cash flow, is consistent with our efforts to efficiently manage our capital resources.

Share Repurchase Program
In May 2010, our Board of Directors authorized the repurchase of up to $10 million of Cumberland s outstanding common stock. Pursuant to the share repurchase program, we are purchasing shares of our common stock from time-to-time on the open market. The timing and amount of purchases are determined by us based on evaluation of market conditions, stock price and other factors. For the period from January 1, 2011 to March 1, 2011, we had repurchased an additional 94,662 shares, or $0.6 million, of our common stock under this program.

In January 2011, our Board of Directors modified the existing repurchase program to provide for the repurchase of $10 million of our outstanding common stock, in addition to the amount repurchased in 2010.

Federal Grant Funding
In November 2010, Cumberland was awarded $860,000 in federal grant funding under the Qualifying Therapeutic Discovery Project, a U.S. healthcare reform initiative designed to support promising research and development programs at small life sciences firms.

Transfer of License Rights
As previously reported, CET has entered into an agreement with Vanderbilt University to in-license rights to a new product candidate. In the third quarter of 2010, Cumberland Pharmaceuticals entered into an option agreement with CET to assume the rights and responsibilities associated with that product

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candidate. Since then, we have commenced product manufacturing and submitted an investigational new drug application for the clinical evaluation of this product candidate. This transferring of product rights from CET to Cumberland is consistent with our goals in establishing CET to give us access to an early-stage development product pipeline.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Accounting Estimates and Judgments

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles 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, provision for income taxes, stock-based compensation, research and development accounting, and intangible assets.

Revenue Recognition

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

Our revenue is derived primarily from the product sales of Acetadote, Caldolor and Kristalose. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our wholesalers for a particular product. Other income, which is a component of net revenues, includes rental and grant income. Other income was less than three percent of net revenues in 2010, and less than one percent in 2009 and 2008.

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, discounts and damaged product as well as provisions for sales related accruals of rebates, product returns and administrative fees and fee for services. Our financial statements reflect accounts receivable allowances of $0.2 million, $0.2 million and $0.1 million as of December 31, 2010, 2009 and 2008, respectively, for chargebacks, discounts and allowances for product damaged in shipment. We had accrued liabilities of $2.6 million, $1.9 million and $1.0 million as of December 31, 2010, 2009 and 2008, respectively, for rebates, product returns, service fees, and administrative fees.

The following table reflects our sales-related accrual activity:

	2010	2009	2008

Balance at January 1	$ 1,863,012	$ 1,040,203	$ 738,362
Current Provision	4,933,553	3,436,208	1,690,134
Current Provision for Prior Period Sales	306,706	75,589	(73,960)
Actual Returns/Credits	(4,476,958)	(2,688,988)	(1,314,333)
Balance at December 31	$ 2,626,313	$ 1,863,012	$ 1,040,203

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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:

- Ø the contractual terms with customers;
- Ø analysis of historical levels of discounts, returns, chargebacks and rebates;
- Ø communications with customers;
- Ø purchased information about the rate of prescriptions being written and the level of inventory remaining in the distribution channel, if known; and
- Ø 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 represent the majority of the balance. Sales related accrued liabilities totaled $2.6 million, $1.9 million and $1.0 million as of December 31, 2010, 2009 and 2008, respectively. Of these amounts, our estimated liability for fee for services represented $0.8 million, $0.7 million and $0.3 million, respectively, while our accrual for product returns totaled $1.4 million, $1.0 million and $0.6 million, respectively. If the actual amount of cash discounts, chargebacks, rebates, and product returns differ 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, 2010. A change in our product return estimate of one percentage point would have impacted net sales by $0.5 million, $0.5 million and $0.4 million for the years ended December 31, 2010, 2009 and 2008, respectively. Any expired product return would be from a prior period, given the shelf-life of the products.

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

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

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

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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, 2010, we have unrecognized federal net operating loss carryforwards associated with the exercise of nonqualified options of $63.1 million.

Stock-Based Compensation

We recognize compensation expense for all share-based payments based on the fair value of the award on the date of grant. In addition, incremental compensation expense is recognized upon the modification, cancellation or repurchase of equity awards. The fair value of stock options and warrants are calculated using the Black-Scholes option-pricing model on the date of grant. We estimate volatility in accordance with SEC Staff Accounting Bulletin (SAB) No. 107, as amended by SAB No. 110. As there was no public market for our common stock prior to our initial public offering and, therefore, a lack of company-specific historical or implied volatility data, we have determined the share-price volatility based on an analysis of certain publicly-traded companies that we consider to be our peers. The comparable peer companies used for our estimated volatility are publicly-traded companies with operations which we believe to be similar to ours. When identifying companies as peers, we consider such characteristics as the type of industry, size and/or type of product(s), research and/or product development capabilities, and stock-based transactions. We intend to continue to consistently estimate our volatility in this manner until sufficient historical information regarding the volatility of our own shares becomes available, or circumstances change such that the identified entities are no longer similar to us. In this latter case, we would utilize other similar entities whose share prices are publicly available. We estimate the expected life of employee share options based on the simplified method allowed by SAB No. 107, as amended by SAB No. 110. Under this approach, the expected term is presumed to be the average between the weighted-average vesting period and the contractual term. The expected term for options granted to nonemployees 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.

The following assumptions were used in calculating the fair value of employee options granted during 2010, 2009 and 2008:

	2010	2009	2008
Dividend yield	%	%	%
Expected term (in years)	2.5-6.0	3.7-6.2	3.5-6.0
Expected volatility	49%-53%	50%-52%	49%-51%
Risk-free interest rate	0.8%-2.8%	1.4%-2.7%	3.1%

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The following assumptions were used in calculating the fair value of nonemployee options granted during 2010, 2009 and 2008:

	2010	2009	2008
Dividend yield	%	%	%
Expected term (in years)	5.0	2.3-10.0	10.0
Expected volatility	52%-53%	51%-67%	68%
Risk-free interest rate	2.2%-2.4%	1.1%-2.7%	3.7%

Research and Development

We account for research and development costs and accrue expenses 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 depending on the level of activity in any particular year.

Intangible Assets

Intangible assets include license agreements, product rights 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 must 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

Description of Operating Accounts

Net revenues consist of net product revenue and other revenue. Net product revenue consists primarily of gross revenue less discounts and allowances, such as cash discounts, rebates, chargebacks and returns. Other revenue includes rental and grant income.

Cost of products sold consists principally of the cost to acquire each unit of product sold. Cost of products sold also includes expense associated with the write-off of slow moving or expired product.

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

Research and development expense consists primarily of clinical trial expenses, salary and wages and related costs of materials and supplies, and certain activities of third-party providers participating in our clinical studies.

General and administrative expense includes finance and accounting expenses, executive expenses, office expenses and business development expenses, including salaries and related costs.

Amortization of product license right resulted from our acquisition of the exclusive U.S. commercialization rights to Kristalose.

Interest income consists primarily of interest income earned on cash deposits.

Interest expense consists primarily of interest incurred on debt and other long-term obligations.

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Income tax expense consists primarily of current and deferred income taxes on our taxable income for financial reporting purposes.

