CUMBERLAND PHARMACEUTICALS INC
Form 10-K
March 14, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015
of

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

2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
(615) 255-0068

Cumberland Pharmaceuticals Inc. Common Stock, no par value, shares are registered pursuant to Section 12(b) of the Act and are listed on the Nasdaq Global Select Market.

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates as of June 30, 2015 was $60,943,000. The number of shares of the registrant’s Common Stock, no par value, outstanding as of March 4, 2016 was 16,306,980.

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 2016 annual meeting of shareholders.

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Index

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 medical specialties are characterized by relatively concentrated prescriber bases that we believe can be penetrated effectively by small, targeted sales forces. Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet or poorly met medical needs. We market and sell our approved products through our hospital and gastroenterology sales forces in the United States and are establishing a network of international partners to bring our products to patients in their countries.

Our product portfolio includes:

- Acetadote® (acetylcysteine) Injection, for the treatment of acetaminophen poisoning;
- Caldolor® (ibuprofen) Injection, for the treatment of pain and fever; recently approved for use in pediatric patients
- Kristalose® (lactulose) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- Omeclamox®-Pak, (omeprazole, clarithromycin, amoxicillin) for the treatment of Helicobacter pylori (H. pylori) infection and related duodenal ulcer disease;
- Vaprisol® (conivaptan) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- Hepatoren® (ifetroban) Injection, a Phase II candidate for the treatment of critically ill hospitalized patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS"); and
- Boxaban® (ifetroban) oral capsules, a Phase II candidate for the treatment of patients with aspirin-exacerbated respiratory disease (AERD).

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

Cumberland's growth strategy involves maximizing the potential of our existing brands while continuing to build a portfolio of differentiated products. We currently market five products approved for sale in the United States. Through our international partners, we are working to bring our products to patients in countries outside the U.S. We also look for opportunities to expand our products into additional patient populations through clinical trials, new indications, and select investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products as well as late-stage development product candidates in our target medical specialties. Further, we are supplementing these activities with the pipeline drug development activities at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with universities and other research organizations to identify and develop promising, early-stage product candidates, which Cumberland has the opportunity to further develop and commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. During 2009, we completed an initial public offering of our common stock and listing on the NASDAQ exchange. Our website address is www.cumberlandpharma.com. We make available through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all other press releases, filings and amendments to those reports as soon as reasonably practicable after their filing with the U.S. Securities and Exchange Commission, ("SEC"). These filings are also available to the public at www.sec.gov.

PRODUCTS

Our key products include:

Products	Indication	Status
Acetadote®	Acetaminophen Poisoning	Marketed
Caldolor®	Pain and Fever, including pediatric patients	Marketed
Kristalose®	Chronic and Acute Constipation	Marketed
Omeclamox®-Pak	H. pylori infection and related Duodenal Ulcer disease	Marketed
Vaprisol®	Euvolemic and Hypervolemic Hyponatremia	Marketed
Hepatoren®	Hepatorenal Syndrome	Phase II
Boxaban®	Aspirin-Exacerbated Respiratory Disease	Phase II

Acetadote

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

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. Completion of our first Phase IV commitment resulted in the FDA's 2006 approval of expanded labeling for the product for use in pediatric patients. Completion of our second Phase IV commitment in 2006 resulted in further revised labeling for the product with FDA approval of additional safety data in 2008. Completion of our third and final Phase IV commitment in 2010 culminated in the FDA’s approval of a new formulation for the product. The next generation formulation, contains no ethylene diamine tetracetic acid ("EDTA") or other stabilization agent, chelating agent or preservative. In early 2011, Cumberland introduced this new Acetadote formulation replacing the original formulation which we no longer manufacture.

In June 2013, the FDA approved updated labeling for Acetadote revising the product's indication and providing new dosing guidance for specific patient populations. As a result, dosing guidance is now included for patients weighing over 100 kg and new language has been added to alert health care providers that in certain clinical situations, therapy should be extended for some patients.

