CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 12, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

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Form 10-K
(Mark One)

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012
or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to _____

Commission file number 001-33637

_____

CUMBERLAND PHARMACEUTICALS INC.
(Exact Name of Registrant as Specified in Its Charter)

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

2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
(Address of Principal Executive Offices) (Zip Code)
(615) 255-0068
(Registrant's telephone number, including area code)

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

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

_____

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

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer ý

Non-accelerated filer ¨ (Do not check if smaller reporting company) Smaller reporting company ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.) Yes ¨ No ý
The aggregate market value of common stock held by non-affiliates as of June 30, 2012 was $62,366,000. The number of shares of the registrant's Common Stock, no par value, outstanding as of March 1, 2013 was 18,717,786.
DOCUMENTS INCORPORATED BY REFERENCE
Certain information required in Part III of Form 10-K is incorporated by reference from the registrant's Proxy Statement for its 2013 annual meeting of shareholders.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
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PART I

Item 1. Business.

THE COMPANY

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

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

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

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

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

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

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our website address is www.cumberlandpharma.com. We make available through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all other press releases, filings and amendments to those reports as soon as reasonably practicable after their filing with the U.S. Securities and Exchange Commission, or SEC. These filings are also available to the public at www.sec.gov.

PRODUCTS

Our key products include:

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

Acetadote

Acetadote is an intravenous formulation of N-acetylcysteine, or NAC, indicated for the treatment of acetaminophen poisoning. Acetadote, which has been available in the United States since Cumberland's 2004 introduction of the product, is currently used in hospital emergency departments to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter and prescription pain relief and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

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

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

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

Supplemental New Drug Application for Acetadote

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

Caldolor

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

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

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

Kristalose

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

In November 2011, through a series of transactions, we entered into an agreement with Mylan Inc. to acquire certain assets associated with the Kristalose brand including the Kristalose trademark and the FDA registration. We also entered into a long-term supply agreement for the product. By entering into these transactions, we streamlined the supply chain for the product and are exploring opportunities to further develop the product.

Hepatoren

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

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

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

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OUR STRATEGY

Continue to build a high-performance sales organization to address our target markets

We believe that our commercial infrastructure can help drive prescription volume and product sales. We currently utilize two distinct sales teams to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the gastroenterology market.

Hospital market: We promote Acetadote and Caldolor through our dedicated hospital sales team. This team targets key hospitals across the U.S., and is comprised of sales professionals with substantial experience in the hospital market. According to IMS Health, U.S. hospitals accounted for approximately $28 billion, or 9%, of U.S. pharmaceutical sales in 2011. However, IMS also reports that only 2% of approximately $23 billion total pharmaceutical industry promotional spending was focused on hospital-use drugs in 2011. The majority of promotional spending is directed toward large, outpatient markets on drugs intended for chronic use rather than short-term, hospital use. We believe the hospital market is underserved and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity.

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

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

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

Expand our global presence through select international partnerships

We have established our own commercial capabilities, including a sales organization to cover the U.S. market for our products. We are also building a network of select international partners to register our products and make them available to patients in their countries.

Develop a pipeline of early-stage products through CET

In order to build our product pipeline, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities of CET, our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland has the opportunity to negotiate rights to further develop and commercialize them.

CLINICAL DEVELOPMENT OVERVIEW

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

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

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

The second of two registry studies was a phase IV multi-center, open-label, single or multiple-dose surveillance clinical study to assess the safety of ibuprofen administered intravenously over five to ten minutes to adult hospitalized patients undergoing surgical procedures. Eligible patients were enrolled to receive 800 mg intravenous ibuprofen administered at induction of anesthesia. 300 patients from 21 clinical sites were enrolled in this study. The shortened infusion time was well tolerated.

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

Phase IV Required Pediatric Assessment

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

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

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

No additional Phase IV commitments were required by the FDA.

Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated intravenous ibuprofen safety database combining data from our clinical trials as well as previously published study data. We used this data to support our NDA filing and will continue to use and update the data as a part of our ongoing safety evaluation. In addition, this data will be used by our sales force and in our marketing materials to promote Caldolor.