Year ended December 31, 2010 compared to year ended December 31, 2009

Net revenues. Net revenues for 2010 totaled approximately $45.9 million, representing an increase of approximately $2.3 million, or 5%, over the same period in 2009. Net revenue increased $4.9 million for Acetadote and decreased $0.2 million and $3.2 million for Kristalose and Caldolor, respectively. The increase in Acetadote revenue was positively impacted by a 4% increase in volume and an increase in the average selling price, offset by an increase in fee-for-service deductions due to additional arrangements with our wholesalers. While Kristalose gross revenue increased, net revenue was impacted by an increase in the gross-to-net revenue deductions primarily associated with rebates and expired product returns. Additionally, in the third quarter of 2009, we completed the commercial launch of Caldolor, and recognized $3.3 million of net revenue in 2009. Our sales forces continue to maintain a consistent level of focus on Acetadote and Kristalose while they progress the promotion of Caldolor.

In 2010, we focused our sales and marketing efforts primarily on securing formulary approval and stocking nationally for Caldolor. During the first quarter of 2011, we initiated a shift in focus and began transitioning part of our sales and marketing resources to driving pull-through use of Caldolor in facilities stocking the product.

In 2010, we recognized approximately $0.9 million in federal grant funding from the Qualifying Therapeutic Discovery Project, a component of the healthcare reform legislation enacted in 2010.

Cost of products sold. Cost of products sold as a percentage of net revenues decreased from 9.5% for 2009 to 7.8% for the same period in 2010. This decrease was primarily due to the sales mix in the periods.

Kristalose is manufactured by Inalco. In 2010, Inalco sold its facility that manufactured the API for Kristalose. We are currently in discussions with Inalco regarding supply prices for 2011. We expect cost of products sold for Kristalose to increase.

Selling and marketing. Selling and marketing expense for 2010 totaled approximately $22.7 million, representing an increase of approximately $2.5 million, or 12%, over the same period in 2009. The increase was primarily due to the expansion of our hospital sales force during the third quarter of 2009, and the resulting increases in payroll and related taxes, travel, meals and promotional activities. These increases were offset by a decrease in marketing, advertising and hiring expenses related to Caldolor in 2010 as compared to the significant investment made in 2009 related to the launch.

Research and development. Research and development expense for 2010 totaled approximately $4.3 million, representing a decrease of approximately $0.7 million, or 13%, over the same period in 2009. The decrease was primarily due to the inclusion in 2009 of approximately $2.0 million of milestone expenses incurred upon the FDA approval of Caldolor in June 2009. This decrease was offset by additional costs incurred in 2010 related to annual FDA product and establishment fees, increased salary and related expenses resulting from an increase in personnel and increased costs related to furthering our development efforts for our products and product candidates. Research and development expense is expected to increase in 2011 as we pursue more clinical studies for our products and product candidates. As a part of our Phase IV commitments to the FDA, we have initiated two multi-center trials evaluating Caldolor for treatment of pain and fever in pediatric patients. In addition, we have initiated two new registry studies related to the administration of Caldolor, primarily related to the rapid infusion of Caldolor to patients.

General and administrative. General and administrative expense for 2010 totaled approximately $8.0 million, representing an increase of approximately $0.3 million, or 5%, over the same period in

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2009. The increase is primarily due to additional expenses associated with being an SEC registrant, including legal, accounting and insurance costs.

Interest income. Interest income for 2010 totaled approximately $0.2 million, representing an increase of approximately $0.1 million, or 152%, over the same period in 2009. The increase was primarily due to the higher cash balances maintained in 2010 as a result of the proceeds received from the initial public offering in the third quarter of 2009.

Interest expense. Interest expense for 2010 totaled approximately $1.4 million, representing an increase of approximately $0.7 million as compared to the same period in 2009. The increase is primarily attributable to (1) an average higher outstanding debt balance in 2010 as compared to 2009 and (2) the inclusion of approximately $0.1 million of deferred financing costs and approximately $0.2 million of prepayment fees associated with the early extinguishment and amendment of our term debt facility in September 2010.

Income tax expense. Income tax expense for 2010 totaled approximately $2.9 million, representing an increase of approximately $0.8 million, over the same period in 2009. As a percentage of income before income taxes, income tax expense increased from 39.8% for the year ended December 31, 2009 to 54.0% for the same period in 2010. The increase in the percentage was primarily due to (1) research and development expenses utilized in the Therapeutic Discovery Tax Credit not being deductible for federal income tax purposes, (2) an increase in stock compensation expense that is not deductible for income tax purposes and (3) an increase in nondeductible meals and entertainment expenses associated with the expansion of our sales force.

Year ended December 31, 2009 compared to year ended December 31, 2008

Net revenues. Net revenues for 2009 totaled $43.5 million, representing an increase of $8.5 million, or 24%, over the same period in 2008. Of this increase, approximately $4.7 million related to Acetadote, $3.3 related to the launch of Caldolor and $0.2 million related to Kristalose. The remaining increase was due to increased grant and rental revenue. The increase in revenues for Acetadote was primarily due to increased volume as our products continued to grow in our target markets.

Gross product sales were reduced by $5.2 million and $2.8 million in 2009 and 2008, respectively. In 2009, this reduction included $1.6 million for damaged and expired product returns, $1.0 million for cash discounts, $1.7 million related to fee-for-service costs and $0.9 million for estimated rebates, chargebacks and discounts related to our products. For 2008 this reduction included $1.1 million for damaged and expired product returns, $0.7 million for cash discounts, $0.7 million related to fee-for-service costs and $0.3 million for estimated rebates, chargebacks and discounts related to Kristalose.

Cost of products sold. Cost of products sold totaled $4.1 million, representing an increase of $1.1 million, or 36%, over cost of products sold in 2008 of $3.0 million. Of this increase, approximately $1.0 million related to Caldolor which was launched during the second half of 2009. As a percentage of net revenues, cost of products sold increased from 8.7% in 2008 to 9.5% for 2009. The increase in cost of products sold, as a percentage of net revenues, was primarily due to a shift in the sales mix between the periods.

Selling and marketing. Selling and marketing expense for 2009 totaled $20.2 million, representing an increase of $5.8 million, or 40%, over 2008. The increase was primarily due to $1.9 million for the expansion and ongoing costs of our sales forces as we launched our new product Caldolor, continued to grow our products in our target markets and

expanded our territories. Our marketing and advertising expense increased $1.7 million due to our marketing campaign for the commercial introduction of Caldolor. In addition, our field promotions expense increased $0.9 million primarily due to our launch of Caldolor, royalty expense increased $0.3 million, sales meeting expense increased $0.2 million, and

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hiring expense increased $0.3 million. We expect selling and marketing expense to increase in 2010 as we continue our efforts to promote our products.

Research and development. Research and development expense for 2009 totaled $5.0 million, representing an increase of $0.6 million, or 13%, over 2008. The increase was primarily due to approximately $2.0 million in milestone expenses associated with the FDA approval of Caldolor. This expense was partially offset by reduced studies costs in 2009 as compared to 2008 noting 2008 included $1.2 million for the new drug application fee associated with Caldolor.

General and administrative. General and administrative expense for 2009 totaled $7.6 million, representing an increase of $2.5 million, or 49%, over the same period in 2008. The increase was primarily due to increased payroll tax expense of $1.1 million associated with the employer s portion of payroll taxes that resulted from the exercise of nonqualified options. Additionally, we incurred increased salary and bonus expense of $0.5 million as we continue to increase our infrastructure, increased stock compensation expense of $0.2 million, increased D&O insurance expense of $0.1 million for additional public-company coverage, increased consulting expense of $0.2 million and increased bank service charges of $0.1 million. The additional payroll tax expense of $1.1 million noted above resulted from the exercise of approximately 4.7 million nonqualified options held by employees. As of December 31, 2009, employees held 201,000 nonqualified options with a weighted-average exercise price of $6.68 per share for which we are required to pay payroll-related taxes upon exercise, provided the holder is still an employee at the time of exercise. If all outstanding nonqualified options held by employees were exercised at December 31, 2009, the maximum exposure to us would have been approximately $0.1 million.

