CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 07, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x **Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2011

¨ **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 ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ¨ No x

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 x No ¨

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 x No ¨

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. ¨

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

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.)

Yes ¨ No x

The aggregate market value of common stock held by non-affiliates as of June 30, 2011 was $74,531,644. The number of shares of the registrant s Common Stock, no par value, outstanding as of March 1, 2012 was 19,987,511.

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 2012 annual meeting of shareholders.

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CUMBERLAND PHARMACEUTICALS INC.

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PART I

Item 1: Business

THE COMPANY

Cumberland Pharmaceuticals Inc. (Cumberland, the Company, or as used in the context of we, us or our), is a growing specialty pharmaceut 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. We are dedicated to providing innovative products that improve quality of care for patients and address poorly met medical needs.

Our product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, and Hepatoren (*ifetroban*) injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome (HRS). We market and sell our 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, 2012.

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.

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

	September 30, 2011	September 30, 2010	September 30, 2009
	For the Years Ended December 31,		
	(in millions, except per share data)		
Total revenues, net	$ 51.1	$ 45.9	$ 43.5
Research and development expense	5.0	4.3	5.0
Net income attributable to common shareholders	5.7	2.5	3.1
Earnings per share, basic	$ 0.28	$ 0.12	$ 0.22
Earnings per share, diluted	$ 0.28	$ 0.12	$ 0.17

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 further facilitate our 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, or CET, our 85% owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, which we have 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, free of charge through our website our press releases, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after we file them or furnish them to the U.S. Securities and Exchange Commission, or SEC. These filings are also available to the public at *www.sec.gov*.

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PRODUCTS

Our key products include:

Products	Indication	Status
Acetadote	Acetaminophen Poisoning	Marketed: Approved by the FDA and launched in 2004; new formulation FDA approved in 2011.
Caldolor	Pain and Fever	Marketed: Approved in 2009.
Kristalose	Chronic and Acute Constipation	Marketed: Approved in 2006.
Hepatoren	Hepatorenal Syndrome	In Phase II clinical development.

Acetadote

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

Originally approved in January 2004, Acetadote received U.S. Food and Drug Administration, or 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 culminated in the approval and launch of a new, next generation formulation of the product.

In October 2010, we submitted a supplemental new drug application (sNDA) to the FDA for approval of a new formulation of Acetadote designed to replace the original formulation. The new formulation, which is the result of the aforementioned Phase IV commitment made to the FDA, addresses the FDA s safety concerns and contains no Ethylene diamine tetracetic acid or other stabilization and chelating agents and is preservative-free. In January 2011, we received FDA approval and commenced U.S. launch activities for this new Acetadote formulation. The original formulation has been removed from FDA reference materials and we no longer manufacture it. We filed a patent application with the U.S. Patent and Trademark Office, or USPTO, to protect the proprietary new formulation in 2011. In February 2012, we received a Notification of Allowance from the USPTO for the new formulation of Acetadote. This Notice of Allowance is a composition of matter patent that enables us to protect the product and its formula as we continue to grow the brand. Upon issuance, the patent will expire in August 2025.

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.

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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 2010, 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, or OTC, 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 2009. 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 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 and substantial cost disparity between the treatments.

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New Formulation

In January 2011, the FDA approved our sNDA for our new formulation of Acetadote, which was the result of a Phase IV commitment we made to the FDA upon receipt of initial marketing approval of the product. The new formulation does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives. We launched the next generation product, which replaced the previously marketed formulation, in the first quarter of 2011 and continued to support the transition to this new product during the second and third quarters of 2011.

In July 2011, we filed a response with the USPTO for a patent to protect our proprietary discoveries related to the new Acetadote formulation. This formulation patent was allowed and issued in China in April 2011. We also filed a second U.S. patent application related to the safety profile of the new formulation.

Acetadote was issued a patent for market use in Australia in late 2011 through Phebra Pharmaceuticals, our Australian commercial partner.

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 800mg vials. In early 2010, we focused on securing formulary approval and stocking nationally for Caldolor. Our sales group worked with members of hospital pharmacy and therapeutic committees to secure placement on committee agendas to continue growing formulary approval.

Later in 2011, we began 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 2011, with results from those trials appearing in peer-reviewed journals. In December 2011, we announced the decision to phase out the 400mg vial of Caldolor. This decision was based on our ongoing refinement of the Caldolor strategy.

