CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 19, 2010

Table of Contents

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, 2009

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 Noo

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 definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

Smaller reporting company o

(Do not check if 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 16, 2010 was 20,365,366.

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 2010 annual meeting of shareholders.

CUMBERLAND PHARMACEUTICALS INC. INDEX

Table of Contents

PART I

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.

Our product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever available 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 113 sales representatives and managers as of March 1, 2010, and work to partner our products to reach international markets. Our net revenue for our products for the years ended December 31, 2009, 2008 and 2007 were $43.1 million, $34.9 million and $27.8 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 and accounting. Our internal product development and regulatory experts develop proprietary product formulations, design and manage our clinical trials, prepare all regulatory submissions and manage our medical call center. Cumberland s quality and manufacturing professionals play an active role in overseeing the manufacture of its products by third parties. All aspects of commercialization are handled by our sales and marketing professionals, and we work closely with our third party distribution partner to make our products available across the United States.

We have been profitable since 2004, and have generated 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 further growth of the company. Our strategy includes maximizing potential of our existing products and continuing to build a portfolio of new, differentiated products. Our current products are approved for sale in the United States, and we are working 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 resources 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 the aforementioned growth strategies with the early-stage drug development activities of Cumberland Emerging Technologies, Inc. (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.

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 their filing with the SEC. These filings are also available to the public through the Internet of the SEC, 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. According to Wolters Kluwer Health Source™ Pharmaceutical Audit Suite, Acetadote sales to hospitals grew 25% to $30 million from 2008 to 2009. We recently expanded our hospital sales force in preparation for the launch of Caldolor, and believe we can leverage this

Table of Contents

expansion to increase Acetadote sales. We are also supporting several studies to explore other potential indications for Acetadote.

Kristalose competes in the 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. This marketing program is designed to enhance brand awareness through increased promotional activity and highlights Kristalose s many positive, competitive attributes.

Successfully commercialize Caldolor

We believe Caldolor currently represents our most significant product based on the large potential markets for intravenous treatment of pain and fever, as well as clinical results for the product to date. We have retained exclusive commercialization rights for Caldolor in the U.S. and in September 2009 began marketing the product through our expanded hospital sales force. In addition, we hold international patent rights for Caldolor, and in connection with certain current and potential future third-party partners, we intend 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 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 77 representatives and managers. This team covers U.S. hospitals across the country, 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 contract field sales force of 36 sales representatives and district managers covering approximately 8,000 targeted physicians who are responsible for approximately 60% of total retail Kristalose prescriptions nationally. By investing in our marketing program and expanding this sales force, 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 a wide variety of product opportunities but can also be penetrated with a modest sales force.

Expand our product portfolio by acquiring rights to additional products and late-stage product candidates

We intend to build a portfolio of complementary, niche products largely through product acquisitions. We focus on under-promoted, FDA-approved drugs with existing brand recognition as well as late-stage development products which address unmet medical needs, a strategy which we believe helps minimize our exposure to the significant 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 cost-effectively develop promising, early-stage product candidates, and Cumberland Pharmaceuticals negotiates the rights to commercialize them.

Table of Contents

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. In January 2004, Acetadote received U.S. Food and Drug Administration (FDA) approval as an orphan drug, designation which provides for seven years of marketing exclusivity from date of approval. 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 the substantial cost disparity between the treatments. To provide assistance in evaluating potential savings for individual hospitals, we developed an online tool for our website to help medical professionals compare Acetadote and oral treatment using their own data.

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 2007. 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. Patients taking acetaminophen in combination with opiates on a chronic basis often eventually require increasing amounts to achieve the same level of pain relief, which can also lead to liver failure.

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.

Table of Contents

Clinical Development

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 and accepted by the FDA in December 2004. Our second Phase IV commitment (clinical) was completed and accepted by the FDA in August 2006. We completed our third and final Phase IV commitment (manufacturing) for Acetadote in 2007 and have submitted the appropriate documentation to the FDA. We are currently awaiting FDA review of this documentation.

Subsequent to our original FDA approval for Acetadote, in 2006 the FDA approved revised labeling for the product including an expanded indication for dosing in pediatric patients. In 2008, we obtained further revised labeling for the product from FDA, which included additional safety data from a post-marketing study. We are also supporting a number of studies to explore other potential indications for Acetadote.

Caldolor®

Caldolor, our intravenous formulation of ibuprofen, is 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, the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever. Following FDA approval, Cumberland conducted comprehensive market research, prepared a full package of educational materials, optimized territory design and launched the product website. We expanded our hospital sales force to 77 representatives and managers to prepare for the launch, and enlisted the services of our field sales force of 36 representatives and managers to promote the product.

In September 2009, we successfully implemented the U.S. launch of Caldolor, with 113 experienced sales professionals promoting the product across the country. Caldolor is stocked at wholesalers serving hospitals nationwide, available in both 400mg and 800mg vials. We are working to secure formulary approval nationally for Caldolor, and the product is already stocked in approximately 100 hospital facilities.

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 5% of the market in 2004 to 7% of the market in 2009, according to IMS Health, with 48 million units sold in 2009. 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.

There are currently no U.S.-approved injectable treatments for fever other than Caldolor. 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

Table of Contents

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.

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 are currently included 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	6	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)

(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

Table of Contents

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 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 5-7 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. As shown in the graph below, 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. 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. In the second half of 2009, we commenced the first Phase IV pediatric study. 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 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.

Table of Contents

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.

Commercialization Strategy

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. We have agreements for commercial manufacturing of Caldolor with Hospira Australia Pty. Ltd., formerly known as Mayne Pharma Pty. Ltd., and Bayer Healthcare, LLC in the United States.

In preparation for the launch of Caldolor in the United States we performed extensive market research and developed a comprehensive launch and marketing plan. In conjunction with scientific and medical advisory boards as well as leading pain and fever specialists, we developed and tested what we believe are appropriate and effective marketing messages for our carefully selected targets, including physicians in several specialties, nurses and pharmacists in high-use institutions. We completed price-sensitivity research to select an appropriate pricing strategy and produced appropriate commercial launch supplies.

We expanded our existing hospital sales force from 30 to 77 experienced hospital sales representatives and managers to promote Caldolor, and developed a comprehensive training program to support them. These representatives are responsible for territories designed through computer modeling to optimize both hospital targeting and coverage. Marketing support materials include new clinical papers, journal ads, in-service programs and an information package designed for Pharmacy and Therapeutic committees and a range of sales support literature. We expanded our professional affairs team to handle increased medical inquiries, and we culminated our launch preparations with a national launch meeting to finalize training and maximize motivation prior to the Caldolor launch in the third quarter of 2009.

With our September 2009 launch of Caldolor our sales representatives began promoting the product in the United States. Our sales group is highly focused on meeting with key members of hospital Pharmacy and Therapeutic committees to secure placement on upcoming committee agendas and obtain the necessary approvals for Caldolor to be placed on hospital formularies. We have also commenced a publication initiative for our clinical data on Caldolor, and results from those trials have begun to be published in peer-reviewed journals as well as presented at appropriate medical meetings around the country.

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.

Table of Contents

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.

Early-stage product candidates

Our pre-clinical product candidates are being developed through CET, our 85%-owned subsidiary. Cumberland 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.

Four of the more advanced CET development programs are:

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.

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.

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.

In collaboration with Vanderbilt University, we recently signed an agreement 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 markedly reduce renal blood flow in association with acute kidney failure.

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 both 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

Table of Contents

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. Our primary targets are under-promoted, FDA-approved drugs with existing brand recognition and late-stage development products that address unmet medical needs in the hospital acute care and gastroenterology markets. We also plan to explore opportunities to acquire rights to and seek approval for new uses of pharmaceutical products. 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, we believe that they are not material to our business at this time.

CLINICAL AND REGULATORY AFFAIRS

We have established 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. They were responsible for devising the regulatory and clinical strategies and obtaining FDA approvals for Acetadote and Caldolor.

Clinical development

Our in-house 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

Table of Contents

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 2006, we expanded our clinical and regulatory capabilities and brought our call center in-house in an effort to ensure the highest level of quality and service. In addition to coordinating the call center, our clinical and 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. They manage our dedicated hospital and gastroenterology sales forces, 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. The hospital sales team is comprised of 77 sales representatives and managers as of March 1, 2010, covering hospitals across the United States.

The gastroenterology-focused team, formed in September 2006 with our re-launch of Kristalose, is a field sales force comprised of 36 representatives and district managers as of March 1, 2010 covering high prescribers of laxatives. This gastroenterology sales force is contracted to us by Ventiv Commercial Services, LLC, or Inventiv. Under our agreement, we pay Inventiv a monthly fee of $0.4 million, a portion of which is used to compensate the sales force. In addition to this monthly fee, we provide Inventiv with payment for bonuses and expenses during the existence of this agreement. This agreement terminates in March 2010. We have the option, with Inventiv s consent, to extend the contract for one additional year. We also have the option to bring this sales force in-house.

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 medical conferences 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

Consistent with our strategy to outsource non-core functions, 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 have 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 South 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.

10

Table of Contents

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 have 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 payments. This license terminates seven years after the first sale of Acetadote in Australia.

MANUFACTURING AND DISTRIBUTION

We outsource certain non-core, capital-intensive functions, including manufacturing and distribution. Our executives are experienced in these areas and manage these third-party relationships with a focus on quality assurance.

Manufacturing

Our key manufacturing relationships include:

In July 2000, we established an international manufacturing alliance with a predecessor to Hospira Australia Pty. Ltd., or Hospira. Hospira sources active pharmaceutical ingredients, or APIs, and manufactures Caldolor for us under an agreement that expires in June 2014, subject to early termination upon 45 days prior notice in the event of uncured material breach by us or Hospira. The agreement will automatically renew for successive three-year terms unless Hospira or we provide at least 12 months prior written notice of non-renewal. Under the agreement, we pay Hospira a transfer price per unit of Caldolor supplied. In addition, we reimburse Hospira for agreed-upon development, regulatory and inspection and audit costs. We have granted Hospira a right of first negotiation for manufacture and distribution of all future pharmaceutical products we intend to sell in Australia, New Zealand, Canada and mutually agreed Southeast Asian and Latin American countries.