Interest income. Interest income totaled $0.1 million for 2009, representing a decrease of $0.2 million, or 67%, over 2008. The decrease was primarily due to lower interest rates throughout 2009.

Interest expense. Interest expense totaled $0.8 million for 2009, representing an increase of $0.6 million, or 262%, over 2008. The increase was primarily due to additional borrowings during 2009. In July 2009, we amended our loan agreement to provide for an $18 million term loan and a $4 million line of credit.

Income tax expense. Income tax expense for 2009 totaled $2.0 million, representing a decrease of $0.5 million, or 20%, over 2008. As a percentage of net income before income taxes, income tax expense increased from 34.8% for 2008 to 39.8% for 2009. The increase in the tax rate was primarily due to the recognition in 2008 of previously unrecognized tax benefits.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity are cash flows provided by our operations, our borrowings and the cash proceeds from our initial public offering of common stock. We believe that our internally generated cash flows and amounts available under our debt agreements will be adequate to service existing debt, finance internal growth and fund capital expenditures. As of December 31, 2010 and 2009, our cash and cash equivalents was $65.9 million and $78.7 million, respectively, working capital (current assets minus current liabilities) was $71.8 million and $74.5 million, respectively, and our current ratio (current assets to current liabilities) was 8.8x and 5.0x. As of December 31, 2010 and 2009, we also had the ability to make additional draws of up to approximately $4.2 million and $2.2 million, respectively, on our line of credit.

The information included in footnote 6 to the consolidated financial statements included in this annual report on Form 10-K is hereby incorporated by reference into this Item.

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The following table summarizes our net changes in cash and cash equivalents for the years ended December 31, 2010, 2009 and 2008:

	Years ended December 31,		
	2010	2009	2008
	(in thousands)		
Cash provided by (used in):			
Operating activities	$ 347	$ 405	$ 6,397
Investing activities	(769)	(712)	(134)
Financing activities	(12,386)	67,180	(5,248)
Net (decrease) increase in cash and cash equivalents[(1)]	$ (12,808)	$ 66,872	$ 1,015

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

The net decrease in cash and cash equivalents of $12.8 million for year ended December 31, 2010 was primarily due to cash used in financing activities, which included principal payments on our term debt of $12.7 million and the repurchase of common stock of approximately $4.8 million. These expenditures were offset by proceeds from the exercise of stock options of approximately $1.4 million and the excess tax benefit derived from the exercise of nonqualified options of approximately $3.9 million. Cash provided by operating activities for the year ended December 31, 2010 was primarily due to net income for the period and the collection of accounts receivable offset by (1) the purchase of inventory, (2) the decrease in accounts payable and (3) the excess tax benefit derived from the exercise of stock options. 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. We expect to pay minimal income taxes in 2011 due to the continued usage of the unrecognized tax benefit related to the excess tax deduction described in footnote 8 to the consolidated financial statements included in this annual report on Form 10-K.

The net increase in cash and cash equivalents of $66.9 million for the year ended December 31, 2009 was primarily due to the net cash proceeds from our initial public offering in August 2009 of $77.5 million and additional debt proceeds of $13.0 million, offset by the repurchase of common shares of $27.3 million associated with the tendering of shares to settle the minimum statutory tax withholding requirement resulting from the exercise of nonqualified options by an employee. In addition, we received a tax benefit of approximately $4.0 million related to nonqualified options exercised in 2009.

The net increase in cash and cash equivalents of $1.0 million for the year ended December 31, 2008 was primarily due to cash generated from operations offset by cash paid for our $5.0 million share repurchase.

In July 2009, we amended our debt agreement with Bank of America, N.A. (the Fourth Amended and Restated Loan Agreement) to provide for $18.0 million in term debt and a $4.0 million revolving credit facility, both with an interest rate of LIBOR plus an applicable margin based on the Company s Leverage Ratio, as defined in the agreement. The

interest rate at December 31, 2009 was 5.73% per annum. In addition, we were required to pay a commitment fee of 0.75% per annum on the unused portion of the commitment. The term debt was payable in quarterly installments of $1.5 million beginning on March 31, 2010 and continuing until December 31, 2012. The revolving credit facility was due on December 31, 2012. We may be required to make additional principal payments on the term debt if the Leverage Ratio, as defined, exceeds 1.75 to 1.0 on an annual basis. The borrowings were collateralized by a first lien against all of the Company s assets. The proceeds from the term debt were restricted for the payment, in part, of the minimum statutory tax withholding requirements of approximately $24.6 million due from option holders who exercised options to purchase shares of our common stock at the pricing of the Company s initial public offering. The consideration for that

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payment was the transfer to the Company of shares acquired upon exercise at the then-current fair market value of the Company s common stock. In connection with the amendment of the debt agreement, we capitalized approximately $0.5 million of debt issue costs, of which $0.1 million related to the fair value of common stock and $0.1 million related to the fair value of warrants issued to the lender. Deferred financing costs were being expensed to interest expense using the effective-interest method over the term of the debt agreement.

The Fourth Amended and Restated Loan Agreement contained restrictive covenants, which we were in compliance with during 2010 and 2009.

The Fourth Amended and Restated Loan Agreement required us to make an additional principal payment within 120 days after the end of the fiscal year in an amount equal to its Excess Cash Flow, as defined in the agreement. The additional principal payment of $3.1 million, which was included as a current portion of long-term debt in the consolidated balance sheet at December 31, 2009, was paid during the first quarter of 2010.

In September 2010, we further amended our loan agreement with Bank of America, N.A. (the Agreement). The amendment provided for an increase in the availability under the existing line of credit from $4.0 million to $6.0 million, with interest payable monthly at LIBOR plus an Applicable Margin, as defined in the Agreement (4.76% at December 31, 2010). In addition, the term debt was reduced to $6.0 million, with quarterly payments under the term debt reduced to $666,667, plus interest at the same rate as the line of credit, beginning December 31, 2010. We reduced the commitment fee from three-quarters of one percent (0.75%) to one-half of one percent (0.50%) per annum on the unused line of credit. The borrowings are collateralized by a first priority lien on all of our assets. Concurrent with the amendment of the Agreement, we elected to prepay approximately $5.9 million of its term debt, incurring a prepayment penalty of approximately $0.2 million. At December 31, 2010, the outstanding term loan and line of credit balances were $5.3 million and $1.8 million, respectively.

The Agreement s covenants include a Leverage Ratio, as defined in the Agreement, of 2.00 to 1.00 for the quarter ended December 31, 2010, 1.75 to 1.00 for each of the three quarters ended March 31, 2011, June 30, 2011 and September 30, 2011 and 1.25 to 1.00 for quarter ending December 31, 2011 and thereafter, as well as a Fixed Charge Coverage Ratio, as defined in the Agreement, of at least 1.25 to 1.00 at each quarter-annual reporting period. In addition, we must maintain deposits with Bank of America, N.A. at amounts equal to at least the sum of (a) the maximum amount of the line of credit plus (b) the aggregate principal amount then outstanding under the term debt. We were in compliance with all restrictive covenants at December 31, 2010.