Beginning in 2012, the United States Patent and Trademark Office (the "USPTO") issued us a series of patents associated with our Acetadote product. These patents are discussed in Part I, Item I, "Business - Trademarks and Patents" of this Form 10-K. On November 8, 2012, we learned that the FDA approved an abbreviated new drug

application (ANDA) filed by InnoPharma, Inc. and referencing Acetadote. That product, with the old formulation containing EDTA, was subsequently introduced by APP, a division of Fresenius Kabi USA, at the end of 2012. In early 2013, we entered into an agreement with Perrigo Company resulting in the distribution of our Authorized Generic acetylcysteine injection (the "Authorized Generic") product. Both Acetadote and our Authorized Generic utilize the new, EDTA-free formulation which accounted for continued significant market share during 2015. We are seeking additional claims to protect our intellectual property associated with Acetadote through patent applications which are pending with the USPTO.

In November 2015, an Illinois judge issued a final ruling in favor of Cumberland Pharmaceuticals Inc. in a patent case associated with Acetadote. By ruling in Cumberland's favor, the court upheld the validity of the patent which encompasses our EDTA-Free formulation and has a term until August 2025. The court also granted a permanent injunction preventing challengers from marketing a generic version of our Acetadote product before the expiration of Cumberland’s patent in August 2025.

Caldolor

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the United States for the treatment of both pain and fever. We conducted a series of clinical studies in over nine hundred adult patients to develop the data to support our submission for FDA approval. The FDA approved Caldolor for marketing in the United States during the middle portion of 2009 following a priority review. The product is indicated for use by adults and pediatric patients six months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA-approved intravenous therapy for fever. At December 31, 2015, Caldolor has been purchased by over 1,300 health care facilities in the United States.

In late 2009, we launched Caldolor and stocked the product at major wholesalers serving hospitals nationwide. We initially worked to establish a core group of medical facilities approving and purchasing the product and then focused on building more sales volume and treating a broader range of patients within those stocked facilities. We promote Caldolor in the United States through our dedicated hospital sales force.

We completed a series of Phase IV studies to gather additional data to support our Caldolor product. Those completed studies involved another 1,000 patients. The studies included evaluation of the product for the treatment of pediatric pain and pediatric fever in order to address our Phase IV commitment to the FDA for Caldolor. Also included in these studies was an evaluation of a shortened infusion time for the product and pre-surgical administration. The data from these Phase IV studies, including an updated integrated safety database, was submitted to the FDA in early 2015 with a request for updated labeling for the product. In late 2015, we received FDA approval of Caldolor for use in pediatric patients six months of age and older. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients. Caldolor’s pediatric approval came after the FDA’s review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. We also continue to pursue and evaluate potential improvements to the product’s packaging.

Kristalose

Kristalose is a prescription laxative administered orally for the treatment of acute and chronic constipation. An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient compliance and acceptance. Kristalose is the only prescription laxative available in pre-measured powder packets. Kristalose dissolves easily in four ounces of water, offering patients a virtually taste-free, grit-free and essentially calorie-free alternative to lactulose syrups. We conducted a preference study which indicated that seventy seven percent of patients surveyed prefer the taste, consistency and portability of Kristalose over similar products in syrup forms.

We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a dedicated field sales force and re-launched the product in September 2006 as a Cumberland brand. We direct our sales efforts to physicians who are the most prolific writers of prescription laxatives, including gastroenterologists and internists. Using the preference data as a cornerstone of our marketing efforts, we have made significant gains following our repositioning of the brand

3

in early 2014. The new marketing strategy includes an enhanced patient coupon program and expanded managed care coverage for the product.

In late 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. During 2014, we also entered into a long-term supply agreement and new packaging agreements for the product. By entering into these transactions, we streamlined the supply chain for the product and are exploring opportunities to further develop the brand.