Bioniche Teoranta, or Bioniche, sources APIs and manufactures Acetadote for us 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 expiring in January 2011. This agreement is subject to early termination upon prior written notice in the event of an uncured material default by us or Bioniche. We have an option to renew the agreement for a five-year term upon expiration. Under the agreement, we pay Bioniche a transfer price per unit of Acetadote supplied, which transfer price is subject to annual adjustment, and a percentage royalty in the mid-single digits throughout the term of the agreement based on our net sales of the product. In addition, we are required to purchase minimum quantities of Acetadote.

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.

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.

11

Table of Contents

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 are entitled to seven years of marketing exclusivity for the treatment of this approved indication. We have applied for patent protection for a new formulation of Acetadote 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.

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.

Table of Contents

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.

Caldolor

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

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

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 the companies developing injectable, non-narcotic analgesics for the treatment of post-surgical pain are the primary potential competitors to Caldolor. Cadence Pharmaceuticals Inc. has filed for FDA regulatory approval of an injectable formulation of acetaminophen for the treatment of pain and fever, and Javelin Pharmaceuticals Inc. has filed for FDA approval of its injectable form of an NSAID, diclofenac, for the treatment of pain.

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

Table of Contents

indicated for the treatment of fever in the U.S. other than Caldolor. There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including acetaminophen, ibuprofen 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.

FDA Approval Process

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

- completion of pre-clinical laboratory and animal testing;
- 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;
- 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 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.

Table of Contents

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.

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.

Table of Contents

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 is 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.

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.

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 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.

Table of Contents

EMPLOYEES

As of March 1, 2010, we had 108 full-time employees, which included 76 hospital sales force representatives and managers. We also have a dedicated gastroenterology field sales force under contract that is comprised of 35 dedicated sales representatives and district managers. We believe that employing experienced, independent contractors and consultants is a cost-efficient and effective way to accomplish our goals. A number of additional 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.

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:

- The prices of our products relative to other drugs or competing treatments;
- Any unfavorable publicity concerning us, our products, or the markets for these products such as information concerning product contamination or other safety issues in either of our product markets, whether or not directly involving our products;
- Perception by physicians and other members of the healthcare community of the safety or efficacy of our products or competing products;
- Regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products;
- The inability of the orphan drug designation of Acetadote (under which the FDA granted seven years marketing exclusivity for intravenous treatment of moderate to severe acetaminophen overdose) to prevent development and marketing of a different product that competes with Acetadote;
- Changes in intellectual property protection available for our products or competing treatments;
- The availability and level of third-party reimbursement for sales of our products; and
- The continued availability of adequate supplies of our products to meet demand.

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

Table of Contents

If any manufacturer we rely upon fails to produce our products in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.

We do not manufacture any of our products, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of products could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to sell our products as planned. Furthermore, if we encounter delays or difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected.

Caldolor is manufactured at Hospira Australia Pty. Ltd. s facility in Australia and Bayer s facility in Kansas. Acetadote is manufactured primarily at a facility in Ireland and Bayer s manufacturing plant in Kansas 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:

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

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

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

- Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which warehouses and ships our marketed products;
- Ventiv Commercial Services, LLC, which provides a field sales force that is the primary selling team for Kristalose; and
- Vanderbilt University and the Tennessee Technology Development Corporation, co-owners with us of CET, and the universities that collaborate with us in connection with CET s research and development programs.

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

Table of Contents

Competitive pressures could reduce our revenues and profits.

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

Our competitors may sell or develop drugs that are more effective and useful 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. As of March 1, 2010, our hospital sales force was comprised of 76 representatives and managers. 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.

Table of Contents

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 we 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. Future cost control initiatives could decrease the price that we would receive for any products, which would limit our revenue and profitability. In addition, legislation and regulations affecting the pricing of pharmaceutical products might change.

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.

Table of Contents

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

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

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

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

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

- CET investigates early-stage products, which have the greatest risk of failure prior to FDA approval and commercialization;
- In some programs, we do not have pre-set rights to product candidates developed by CET. We would need to agree with CET and its collaborators on the terms of any product licensed to, or acquired by, us;
- We rely principally on government grants to fund CET s research and development programs. If these grants were no longer available, we or our co-owners might be unable or unwilling to fund CET operations at current levels or at all;
- We may become involved in disputes with our co-owners regarding CET policy or operations, such as how best to deploy CET assets or which product opportunities to pursue. Disagreement could disrupt or halt product development; and
- CET may disagree with one of the various universities with which CET is collaborating on research. A disagreement could disrupt or halt product development.

We depend on our key personnel, the loss of whom would adversely affect our operations. If we fail to attract and retain the talent required for our business, our business will be materially harmed.

We are a relatively small company, and we depend to a great extent on principal members of our management and scientific staff. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, it could have a material adverse effect on our business prospects. 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.

Table of Contents

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

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

decreased demand for our products;

injury to our reputation;

withdrawal of clinical trial participants;

significant litigation costs;

substantial monetary awards to or costly settlement with patients;

product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

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

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

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

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.

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 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.

Table of Contents

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.

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 has been designated as an orphan drug and 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. The FDA is authorized to grant orphan drug designation to drugs intended to treat a rare disease or condition. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market another drug using the same active ingredients for the same indication, except in very limited circumstances, for seven years. To this extent, Acetadote is protected until 2011 against competition from another drug using the same active ingredient to treat the same indication. Orphan drug marketing exclusivity does not, however, protect a drug from competition by a different drug marketed for the same indications.

Table of Contents

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 an 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, 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

Table of Contents

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.

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.

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

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

Table of Contents

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, 2009, 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 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 16, 2010, the closing price of our common stock has ranged from a low of $11.10 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

Table of Contents

or abandon clinical developments plans. There is a risk that one or more of our current service providers, manufacturers and other partners may encounter difficulties during challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

We are experiencing increased costs 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), as well as 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:

- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval;
- advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders;
- limitations on persons authorized to call a special meeting of shareholders;
- a staggered board of directors;
- a restriction prohibiting shareholders from removing directors without cause;
- a requirement that vacancies in directorships are to be filled by a majority of the directors then in office and the number of directors is to be fixed by the board of directors; and
- no cumulative voting.

These and other provisions contained in our third amended and restated charter and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our shareholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of shareholders to remove our current management or approve transactions that our shareholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

Table of Contents

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 provision 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.

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:

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

Item 1B: Unresolved Staff Comments

None

Item 2: Properties

As of December 31, 2009, we leased approximately 18,400 square feet of office space in Nashville, Tennessee for our headquarters. These leases expire in October 2010 for approximately 9,100 square feet, in December 2010 for approximately 6,300 square feet and in December 2015 for approximately 3,000 square feet. Of the 18,400 square feet of leased office space, we have subleased to others approximately 4,600 square feet. We believe our current negotiations with the landlord to maintain leases for our existing office space will be successful. We believe that 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.

Item 3: Legal Proceedings

We are not currently engaged in any legal proceedings.

Table of Contents

PART II

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

Market Information

Our common stock, no par value, has been traded on the Nasdaq Global Select Market since August 11, 2009 under the symbol CPIX. Prior to that time, there was no public market for our common stock. As of March 16, 2010, there were 256 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 16, 2010 was $11.35 per share. The following table sets forth the high and low closing 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:

	High	Low
Fiscal year ended December 31, 2009:		
Fourth quarter	$ 16.77	$ 11.78

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 the consolidated financial statements for the year ended December 31, 2009 beginning on page F-2 of this Annual Report on Form 10-K.

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.

Table of Contents

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 the Company s initial public offering. On August 10, 2009 and pursuant to the Registration Statement, we sold 5,000,000 shares of common stock, no par value, at a public offering price of $17.00 per share. The managing underwriters were UBS Investment Bank, Jefferies & Company, Wells Fargo Securities and Morgan Joseph.

As a result of the initial public offering, we received gross proceeds of $85.0 million. After deducting underwriting discounts and commissions of approximately $6.0 million and offering costs of approximately $4.2 million paid by us, we received net proceeds of approximately $74.8 million. None of such payments were direct or indirect payments to directors, officers, general partners of the Company or their associates, to persons owning 10 percent or more of any class of equity securities of the Company or to affiliates of the Company.

As of December 31, 2009, we have used approximately $4.2 million of the net proceeds to pay off the existing term debt with Bank of America, approximately $6.7 million for the commercialization of Caldolor, approximately $2.4 million for the expansion of our sales force and approximately $1.3 million for ongoing clinical work, product development and other costs related to Caldolor. The remaining proceeds have been invested in money market accounts. There have been no material changes in the planned expected use of the net proceeds from the offering.

Purchases of Equity Securities

During the fourth quarter of 2009, certain options were exercised whereby the holder tendered mature shares of common stock to us at the then current fair market value in satisfaction of the exercise price. The following table summarizes the activity, by month, during the fourth quarter of 2009:

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				
November 1 November 30				
December 1 December 31	25,739	$ 13.59		
Total	25,739			

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.

Table of Contents

Statement of income data:	Years Ended December 31, 2009	2008	2007	2006	2005
		(in thousands, except per share data)			
Net revenues	$ 43,537	$ 35,075	$ 28,064	$ 17,815	$ 10,690
Cost of products sold	4,137	3,046	2,670	2,399	533
Selling and marketing	20,194	14,387	10,053	7,349	5,647
Research and development	4,993	4,429	3,694	2,233	1,158
General and administrative	7,643	5,140	4,138	2,999	2,588
Other operating expenses	794	791	783	612	13
Operating income	5,777	7,282	6,725	2,224	750
Earnings per share basic	$ 0.22	$ 0.47	$ 0.40	$ 0.45	$ 0.21
Earnings per share diluted	$ 0.17	$ 0.29	$ 0.24	$ 0.27	$ 0.12

Balance sheet data:	As of December 31, 2009	2008	2007	2006	2005
			(in thousands)		
Cash and cash equivalents	$ 78,702	$ 11,830	$ 10,815	$ 6,255	$ 5,536
Working capital	74,549	10,104	6,669	3,945	5,640
Total assets	103,724	31,119	28,919	26,481	10,173
Total long-term debt and other long-term obligations (including current portion)	20,155	7,666	7,623	10,543	2,398
Convertible preferred stock		2,604	2,743	2,743	2,743
Retained earnings (accumulated deficit)	4,542	1,451	(3,316)	(7,360)	(11,764)
Total equity	72,221	17,555	16,746	11,126	6,234

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

Our product portfolio includes Caldolor® *(ibuprofen)* Injection, the first injectable treatment for pain and fever available 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.