We are subject to additional loan fees if certain performance metrics measured at March 31, 2011 and September 30, 2011 are not met. If required, the additional loan fee amounts of $102,000 each are due within 45 days of the end of the respective period. As of December 31, 2010, we have not recognized any additional loan fees.

Our manufacturing and supply agreement with one manufacturer, which expires in 2021, contains a minimum purchase obligation which requires us to purchase 25% of its prior year purchases, or $0.5 million, during 2011. We expect our normal inventory purchasing levels to be above the required minimum amounts. As of December 31, 2010, we had met our purchase obligations for 2010 under this agreement.

During 2001, we signed an agreement with Cato Research Ltd., or Cato, to cover a variety of development efforts related to Caldolor, including preparation of submissions to the FDA. Under the terms of the agreement, we deferred a portion of each bill from Cato. One-third of the deferred amount accrued interest at an annual rate of 12.5% and was

due after eighteen months. The remaining two-thirds were due upon specific milestone events, one of which was Caldolor obtaining marketing approval from the FDA. We received such approval in June 2009, triggering a milestone obligation of

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approximately $1.0 million. The milestone was payable as follows: approximately $0.8 million was paid in the third quarter of 2009 and the remaining $0.2 million was paid in equal monthly installments through July 2010. In addition to the milestone payments, Cato vested in options to purchase 60,000 shares of our common stock with an exercise price of $1.625 per share.

The following table sets forth a summary of our contractual cash obligations as of December 31, 2010:

		Payments due by year				
Contractual obligations	**Total[1]**	**2011**	**2012**	**2013**	**2014**	**2015+**
			(in thousands)			
Amounts reflected in the balance sheet:						
Term loan[2]	$ 5,333	$ 2,667	$ 2,667	$	$	$
Line of credit	1,826		1,826			
Estimated interest on debt[3]	459	293	166			
Other cash obligations not reflected on the balance sheet:						
Operating leases[4]	5,204	833	860	886	913	1,712
Purchase obligations[5]	689	517	129	32	8	3
Total[1]	$ 13,512	$ 4,309	$ 5,648	$ 918	$ 921	$ 1,715

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

(2) The term debt is payable in quarterly installments of $666,667.

(3) Represents the estimated interest payments on our line of credit and term loan based on the December 31, 2010 interest rate of LIBOR plus an applicable margin, or 4.76%. Interest payments are due and payable quarterly in arrears. The line of credit becomes due and payable in December 2012. Estimated interest for the line of credit is based on the assumption of a consistent outstanding balance.

(4) Includes minimum lease commitments for the CET facility for the five-year option renewal beginning in July 2011 for which we have notified the landlord in January 2011 of our intent to exercise.

(5) Represents minimum purchase obligations under our manufacturing agreements. The agreement requires us to purchase 25% of our prior year purchases.

OFF-BALANCE SHEET ARRANGEMENTS

During 2010, 2009 and 2008, we did not engage in any off-balance sheet arrangements.

RECENTLY ISSUED BUT NOT YET ADOPTED ACCOUNTING PRONOUNCEMENTS

In October 2009, the Financial Accounting Standards Board (FASB) issued guidance setting forth requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. The overall arrangement fee will be allocated to each element based on their relative selling prices. If an entity does not have a selling price for an element, then management must estimate the selling price. This guidance is effective for us for all revenue arrangements entered into or materially modified after January 1, 2011. Early adoption is permitted. The future impact of adopting this standard will depend on the nature and extent of transaction covered by this standard. This standard would not have materially impacted the consolidated financial statements as of December 31, 2010.

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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, our revolving credit facility and our term note payable. 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 portfolio of money market accounts is not material. Additionally, we have immediate access to these funds and could shift these funds to certificates of deposits with guaranteed rates. The risk related to interest rates for our money market accounts is that 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 interest on our money market accounts.

The interest rate risk related to borrowings under our line of credit and term debt is a variable rate of LIBOR plus an applicable margin, as defined in the loan agreement (4.76% at December 31, 2010). As of December 31, 2010, we had outstanding borrowings of $7.2 million under our line of credit and term debt combined. If interest rates increased by 1.0%, the impact on interest expense in future periods would be less than $0.1 million.

EXCHANGE RATE RISK

While we operate primarily in the U.S., we are exposed to foreign currency risk. During 2010, our primary manufacturer of Acetadote denominated supply prices in Canadian dollars. In 2011, our primary supplier of Acetadote will be denominating the prices in U.S. dollars. One of our supply agreements for Caldolor is denominated in Australian dollars. Additionally, a portion of our research and development is performed abroad. As of December 31, 2010, our outstanding payables denominated in a foreign currency totaled approximately $0.2 million.

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 2010 and 2009. Neither a 5% 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 report of the independent registered public accounting firm, starting on page F-1.

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

None.

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Item 9A: Controls and Procedures

Cumberland s 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, 2010. Based on that evaluation, they have concluded that our disclosure controls and procedures are effective to ensure that material information relating to Cumberland 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.

During our fourth quarter of 2010, 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

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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 2011 annual meeting of shareholders, which will be filed with the SEC not later than April 30, 2011 (120 days after the end of the fiscal year covered by this report).

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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

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Exhibit Number	Description
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 2007 Long-Term Incentive Compensation Plan of 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
4.6.2#	Form of Nonstatutory Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of 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
4.7#	Form of Nonstatutory Stock Option Agreement under 2007 Directors Compensation Plan of 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
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
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

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Part IV

Exhibit Number	Description
10.7	Exclusive Distribution Agreement, effective as of July 1, 2010, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit of the Registrant s Current Report on Form 8-K (File No. 001-33637) as filed with the SEC on August 13, 2010
10.8	Strategic Alliance Agreement, dated July 21, 2000, by and between F.H. Faulding & Co. Limited and Cumberland Pharmaceuticals Inc., including notification of assignment from F.H. Faulding & Co. Limited to Mayne Pharma Pty Ltd., dated April 16, 2002, incorporated herein by reference to the corresponding exhibit to Amendment No. 4 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 23, 2007
10.9	Kristalose Agreement, dated April 7, 2006, by and among Inalco Biochemicals, Inc., Inalco S.p.A., 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
10.9.1	Amendment to Kristalose Agreement, dated April 3, 2008, by and between Inalco S.p.A., Inalco Biochemicals, Inc., 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
10.9.2	Second Amendment to Kristalose Agreement, dated July 1, 2008, by and among Inalco Biochemicals, Inc., Inalco S.p.A., and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 13 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on August 12, 2008
10.9.3	Third Amendment to Kristalose Agreement, dated April 6, 2009, by and between Inalco S.p.A., Inalco Biochemicals, Inc., and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 18 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 12, 2009
10.9.4	Fourth Amendment to Kristalose Agreement, effective January 1, 2010, by and between Inalco S.p.A., Inalco Biochemicals, Inc., 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
10.10	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.11#	Employment Agreement dated March 9, 2011, effective as of January 1, 2011, by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10.12#	Employment Agreement dated March 9, 2011, effective as of January 1, 2011, by and between Jean W. Marstiller and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement dated March 9, 2011, effective as of January 1, 2011, by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.
10.15#	

Employment Agreement dated March 9, 2011, effective as of January 1, 2011, by and between David L. Lowrance and Cumberland Pharmaceuticals Inc.