Omeclamox-Pak

We launched our promotion and distribution efforts to support Omeclamox-Pak in early 2014. Our field sales force promotes Omeclamox-Pak to the gastroenterologist segment, which accounts for the largest component of the prescriber base for this product. Omeclamox-Pak is a branded prescription product used for the treatment of Helicobacter pylori (H. pylori) infection and duodenal ulcer disease. This innovative product combines three well-known and widely prescribed medications: omeprazole, clarithromycin, and amoxicillin. Omeclamox-Pak is the first FDA approved triple therapy combination medication to contain omeprazole as the proton pump inhibitor, which works to decrease the amount of acid the stomach produces. Clarithromycin and amoxicillin are both antibiotic agents which hinder the growth of H. pylori. Interaction of these agents allows the stomach lining to heal effectively. The medications are packaged together on convenient daily dosing cards, making it simple to follow the twice a day dosing before meals.

While there are competing products, Omeclamox-Pak is one of the few actively marketed products for this condition. In addition, compared to the competing branded products, Omeclamox-Pak combines the lowest pill burden and fewest days of therapy. Our involvement with Omeclamox-Pak began in October 2013, through an agreement with Pernix Therapeutics ("Pernix"). In November 2015, Cumberland entered into an exclusive license and supply agreement with Gastro-Entero Logic, LLC (“GEL”) and assumed full commercial responsibility for Omeclamox-Pak in the United States and terminated our Agreement with Pernix. Cumberland is now responsible for the supply chain, national accounts and all sales promotion of Omeclamox-Pak as part of the GEL agreement. Cumberland will also now seek a new co-promotion partner to support the product with primary care physicians.

Vaprisol

In early 2014, we entered into an agreement with Astellas Pharma US, Inc. ("Astellas") to acquire Vaprisol, including certain product rights, intellectual property and related assets. Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the only intravenously administered branded treatment.

Hyponatremia, an imbalance of serum sodium to body water, is the most common electrolyte disorder among hospitalized patients. These electrolyte disturbances occur when the sodium ion concentration in the plasma is lower than normal and are often associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia. Vaprisol raises serum sodium to appropriate levels and promotes free water secretion.

We re-launched active promotion of the brand during the middle of 2014 utilizing our hospital sales force, which also features our Caldolor and Acetadote products.

Hepatoren

In 2011, we entered into an agreement to acquire the rights to ifetroban, a new Phase II product candidate. 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.

4

We have commenced manufacturing of an intravenous formulation of ifetroban and the FDA has cleared our IND application for this product candidate. We have initiated clinical development under the brand name Hepatoren (ifetroban) Injection and are evaluating this candidate for the treatment of critically ill hospitalized patients suffering from hepatorenal syndrome ("HRS"), a life-threatening condition involving progressive kidney failure for which there is no U.S. approved pharmaceutical treatment. We would also seek orphan drug status and the associated seven years of marketing exclusivity for this indication.

Boxaban

We have also completed the manufacturing of an oral formulation of ifetroban and the FDA has cleared an IND amendment for this product candidate. We have initiated clinical development under the brand name Boxaban (ifetroban) capsules and are evaluating this candidate for patients suffering from aspirin-exacerbated respiratory disease (AERD) a condition for which there is no U.S. approved pharmaceutical treatment. Also known as Samter's Triad, AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin or nonsteroidal anti-inflammatory drugs. Approximately one in twenty asthmatic adults in the U.S. suffer from AERD and awareness of the disease is growing within the medical community.

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. We believe that active promotion of our products, supported by non-personal promotional activities developed and implemented by our marketing team, can maximize the opportunity for our brands.

Further develop our existing products and develop new late stage product candidates

We continue to evaluate our products following FDA approval to determine if further clinical work could expand the potential market opportunities for our products and help new patient populations. In addition, we may explore further clinical work that could be used to support our sales and marketing activities and maximize their efforts to further penetrate existing markets. Our clinical team is also working to develop late stage product candidates that could further expand our product portfolio if approved by the FDA.

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 brands. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that address poorly met medical needs. We plan to continue to target product acquisition candidates that are competitively differentiated, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. We will also continue to explore opportunities for label expansion to bring our products to new patient populations. The Caldolor pediatric approval reflects our successful implementation of this strategy.

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 building a network of select international partners to register our products and make them available to patients in their countries. We will continue to expand our network of international partners and continue to support our partners' registration and commercialization efforts in their respective territories. The 2015 launch of Caldolor in Australia by Seqirus is an example of our international partnerships.