We are currently enrolling patients in four clinical studies designed to support marketing of Caldolor. Two of these clinical trials are designed to support pediatric use, including a pediatric fever study to evaluate safety, efficacy and pharmacokinetics of Caldolor in hospitalized children as well as a pediatric pain study. Two registry studies with Caldolor are also underway and are designed to gather additional safety and efficacy data on use of the product in adults. The first of these studies is evaluating Caldolor in treating pain and fever in a wide range of hospitalized patients and the second evaluates the product for management of pain in surgical patients.

We have worldwide commercial rights to Caldolor. We market Caldolor in the United States through our existing hospital sales force, and have partnered with institutions to reach 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 $331 million, or 599 million units, in 2011. 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,

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reduced gastro intestinal 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 40 million units in 2011, 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.

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 from Inalco S.p.A., assembled a 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, internists and colon and rectal surgeons.

Effective November 15, 2011 through a series of transactions, we have entered into an agreement with Mylan Inc. to obtain certain assets associated with the Kristalose brand including the Kristalose trademark and the FDA registration. We have also entered into a long-term supply agreement for the product.

As a result of these agreements, we have terminated our license agreement and supply agreement with Inalco S.p.A. By entering into these transactions, we now have streamlined the supply chain for the product and expect to further develop the brand.

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 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 $689 million in 2011.

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 crossover patient preference study evaluating Kristalose compared to similar products in liquid forms. 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. We are also exploring opportunities to expand into new indications with Kristalose.

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OUR PRODUCT PIPELINE

Our pre-clinical product candidates are being developed through CET. We negotiate rights to develop and commercialize CET product candidates, and in conjunction with research institutions have obtained nearly $1 million in grant funding from the National Institutes of Health to support the development of these programs.

Hepatoren

In April 2011, we entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. We have initiated clinical development under the brand name Hepatoren (ifetroban) Injection and are evaluating this candidate for the treatment of critically ill hospitalized patients suffering from HRS, a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment.

Our acquisition of the rights to the ifetroban program includes an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property. Ifetroban was initially developed by Bristol-Myers Squibb, or BMS, for significant cardiovascular indications. BMS conducted extensive preclinical and clinical studies for its own target indications and eventually donated the entire program to Vanderbilt University. Researchers at Vanderbilt identified ifetroban as a potentially valuable compound in treating patients for several niche indications. We acquired the rights to the ifetroban program from Vanderbilt through CET and intend to develop it for several potential indications, including as an Orphan Drug for HRS for which we will pursue seven years of marketing exclusivity.

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

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 $42.5 million in 2011, 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. The Acetadote patent was approved by the USPTO in February 2012 and, upon issuance, will expire in August 2025, allowing us to protect the product and its formula as we continue to grow the product.

Kristalose competes in the high growth U.S. prescription laxatives market which, based on data from IMS Health, had sales of approximately $689 million in 2011. 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.

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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. 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 $28 billion, or 9%, of U.S. pharmaceutical sales in 2011. However, IMS also reports that only 2% of approximately $23 billion total pharmaceutical industry promotional spending was focused on hospital-use drugs in 2011. The majority of promotional spending is directed toward large, outpatient markets on drugs intended for chronic use rather than short-term, hospital use. We believe the hospital market is underserved and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity.

Gastroenterology market: We promote Kristalose through a dedicated field sales force addressing a targeted group of physicians who are responsible for a majority of total retail Kristalose prescriptions nationally. By investing in our marketing program, we believe that we will be able to increase market share for Kristalose and that we will be equipped to promote any further gastroenterology product 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. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and we have the opportunity to negotiate rights to further develop and commercialize them.

CLINICAL DEVELOPMENT OVERVIEW

Two registry studies with Caldolor are underway and are designed to gather additional safety and efficacy data on use of the product in adults.

The first of two registry studies is a Phase IV multi-center, open-label, single-dose surveillance clinical study to assess the safety and efficacy of ibuprofen administered intravenously over five to ten minutes to adult patients in the hospital setting with fever (temperature >101ºF) and/or pain (visual analog scale (VAS) assessment >3). Eligible patients will be enrolled to receive one of two dose strengths (400mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen. One hundred fifty patients will be enrolled in this study.