Table of Contents

Our strategy to grow our company includes maximizing the potential of our existing products and continuing to build a portfolio of differentiated products. Our current products are approved for sale in the United States, and we are working to bring them to select international markets. We also look for opportunities to expand into additional patient populations through new product indications, whether through our own 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 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, pursuit of our growth strategy and other factors. As a result of these fluctuations, our historical financial results are not necessarily indicative of future results.

Recent Developments

Caldolor®

In June 2009, the FDA approved Caldolor, an intravenous formulation of ibuprofen, for marketing in the United States through a priority review. Caldolor is the first and only injectable product approved for sale in the United States for the treatment of both pain and fever. Following FDA approval, in preparation for the product launch, we conducted comprehensive market research, prepared a full package of educational materials, optimized territory design and launched the product website. We expanded our hospital sales force to 77 representatives and managers to prepare for the launch, and enlisted the services of our field sales force of 36 representatives and managers to promote the product. We also expanded our internal professional affairs group to support the product.

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. We are working to secure formulary approval nationally for Caldolor, and the product is already stocked in a number of medical facilities.

We also filed the first of several expected new patent applications for Caldolor in September 2009. A part of an ongoing initiative to protect the value of our intellectual property, this new application addresses our proprietary method of dosing intravenous ibuprofen.

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. This license terminates on the seventh anniversary of the date that Caldolor is first sold in Australia.

We have 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 payments. This license terminates seven years after the first sale of Acetadote in Australia.

In December 2009, we announced that we have 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

Table of Contents

transfer price, and we will receive royalties on any future sales of Caldolor in South Korea. This license terminates on the fifth anniversary of the date that Caldolor is launched in South Korea.

Initial Public Offering

In August 2009, we completed our initial public offering of 5,000,000 shares of common stock at a price to the public of $17.00 per share, raising $85.0 million in gross proceeds. After deducting underwriting discounts and offering costs, the net proceeds to us were approximately $74.8 million. The proceeds from this offering are primarily for potential acquisitions, the launch of Caldolor, expansion of our hospital sales force, product development, debt repayment and general corporate purposes.

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 included in net revenues, includes rental and grant income. Other income was less than one percent of net revenues in 2009, 2008 and 2007.

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, $0.1 million and $0.1 million as of December 31, 2009, 2008 and 2007, respectively, for chargebacks, discounts and allowances for product damaged in shipment. We had accrued liabilities of $1.9 million, $1.0 million and $0.7 million as of December 31, 2009, 2008 and 2007, respectively, for rebates, product returns, service fees, and administrative fees.

The following table reflects our sales-related accrual activity:

	2009	2008	2007
Balance at January 1	$ 1,040,203	$ 738,362	$ 742,678
Current Provision	3,436,208	1,690,134	1,194,869
Current Provision for Prior Period Sales	75,589	(73,960)	(44,252)
Actual Returns/Credits	(2,688,988)	(1,314,333)	(1,154,933)
Balance at December 31	$ 1,863,012	$ 1,040,203	$ 738,362

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

Table of Contents

of sale based on each product s historical experience, adjusted to reflect known changes in the factors that impact such allowances and accruals. Additionally, these allowances and accruals are established based on the following:

- the contractual terms with customers;
- analysis of historical levels of discounts, returns, chargebacks and rebates;
- communications with customers;
- purchased information about the rate of prescriptions being written and the level of inventory remaining in the distribution channel, if known; and
- expectations about the market for each product, including any anticipated introduction of competitive products.

The allowances for chargebacks and accruals for rebates and product returns are the most significant estimates used in the recognition of our revenue from product sales. Of the accounts receivable allowances and our sales related accruals, our accrual for fee for services and product returns represent the majority of the balance. Sales related accrued liabilities totaled $1.9 million, $1.0 million and $0.7 million as of December 31, 2009, 2008 and 2007, respectively. Of these amounts, our estimated liability for fee for services represented $0.7 million, $0.3 million and $0.2 million, respectively, while our accrual for product returns totaled $1.0 million, $0.6 million and $0.3 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, 2009. A change in our product return estimate of one percentage point would have impacted net sales by $0.5 million, $0.4 million and $0.3 million for the years ended December 31, 2009, 2008 and 2007, 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 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. In order to fully utilize the deferred tax asset of $2.0 million as of December 31, 2009, we will need to generate future taxable income of approximately $5.4 million.

Table of Contents

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, 2009, the Company has unrecognized benefits associated with the exercise of nonqualified options of $26.1 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 2009, 2008 and 2007:

	2009	2008	2007
Dividend yield	%	%	%
Expected term (in years)	3.7 6.2	3.5 6.0	5.5 6.4
Expected volatility	50% 52%	49% 51%	58% 64%
Risk-free interest rate	1.4% 2.7%	3.1%	4.6% 4.8%

The following assumptions were used in calculating the fair value of nonemployee options granted during 2009, 2008 and 2007:

	2009	2008	2007
Dividend yield	%	%	%
Expected term (in years)	2.3 10	10	10
Expected volatility	51% 67%	68%	74%
Risk-free interest rate	1.1% 2.7%	3.7%	4.8%

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

Table of Contents

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.

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

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

Table of Contents

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 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.

Year ended December 31, 2008 compared to year ended December 31, 2007

Net revenues. Net revenues for 2008 totaled $35.1 million, representing an increase of $7.0 million, or 25%, over the same period in 2007. Of this increase, approximately $6.6 million related to Acetadote and $0.5 million related to Kristalose. These increases were partially offset by lower grant revenue in 2008. The increase in revenues for Acetadote and Kristalose was primarily due to increased volume as our products continued to grow in our target markets.

Gross product sales were reduced by $2.8 million and $2.4 million in 2008 and 2007, respectively. In 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. For 2007, this reduction included $1.1 million for damaged and expired product returns, $0.6 million for cash discounts, $0.4 million related to fee-for-service costs and $0.2 million for estimated rebates, chargebacks and discounts related to Kristalose.

Cost of products sold. Cost of products sold totaled $3.0 million, representing an increase of $0.4 million, or 14%, over cost of products sold in 2007 of $2.7 million. Of this increase, approximately $0.3 million related to Acetadote and $0.1 million related to Kristalose. As a percentage of net revenues, cost of products sold decreased from 9.5% in 2007 to 8.7% for 2008. The decrease in cost of products sold, as a percentage of net revenues, was due to a shift in the sales mix between the periods.

Selling and marketing. Selling and marketing expense for 2008 totaled $14.4 million, representing an increase of $4.3 million, or 43%, over 2007. The increase was primarily due to $3.1 million for the expansion and ongoing costs of our sales

Table of Contents

forces as we continue to grow our products in our target markets and expand our territories. We also incurred an increase of $0.4 million in advertising expense primarily associated with a new marketing campaign for Kristalose and $0.4 million of additional royalty expense.

Research and development. Research and development expense for 2008 totaled $4.4 million, representing an increase of $0.7 million, or 20%, over 2007. The increase was primarily due to $1.2 million expended for the application fee associated with regulatory approval of one of our products, and was offset by a decrease in clinical studies and supplies expense as we completed development activity intended to support regulatory approval of that product.

General and administrative. General and administrative expense for 2008 totaled $5.1 million, representing an increase of $1 million, or 24%, over general and administrative expenses in 2007 of $4.1 million. The increase was primarily due to increased rent expense as we acquired additional office space, increased business development expense as we evaluated potential acquisition candidates and agreements and increased salary and related expenses, including share-based compensation, due to personnel additions.

Interest income. Interest income totaled $0.2 million for 2008, representing a decrease of $0.1 million, or 37%, over 2007. The decrease was primarily due to lower interest rates and lower cash balances due to the repayment of our remaining product license right obligation in April 2008.

Interest expense. Interest expense totaled $0.2 million for 2008, representing a decrease of $0.4 million, or 67%, over 2007. The decrease was primarily due to lower outstanding debt during 2008 as compared to 2007. In April 2008, we amended our agreement to pay the remaining obligation related to the purchase of our product license right for Kristalose, resulting in lower interest expense in 2008 associated with this obligation.

Income tax expense. Income tax expense for 2008 totaled $2.5 million, representing a decrease of $0.1 million, or 5%, over 2007. As a percentage of net income before income taxes, income tax expense decreased from 37.5% for 2007 to 34.8% for 2008. The decrease in the tax rate was primarily due to the reversal of the Company s 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, 2009, cash and cash equivalents was $78.7 million, working capital was $74.5 million and our current ratio (current assets to current liabilities) was 5.0 to 1. As of December 31, 2009, we also had the ability to make additional draws of up to approximately $2.2 million on our line of credit.

The following table summarizes our net changes in cash and cash equivalents for the years ended December 31, 2009, 2008 and 2007:

	Years Ended December 31,		
	2009	2008	2007
		(in thousands)	
Cash provided by (used in):			
Operating activities	$ 405	$ 6,397	$ 8,627
Investing activities	(712)	(134)	(163)
Financing activities	67,180	(5,248)	(3,904)
Net increase in cash and cash equivalents [1]	$ 66,872	$ 1,015	$ 4,559

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

rounding.

Cash provided by operating activities of approximately $0.4 million for the year ended December 31, 2009 was primarily due to net income of approximately $3.1 million adjusted for (1) non-cash expenses of approximately $2.1 million and (2) a decrease in working capital of approximately $0.8 million. Also impacting cash provided by operating activities is the requirement that the cash retained as a result of excess tax benefits related to share-based payments be presented as a

Table of Contents

cash outflow from operating activities and a cash inflow from financing activities. During 2009, option holders exercised approximately 4.7 million nonqualified options that resulted in a recognized tax benefit to us of approximately $4.0 million.

Cash used in investing activities was approximately $0.7 million for the year ended December 31, 2009, and was used for additions of property, equipment and patents.