In clinical trials supporting our proposed indications, the number and percentage of all patients in pivotal studies who reported treatment emergent adverse events was comparable between IV ibuprofen and placebo treatment groups. Additionally, there have been no safety related differences between Caldolor and placebo involving side effects sometimes observed with oral Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), such as changes in renal function, bleeding events or gastrointestinal disorders.

BUSINESS DEVELOPMENT

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

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

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

Through CET, we are collaborating with a select group of academic research institutions located in the mid-south region of the U.S. Our business development team is responsible for identifying appropriate CET product candidates and negotiating with our university partners to secure rights to these candidates. Although we believe that these collaborations may be important to our business in the future, they are not material to our business at this time.

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

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

CLINICAL AND REGULATORY AFFAIRS

We have in-house capabilities for the management of our clinical, professional and regulatory affairs. Our team develops and manages our clinical trials, prepares regulatory submissions, manages ongoing product-related regulatory responsibilities and manages our medical information call center. Team members have been responsible for devising the regulatory and clinical strategies and obtaining FDA approvals for Acetadote and Caldolor.

Clinical development

Our clinical development personnel are responsible for:

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

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- preparing and submitting INDs for clearance to begin patient studies;
- preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- maintaining investigational and marketing applications through the submission of appropriate reports;
- submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;

- monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices ("GCP"), and performing periodic audits of such vendors; and
- maintaining systems for document control, product and process change control, customer complaint handling, product stability studies and annual drug product reviews.

PROFESSIONAL AND MEDICAL AFFAIRS

Our medical team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. Prior to the launch of Caldolor, we expanded our medical affairs staff to support inquiries from medical professionals regarding the appropriate use of Caldolor as well as to support the efforts of our expanded hospital sales force. In addition to coordinating the call center, our clinical/regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including more than 65 sales representatives and district managers, direct our national marketing campaigns and maintain key national account relationships. In January 2007, we converted our hospital sales force, which had previously been contracted to us by Cardinal Health Inc., to Cumberland employees through our wholly-owned subsidiary, Cumberland Pharma Sales Corp.

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

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

INTERNATIONAL PARTNERSHIPS

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

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

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

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

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

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

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

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

MANUFACTURING AND DISTRIBUTION

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

Manufacturing

Our key manufacturing relationships include:

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

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

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

Distribution

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

TRADEMARKS, PATENTS AND PROPRIETARY RIGHTS

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

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

Acetadote and related litigation

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

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, we responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. in the United States District Court for the Northern District of Illinois, Eastern Division. The second lawsuit was filed against InnoPharma, Inc. in the United States District Court for the District of Delaware.

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The third lawsuit was also filed in the United States District Court for the District of Delaware against Paddock Laboratories, LLC (“Paddock”). By statute, where the Paragraph IV certification is to a patent timely listed before an ANDA is filed, a company has 45 days to institute a patent infringement lawsuit during which period the FDA may not approve another application. In addition, such a lawsuit for patent infringement filed within such 45-day period may stay, or bar, the FDA from approving another product application for two and a half years or until a district court decision that is adverse to the asserted patents, whichever is earlier. On May 18, 2012, we requested the aforementioned bar or stay in connection with the filing of the three lawsuits on May 17, 2012. The aforementioned bar or stay may or may not be available to us.

On May 20, 2012, we received a fourth Paragraph IV certification notice from Sagent Agila LLC challenging the Acetadote Patent. On June 26, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Sagent Agila LLC and Sagent Pharmaceuticals, Inc. in the United States District Court for the District of Delaware. On July 9, 2012, we received a Paragraph IV certification notice from Perrigo Company. On August 9, 2012, we filed a lawsuit for infringement of the Acetadote Patent against Perrigo Company (“Perrigo”) in the United States District Court for the Northern District of Illinois, Eastern Division.

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

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

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

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

On January 7, 2013, Perrigo announced initial distribution of our authorized generic acetylcysteine injection product. We intend to continue to vigorously defend and protect our Acetadote product and related intellectual property rights.

Caldolor

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

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

COMPETITION

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

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

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

Acetadote

Acetadote is our injectable formulation of NAC for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC including, but not limited to, Geneva Pharmaceuticals, Inc., Bedford Laboratories division of Ben Venue Laboratories, Inc., Roxane Laboratories, Inc., InnoPharma Inc., and Hospira Inc.