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 at CET. 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 in the U.S and other markets.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including approximately 50 sales representatives and district managers, direct our national marketing campaigns and maintain key national account relationships.

Hospital market: We promote Caldolor, Vaprisol and Acetadote through our dedicated hospital sales team. This team targets key hospitals across the U.S. and is comprised of sales professionals with substantial experience in the hospital market. Outside market data continues to indicate that the majority of pharmaceutical 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 under-served and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity. Our position within the acute care market and existing hospital sales team provided the rationale for adding Vaprisol as a third acute care product. Our strategy has been to increase the focus of our hospital sales team on targeted, high priority accounts.

In November 2015 we announced a co-promotion agreement with Piramal Critical Care ("Piramal"). Through this agreement, Piramal co-promotes two of Cumberland’s branded hospital products, Caldolor and Vaprisol throughout the United States. Piramal will help expand Cumberland’s reach for these products by providing coverage to an additional group of hospitals where Piramal’s critical care sales force has existing relationships. Cumberland will maintain its promotional efforts supporting the products, continue its focus on its existing group of medical centers across the United States and continue to provide the marketing, national accounts, distribution, and medical support for the brands. The multi-year collaboration will provide expanded sales promotion for the two brands, increased communication to medical professionals and enhanced availability of the products to support patient care.

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

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

INTERNATIONAL PARTNERSHIPS

We have established our own capabilities to support the commercialization of our products in the U.S. Our international strategy is to identify and partner with other companies that have the appropriate capabilities to support our products in their respective countries. We have entered into a series of agreements to establish a network, which is summarized in the table below, which includes information on the company, licensed product, territory and status:

International Partner	Product(s)	Territory	Status
Phebra Pty Ltd	Acetadote	Australia and New Zealand	Marketed
Alveda Pharmaceuticals, Inc.	Caldolor	Canada	Marketed
DB Pharm Korea Co., Ltd.	Caldolor & Vaprisol	South Korea	Marketed
Alliance Pharm PTE Ltd.	Vaprisol	Singapore	Distributing
Seqirus (a CSL company)	Caldolor	Australia and New Zealand	Marketed
Sandor Medicaids Pvt. Ltd.	Caldolor	India	Registration
GerminMED	Caldolor & Acetadote	Qatar and Arabian Peninsula	Registration
PT. SOHO Industri Pharmasi	Caldolor	Pacific Rim	Registration
PT. ETHICA Industri Farmasi	Caldolor	Indonesia	Registration
Laboratorios Grifols, S.A.	Caldolor	Spain, Portugal and the majority of South America	Development
Gloria Pharmaceuticals Co. Ltd.	Caldolor & Acetadote	China	Development
Clinigen Healthcare Limited	Vaprisol	Most territories outside the U.S. and Singapore	Pending
Laboratorios Valmorca, C.A.	Caldolor	Venezuela	Registration

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

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

- Seeking regulatory approvals for the products;
- Launching the brand;
- Managing the ongoing marketing, sales and product distribution;
- Addressing the ongoing regulatory requirements in the international territories;
- Remitting any upfront, regulatory and sales milestone payments;
- Providing the transfer price for supplies of product; and
- Calculating and paying any royalties, as applicable.

Our responsibilities include:

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

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

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 for all our products as well as obtaining FDA approvals for Acetadote and Caldolor.

Clinical development

Our clinical development personnel are responsible for:

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

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- preparing and submitting INDs for clearance to begin patient studies;
- preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- maintaining investigational and marketing applications through the submission of appropriate reports;
- submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;
- monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices ("GMPs"), Good Laboratory Practices ("GLPs"), and Good Clinical Practices ("GCPs"), and performing periodic audits of such vendors; and
- maintaining systems for document control, product and process change control, customer complaint handling, product stability studies and annual drug product reviews.

PROFESSIONAL AND MEDICAL AFFAIRS

Our medical team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center and medical science liaisons. 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.