Cash provided by financing activities for the year ended December 31, 2009 of approximately $67.2 million was primarily due to (1) gross proceeds from our initial public offering of $85.0 million, net of offering costs and underwriting discounts of $7.5 million, (2) additional borrowings of $18.0 million of term debt, (3) principal payments of $5.0 million related to the payoff of our old term debt balance, (4) the excess tax benefit of $4.0 million derived from the exercise of nonqualified stock options that is required to be presented as a cash inflow from financing activities and (5) payments of approximately $27.3 million in connection with the repurchase of common shares that were tendered at the time of exercise to settle the minimum statutory withholding tax requirements associated with the exercise of nonqualified stock options in 2009.

In April 2006, we completed our transaction with Inalco to acquire exclusive U.S. commercialization rights for Kristalose. In order to complete this transaction, funding was obtained from Bank of America in the form of a three-year term loan for $5.5 million and a two-year revolving line of credit agreement, both with an interest rate of LIBOR plus 2.5%. The term loan was due in 2009, and was being paid off in quarterly principal installments of $458,334, plus interest. In April 2008, we amended our revolving line of credit agreement to extend the maturity date to April 2009. In conjunction with the agreement, we issued warrants to purchase up to 3,958 shares of common stock at an exercise price of $9.00 per share, which expire in April 2016 and were outstanding and exercisable as of December 31, 2009.

On December 30, 2008, we amended our debt agreement (Third Amended and Restated Loan Agreement) to provide for $5.0 million of term debt and up to $7.5 million under our revolving line of credit, both with an interest rate of LIBOR plus an applicable margin based on our Leverage Ratio, as defined in the agreement. This agreement expired in December 2011. The term loan was being paid off in quarterly installments of $416,667, plus interest, beginning April 2009. The credit agreement provided that borrowings are collateralized by a first priority lien on all of our assets. The credit agreement contained an adverse subjective acceleration clause and also required us to maintain bank accounts and a lockbox at the lender. However, cash received in the lockbox is not required to be applied against amounts borrowed under the line of credit. This credit agreement contained various covenants that we were in compliance with at December 31, 2008.

In July 2009, we amended our debt agreement (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 our Leverage Ratio, as defined in the agreement. The interest rate at December 31, 2009 was 5.73% per annum. In addition, we must pay a commitment fee of 0.75% per annum on the unused portion of the commitment. The term debt is payable in quarterly installments of $1.5 million beginning on March 31, 2010 and continuing until December 31, 2012. The revolving credit facility is due on December 31, 2012. We may be required to make additional principal payments on the term debt if the Leverage Ratio, as defined in the agreement, exceeds 1.75 to 1.0 on an annual basis. The borrowings are collateralized by a first lien against all of our 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 us of shares acquired upon exercise at the then-current fair market value of our common stock.

The Fourth Amended and Restated Loan Agreement contains restrictive covenants, including: maintaining a Leverage Ratio not exceeding 2.75 to 1.00 as of December 31, 2009 and decreasing to 1.00 to 1.00 as of December 31, 2011; maintaining a Fixed Charge Coverage Ratio of at least 1.25 to 1.00; maintaining liquidity of at least $2.0 million as of the end of a quarter-annual period; limiting capital expenditures during any fiscal year; maintaining adequate insurance; and prohibiting the payment of dividends on common stock. We were in compliance with all covenants as of December 31, 2009.

The Fourth Amended and Restated Loan Agreement requires 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. As of December 31, 2009, the additional principal payment due was $3.1 million.

Under our agreements with Inalco and Bioniche for the manufacturing of Kristalose and Acetadote, we are obligated to purchase minimum amounts of inventory each year. These obligations require us to purchase approximately $0.5 million of Kristalose and Acetadote combined during 2010, $0.1 million of Kristalose and Acetadote combined during 2011, and

Table of Contents

$17,000 of Kristalose during 2012. Beginning in 2013 and continuing through the life of the Kristalose agreement, our minimum purchase requirements will be based on not less than 25% of each prior year s purchases. We expect our normal inventory purchasing levels to be above the required minimum amounts. As of December 31, 2009, we had met our purchase obligations for 2009 under these agreements.

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 will be due upon specific milestone events. Upon meeting the first milestone, an amount equal to one-third of the original deferred amount, or approximately $0.2 million, will become due and payable. Upon completion of the final milestone event, an amount equal to five times one-third of the original deferred amount, or approximately $1.0 million, will become due and payable to Cato. Since the application of these factors is contingent upon specific events which may or may not occur in the future and which did not occur as of December 31, 2006, the expense for these factors was not recognized in the 2006 consolidated financial statements. During the third quarter of 2007, we progressed our studies and NDA application to the extent that we determined it was probable the first milestone will be met. As such, we recorded the obligation related to the first milestone of approximately $0.2 million as a current liability as of December 31, 2007. As of December 31, 2008, the total liability recorded related to Cato was approximately $0.6 million. In June 2009, the Company received marketing approval for Caldolor from the FDA. The approval triggered a milestone obligation of approximately $1.0 million and is payable as follows: approximately $0.8 million was paid in the third quarter of 2009 and the remaining $0.2 million is payable in equal monthly installments through July 2010. In addition to the cash bonus, 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, 2009:

		Payments Due by Year				
Contractual obligations	**Total**[1]	**2010**	**2011**	**2012**	**2013**	**2014+**
			(in thousands)			
Amounts reflected in the balance sheet:						
Term loan [2]	$ 18,000	$ 9,062	$ 6,000	$ 2,938		
Line of credit	1,826			1,826		
Estimated interest on debt [3]	1,575	919	488	167		
Other cash obligations not reflected on the balance sheet:						
Operating leases	1,088	559	138	93	96	201
Purchase obligations [4]	544	452	69	17	4	1
Total [1]	$ 23,032	$ 10,992	$ 6,695	$ 5,042	$ 101	$ 203

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

(2) The term debt is payable in quarterly installments of

$1.5 million beginning in March 2010. In addition to the scheduled quarterly payments, we must make an additional principal payment within 120 days of the end of the year equal to the Excess Cash Flows, as defined in the agreement. At December 31, 2009, the Excess Cash Flow payment was $3.1 million and is included in the 2010 amount above.

(3) Represents the estimated interest payments on our line of credit and term loan based on the December 31, 2009 interest rate of LIBOR plus an applicable margin, or 5.73%. 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) Represents minimum purchase obligations under Kristalose and Acetadote manufacturing agreements. Beginning in January 2013 and continuing through the life of the agreement, which expires in 2021, our minimum purchases for Kristalose will be based on not less than 25% of each prior year s purchases.

OFF-BALANCE SHEET ARRANGEMENTS

During 2009, 2008 and 2007, we did not engage in any off-balance sheet arrangements.

Table of Contents

RECENTLY ISSUED 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, 2009.

RECENTLY ADOPTED ACCOUNTING STANDARDS

Effective January 1, 2009, we adopted a new accounting standard that requires noncontrolling interests in a subsidiary be classified as a component of equity in the consolidated balance sheet. In addition, the consolidated results of operations must include amounts attributable to both the parent and the noncontrolling interests. As of the date of adoption, the equity balance of the noncontrolling interests in CET, the Company s 85%-owned subsidiary, had been reduced to zero. In accordance with the new standard, the operating loss at CET for the year ended December 31, 2009 was allocated between us and the noncontrolling interests.

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 the Company is exposed to significant downside risk.

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 (5.73% at December 31, 2009). As of December 31, 2009, we had outstanding borrowings of $19.8 million under our line of credit and term debt combined. If interest rates increased by 1.0%, our annual interest expense on our borrowings would have increased by approximately $0.2 million for the year ended December 31, 2009.

Exchange Rate Risk

While we operate primarily in the U.S., we are exposed to foreign currency risk. Our primary manufacturer of Acetadote denominates supply prices in Canadian 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, 2009, our outstanding payables denominated in a foreign currency totaled approximately $0.9 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 2009 and 2008. Neither a 5% increase nor decrease from current exchange rates would have a material effect on our operating results or financial condition.

Table of Contents

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.

Item 9A: Controls and Procedures

The Company s Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of the Company s disclosure controls and procedures as of December 31, 2009. Based on that evaluation, they have concluded that the Company s disclosure controls and procedures are effective to ensure that material information relating to the Company and the Company s consolidated subsidiaries is made known to officers within these entities in order to allow for timely decisions regarding required disclosure.

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s registered public accounting firm due to a transition period established by the rules of the Securities Exchange Commission for newly public companies.

During the Company s fourth quarter of 2009, there have been no changes in the Company s internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f)).

Item 9B: Other Information

None

PART III

The information called for by Part III of Form 10-K (Item 10 Directors, Executive Officers and Corporate Governance, Item 11 Executive Compensation, Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13 Certain Relationships and Related Transactions, and Director Independence, Item 14 Principal Accounting Fees and Services), is incorporated by reference from our proxy statement related to our 2010 annual meeting of shareholders, which will be filed with the SEC not later than April 30, 2010 (120 days after the end of the fiscal year covered by this report).