In November 2012, InnoPharma Inc. was granted approval by the FDA to distribute their generic form of the old formulation of the Acetadote containing EDTA. In late 2012, we entered into a settlement agreement with Paddock Laboratories and the Perrigo Company that included the right to distribute our authorized generic Acetadote injection product.

Caldolor

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

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

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

We are aware of other product candidates in development to treat acute pain including injectable NSAIDs, novel opioids, new formulations of existing therapies and extended release anesthetics. We believe non-narcotic analgesics for the treatment of post-surgical pain are the primary potential competitors to Caldolor.

In addition to the injectable analgesic products above, many companies are developing analgesics for specific indications such as migraine and neuropathic pain, oral extended-release forms of existing narcotic and non-narcotic products, and products with new methods of delivery such as transdermal. We are not aware of any approved injectable products indicated for the treatment of fever in the U.S. other than Caldolor and Ofirmev. There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including ibuprofen, acetaminophen, and aspirin. These drugs are manufactured by numerous pharmaceutical companies.

Kristalose

Kristalose is a dry powder crystalline prescription formulation of lactulose indicated for the treatment of constipation. The U.S. constipation therapy market includes various prescription and over the counter, or OTC, products. The prescription products which we believe are our primary competitors are Amitiza and liquid lactuloses. Amitiza is indicated for the treatment of chronic idiopathic constipation in adults and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. Liquid lactulose products are marketed by a number of pharmaceutical companies.

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

GOVERNMENT REGULATION

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

We and our manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries.

FDA Approval Process

The FDA is a regulatory agency within the Department of Health and Human Services. A key responsibility is to regulate the safety and effectiveness of drugs sold in the United States. The FDA divides that responsibility into two phases: pre-approval (premarket) and post approval (post market). The FDA reviews manufacturers' applications to market drugs in the United States; a drug may not be sold unless it has FDA approval. The agency continues its oversight of drug safety and effectiveness as long as the drug is on the market.

To market a prescription drug in the United States, a manufacturer needs FDA approval. To get that approval, the manufacturer must demonstrate the drug's safety and effectiveness according to criteria specified in law and agency regulations, ensure that its manufacturing plant passes FDA inspection, and obtain FDA approval for the drug's labeling, a term that includes all written material about the drug, including, for example, packaging, prescribing information for physicians, and patient brochures.

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

The FDCA and associated regulations detail the requirements at each step. The FDA uses a few special mechanisms to expedite drug development and the review process when a drug might address an unmet need or a serious disease or condition. Those mechanisms include accelerated approval, animal efficacy approval, fast track applications, and priority review.

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

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

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

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Section 505(b) (2) new drug applications

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

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

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

Special protocol assessment process

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

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

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

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Orphan drug designation

The Orphan Drug Act of 1983, or Orphan Drug Act, encourages manufacturers to seek approval of products intended to treat “rare diseases and conditions” with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval. Acetadote received Orphan Drug designation in October 2001 and was approved in 2004 by the FDA to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetadote was entitled to marketing exclusivity until January 2011 for the treatment of this approved indication, and we intend to seek additional exclusivity for this product through new potential indications. This exclusivity would not prevent a product with a different formulation from competing with Acetadote.

Section 505(j) abbreviated new drug applications

An ANDA is a type of NDA where approval of a generic drug is based on demonstrating comparability to an innovator drug product (the RLD or Reference Listed Drug). Applications are "abbreviated" because they generally don't include preclinical and clinical data to establish safety and effectiveness. Generics must demonstrate that the product is bioequivalent (i.e., performs in same manner and is comparable to 'innovator' product in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use). Abbreviated applications may be submitted for drug products that are the same as a listed drug and must be identical in active ingredient(s), form, strength, route of administration, and identical in conditions of use (non-exclusive uses). Products are declared suitable based on a suitability petition to the FDA. If the petition is approved, the Sponsor may then submit the ANDA.

The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act", is a 1984 United States federal law which established the modern system of generic drugs. Hatch-Waxman amended the Federal Food, Drug, and Cosmetic Act. Section 505(j) 21 U.S.C. 355(j) sets forth the process by which would-be marketers of generic drugs can file ANDAs to seek FDA approval of the generic. Section 505(j)(2)(A)(vii)(IV), the so-called Paragraph IV, allows 180 day exclusivity to companies that are the "first-to-file" an ANDA against holders of patents for branded counterparts.