CLINICAL DEVELOPMENT

Caldolor Approved for Pediatric Use

During November 2015, Caldolor received FDA approval for use in pediatric patients six months and older for management of pain and reduction of fever. The approval was based on data submitted to the U.S. Food and Drug Administration (FDA) as part of a post-marketing commitment following approval of Caldolor in adults in 2009. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.

Caldolor’s pediatric approval came after the FDA’s review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. The pivotal fever study demonstrated a statistically significant greater reduction in temperature for patients receiving Caldolor, as compared to acetaminophen. Seventy-four percent of Caldolor treated patients became afebrile by the end of the first dosing interval. A total of 143 pediatric patients, ages six months and older, have received Caldolor in controlled clinical trials. The most common adverse reactions (incidence greater than or equal to 2%) in pediatric patients treated with Caldolor were infusion site pain, vomiting, nausea, anemia and headache.

The recommended dosing for pediatric patients ages six months to twelve years of age is 10 mg/kg up to a maximum single dose of 400 mg Caldolor every four to six hours as necessary. For patients ages twelve to seventeen years of age, the recommended dosing is 400 mg of Caldolor every four to six hours as necessary for management of pain and/or reduction of fever. The product is diluted and administered intravenously over a ten minute infusion and the maximum daily dose in pediatric patients is 2,400 mg.

Caldolor Safety Summary

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

Publication of Caldolor Shortened Infusion Time Studies

In January 2015, Clinical Therapeutics, The International Peer-Reviewed Journal of Drug Therapy, published two articles with data from two Caldolor (ibuprofen) registry studies. One study entitled, "A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety and Efficacy" provided for eligible enrolled patients to receive one of two dose strengths (400 mg for treatment of fever, 800 mg for treatment of pain) of intravenous ibuprofen for up to a 24-hour dosing period. One hundred fifty patients from thirteen clinical sites were enrolled in this study. Intravenous ibuprofen reduced fever and pain and the shortened infusion time was well tolerated.

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

Publication of Caldolor Integrated Safety Analysis

In October 2015 there was a publication of an integrated safety analysis adding to the growing body of literature that support the safety of Caldolor. The data in this cumulative safety analysis is derived from ten sponsored clinical studies investigating intravenous ibuprofen for the treatment of pain and/or fever in adult patients. Over 1,750 adult patients have been included in safety and efficacy trials over eleven years. The publication is available as an open access article in the Journal of Pain Research.

The incidence of adverse events, changes in vital signs and clinically significant laboratory parameters were summarized and compared to patients receiving placebo or active comparator drug. Patients receiving Caldolor required less morphine and experienced fewer adverse events relative to those who received placebo with morphine rescue. Results from the integrated analysis continue to demonstrate the safety of Caldolor, supporting its use in hospitalized patients.

Caldolor Label Safety Update

In July 2015, the FDA decided to strengthen the existing cardiovascular warning for nonsteroidal anti-inflammatory drugs (NSAIDs). This is a class label change for all NSAIDs including over-the-counter and prescription products. It was previously thought that all NSAIDs may have similar cardiovascular risks. While newer information makes it less clear that the cardiovascular risks are similar for all NSAIDs, this information is not sufficient for the FDA to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular

NSAID. While we have not seen a cardiovascular side effect in our extensive Caldolor safety database, we will update our Caldolor label for this requested information once it becomes finalized by the FDA.

Caldolor Continuing Education

We have extended the availability of a web-based, accredited, continuing education seminar featuring the benefits of preoperative use of Caldolor in the hospital setting. The seminar has been distributed to over 60,000 health providers with a growing number of participants completing the seminar for continuing education credit.

Hepatoren Top Line Study Results

We are developing Hepatoren as a potential treatment for Hepatorenal Syndrome ("HRS") - a life threatening condition, with a high mortality rate and no approved pharmaceutical therapy in this country. We initiated a sixty four patient Phase II study to evaluate the safety, efficacy and pharmacokinetics of Hepatoren for this unmet medical need. The study was designed to evaluate escalating dose levels of Hepatoren in HRS patients. Progression to higher dose levels is reviewed and approved by an independent safety committee. The study was stratified into Type I or Type II patients with HRS based upon the progression of their disease.