PART IV

Item 15: Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report:

(1) Financial Statements

(2) Financial Statement Schedule

(b) Exhibits

Exhibit Number	Description
3.1	Third Amended and Restated Charter of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
3.2	Second Amended and Restated Bylaws of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 19 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
4.1	Specimen Common Stock Certificate of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 5 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on August 6, 2007
4.2	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on October 21, 2003, incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
4.3	Stock Purchase Warrant, issued to S.C.O.U.T. Healthcare Fund L.P. on April 15, 2004, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on June 22, 2007
4.4	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on April 6, 2006, incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
4.5#	Form of Option Agreement under 1999 Stock Option Plan of Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement

on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007

4.6.1# Form of Incentive Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of 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

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 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

Table of Contents

Exhibit Number	Description
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 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
4.8	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on July 22, 2009, filed herewith
10.1	Manufacturing and Supply Agreement for N-Acetylcysteine, dated January 15, 2002, by and between Bioniche Life Sciences, Inc. and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 5 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on August 6, 2007
10.2	Novation Agreement, dated January 27, 2006, by and among Bioniche Life Sciences, Inc., Bioniche Pharma Group Ltd., and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.3	First Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated November 16, 2006, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.3.1	Second Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated March 25, 2008, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.4	Cardinal Health Contract Sales and Services for Cumberland Pharmaceuticals Inc. Dedicated Sales Force Agreement, dated May 16, 2006, by and between Cardinal Health PTS, 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
10.5	First Amendment to Contract Sales and Service Agreement, dated July 19, 2006, by and between Cardinal Health PTS, 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
10.6	Second Amendment to Contract Sales and Service Agreement, dated June 1, 2007, by and between Cumberland Pharmaceuticals Inc. and Inventiv Commercial Services, LLC, as successor in interest to Cardinal Health PTS, LLC, 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
10.6.1	

Third Amendment to Contract Sales and Service Agreement, dated March 26, 2008, by and between Cumberland Pharmaceuticals Inc. and Ventiv Commercial Services, LLC, 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

10.6.2 Fourth Amendment to Service Agreement, dated April 1, 2009, by and between Ventiv Commercial Services, LLC 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

10.7 Distribution Services Agreement, dated August 3, 2000, by and between CORD Logistics, Inc. 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

10.8 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

Table of Contents

Exhibit Number	Description
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
10.10	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 effective as of January 1, 2009 by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 15 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on February 18, 2009
10.12#	Employment Agreement effective as of January 1, 2009 by and between Jean W. Marstiller and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 15 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on February 18, 2009
10.13#	Employment Agreement effective as of January 1, 2009 by and between Leo Pavliv and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 15 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on February 18, 2009
10.13.1#	Amendment dated June 30, 2009 to Employment Agreement by and between Leo Pavliv and 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
10.15#	

Employment Agreement effective as of January 1, 2009 by and between David L. Lowrance and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 15 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on February 18, 2009

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

10.17# 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., incorporated herein by reference to of 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

10.19# 2007 Directors Compensation Plan of Cumberland Pharmaceuticals Inc., 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

Table of Contents

Exhibit Number	Description
10.20	Form of Indemnification Agreement between Cumberland Pharmaceuticals Inc. and all members of its Board of Directors, incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.21	Lease Agreement, dated September 10, 2005, by and between Nashville Hines Development, LLC and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 11, 2007
10.21.1	First Amendment to Office Lease Agreement, dated April 25, 2008, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 10 of the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 21, 2008
10.22.1	Sublease Agreement, dated December 14, 2006, by and between Robert W. Baird & Co. Incorporated 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
10.22.2	Addendum to Sublease Agreement, dated May 5, 2007, by and between Robert W. Baird & Co. Incorporated and Cumberland Pharmaceuticals Inc. and consented to by Nashville Hines Development, LLC, 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
10.23	Amended and Restated Lease Agreement, dated November 11, 2004, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.24	First Amendment to Amended and Restated Lease Agreement, dated August 23, 2005, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on May 1, 2007
10.24.1	Second Amendment to Amended and Restated Lease Agreement, dated January 9, 2006, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc., incorporated herein by reference to Amendment No. 10 of the corresponding exhibit to 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 Amendment No. 12 of the corresponding exhibit to 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 effective as of July 1, 2009 by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc., incorporated herein by reference to Amendment No. 19 of the corresponding exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-142535) as filed with the SEC on July 17, 2009
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.

Table of Contents

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 19th day of March, 2010.

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 19, 2010
/s/ David L. Lowrance David L. Lowrance	Vice President and CFO *(Principal Financial and Accounting Officer)*	March 19, 2010
/s/ Robert G. Edwards Robert G. Edwards	Director	March 19, 2010
/s/ Thomas R. Lawrence Thomas R. Lawrence	Director	March 19, 2010
/s/ Lawrence W. Greer Lawrence W. Greer	Director	March 19, 2010
/s/ Martin E. Cearnal Martin E. Cearnal	Director	March 19, 2010

Table of Contents

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, 2009 and 2008, 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, 2009. 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, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

/s/ KPMG LLP
Nashville, Tennessee
March 19, 2010

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2009 and 2008

ASSETS	**2009**	**2008**
Current assets:		
Cash and cash equivalents	$ 78,701,682	$ 11,829,551
Accounts receivable, net of allowances	6,176,585	3,129,347
Inventories	4,822,873	1,762,776
Prepaid and other current assets	2,746,259	481,312
Deferred tax assets	726,196	507,212
Total current assets	93,173,595	17,710,198
Property and equipment, net	918,412	432,413
Intangible assets, net	7,956,009	8,528,732
Deferred tax assets	1,306,514	1,000,031
Other assets	369,790	3,447,813
Total assets	$ 103,724,320	$ 31,119,187
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 9,061,973	$ 1,250,000
Current portion of other long-term obligations	144,828	457,915
Accounts payable	5,632,796	3,257,164
Other accrued liabilities	3,784,777	2,640,855
Total current liabilities	18,624,374	7,605,934
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	8,938,027	3,750,000
Other long-term obligations, excluding current portion	184,632	382,487
Total liabilities	29,572,984	13,564,372
Commitments and contingencies		
Redeemable common stock	1,930,000	
Shareholders equity:		
Cumberland Pharmaceuticals Inc. shareholders equity:		
Convertible preferred stock no par value; 3,000,000 shares authorized; 812,749 shares issued and outstanding as of December 31, 2008		2,604,070
Common stock no par value; 100,000,000 shares authorized; 20,180,486[1] and 9,903,047 shares issued and outstanding as of December 31, 2009 and 2008, respectively	67,711,746	13,500,034
Retained earnings	4,542,126	1,450,711
Total shareholders equity	72,253,872	17,554,815
Noncontrolling interests	(32,536)	

Total equity	72,221,336	17,554,815
Total liabilities and equity	$ 103,724,320	$ 31,119,187

(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.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Statements of Income
Years ended December 31, 2009, 2008 and 2007

	2009	2008	2007
Revenues:			
Net product revenue	$ 43,142,350	$ 34,889,967	$ 27,821,646
Other revenue	394,928	185,193	241,943
Net revenues	43,537,278	35,075,160	28,063,589
Costs and expenses:			
Cost of products sold	4,136,541	3,045,672	2,669,628
Selling and marketing	20,194,074	14,387,153	10,053,355
Research and development	4,993,278	4,429,064	3,693,917
General and administrative	7,643,070	5,139,937	4,137,942
Amortization of product license right	686,904	686,904	686,905
Other	106,776	104,209	96,524
Total costs and expenses	37,760,643	27,792,939	21,338,271
Operating income	5,776,635	7,282,221	6,725,318
Interest income	79,363	241,282	382,919
Interest expense	(772,927)	(213,303)	(639,590)
Income before income taxes	5,083,071	7,310,200	6,468,647
Income tax expense	(2,024,192)	(2,543,951)	(2,424,261)
Net income	3,058,879	4,766,249	4,044,386
Net loss at subsidiary attributable to noncontrolling interests	32,536		
Net income attributable to common shareholders	$ 3,091,415	$ 4,766,249	$ 4,044,386
Earnings per share attributable to common shareholders			
- Basic	$ 0.22	$ 0.47	$ 0.40
- Diluted	$ 0.17	$ 0.29	$ 0.24
Weighted-average shares outstanding			
- Basic	14,199,479	10,142,807	10,032,083
- Diluted	18,234,171	16,539,662	16,581,902

See accompanying notes to consolidated financial statements.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years ended December 31, 2009, 2008 and 2007

	2009	2008	2007
Cash flows from operating activities:			
Net income	$ 3,058,879	$ 4,766,249	$ 4,044,386
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	816,499	786,597	762,222
Deferred tax (benefit) expense	(525,467)	683,914	2,230,596
Nonemployee stock granted for services received	210,740	106,558	222,596
Nonemployee stock option grant expense	845,661	58,646	93,836
Stock-based compensation employee stock options	606,395	397,500	299,212
Excess tax benefit derived from exercise of stock options	(3,968,894)	(398,529)	(449,528)
Noncash interest expense	128,800	71,933	273,714
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	(3,047,238)	(755,810)	2,746,925
Inventory	(3,060,097)	(813,667)	(278,011)
Prepaid, other current assets and other assets	(721,464)	(163,274)	(184,268)
Accounts payable and other accrued liabilities	6,572,098	1,652,911	(811,107)
Other long-term obligations	(510,942)	42,501	(323,691)
Net cash provided by operating activities	404,970	6,396,952	8,626,882
Cash flows from investing activities:			
Additions to property and equipment	(601,802)	(67,572)	(152,420)
Additions to trademarks and patents	(110,541)	(66,576)	(11,069)
Net cash used in investing activities	(712,343)	(134,148)	(163,489)
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)	(2,031,416)
Proceeds from borrowings on long-term debt	18,000,000	4,083,340	
Principal payments on note payable	(5,000,000)	(1,833,336)	(1,833,336)
Net borrowings on line of credit		500,000	500,000
Payment of other long-term obligations		(2,760,000)	(1,500,000)
Costs of financing for long-term debt and credit facility	(189,660)	(29,491)	
Payments made in connection with repurchase of common shares	(27,295,808)	(4,999,995)	
Proceeds from exercise of stock options	175,089	81,159	510,951
Excess tax benefit derived from exercise of stock options	3,968,894	398,529	449,528
Net cash provided by (used in) financing activities	67,179,504	(5,247,771)	(3,904,273)
Net increase in cash and cash equivalents	66,872,131	1,015,033	4,559,120

Cash and cash equivalents, beginning of year	11,829,551	10,814,518	6,255,398
Cash and cash equivalents, end of year	$ 78,701,682	$ 11,829,551	$ 10,814,518
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 677,387	$ 221,000	$ 419,100
Income taxes	196,187	1,486,991	89,075
Noncash investing and financing activities:			
Deferred financing costs	335,075	125,000	
Increase in accounts payable and accrued expenses of initial public offering			645,934

See accompanying notes to consolidated financial statements.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Consolidated Statements of Equity and Comprehensive Income
Years ended December 31, 2009, 2008 and 2007