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Part IV

Exhibit Number	Description
10.16	Fourth Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated July 22, 2009, incorporated herein by reference to the corresponding exhibit to Amendment No. 20 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 29, 2009
10.16.1	Third Amendment to Fourth Amended and Restated Loan Agreement dated as of September 29, 2010 by and between Cumberland Pharmaceuticals, Inc. and Bank of America, N.A., 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 October 5, 2010
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#	2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc., as amended on November 4, 2010, incorporated herein by reference to the corresponding exhibit to the Registrant s Quarterly Report on Form 10-Q (File No. 001-33637) as filed with the SEC on November 15, 2010
10.19#	2007 Directors Compensation Plan of 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
10.20	Form of Indemnification Agreement between Cumberland Pharmaceuticals Inc. and all members of its Board of Directors, incorporated herein by reference to Exhibit 10.20 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

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Part IV

Exhibit Number	Description
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
10.25	Manufacturing Agreement, dated February 6, 2008, by and between Bayer HealthCare, LLC, and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 12 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on June 20, 2008
10.26#	Employment Agreement dated March 9, 2011, effective as of January 1, 2011, by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
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.

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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 the 11th day of March 2011.

CUMBERLAND PHARMACEUTICALS INC.

By: /s/ A. J. Kazimi

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, 2011
/s/ *David L. Lowrance* *David L. Lowrance*	Vice President and CFO *(Principal Financial and Accounting Officer)*	March 11, 2011
/s/ *Robert G. Edwards* *Robert G. Edwards*	Director	March 11, 2011
/s/ *Thomas R. Lawrence* *Thomas R. Lawrence*	Director	March 11, 2011
/s/ *Lawrence W. Greer* *Lawrence W. Greer*	Director	March 11, 2011
/s/ *Martin E. Cearnal* *Martin E. Cearnal*	Director	March 11, 2011
/s/ *Gordon Bernard* *Gordon Bernard*	Director	March 11, 2011
/s/ *Jonathan Griggs* *Jonathan Griggs*	Director	March 11, 2011
/s/ *James Jones*	Director	March 11, 2011

James Jones

/s/ *Joey Jacobs* *Joey Jacobs*	Director	March 11, 2011

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Management 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, 2010. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*.

Based on our assessment we believe that, as of December 31, 2010, the Company s internal control over financial reporting is effective based on those criteria.

Cumberland Pharmaceuticals Inc. s independent registered public accounting firm has issued an audit report on 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, 2011

/s/ *David L. Lowrance*
David L. Lowrance
Chief Financial Officer
March 11, 2011

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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, 2010 and 2009, and the related consolidated statements of income, cash flows, and equity and comprehensive income for each of the years in the three-year period ended December 31, 2010. 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, 2010. 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, 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, 2010 and 2009, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010, 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, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 11, 2011 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

Nashville, Tennessee
March 11, 2011

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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, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of income, cash flows, and equity and comprehensive income for each of the years in the three-year period ended December 31, 2010, and our report dated March 11, 2011 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Nashville, Tennessee
March 11, 2011

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated balance sheets
December 31, 2010 and 2009

	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,893,970	$ 78,701,682
Accounts receivable, net of allowances	5,145,494	6,176,585
Inventories	7,683,842	4,822,873
Prepaid and other current assets	1,336,765	2,746,259
Deferred tax assets	978,771	726,196
Total current assets	81,038,842	93,173,595
Property and equipment, net	1,220,010	918,412
Intangible assets, net	7,427,223	7,956,009
Deferred tax assets	2,265,192	1,306,514
Other assets	102,787	369,790
Total assets	$ 92,054,054	$ 103,724,320
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 2,666,668	$ 9,061,973
Current portion of other long-term obligations	24,692	144,828
Accounts payable	2,124,654	5,632,796
Other accrued liabilities	4,411,606	3,784,777
Total current liabilities	9,227,620	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	2,666,665	8,938,027
Other long-term obligations, excluding current portion	618,343	184,632
Total liabilities	14,338,579	29,572,984
Commitments and contingencies		
Redeemable common stock		1,930,000
Equity:		
Shareholders equity:		
Common stock no par value; 100,000,000 shares authorized; 20,338,461 and 20,180,486[(1)] shares issued and outstanding as of December 31, 2010 and 2009, respectively	70,778,874	67,711,746

Retained earnings	6,998,806	4,542,126
Total shareholders equity	77,777,680	72,253,872
Noncontrolling interests	(62,205)	(32,536)
Total equity	77,715,475	72,221,336
Total liabilities and equity	$ 92,054,054	$ 103,724,320

(1) Number of shares issued and outstanding represents total shares of common stock regardless of classification on the consolidated balance sheet. The number of shares of redeemable common stock as of December 31, 2009 was 142,016.

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated statements of income
Years ended December 31, 2010, 2009 and 2008

	2010	2009	2008
Revenues:			
Net product revenue	$ 44,704,570	$ 43,142,350	$ 34,889,967
Other revenue	1,171,801	394,928	185,193
Net revenues	45,876,371	43,537,278	35,075,160
Costs and expenses:			
Cost of products sold	3,586,646	4,136,541	3,045,672
Selling and marketing	22,674,505	20,194,074	14,387,153
Research and development	4,327,485	4,993,278	4,429,064
General and administrative	7,990,222	7,643,070	5,139,937
Amortization of product license right	686,911	686,904	686,904
Other	108,855	106,776	104,209
Total costs and expenses	39,374,624	37,760,643	27,792,939
Operating income	6,501,747	5,776,635	7,282,221
Interest income	200,207	79,363	241,282
Interest expense	(1,423,523)	(772,927)	(213,303)
Income before income taxes	5,278,431	5,083,071	7,310,200
Income tax expense	(2,851,420)	(2,024,192)	(2,543,951)
Net income	2,427,011	3,058,879	4,766,249
Net loss at subsidiary attributable to noncontrolling interests	29,669	32,536	
Net income attributable to common shareholders	$ 2,456,680	$ 3,091,415	$ 4,766,249
Earnings per share attributable to common shareholders			
Basic	$ 0.12	$ 0.22	$ 0.47
Diluted	$ 0.12	$ 0.17	$ 0.29
Weighted-average shares outstanding			
Basic	20,333,932	14,199,479	10,142,807
Diluted	21,058,577	18,234,171	16,539,662

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated statements of cash flows
Years ended December 31, 2010, 2009 and 2008