We completed the enrollment of Type II patients at the end of 2014. Top line results from these patients indicate that Hepatoren was overall well tolerated with no safety concerns noted. Furthermore, the patients receiving the higher dose levels of Hepatoren were more likely to experience increases in urine output, a signal of improved kidney function, compared to patients who received placebo. Based on these results, we will proceed with clinical development of this product candidate.

We subsequently completed enrollment of the Type I patients during the third quarter of 2015 and the analysis of those patient results is underway.

Boxaban Phase II Program

During 2015, Cumberland announced an expansion of its pipeline with another Phase II development program. The Company is developing Boxaban for the treatment of Aspirin-Exacerbated Respiratory Disease ("AERD"). AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin. It is characterized by sharp increases in inflammatory mediators and platelet activity within the respiratory system. Ifetroban, an active thromboxane receptor antagonist, may interfere with these pathways to modify the disease and provide symptomatic relief.

Cumberland completed manufacturing of Boxaban oral capsules and initiated a Phase II clinical study to evaluate Boxaban in patients suffering AERD. The study was designed to gather initial safety and tolerability data on ifetroban in AERD patients. It was a multicenter study of sixteen patients with enrollment at several U.S. medical centers including the Scripps Clinic. The enrollment in this study was recently completed and top line results indicate that no adverse events were experienced by patients receiving Boxaban when compared to those receiving placebo. Further analysis of the full data set obtained from the study is underway.

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 business development opportunities through our international network of advisory firms and individual pharmaceutical industry and medical advisors. A multi-disciplinary internal management team reviews these opportunities on a regular basis using a list of selection criteria. We have historically focused on product opportunities that are a strategic fit with our commercial organization, development expertise and medical focus, employing a variety of transaction structures. Our additions of Omeclamox-Pak and Vaprisol reflect our business development process and follow our selection criteria.

We intend to continue to build a portfolio of complementary, niche products largely through product acquisitions and late-stage product development. Our primary targets are under-promoted, FDA-approved drugs with existing brand recognition and late-stage development product candidates that address unmet or poorly met medical needs in the

hospital acute care and gastroenterology markets. We believe that by focusing mainly on approved or late-stage products, we can minimize the significant risk, cost and time associated with drug development.

Clinigen Strategic Alliance

In September 2015, we announced our strategic alliance with Clinigen Group plc (AIM: CLIN) ("Clinigen"), a global pharmaceutical and services company. Clinigen is a specialty pharmaceutical and services company focused on providing medicines to patients with high unmet needs through clinical trials, licensed and ethically unlicensed supply.

The alliance will combine the respective strengths, expertise and geographical footprints of Cumberland and Clinigen with respect to potential future products. Under the agreement, we will have the opportunity to support Clinigen products through distribution, marketing and promotion within the United States. Clinigen will be responsible for the marketing, promotion, distribution and sale of our pharmaceutical products in select markets outside of the United States, allowing us to use Clinigen’s international reach to enter new markets for our products. During 2016 we entered into an amendment to this strategic alliance agreement that outlines the support Cumberland will provide to one of Clinigen's product in the United States. Cumberland expects to launch the support for the Clinigen product during the second half of 2016.

CET Collaboration

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

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

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

CET Financing

In 2014, we organized an equity financing to recapitalize and strengthen the financial position of CET. This financing included an investment of approximately $1.0 million from Harbin Gloria Pharmaceuticals Co., Ltd. (“Gloria”) for their participation in CET. As a result, Gloria received shares in CET and joined the CET ownership group. As part of this transaction, Gloria will have the first right to negotiate a license to CET developed products for the Chinese market. The funds from this new investment are being used to support and accelerate the development of CET product candidates. CET’s lead product candidate is ifetroban which is being developed by Cumberland under the brand names Hepatoren and Boxaban.