	Cumberland Pharmaceuticals Inc. Shareholders						
	Preferred stock		Common stock		Retained earnings (accumulated	Non-controlling	Total
	Shares	Amount	Shares	Amount	deficit)	interests	equity
Balance, December 31, 2006	855,495	$ 2,742,994	9,844,150	$ 15,742,590	$ (7,359,924)	$	$ 11,125,660
Stock-based compensation employee stock option grants				299,212			299,212
Issuance of common stock for services received			25,236	222,596			222,596
Stock-based compensation nonemployee stock option grants				93,836			93,836
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price			221,874	960,479			960,479
Net and comprehensive income					4,044,386		4,044,386
Balance, December 31, 2007	855,495	2,742,994	10,091,260	17,318,713	(3,315,538)		16,746,169
Stock-based compensation employee stock option grants				397,500			397,500
Issuance of common stock for services received			7,961	106,558			106,558
				58,646			58,646

Stock-based compensation nonemployee stock option grants						
Conversion of preferred stock into common stock	(42,746)	(138,924)	85,492	138,924		
Repurchase of common shares			(384,615)	(4,999,995)		(4,999,995)
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price			102,949	479,688		479,688
Net and comprehensive income					4,766,249	4,766,249
Balance, December 31, 2008	812,749	2,604,070	9,903,047	13,500,034	1,450,711	17,554,815
Initial public offering of common stock, net of offering costs			5,000,000	74,801,596		74,801,596
Stock-based compensation employee stock option grants				606,395		606,395
Issuance of common stock for services received			20,250	338,240		338,240
Stock-based compensation nonemployee stock option grants				845,661		845,661
Conversion of preferred stock into common stock	(812,749)	(2,604,070)	1,625,498	2,604,070		
Repurchase of common shares			(4,018)	(52,234)		(52,234)
Issuance of common stock				97,575		97,575

warrants						
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price and statutory tax withholdings		3,635,709	(23,099,591)			(23,099,591)
Net and comprehensive income				3,091,415	(32,536)	3,058,879
Reclass of redeemable common stock			(1,930,000)			(1,930,000)
Balance, December 31, 2009	$	20,180,486	$ 67,711,746	$ 4,542,126	$ (32,536)	$ 72,221,336

See accompanying notes to consolidated financial statements.

Table of Contents

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. These losses amounted to approximately $272,000 and $171,000 for the years ended December 31, 2008 and 2007, respectively. 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 2009, approximately $33,000 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. Previously, this sales force was 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 $0.7 million, $0.6 million and $0.9 million for the years ended December 31, 2009, 2008 and 2007, 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.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(b) Cash and Cash Equivalents

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

(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 balances for collectibility. The allowance for uncollectible amounts, cash discounts, chargebacks and credits for damaged product was approximately $0.2 million and $0.1 million as of December 31, 2009 and 2008, respectively.

Cash 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. The Company s inventory was comprised completely of finished goods at December 31, 2009 and 2008. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method.

(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 has recognized an income tax receivable of approximately $1.4 million at December 31, 2009 related to the utilization of net operating losses that will be carried back to recover income taxes that were paid in prior years.

(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

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

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 includes 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 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, 2009.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(i) Costs of Initial Public Offering

Incremental costs directly attributable to the initial public offering of the Company s common stock of approximately $4.2 million were recognized as a reduction of the proceeds received from the offering. In addition to the incremental costs directly attributable to the initial public offering, the Company incurred approximately $6.0 million of underwriting costs. These costs were recognized as a reduction of the proceeds received from the offering. At December 31, 2008, approximately $3.3 million of the offering costs were deferred and included in other assets in the consolidated balance sheet.

(j) 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 and $0.1 million as of December 31, 2009 and 2008, respectively, for chargebacks, discounts and allowances for product damaged in shipment are recorded as a reduction of accounts receivable, and liabilities of $1.9 million and $1.0 million as of December 31, 2009 and 2008, 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, including fee for service costs. These costs have been netted against product revenues.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

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

	Net product revenue		
	2009	**2008**	**2007**
Acetadote	$ 30,176,981	$ 25,438,774	$ 18,817,293
Kristalose	9,688,998	9,468,562	9,012,789
Caldolor[(1)]	3,276,371		
Other		(17,369)	(8,436)
	$ 43,142,350	$ 34,889,967	$ 27,821,646

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

Other revenue is primarily 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 totaled approximately $228,000, $7,000 and $83,000 for the years ended December 31, 2009, 2008 and 2007, respectively.

(k) 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 non-qualified 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.

(l) 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-Scholes option-pricing model, and the expense is recognized over the employee s requisite service period. Restricted stock awards are measured using 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.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(m) 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.

(n) Advertising Costs

Advertising costs are expensed as incurred and amounted to $1.4 million, $0.7 million and $0.6 million in 2009, 2008 and 2007, respectively.

(o) Distribution Costs

The Company expenses distribution costs as incurred. Distribution costs included in selling and marketing expenses amounted to $1.1 million, $1.0 million and $0.8 million in 2009, 2008 and 2007, respectively.

(p) 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.

(q) 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.

(r) 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 conversion of convertible instruments, the vesting of unvested restricted stock and the 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,		
	2009	**2008**	**2007**
Numerator:			
Net income attributable to common shareholders	$ 3,091,415	$ 4,766,249	$ 4,044,386
Denominator:			
Weighted-average shares outstanding basic	14,199,479	10,142,807	10,032,083
Convertible preferred stock shares	986,840	1,710,990	1,710,990
Dilutive effect of other securities	3,047,852	4,685,865	4,838,829

Weighted-average shares outstanding	diluted	18,234,171	16,539,662	16,581,902

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

The calculation of diluted earnings per share excludes 246,332, 206,670 and 144,002 outstanding options and warrants as of December 31, 2009, 2008 and 2007, respectively, because the effect would be antidilutive.

(s) Comprehensive Income

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

(t) 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.

(u) 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, long-term debt, and other long-term obligations. 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. The current portion of other long-term liabilities is primarily related to the milestone payments due to a third party as a result of the FDA approval of Caldolor in June 2009, and approximates fair value due to its short-term nature. The long-term portion of other long-term liabilities is primarily related to the difference between the straight-line rent expense recognized during the course of the operating leases and the amount paid to the lessor, and is not subject to changes in fair value.

(v) Recently Issued Accounting Standards

In October 2009, the 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 the Company 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 transactions covered by this standard. This standard would not have materially impacted the consolidated financial statements as of December 31, 2009.

(w) Subsequent Events

The Company has evaluated events occurring subsequent to December 31, 2009 for accounting and disclosure implications. See additional discussion at footnote 17.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(3) Property and Equipment

Property and equipment consisted of the following at December 31:

	Range of useful lives	2009	2008
Computer hardware and software	3 5 years	$ 343,494	$ 162,515
Office equipment	3 15 years	62,447	30,276
Furniture and fixtures	5 15 years	364,158	242,591
Leasehold improvements	3 15 years, or remaining lease term	607,444	331,557
		1,377,543	766,939
Less accumulated depreciation and amortization		(459,131)	(334,526)
		$ 918,412	$ 432,413

Depreciation expense, including amortization expense related to leasehold improvements, during 2009, 2008 and 2007 was approximately $125,000, $95,000 and $71,000, 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:

	2009	2008
Trademarks	$ 9,020	$ 46,986
Less accumulated amortization	(7,396)	(40,371)
Total trademarks	1,624	6,615
License	10,303,595	10,303,595
Less accumulated amortization	(2,575,895)	(1,888,990)
Total license	7,727,700	8,414,605
Patents	226,685	107,512
	$ 7,956,009	$ 8,528,732

Amortization expense related to trademarks and license rights totaled approximately $0.7 million in 2009, 2008 and 2007, and is expected to be approximately $0.7 million in each of the years 2010 through 2014.

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, 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.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(5) Other Accrued Liabilities

Other accrued liabilities consisted of the following at December 31:

	2009	2008
Rebates, fee for services, and product returns	$ 1,863,012	$ 1,040,204
Employee wages and benefits	919,913	707,638
Costs related to initial public offering		196,746
Outside sales force and related expenses	192,711	181,140
Other	809,141	515,127
	$ 3,784,777	$ 2,640,855

(6) Long-Term Debt

In April 2006, the Company completed its transaction with Inalco to acquire exclusive U.S. commercialization rights for Kristalose. In order to complete this transaction, funding was obtained from Bank of America in the form of a three-year term loan for $5.5 million and a two-year revolving line of credit agreement, both with an interest rate of LIBOR plus 2.5%. The term loan was due in 2009, and was being paid off in quarterly principal installments of $458,334, plus interest. In April 2008, the Company amended its revolving line of credit agreement to extend the maturity date to April 2009. In conjunction with the agreement, the Company issued warrants to purchase up to 3,958 shares of common stock at an exercise price of $9.00 per share, which expire in April 2016 and are outstanding and exercisable as of December 31, 2009. The estimated grant-date fair value of these warrants of $25,680, as determined using the Black-Scholes model utilizing an expected term of 10 years, risk-free interest rate of 4.89%, volatility of 60%, and 0% dividend yield, was recorded as equity and deferred financing costs. Deferred financing costs were being expensed to interest expense using the effective-interest method over the respective terms of the line of credit and term note.

On December 30, 2008, the Company amended its debt agreement (Third Amended and Restated Loan Agreement) to provide for $5.0 million of term debt and up to $7.5 million under its revolving line of credit, both with an interest rate of LIBOR plus an applicable margin based on the Company s Leverage Ratio, as defined in the agreement. This agreement expires in December 2011. The term loan was being paid off in quarterly installments of $416,667, plus interest, beginning April 2009. The credit agreement provided that borrowings are collateralized by a first priority lien on all of the Company s assets. The credit agreement contains an adverse subjective acceleration clause and also requires the Company to maintain bank accounts and a lockbox at the lender. However, cash received in the lockbox is not required to be applied against amounts borrowed under the line of credit. This credit agreement contains various covenants and the Company was in compliance with all covenants at December 31, 2008.

In July 2009, the Company amended its debt agreement (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 must pay a commitment fee of 0.75% per annum on the unused portion of the commitment. The term debt is payable in quarterly installments of $1.5 million beginning on March 31, 2010 and continuing until December 31, 2012. The revolving credit facility is 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 are 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,

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

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 are being expensed to interest expense using the effective-interest method over the term of the debt agreement.