	2010	2009	2008
Cash flows from operating activities:			
Net income	$ 2,427,011	$ 3,058,879	$ 4,766,249
Adjustments to reconcile net income to net cash provided by operating activities:			
Gain on early extinguishment of other long-term obligations			(38,577)
Depreciation and amortization expense	978,398	816,499	786,597
Deferred tax (benefit) expense	(332,349)	(525,467)	683,914
Nonemployee stock granted for services received	37,121	210,740	106,558
Nonemployee stock option grant expense	43,101	845,661	58,646
Stock-based compensation employee stock options	688,408	606,395	397,500
Excess tax benefit derived from exercise of stock options	(3,874,966)	(3,968,894)	(398,529)
Noncash interest expense	352,484	128,800	71,933
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	1,031,091	(3,047,238)	(755,810)
Inventory	(2,860,969)	(3,060,097)	(813,667)
Prepaid, other current assets and other assets	1,342,032	(721,464)	(163,274)
Accounts payable and other accrued liabilities	201,725	6,572,098	1,652,911
Other long-term obligations	313,575	(510,942)	42,501
Net cash provided by operating activities	346,662	404,970	6,396,952
Cash flows from investing activities:			
Additions to property and equipment	(577,159)	(601,802)	(67,572)
Additions to trademarks and patents	(191,483)	(110,541)	(66,576)
Net cash used in investing activities	(768,642)	(712,343)	(134,148)
Cash flows from financing activities:			
Proceeds from initial public offering of common stock		85,000,000	
Costs of initial public offering		(7,479,011)	(687,977)
Proceeds from borrowings on long-term debt		18,000,000	4,083,340
Principal payments on note payable	(12,666,667)	(5,000,000)	(1,833,336)
Net borrowings on line of credit			500,000
Payment of other long-term obligations			(2,760,000)
Costs of financing for long-term debt and credit facility	(110,000)	(189,660)	(29,491)
Payments made in connection with repurchase of common shares	(4,846,791)	(27,295,808)	(4,999,995)
Proceeds from exercise of stock options	1,362,760	175,089	81,159

Excess tax benefit derived from exercise of stock options	3,874,966	3,968,894	398,529
Net cash (used in) provided by financing activities	(12,385,732)	67,179,504	(5,247,771)
Net (decrease) increase in cash and cash equivalents	(12,807,712)	66,872,131	1,015,033
Cash and cash equivalents, beginning of year	78,701,682	11,829,551	10,814,518
Cash and cash equivalents, end of year	$ 65,893,970	$ 78,701,682	$ 11,829,551
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 814,373	$ 677,387	$ 221,000
Income taxes	52,136	196,187	1,486,991
Noncash investing and financing activities:			
Reclass of redeemable common stock to (from) equity	1,930,000	(1,930,000)	
Deferred financing costs		335,075	125,000

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated statements of equity and comprehensive income
Years ended December 31, 2010, 2009 and 2008

	Cumberland Pharmaceuticals Inc. Shareholders						
	Preferred stock		Common stock		Retained earnings (accumulated deficit)	Non-controlling interests	Tot equi
	Shares	Amount	Shares	Amount			
ance, December 31, 7	855,495	$ 2,742,994	10,091,260	$ 17,318,713	$ (3,315,538)	$	$ 16,746,1
ck-based pensation employee k option grants				397,500			397,5
ance of common stock services received			7,961	106,558			106,5
ck-based pensation nonemployee k option grants				58,646			58,6
version of preferred k into common stock	(42,746)	(138,924)	85,492	138,924			
urchase of common es			(384,615)	(4,999,995)			(4,999,9
rcise of options and ted tax benefit, net of ure shares redeemed for exercise price			102,949	479,688			479,6
and comprehensive ome					4,766,249		4,766,2
ance, December 31, 8	812,749	2,604,070	9,903,047	13,500,034	1,450,711		17,554,8
al public offering of mon stock, net of ring costs			5,000,000	74,801,596			74,801,5
ck-based pensation employee k option grants				606,395			606,3
ance of common stock services received			20,250	338,240			338,2
ck-based pensation nonemployee k option grants				845,661			845,6
	(812,749)	(2,604,070)	1,625,498	2,604,070			

version of preferred k into common stock						
urchase of common es	(4,018)	(52,234)				(52,2
ance of common stock rants		97,575				97,5
rcise of options and ted tax benefit, net of ure shares redeemed for exercise price and utory tax withholdings	3,635,709	(23,099,591)				(23,099,5
and comprehensive ome			3,091,415	(32,536)		3,058,8
lass of redeemable mon stock		(1,930,000)				(1,930,0
ance, December 31, 9	20,180,486	67,711,746	4,542,126	(32,536)		72,221,3
k-based pensation employee k option grants		688,408				688,4
ance of common stock services received	5,636	55,140				55,1
k-based pensation nonemployee k option grants		43,101				43,1
urchase of common es	(615,455)	(4,887,247)				(4,887,2
rcise of options and ted tax benefit, net of ure shares redeemed for exercise price and utory tax withholdings	767,794	5,237,726				5,237,7
and comprehensive ome			2,456,680	(29,669)		2,427,0
lass of redeemable mon stock		1,930,000				1,930,0
ance, December 31, 0	$ 20,338,461	$ 70,778,874	$ 6,998,806	$ (62,205)	$	77,715,4

See accompanying notes to consolidated financial statements.

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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 incorporated in Tennessee on January 6, 1999. Its mission is to provide high-quality products to address underserved medical needs. Cumberland is focused on acquiring rights to, developing and commercializing branded prescription products for the hospital acute care and gastroenterology markets.

The Company s corporate operations and product acquisitions have been funded by a combination of equity and debt financings. 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. During 2002, CET s losses reduced its equity to a deficit position. Accordingly, the Company reduced the noncontrolling interest balance to zero and recorded 100% of the losses associated with the joint venture until January 1, 2009. Effective January 1, 2009, the Company adopted a new accounting standard that required the allocation of operating results, including losses, to the noncontrolling interests. During 2010 and 2009, approximately $30,000 and $33,000, respectively, of losses from CET were allocated to the noncontrolling interests.

Effective January 1, 2007, the Company formed a wholly-owned subsidiary, Cumberland Pharma Sales Corp. (CPSC), for the purpose of employing the hospital sales force that promotes the Company s products, Acetadote® and Caldolor®, in the acute care market. In September 2010, the Company converted its field sales force, which promotes Caldolor and Kristalose®, to Cumberland employees. Previously, these sales forces were contracted through a third-party contract sales organization.

The Company operates in a single operating segment of specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. All of the Company s assets are located in the United States. Total revenues are primarily attributable to U.S. customers. Net revenues from non-U.S. customers were approximately $0.1 million, $0.7 million and $0.6 million for the years ended December 31, 2010, 2009 and 2008, respectively.

(2) SIGNIFICANT ACCOUNTING POLICIES

(a) Principles of Consolidation

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

(b) Cash and Cash Equivalents

Cash and cash equivalents include highly liquid investments with an original maturity of three months or less when purchased.

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(c) Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company records allowances for uncollectible amounts, cash discounts, chargebacks and credits to be taken by customers for product damaged in shipments based on historical experience. The Company reviews each customer balance for collectibility.

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

The majority of the Company s products are distributed through independent pharmaceutical wholesalers. Net product revenue 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 under 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 that chargeback is offset against the initial accrual balance.

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

(d) Inventories

The Company works closely with third parties to manufacture and package finished goods for sale, takes title to the finished goods at the time of shipment from the manufacturer and warehouses such goods until distribution and sale. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method.

In the fourth quarter of 2010, the Company purchased certain packaging materials related to the manufacture of Caldolor. As these materials are consumed as part of the manufacturing process, the costs associated with these materials will be used to offset the finished goods price from the manufacturer. As of December 31, 2010 and 2009, inventory was comprised of the following:

	December 31,	
	2010	2009
Raw materials	$ 356,676	$
Finished goods	7,327,166	4,822,873
Total	$ 7,683,842	$ 4,822,873

(e) Prepaids and Other Current Assets

Prepaid and other current assets consist of unamortized deferred financing costs, prepaid insurance premiums, prepaid consulting services, prepaid royalties and annual fees to the U.S. Food and Drug Administration (FDA). The Company expenses all prepaid amounts as used or over the period of benefit on a straight-line basis, as applicable. In addition, the Company recognized an income tax receivable of approximately $1.4 million at December 31, 2009 related to the utilization of net operating losses that was carried back to recover income taxes that were paid in prior years. In 2010, the Company received approximately $1.3 million related to these operating losses. The difference

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reduced equity as an adjustment of the excess tax benefit associated with the underlying exercise of nonqualified stock options.