Hatch-Waxman Amendments grant generic manufacturers the ability to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Hatch-Waxman gives generics considerable leverage in patent litigation.

Recent health care legislation

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010, or HCERA, was enacted into law, which modified the revenue provisions of the PPACA. The PPACA as amended by the HCERA constitutes the healthcare reform legislation. The following highlights certain provisions of the legislation that may affect us.

Pharmaceutical Industry Fee: Beginning in calendar-year 2011, an annual fee was imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs (e.g., Medicare Part D, Medicare Part B, Medicaid, Department of Veterans Affairs programs, Department of Defense programs and TRICARE). The annual fee is allocated to companies based on their previous calendar-year market share using sales data that the government agencies that purchase the pharmaceuticals will provide to the Treasury Department. Although we participate in governmental programs that subject us to this fee, our sales volume in such programs is less than $10 million, with the first $5 million of sales being exempt from the fee. We do not anticipate this fee will have a material impact on our results of operations.

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

Federal grant funding

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

Post approval activities

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

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

The FDA continuously gathers information about possible adverse reactions to the products it has approved for use. The FDA requires all manufacturers to report adverse events. It also provides a procedure for consumers and physicians to voluntarily report their concerns about drugs. The agency collects those reports through MedWatch and uses its Adverse Event Reporting System (AERS) to store and analyze them. Because some events may occur after the use of a drug for reasons unrelated to it, the FDA reviews the events to assess which ones may indicate a drug problem. They then use information gleaned from the surveillance data to determine a course of action. They might recommend a change in drug labeling to alert users to a potential problem, or, perhaps, to require the manufacturer to study the observed association between the drug and the adverse event.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs.

Federal False Claims Act

The Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to

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set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

ICH - International Committee on Harmonization

Outside of the U.S., our ability to market our products will depend on receiving marketing authorizations from the appropriate regulatory authorities. The International Committee on Harmonization (ICH) provides a set of standards that most Regulatory Authorities adhere to (e.g. U.S., Europe, and Japan) allowing greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines. Regulatory harmonization offers many direct benefits to both regulatory authorities and the pharmaceutical industry with beneficial impact for the protection of public health.

ENVIRONMENTAL MATTERS

We are subject to federal, state and local environmental laws and regulation and we believe that our operations comply with such regulations. We anticipate that the effects of compliance with federal, state and local laws and regulations relating to the discharge of materials into the environment will not have any material effect on our capital expenditures, earnings or competitive position.

SEASONALITY

There are no significant seasonal aspects to our business.

BACKLOG

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

EMPLOYEES

As of December 31, 2012, we had approximately 106 full-time employees. We believe that our future will depend in part on our continued ability to attract, hire, and retain qualified personnel, including hospital and sale personnel in particular.

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

Item 1A. Risk Factors.

You should carefully consider the risk factors described below and throughout this report, which could materially affect our business. There are also risks that are not presently known or not presently material, as well as the other information set forth in this report that could materially affect our business. In addition, in our periodic filings with the SEC, press releases and other statements, we discuss estimates and projections regarding our future performance and business outlook. By their nature, such “forward-looking statements” involve known and unknown risks,

uncertainties and other factors that in some cases are out of our control. For a further discussion of forward-looking statements, please refer to the section entitled “Special Note Regarding Forward-Looking Statements.” These factors could cause our actual results to differ materially from our historical results or our present expectations and projections. These risk factors and uncertainties include, but are not limited to the following:

RISKS RELATED TO OUR BUSINESS

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

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

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

If demand for our products weaken, our revenues and profitability will likely decline. Known adverse effects of our marketed products are documented in product labeling, including the product package inserts, medical information disclosed to medical professionals and all marketing-related materials. At this time, no unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products. We currently market and sell three products: Caldolor, Acetadote and Kristalose. A product contamination or other safety or regulatory issues, such as a failure to meet certain FDA reporting requirements involving our products could negatively impact us and possibly lead to a product recall. In addition, changes impacting any of our products in areas such as competition, lack of market acceptance or demand, government regulation, intellectual property, reimbursement and manufacturing could have an adverse impact on our future revenues and profitability.