The Fourth Amended and Restated Loan Agreement contains restrictive covenants, including: maintaining a Leverage Ratio not exceeding 2.75 to 1.00 as of December 31, 2009 and decreasing to 1.00 to 1.00 as of December 31, 2011; maintaining a Fixed Charge Coverage Ratio of at least 1.25 to 1.00; maintaining liquidity of at least $2.0 million as of the end of a quarter/annual period; limiting capital expenditures during any fiscal year; maintaining adequate insurance; and prohibiting the payment of dividends on common stock. The Company was in compliance with all covenants as of December 31, 2009.

The Fourth Amended and Restated Loan Agreement requires 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. As of December 31, 2009, the additional principal payment was $3.1 million, and is included as a current portion of long-term debt in the consolidated balance sheet. The scheduled debt payments, including the additional principal payment, are as follows:

Year ending December 31:	
2010	$ 9,061,973
2011	6,000,000
2012	4,763,978
	$ 19,825,951

(7) Other Long-Term Obligations

Other long-term obligations consisted of the following components at December 31:

	2009	2008
Third-party development costs	$ 101,369	$ 615,846
Other	228,091	224,556
	329,460	840,402
Less current portion	(144,828)	(457,915)
	$ 184,632	$ 382,487

During 2000, the Company signed an agreement with a third party to cover a variety of development efforts related to Caldolor, an injectable form of ibuprofen, including preparation of submissions to the FDA. As of December 31, 2008, the remaining balance of approximately $0.4 million was included in the current portion of other long-term liabilities in the consolidated balance sheet. During 2009, the Company paid the remaining balance.

In June 2009, the Company received marketing approval for Caldolor from the FDA. The approval triggered a milestone obligation of approximately $1.0 million to a third party who assisted in a variety of development efforts related to Caldolor and is payable as follows: approximately $0.8 million was paid in the third quarter of 2009 and the remaining $0.2 million is payable in equal monthly installments through July 2010. The remaining balance of $0.1 million at December 31, 2009 is included in the current portion of other long-term obligations in the consolidated balance sheet. The milestone expense is included in research and development expenses in the consolidated statement of income for the year ended December 31, 2009.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

In addition to the milestone obligation discussed above, the third party immediately vested in performance-based options to acquire 60,000 common shares with an exercise price of $1.63 per share. The Company calculated the fair value of this award to be $13.41 per share using the Black-Scholes methodology and the following assumptions: expected term of 2.3 years, risk-free interest rate of 1.1%, volatility of 51% and an expected dividend yield of 0%. For the year ended December 31, 2009, the Company recognized approximately $0.8 million of research and development expense associated with this award.

(8) Income Taxes

Income tax benefit (expense) includes the following components:

	2009	2008	2007
Current:			
Federal	$ (2,240,827)	$ (1,593,865)	$ (543,115)
State	(308,832)	(266,172)	(100,078)
	(2,549,659)	(1,860,037)	(643,193)
Deferred:			
Federal	528,602	(571,114)	(1,646,209)
State	(3,135)	(112,800)	(134,859)
	525,467	(683,914)	(1,781,068)
	$ (2,024,192)	$ (2,543,951)	$ (2,424,261)

The Company s deferred tax expense in 2007 was primarily the result of the utilization of the deferred tax assets from federal and state net operating loss carryforwards. The deferred tax expense for 2008 was primarily due to the utilization of deferred tax assets from federal tax credit carryforwards. The deferred tax benefit for 2009 was primarily due to the expense for non-qualified stock options issued to employees.

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

	2009	2008	2007
Deferred tax benefit (expense) exclusive of components listed below	$ 170,648	$ 158,864	$ 458,806
Utilization of operating loss carryforwards	(60,266)	(248,651)	(2,002,955)
Utilization of tax credit carryforwards	7,172	(626,956)	(191,191)
Change in valuation allowance due to changes in net deferred tax asset balances	(11,342)	(11,291)	(7,867)
Benefits of non-qualified stock options	419,255	44,120	(37,861)
Deferred income tax benefit (expense)	$ 525,467	$ (683,914)	$ (1,781,068)

The valuation allowance at December 31, 2009 and 2008 is primarily related to state tax benefits at CET that will likely not be realized.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

The Company s effective income tax rate for 2009, 2008 and 2007 reconciles with the federal statutory tax rate as follows:

	2009	2008	2007
Federal tax expense at statutory rate	34%	34%	34%
State income tax benefit (net of federal income tax benefit)	4	4	3
Permanent differences	3	2	1
Recognition of previously unrecognized tax benefits		(4)	
Other	(1)	(1)	(1)
Net income tax expense	40%	35%	37%

Components of the net deferred tax assets at December 31 are as follows:

	2009	2008
Net operating loss and tax credits	$ 72,532	$ 125,626
Property and equipment	169,852	123,227
Allowance for accounts receivable	89,160	55,425
Reserve for expired product	386,669	239,790
Inventory	80,462	
Deferred charges	257,413	394,467
Cumulative compensation costs incurred on nonqualified options	1,046,734	627,478
Total deferred tax assets	2,102,822	1,566,013
Less deferred tax asset valuation allowance	(70,112)	(58,770)
Net deferred tax assets	$ 2,032,710	$ 1,507,243

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. In order to fully realize the deferred tax assets, the Company will need to generate future taxable income of approximately $5.4 million. Taxable income, excluding tax deductions generated by the exercise of nonqualified options, for the years ended December 31, 2009, 2008 and 2007 was approximately $7.0 million, $7.9 million and $7.1 million, respectively. Based upon the level of taxable income over the last three years and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will realize the benefits of these deductible differences, net of the existing valuation allowances, at December 31, 2009. The amount of the deferred tax assets considered realizable, however, could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

At December 31, 2009, the Company has $65.5 million of federal net operating loss carryforwards that expire in 2029. All of the federal net operating loss originated from the exercise of nonqualified options in 2009. As of December 31, 2009, the Company has unrecognized tax benefits associated with the exercise of nonqualified stock options of approximately $26.1 million. The benefit will be recognized when the deduction reduces income taxes payable in future periods.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

At December 31, 2009, the Company has $59.7 million of state net operating loss carryforwards. This amount includes $58.2 million from the exercise of nonqualified stock options in 2009, of which $3.2 million will expire in 2014. The remaining carryforwards begin to expire in 2018. The remaining state net operating loss carryforward of $1.5 million is subject to a full valuation allowance. Approximately $0.5 million of these state net operating losses are set to expire between 2015 and 2017. The remaining state net operating losses will begin expiring in 2018.

Federal tax years that remain open to examination are 2007 to 2009. State tax years that remain open to examination are 2004 to 2009. The Company is currently undergoing an examination by the Internal Revenue Service of its 2007 and 2008 federal tax returns.

(9) Shareholders Equity

(a) Initial Public Offering

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

(b) Stock Split

On July 6, 2007, the Board of Directors declared a two-for-one stock split of the Company s common stock effective on that date. All applicable common stock share and per share amounts have been retroactively adjusted in the accompanying consolidated financial statements for the stock split. In accordance with the anti-dilution provisions of the respective agreements, the share and per share amounts associated with the Company s stock option grants, warrants and preferred stock conversion rights reflected in the accompanying consolidated financial statements have also been adjusted to reflect the effects of the stock split.

(c) Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock. The Board of Directors is authorized to divide these shares into classes or series, and to fix and determine the relative rights, preferences, qualifications and limitations of the shares of any class or series so established. At December 31, 2009, there is no preferred stock outstanding.

(d) Common Stock

During 2009, 2008 and 2007, the Company issued 2,750, 7,961 and 25,236 shares of common stock, respectively, valued at $39,750, $107,000 and $223,000, respectively, to executives, related parties, and advisors as compensation for services, and is included in general and administrative expenses in the consolidated statements of income. Included in these amounts are shares of common stock granted to board members of 0, 3,461 and 11,036 in 2009, 2008 and 2007, respectively, for services rendered. The expense associated with these grants to board members was approximately $0, $45,000 and $121,000 in 2009, 2008 and 2007, respectively. In addition, the Company issued 2,924,202, 87,142 and 10,304 net shares of common stock to a key executive and an advisor upon exercise of options in 2009, 2008 and 2007, respectively.

In April 2007, the shareholders approved an amendment to the Company s charter, which increased the number of authorized shares to 100,000,000.

Table of Contents

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

(e) Warrants

In 2003, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of $6.00 per share as partial consideration for a modification to its line of credit. The warrants expire 10 years from the date of issuance. All of these warrants were outstanding and exercisable as of December 31, 2009.

In connection with the issuance of shares of stock to a related party in 2004, the Company issued warrants to purchase 40,000 shares of stock at $6.00 per share at any time within ten years of issuance. All of these warrants were outstanding and exercisable as of December 31, 2009.

In 2006, the Company signed a new line of credit agreement along with a term loan agreement with a financial institution. In conjunction with these agreements, the Company issued warrants to purchase up to 3,958 shares of common stock at $9.00 per share, which expire in April 2016, and which are outstanding and exercisable as of December 31, 2009. In connection with the Fourth Amended and Restated Loan Agreement, the Company issued warrants to purchase up to 7,500 shares of common stock at $17.00 per share, which expire in July 2019. The fair value of these warrants of $97,575, as determined using the Black-Scholes methodology and utilizing an expected term of 10 years, risk-free interest rate of 4.0%, volatility of 67% and an expected dividend yield of 0%, was recorded in the consolidated balance sheet as equity and deferred financing costs.

(f) Share Repurchase

On December 12, 2008, the Board of Directors authorized the Company to repurchase up to 384,615 shares of common stock at $13.00 per share. On December 30, 2008, the Company completed its $5.0 million repurchase of common stock. In connection with the repurchase, 42,746 shares of preferred stock were converted into 85,492 shares of common stock. The repurchase was financed, in part, by additional borrowings under its term debt with Bank of America.

(10) Stock Options

The Cumberland Pharmaceuticals Inc. 1999 Stock Option Plan (the 1999 Plan), which allowed for both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, directors and affiliates of the Company, was superseded and replaced by the 2007 Long-Term Incentive Compensation Plan (the 2007 Plan) and 2007 Directors Incentive Plan (the Directors Plan). The new plans were approved by the Company s Board of Directors and shareholders in April 2007. The implementation of the new plans did not result in a modification of the terms and conditions of the outstanding awards granted under the 1999 Plan that would result in the awards being treated as an exchange of the original award for a new award.