(f) Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is provided 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 its renewal options, if renewal is reasonably assured, or the remaining useful life of the asset. Upon retirement or disposal of assets, the asset and accumulated depreciation or amortization accounts are adjusted accordingly and any gain or loss is reflected as a component of operating income in the consolidated statement of income. Repairs and maintenance costs are expensed as incurred. Improvements that extend an asset s useful life are capitalized.

(g) Intangible Assets

The Company s intangible assets consist of costs incurred related to licenses, trademarks and patents.

In 2006, the Company acquired the exclusive U.S. commercialization rights (license) to Kristalose®. The cost of acquiring the licenses of products that are approved for commercial use are capitalized and amortized ratably over the estimated economic life of the products. At the time of acquisition, the product life is estimated based upon the term of the license agreement, patent life or market exclusivity of the products and our assessment of future sales and profitability of the product. We assess this estimate regularly during the amortization period and adjust the asset value or useful life when appropriate. The total purchase price for Kristalose, which included the cost of the U.S. commercialization rights and other related costs of obtaining the licenses, is being amortized on a straight-line basis over 15 years, which is management s estimate of the asset s useful life.

Trademarks are amortized on a straight-line basis over 10 years, which is management s estimate of the asset s useful life.

Patents consist of outside legal costs associated with obtaining patents for products that have already been approved for marketing by the FDA. Upon issuance of a patent, the finite useful economic life of the patent (or family of patents) is determined, and the patent is amortized on a straight-line basis over such useful life. If it becomes probable that a patent will not be issued, related costs associated with the patent application will be 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.

When the Company acquires license agreements, product rights and other identifiable intangible assets, it records the aggregate purchase price as an intangible asset. The Company allocates the purchase price to the fair value of the various intangible assets in order to amortize their cost as an expense in its consolidated statements of income over the estimated useful lives of the related assets.

(h) Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and purchased 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 circumstances require a long-lived asset to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by an asset to the carrying value of the asset. 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

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that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including quoted market prices, third-party independent appraisals and discounted cash flow models, as considered necessary. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and would no longer be depreciated. The assets and liabilities of a disposed group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet. The Company recorded no impairment charges during the three-year period ended December 31, 2010.

(i) Revenue Recognition

Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility 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.

The Company s net product revenue reflects reduction from gross product revenue for estimated allowances for chargebacks, discounts, and damaged goods and for accruals for rebates, product returns, certain administrative fees and fee for services. Allowances of $0.2 million as of December 31, 2010 and 2009 for chargebacks, discounts and product damaged in shipment are recorded as a reduction of accounts receivable, and liabilities of $2.6 million and $1.9 million as of December 31, 2010 and 2009, respectively, for rebates, product returns and administrative fees are included in other accrued liabilities.

As discussed in 2(c) above, the allowances for chargebacks, discounts and damaged goods are determined on a product-by-product basis, and are 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 product or reimbursements for filled prescriptions. These entities represent indirect customers of the Company. In addition, the Company may provide rebates to the end-user. In conjunction with recognizing a sale to a wholesaler, sales revenues are reduced and accrued liabilities are increased by the Company s estimates of the rebates that will be owed.

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 is recognized in the period those assumptions were changed.

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

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The Company s net product revenue consisted of the following as of December 31:

	Net product revenue		
	2010	2009	2008
Acetadote	$ 35,092,796	$ 30,176,981	$ 25,438,774
Kristalose	9,510,275	9,688,998	9,468,562
Caldolor[1]	101,499	3,276,371	
Other			(17,369)
	$ 44,704,570	$ 43,142,350	$ 34,889,967

(1) The Company obtained FDA approval for Caldolor in June 2009 and launched the product in September 2009.

Other revenue is comprised of revenue generated by CET through grant funding from federal Small Business (SBIR/STTR) grant programs, 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. Revenue related to grants is recognized when all conditions related to such grants have been met. Grant revenue from SBIR/STTR programs totaled approximately $133,000, $228,000 and $7,000 for the years ended December 31, 2010, 2009 and 2008, respectively.

In addition to the items identified above, other revenue in 2010 includes approximately $0.9 million of federal grants associated with the Therapeutic Discovery Project Credit, a component of the U.S. health care reform act enacted in March 2010. The Therapeutic Discovery Project Credit allowed entities to apply for funding based on qualified research activities. Funds were then granted to entities based on their qualified research expenses. Revenue was recognized after the application was approved and as qualified research expenses were incurred.

(j) 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 depreciation, amortization and expense for nonqualified stock options. Deferred tax assets and liabilities are measured using enacted tax rates that are expected to apply to taxable income in the years such 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 income in the period of enactment. The Company does not recognize income tax benefits associated with any income tax position where it is not more likely than not that the position would be sustained upon examination by the taxing authorities.

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.

(k) Share-Based Payments

The Company recognizes compensation cost for all share-based payments issued, modified, repurchased or cancelled. The cost of stock options is measured based on the grant-date fair value using the Black-

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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, the fair value is measured on the last day of the reporting period.

(l) Research and Development

Research and development costs are expensed in the period incurred. Research and development costs are comprised mainly of clinical trial expenses, salary 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 fee for services.

(m) Advertising Costs

Advertising costs are expensed as incurred and amounted to $0.8 million, $1.4 million and $0.7 million in 2010, 2009 and 2008, respectively.

(n) Selling and Marketing Expense

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

(o) Distribution Costs

The Company expenses distribution costs as incurred. Distribution costs included in selling and marketing expenses amounted to $1.2 million, $1.1 million and $1.0 million in 2010, 2009 and 2008, respectively.

(p) 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-off of slow-moving or expired product.

(q) Earnings per Share

Basic earnings per share is calculated by dividing net income 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

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exercise of stock options and warrants, as well as their related income tax benefits. The following table reconciles the numerator and the denominator used to calculate diluted earnings per share:

	Year Ended December 31,		
	2010	2009	2008
Numerator:			
Net income attributable to common shareholders	$ 2,456,680	$ 3,091,415	$ 4,766,249
Denominator:			
Weighted-average shares outstanding basic	20,333,932	14,199,479	10,142,807
Convertible preferred stock shares		986,840	1,710,990
Dilutive effect of other securities	724,645	3,047,852	4,685,865
Weighted-average shares outstanding diluted	21,058,577	18,234,171	16,539,662

The calculation of diluted earnings per share excludes 640,718, 246,332 and 206,670 outstanding options and warrants as of December 31, 2010, 2009 and 2008, respectively, because the effect would be antidilutive.

(r) Comprehensive Income

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

(s) 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. Significant items subject to estimates and assumptions include those related to chargebacks, rebates, discounts, credits for damaged product and returns, the valuation and determination of useful lives of intangible assets and the rate such assets are amortized, the realization of deferred tax assets and stock-based compensation. Actual results could differ from those estimates.

(t) Fair Value of Financial Instruments

The Company s financial instruments include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, revolving line of credit and long-term debt. The carrying values for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short-term nature. The terms of the revolving line of credit and term debt include variable interest rates, which approximate current market rates.