In 2011, the FDA issued a press announcement asking manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury. The actions the FDA is taking for prescription acetaminophen combination products do not affect over-the-counter acetaminophen products. The FDA's regulation of acetaminophen in prescription combination products and over-the-counter products may reduce the number of acetaminophen overdoses which could result in a lower demand for Acetadote. If the demand for Acetadote decreases, it could have an adverse impact on our future revenues and profitability.

Caldolor was approved by the FDA in June 2009, and we started commercializing Caldolor in the United States in September 2009. The commercial success of Caldolor is dependent on many third-parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P&T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to be administered primarily to hospitalized patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals’ formulary lists by their P&T committees. A hospital’s P&T committee generally

governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. Because Caldolor is a new drug, any mistakes made in the timely supply of Caldolor, education about how to properly administer Caldolor or any unexpected side effects that develop from use of the drug, may lead physicians to not accept Caldolor as a viable treatment alternative. The commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. We have set a price for Caldolor that we believe hospitals and other purchasers are willing to pay, but that will also generate sufficient profits. If we have set a price for Caldolor that hospitals consider too high, we may need to subsequently reduce the price for Caldolor. As with our other products, if the price for Caldolor is not accepted in the marketplace, it could have an adverse impact on our future revenues and profitability.

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

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

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

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

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

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

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

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

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

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

Competitive pressures could reduce our revenues and profits.

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

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

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

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

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

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

In addition, we have only obtained regulatory approval to market our products in the United States. In foreign jurisdictions, we have licensed the right to market some of our products to third parties. These third parties are responsible for seeking regulatory approval for the products in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for our products will be obtained outside the United States.

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

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

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

Our Hepatoren product candidate has not been approved for sale and may never be successfully commercialized.

We anticipate that a portion of our future revenue growth will come from sales of our Hepatoren product candidate. Hepatoren, which is injectable ifetroban, is a drug used to treat HRS. However, Hepatoren has not been approved by the FDA for marketing, and it is still subject to risks associated with its development.

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

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

Even if Hepatoren is eventually successfully developed and approved by the FDA, it may never gain significant acceptance in the marketplace and therefore never generate substantial revenue or profits for us. Physicians may determine that existing drugs are adequate to address patients' needs. The extent to which Hepatoren will be reimbursed by the U.S. government or third-party payors is also currently unknown.

As a result of the foregoing and other factors, we do not know the extent to which Hepatoren will contribute to our future growth.

If we are unable to maintain, train and build an effective sales and marketing infrastructure, we will not be able to commercialize and grow our products and product candidates successfully.

As we grow, we may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully market and sell our products. This risk would be accentuated if we acquire products in areas outside of hospital acute care and gastroenterology since our sales forces specialize in these areas. If we are unable to expand our sales and marketing capability, train our sales force effectively or provide any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. We must train our employees on proper regulatory compliance, including, but not limited to, “fair balance” promotion of our products and anti-kickback laws. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses, may have regulatory compliance issues and may not continue to be profitable.

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

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

In March 2010, the U.S. government passed into law and enacted the PPACAt, as amended by the HCERA, or collectively the Healthcare Reform Act. Among other provisions, the Healthcare Reform Act calls for an increase in certain Medicare drug rebates paid by pharmaceutical manufacturers and an industry fee imposed on pharmaceutical manufacturers according to the individual manufacturer’s relative percentage of total industry sales to specified government programs. At this time no assurances can be given that these measures, or any other measures included in the Healthcare Reform Act, will not have an adverse effect on our revenues in the future. Furthermore, future cost control initiatives, legislation and regulations could decrease the price that we would receive for any products, which would limit our revenue and profitability.

Also, reimbursement practices of third-party payors might preclude us from achieving market acceptance for our products or maintaining price levels sufficient to realize an appropriate return on our investment in product acquisition and development. If we cannot obtain adequate reimbursement levels, our business, financial condition and results of operations would be materially and adversely affected.

Our employees have been trained to submit accurate and correct pricing information to payors. If, despite the training, our employees provide incorrect or fraudulent information, then we will be subject to various administrative and judicial investigations and litigation.