The purposes of the 2007 Plan are to encourage the Company s employees and consultants to acquire stock and other equity-based interests and to replace the 1999 Plan. The Company has reserved 2.4 million shares of common stock for issuance under the 2007 Plan.

The purposes of the Directors Plan are to strengthen the Company s ability to attract, motivate, and retain Directors with experience and ability, and to encourage the highest level of performance by providing Directors with a proprietary interest in the Company s financial success and growth. The Directors Plan supersedes and replaces the provisions pertaining to grants of stock options to Directors in the 1999 Plan, but does not impair the vesting or exercise of any options granted under the 1999 Plan. The Company has reserved 250,000 shares of common stock under the Directors Plan.

Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. Options granted to shareholders owning more than 10% of the common stock on the grant

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

date must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date.

The options are exercisable on the dates established by each grant; however, options granted to officers or directors are not exercisable until at least six months after grant date. The maximum exercise life of an option is ten years from grant date and is five years for stock options issued to shareholders who own 10% or more of the Company s common stock. Vesting is determined on a grant-by-grant basis in accordance with the terms of the plans and the related grant agreements. Upon exercise, the Company issues new shares of common stock.

Stock option activity for the year ended December 31, 2009 was as follows:

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding, December 31, 2008	7,910,986	$ 1.65		
Options granted	146,430	13.48		
Options exercised	(5,460,918)	0.55		
Options forfeited/expired	(86,913)	3.42		
Outstanding, December 31, 2009	2,509,585	4.65	3.31	$ 22,497,039
Exercisable at December 31, 2009	2,336,148	$ 4.02	2.94	$ 22,389,117

Information related to the stock option plans during 2009, 2008 and 2007 was as follows:

	2009	2008	2007
Intrinsic value of options exercised	$ 86,155,328	$ 1,162,796	$ 1,929,259
Weighted-average fair value of options granted	$ 6.42	$ 6.27	$ 7.21

Of the options outstanding at December 31, 2009, 2008 and 2007, 86,930, 4,795,420 and 4,771,420, respectively, were options issued to a key executive.

The fair value of employee options granted during 2009, 2008, and 2007 were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2009	2008	2007
Dividend yield			
Expected term (years)	3.7 6.2	3.5 6.0	5.5 6.4
Expected volatility	50% 52%	49% 51%	58% 64%
Risk-free interest rate	1.4% 2.7%	3.1%	4.6% 4.8%

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

The fair value of nonemployee options granted during 2009, 2008, and 2007 were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2009	2008	2007
Dividend yield			
Expected term (years)	2.3 10.0	10.0	10.0
Expected volatility	51% 67%	68%	74%
Risk-free interest rate	1.1% 2.7%	3.7%	4.8%

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

Stock compensation expense is presented as a component of general and administrative expenses in the accompanying consolidated statements of income. At December 31, 2009, there was approximately $1.1 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted-average period of 2.39 years. This amount relates primarily to unrecognized compensation cost for employees.

In January 2009, options to purchase 773,556 shares of common stock were exercised with a weighted-average exercise price of $0.11 per share. A portion of the options were exercised using a net-share settlement feature that provided for an option holder to use 204,245 shares acquired upon exercise to settle the minimum statutory tax withholding requirements of approximately $2.7 million.

During the third quarter of 2009, options to purchase 4,605,962 shares of common stock were exercised with a weighted-average exercise price of $0.55 per share. A portion of the options were exercised using a net-share settlement feature that provided for an option holder to use 1,445,074 shares acquired upon exercise to settle the minimum statutory tax withholding requirements of approximately $24.6 million. The payment of the exercise price for these options of approximately $2.6 million was settled by cash and the tendering of 140,788 shares of common stock by the optionees.

In connection with these exercises, the Company agreed to repurchase up to $1.9 million in common stock during the first quarter of 2010 to provide for the settlement of the remaining tax liabilities associated with the exercise. The estimated repurchase amount is presented as redeemable common stock in the condensed consolidated balance sheet.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(11) Leases

The Company is obligated under long-term real estate leases for office space expiring at various times through July 2011. The Company also subleases a portion of the space under these leases. Rent expense is recognized over the expected term of the lease, including renewal option periods, if applicable, on a straight-line basis. Rent expense for 2009, 2008 and 2007 was approximately $575,000, $526,000 and $388,000, respectively, and sublease income was approximately $203,000, $170,000 and $77,000, respectively. Future minimum lease payments under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are:

Year ending December 31:	
2010	559,113
2011	137,781
2012	93,481
2013	96,288
2014 and thereafter	201,315
Total minimum lease payments	$ 1,087,978

(12) Manufacturing and Supply Agreements

The Company utilizes one primary supplier to manufacture each of its respective products and product candidates. In February 2008, the Company entered into an agreement with a second supplier of Acetadote. The agreement for the second supplier expires in February 2013. Although there are a limited number of manufacturers of pharmaceutical products, the Company believes it could utilize other suppliers to manufacture its prescription products on comparable terms. A change in suppliers, any problems with such manufacturing operations or capacity, or contract disputes with the suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

The Company s manufacturing and supply agreements with the manufacturers of some of its products contain minimum purchase obligations. These obligations require the Company to purchase approximately $0.5 million during 2010, $0.1 million during 2011 and $17,000 during 2012. Beginning in January 2013 and continuing through the life of the agreement, which expires in 2021, one of the manufacturing and supply agreements requires minimum purchases of not less than 25% of prior year purchases. The Company met its purchase obligations for 2009 under these agreements.

(13) Commitments and Contingencies

The Company outsources some of its sales force activities through an agreement with a third party. Under the terms of the agreement, the Company makes monthly payments to the third party of approximately $393,000 for these activities. The agreement expires on March 31, 2010. Should the Company not continue to receive these services from this third party, the Company would have to consider an alternative source such as another service organization or hiring an internal sales force.

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

(14) Employment Agreements

The Company has entered into employment agreements with its full-time and part-time employees. Each employment agreement provides for a salary for services performed, a potential annual bonus and, if applicable, a grant of incentive options to purchase the Company s common shares pursuant to an option agreement. Two of the employment agreements

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

address expense reimbursements for relevant and applicable licenses and continuing education. Employment agreements are amended each successive one-year period, unless terminated.

(15) Market Concentrations

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

The Company s primary customers are wholesale pharmaceutical distributors in the U.S. Total revenues from customers representing 10% or more of total revenues for the respective years are summarized as follows:

	2009	2008	2007
Customer 1	37%	37%	35%
Customer 2	29	25	26
Customer 3	27	31	31

Additionally, 96% and 93% of the Company s accounts receivable balances were due from these three customers at December 31, 2009 and 2008, respectively.

(16) Employee Benefit Plan

The Company sponsors an employee benefit plan that was established on January 1, 2006, the Cumberland Pharmaceuticals 401(k) Plan (the Plan), under Section 401(k) of the Internal Revenue Code of 1986, as amended, for the benefit of all employees over the age of 21, having been employed by the Company for at least six months. The Plan provides that participants may contribute up to the maximum amount of their compensation as set forth by the Internal Revenue Service each year. Employee contributions are invested in various investment funds based upon elections made by the employees. In 2008, the Company s Board of Directors adopted a plan to match 20% of the first 5% of participant s annual deferrals to the Plan. During 2009, the Company contributed $13,800 to the Plan.

(17) Subsequent Events

In January 2010, an executive exercised a put right to sell $1.8 million, or 153,543 shares, of common stock to the Company to provide for the settlement of the remaining tax liabilities associated with the exercise of options in 2009. The purchase price was the fair-market value of the common stock as reported by Nasdaq on the date of settlement.

Table of Contents

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

(18) Quarter Financial Information (Unaudited)

The following table sets forth the unaudited operating results for each fiscal quarter of 2009 and 2008:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2009					
Net revenues	$ 9,404,599	$ 9,820,613	$ 13,597,760(2)	$ 10,714,306	$ 43,537,278
Operating income	2,117,025	594,116	2,372,059	693,435	5,776,635
Net income attributable to common shareholders	1,218,090	295,871	1,288,137	289,317	3,091,415
Earnings per share attributable to common shareholders (1)					
- Basic	$ 0.12	$ 0.03	$ 0.08	$ 0.01	$ 0.22
- Diluted	$ 0.08	$ 0.02	$ 0.07	$ 0.01	$ 0.17
2008					
Net revenues	$ 8,303,827	$ 8,357,532	$ 8,602,709	$ 9,811,092	$ 35,075,160
Operating income	1,793,539	1,838,488	2,150,508	1,499,686	7,282,221
Net income attributable to common shareholders	1,395,250	1,058,423	1,209,009	1,103,567	4,766,249
Earnings per share attributable to common shareholders (1)					
- Basic	$ 0.14	$ 0.10	$ 0.12	$ 0.11	$ 0.47
- Diluted	$ 0.09	$ 0.07	$ 0.07	$ 0.07	$ 0.29

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

(2) Includes $3.3 million of net revenue associated with the launch of Caldolor in September 2009.

Table of Contents

Schedule II

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Valuation and Qualifying Accounts

Years ended December 31, 2009, 2008 and 2007

Description	Column A Balance at beginning of period	Column B Charged to costs and expenses	Column C Charged to other accounts describe	Column D Deductions describe [1]	Column E Balance at end of period
Allowance for uncollectible amounts, cash discounts, chargebacks, and credits issued for damaged products:					
For the period ended:					
December 31, 2007	$ 298,913	$ 1,184,711	$	$ (1,336,652)	$ 146,972
December 31, 2008	146,972	1,242,300		(1,242,226)	147,046
December 31, 2009	147,046	1,734,521		(1,646,287)	235,280
Valuation allowance for deferred tax assets:					
For the period ended:					
December 31, 2007	$ 39,612	$ 7,867	$	$	$ 47,479
December 31, 2008	47,479	11,291			58,770
December 31, 2009	58,770	11,342			70,112

(1) Actual discounts, chargebacks, and credits taken by customers.