The second of two registry studies is a Phase IV multi-center, open-label, single or multiple-dose surveillance clinical study will assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients will enroll to receive 800 mg intravenous ibuprofen administered at induction of anesthesia. Three hundred patients will be enrolled in this study.

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Phase IV Required Pediatric Assessment

The required pediatric assessment for the Caldolor new drug application, or NDA, was deferred for the treatment of fever and for the management of pain. Two clinical studies are currently underway to address the Phase IV requirements.

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

The second of two pediatric studies is a multi-center, randomized, double-blind placebo-controlled, single-dose study conducted in pediatric patients 6 to 17 years of age undergoing tonsillectomy to assess the safety and efficacy of intravenous ibuprofen. One hundred sixty patients will be enrolled in this study.

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 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.

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 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.

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

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

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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, implementing and monitoring our clinical trials; and
- creating case report forms and other study-related documents.

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- preparing and submitting INDs for clearance to begin patient studies;
- preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- maintaining investigational and marketing applications through the submission of appropriate reports;
- submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;
- monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices, 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 medical team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. Prior to the launch of Caldolor, we

expanded our medical affairs staff to support inquiries from medical professionals regarding the appropriate use of Caldolor as well as to support the efforts of our expanded hospital sales force. In addition to coordinating the call center, our clinical/regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including more than 100 sales representatives and district managers, direct our national marketing campaigns and maintain key national account relationships. In January 2007, we converted our hospital sales force, which had previously been contracted to us by Cardinal Health Inc., 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.

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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 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, we received an upfront payment and will receive milestone payments and a transfer price upon sale of the product to our partner. We will also 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, we received an upfront payment and will receive milestone payments and a transfer price upon sale of the product to our partner. We will also 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 upon Phebra s achieving specified milestones as well as royalty payments. In April 2010, the Therapeutic Goods Administration granted approval for the commercialization of Acetadote in Australia and in October 2010, Phebra commenced with the Australian launch of the product. This introduction of Acetadote in Australia marked the introduction of our products into international markets. In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country.

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

The application for regulatory approval of Caldolor in Canada was submitted by our partner Alveda Pharma and approved in December 2011. Review of the application for approval of Caldolor in Australia submitted by our partner Phebra Pty Ltd is under review by the Australian regulatory authorities. We are also currently working to identify appropriate arrangements for the registration and commercialization of our products in other markets.

Net revenues from non-U.S. customers were approximately $0.1 million for each of the years ended December 31, 2011 and 2010, and approximately $0.7 million for the year ended December 31, 2009.

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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

We have entered into manufacturing agreements for all of our products. For Kristalose, we purchase and maintain an inventory of the active pharmaceutical ingredient, or API, used in production. The API is produced by a single supplier based in Italy, for which we are currently negotiating a long-term supply arrangement. All suppliers of APIs must be approved by the FDA prior to utilizing them. We continuously monitor the production capacity of our supplier and their ability to continue to supply our needs.

Our key manufacturing relationships include:

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

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.

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.

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.

TRADEMARKS, PATENTS AND PROPRIETARY RIGHTS

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.

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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. In 2011, we also applied for a patent for a second indication for Acute Liver Failure, or ALF, and this is pending approval.

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.

COMPETITION

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our continued success in developing and commercializing pharmaceutical products will depend, in part, upon our ability to compete against existing and future products in our target markets. Competitive factors directly affecting our markets include but are not limited to:

- product attributes such as efficacy, safety, ease-of-use and cost-effectiveness;
- brand awareness and recognition driven by sales and marketing and distribution capabilities;
- intellectual property and other exclusivity rights;
- availability of resources to build and maintain developmental and commercial capabilities;
- successful business development activities;
- extent of third-party reimbursements; and

establishment of advantageous collaborations to conduct development, manufacturing or commercialization efforts.

A number of our competitors possess research and development and sales and marketing capabilities as well as financial resources greater than ours. These competitors, in addition to emerging companies and academic research institutions, may be developing, or in the future could develop, new technologies that could compete with our current and future products or render our products obsolete.

Acetadote

Acetadote is our injectable formulation of NAC for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. 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.

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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, including but not limited to:

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

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

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 the U.S. and additional regulations in other 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, but not limited to, 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. generally include:

- completion of pre-clinical laboratory and animal testing;
- the submission to the FDA of an IND, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- 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 condu