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

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

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

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

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

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

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

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

We are a relatively small company, and we depend to a great extent on principal members of our management and scientific staff. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, it could have a material adverse effect on our business prospects. Mr. Kazimi, plays a key role in several operational and strategic decisions such that any loss of his services due to death or disability would adversely effect our day-to-day operations. We currently have a key man life insurance policy covering the life of Mr. Kazimi. We have entered into agreements with each of our employees that contain restrictive covenants relating to non-competition and non-solicitation of our customers and suppliers for one year after termination of employment. Nevertheless, each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason, and so as a practical matter these agreements do not guarantee the continued service of these employees. Our success depends on our ability to attract and retain highly qualified scientific, technical and managerial personnel and research partners. Competition among pharmaceutical companies for qualified employees is intense, and we may not be able to retain existing personnel or attract and retain qualified staff in the future. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results.

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

As of December 31, 2012, we had 106 full-time employees. We may need to continue to expand our managerial, operational, financial and other resources in order to increase our marketing efforts with regard to our currently marketed products, continue our business development and product development activities and commercialize our product candidates. We have experienced, and may continue to experience, growth and increased expenses in the scope of our operations in connection with the continued marketing and development of our products. Our financial performance will depend, in part, on our ability to manage any such growth and expenses of the current organization effectively.

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

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products. An individual may bring a liability claim against us if one of our product candidates

or products causes,

or appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

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

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

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

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

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

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

Our business and operations would suffer in the event of system failures or adverse events at our corporate headquarters.

Despite the implementation of security measures, our internal computer systems, including those at our corporate headquarters, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In the event that our corporate headquarters and/or our computer systems are disabled or materially damaged, it would have a substantial and material negative effect on our operations. Furthermore, any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our products or product candidates may be delayed.

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RISKS RELATING TO GOVERNMENT REGULATION

We are subject to stringent government regulation. All of our products face regulatory challenges.

Virtually all aspects of our business activities are regulated by government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution, promotion and sampling, advertising of our products, and disposal of waste products arising from such activities are subject to governmental regulation. These activities are regulated by one or more of the FDA, the Federal Trade Commission, or the FTC, the Consumer Product Safety Commission, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency, or the EPA, as well as by comparable agencies in foreign countries. These activities are also regulated by various agencies of the states and localities in which our products are sold. For more information, see "Business—Government Regulation.

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

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

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

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

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

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

In previous years, legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, if enacted, could decrease the price we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

RISKS RELATING TO INTELLECTUAL PROPERTY

Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited protection from competition.

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product formulation.

Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. As discussed in Part I, Item 1, Business - Trademarks, Patents and Proprietary Rights, of this Form 10-K, in April 2012, the USPTO issued the Acetadote Patent which is assigned to us and is scheduled to expire in May 2026. Following the issuance of the Acetadote Patent, we received Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC, Mylan Institutional LLC, Sagent Agila LLC and Perrigo Company challenging the Acetadote Patent. We responded by filing five separate infringement lawsuits. Further, on November 13, 2012, we brought suit against the FDA alleging that the FDA's denial of our Citizen Petition, which requested that the FDA refrain from approving any applications for acetylcysteine injection containing EDTA, and acceptance for review and approval of any InnoPharma, Inc. product containing EDTA was arbitrary and in violation of law. Although we have settled the litigation with Paddock Laboratories, LLC and Perrigo Company, the remaining lawsuits are still pending. In addition, on November 5, 2012, we received a Notice of Allowance from the USPTO for the Second Acetadote Patent, which is set to expire in August 2025. If we are unable to successfully defend the Acetadote patents and related intellectual property rights with respect to our Acetadote product, our financial condition and results of operations could be adversely affected.

Following the issuance of the Acetadote Patent, we received separate Paragraph IV certification notices from InnoPharma, Inc., Paddock Laboratories, LLC and Mylan Institutional LLC challenging the Acetadote Patent on the basis of non-infringement and/or invalidity. On May 17, 2012, we responded to the Paragraph IV certification notices by filing three separate lawsuits for infringement of the Acetadote Patent. The first lawsuit was filed against Mylan Institutional LLC and Mylan Inc. in the United States District Court for the Northern District of Illinois, Eastern Division.