(u) Recently Adopted Accounting Standards

In March 2010, the Financial Accounting Standards Board, or FASB, issued guidance providing for the recognition of revenue using the milestone method. Under this new guidance, an entity can recognize revenue associated with milestones if the milestones are substantive and there is substantive uncertainty about whether the milestone will be achieved. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance and (3) should be reasonable relative to all

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deliverables and payment terms in the arrangement. The new guidance was effective for our third quarter ended September 30, 2010. The adoption of this guidance did not have a material impact on our consolidated financial position or results of operations.

(3) PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31:

	Range of useful lives	2010	2009
Computer hardware and software	3-5 years	$ 417,681	$ 343,494
Office equipment	3-15 years	108,140	62,447
Furniture and fixtures	5-15 years	488,982	364,158
Leasehold improvements	3-15 years, or remaining lease term	931,097	607,444
		1,945,900	1,377,543
Less accumulated depreciation and amortization		(725,890)	(459,131)
		$ 1,220,010	$ 918,412

Depreciation expense, including amortization expense related to leasehold improvements, during 2010, 2009 and 2008 was approximately $0.3 million, $0.1 million and $0.1 million, respectively, and is included in general and administrative expense in the consolidated statements of income.

(4) INTANGIBLE ASSETS

Intangible assets consisted of the following at December 31:

	2010	2009
Trademarks	$ 9,020	$ 9,020
Less accumulated amortization	(8,123)	(7,396)
Total trademarks	897	1,624
License	10,303,595	10,303,595
Less accumulated amortization	(3,262,805)	(2,575,895)

Total license	7,040,790	7,727,700
Patents	409,536	226,685
Less accumulated amortization	(24,000)	
Total patents	385,536	226,685
	$ 7,427,223	$ 7,956,009

Amortization expense related to trademarks and license rights totaled approximately $0.7 million in 2010, 2009 and 2008, and is expected to be approximately $0.8 million in each of the years 2012 through 2016.

In April 2006, the Company acquired the exclusive U.S. commercialization rights (product license) for Kristalose from Inalco Biochemicals, Inc. and Inalco S.p.A. (collectively Inalco) for $10,303,595. This amount included cash paid on the effective date of the agreement of $6,500,000, discounted future obligations totaling $3,823,937 due in April 2007 and April 2009, and acquisition costs of $13,775,

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and was net of the fair value of services received by the Company in 2006 of $34,117 under a transition service agreement. The fair value of these services was expensed over the transition period in 2006. In April 2007, the Company made an installment payment of $1,500,000 (inclusive of $102,440 of imputed interest). In April 2008, the Company amended its agreement and paid the remaining obligation related to the purchase of the Kristalose rights. The terms of the amendment provided for an 8% discount on the $3,000,000 face value of the obligation for a net payment of $2,760,000. The gain of approximately $39,000 was recognized as a component of interest expense in the consolidated income statement for the year ended December 31, 2008.

(5) OTHER ACCRUED LIABILITIES

Other accrued liabilities consisted of the following at December 31:

	2010	2009
Rebates, fee for services, and product returns	$ 2,626,383	$ 1,863,012
Employee wages and benefits	1,078,367	919,913
Outside sales force and related expenses		192,711
Other	706,856	809,141
	$ 4,411,606	$ 3,784,777

(6) LONG-TERM DEBT

In July 2009, the Company amended its debt agreement with Bank of America, N.A. (the Fourth Amended and Restated Loan Agreement) to provide for $18.0 million in term debt and a $4.0 million revolving credit facility, both with an interest rate of LIBOR plus an applicable margin based on the Company s Leverage Ratio, as defined in the agreement. The interest rate at December 31, 2009 was 5.73% per annum. In addition, the Company was required to pay a commitment fee of 0.75% per annum on the unused portion of the commitment. The term debt was payable in quarterly installments of $1.5 million beginning on March 31, 2010 and continuing until December 31, 2012. The revolving credit facility was due on December 31, 2012. The Company may be required to make additional principal payments on the term debt if the Leverage Ratio, as defined, exceeds 1.75 to 1.0 on an annual basis. The borrowings were collateralized by a first lien against all of the Company s assets. The proceeds from the term debt were restricted for the payment, in part, of the minimum statutory tax withholding requirements of approximately $24.6 million due from option holders who exercised options to purchase shares of our common stock at the pricing of the Company s initial public offering. The consideration for that payment was the transfer to the Company of shares acquired upon exercise at the then-current fair market value of the Company s common stock. In connection with the amendment of the debt agreement, the Company capitalized approximately $0.5 million of debt issue costs, of which $0.1 million related to the fair value of common stock and $0.1 million related to the fair value of warrants issued to the lender. Deferred financing costs were being expensed to interest expense using the effective-interest method over the term of the debt agreement.

The Fourth Amended and Restated Loan Agreement contained restrictive covenants, which the Company was in compliance with during 2010 and 2009.

The Fourth Amended and Restated Loan Agreement required the Company to make an additional principal payment within 120 days after the end of the fiscal year in an amount equal to its Excess Cash Flow, as defined in the agreement. The additional principal payment of $3.1 million, which was included as a current portion of long-term debt in the consolidated balance sheet at December 31, 2009, was paid during the first quarter of 2010.

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On September 29, 2010, the Company further amended its loan agreement with Bank of America, N.A. (the Agreement). The amendment provided for an increase in the availability under the existing line of credit from $4.0 million to $6.0 million, with interest payable monthly at LIBOR plus an Applicable Margin, as defined in the Agreement (4.76% at December 31, 2010). In addition, the term debt was reduced to $6.0 million, with quarterly payments under the term debt reduced to $666,667, plus interest at the same rate as the line of credit, beginning December 31, 2010. The Company reduced its commitment fee from three-quarters of one percent (0.75%) to one-half of one percent (0.50%) per annum on the unused line of credit. The borrowings are collateralized by a first priority lien on all of the Company s assets.

The Agreement s covenants include a Leverage Ratio, as defined in the Agreement, of 2.00 to 1.00 for the quarter ended December 31, 2010, 1.75 to 1.00 for each of the three quarters ended March 31, 2011, June 30, 2011 and September 30, 2011 and 1.25 to 1.00 for quarter ending December 31, 2011 and thereafter, as well as a Fixed Charge Coverage Ratio, as defined in the Agreement, of at least 1.25 to 1.00 at each quarter-annual reporting period. In addition, the Company must maintain deposits with Bank of America, N.A. at amounts equal to at least the sum of (a) the maximum amount of the line of credit plus (b) the aggregate principal amount then outstanding under the term debt. The Company was in compliance with all restrictive covenants at December 31, 2010.

The Company is subject to additional loan fees if certain performance metrics measured at March 31, 2011 and September 30, 2011 are not met. If required, the additional loan fee amounts of $102,000 each are due within 45 days of the end of the respective period. As of December 31, 2010, the Company has not recognized any additional loan fees.

Concurrent with the amendment of the Agreement, the Company elected to prepay approximately $5.9 million of its term debt, incurring a prepayment penalty of approximately $0.2 million. The prepayment penalty is included as a component of interest expense for the year ended December 31, 2010.

The scheduled debt payments are as follows:

Year ending December 31:	
2011	$ 2,666,668
2012	4,492,616
	$ 7,159,284

(7) OTHER LONG-TERM OBLIGATIONS