Prior to April 2014, we owned 85% of CET, with the balance of the enterprise owned by Vanderbilt University and the Tennessee Technology Development Corporation. In connection with Gloria’s investment in CET, we also provided an additional investment in CET of $1.0 million in cash and $2.4 million in loan forgiveness. Upon completion of the additional investment by Gloria and Cumberland in April 2014, we held an 80% ownership in CET.

MANUFACTURING AND DISTRIBUTION

We partner with third parties for 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 and timely delivery.

Manufacturing

Our key manufacturing relationships include:

Caldolor

- We initiated the manufacturing of Caldolor at two facilities during 2015. Both manufacturers have provided supplies of Caldolor for our international markets. During 2015, we began the process of securing two manufacturers for commercial supply of Caldolor for the United States. All four manufacturers are expected to provide commercial supplies of the product in 2016.

Acetadote

- During the fourth quarter of 2014, we entered into an agreement with a U.S. based manufacturer to supply our Acetadote product. We transferred the Acetadote manufacturing process to this supplier, received FDA clearance and began receiving commercial units from this facility during 2015.

Kristalose

- We have an agreement for the purchase of Kristalose API with an international supplier. This written agreement formalized and extended our existing relationship with this raw materials supplier. We also have manufacturing relationships with two Kristalose packagers. Under these agreements, we provide Kristalose API to these manufactures and they package the API (for both commercial sale and samples) into 10 gram and 20 gram finished product units for our purchase and distribution.

Omeclamox-Pak

- Under the previous agreement, Pernix, was responsible for providing us with the supply of Omeclamox-Pak. Based on our new agreement with GEL, effective in November 2015, Cumberland assumed supply chain responsibilities and now works directly with GEL for the manufacture, packaging and supply of Omeclamox-Pak commercial and sample units.

Vaprisol

- As part of the acquisition of Vaprisol, we purchased an existing supply of raw material inventory. In addition, as part of this transaction, we were assigned a commercial supply agreement with the existing manufacturer who provided supplies of Vaprisol. That manufacturer continues to supply commercial inventory to Cumberland under this agreement.

Distribution

Like many other pharmaceutical companies, we engage a third party contractor with appropriate facilities and logistical expertise to support our distribution efforts. Since August 2002, Cardinal Health ("Cardinal") has exclusively handled U.S. product logistics efforts, including warehousing, shipping, customer billing and collections. We extended our distribution relationship with Cardinal during May 2013, when we entered into the First Amendment ("First Amendment") to the Exclusive Distribution Agreement under which we have operated since August 2010. The Amendment primarily serves to extend the term of the Agreement through June 30, 2016 and revises the fee schedule under the Agreement. Under the Amendment, we have also engaged Cardinal to assist with our physician sample orders based on the Prescription Drug Marketing Act of 1987 (the “PDMA”) for samples shipping. After June 30, 2016, the contract is automatically renewed on a year-to-year basis that is terminable by either party with ninety days' notice. Under the Amendment and Agreement, Cardinal agrees to provide various services, including storage, distribution, returns, customer support, and system access support to us in connection with the distribution of our products under certain guidelines at established fees.

TRADEMARKS AND PATENTS

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

We seek to protect our products from competition through a combination of patents, trademarks, trade secrets, FDA exclusivity and contractual restrictions on disclosure. Proprietary rights, including patents, are an important element of our business. We seek to protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute agreements providing for protection of our confidential information upon

12

commencement of their employment or engagement. We also require confidentiality agreements from entities that receive our confidential data or materials.

Acetadote and related litigation

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

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

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

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

On May 18, 2012, we also submitted a Citizen Petition to the FDA requesting that the FDA refrain from approving any applications for acetylcysteine injection that contain EDTA, based in part on the FDA's request that we evaluate the reduction or removal of EDTA from its original Acetadote formulation. On November 7, 2012, the FDA responded to the Citizen Petition denying our request and on November 8, 2012, we learned that the FDA approved the ANDA referencing Acetadote filed by InnoPharma, Inc. We brought suit against the FDA contesting the FDA's decision to approve the InnoPharma generic on November 13, 2012. On September 30, 2013, the United States District Court filed an opinion granting a summary judgment in favor of the FDA regarding this suit.

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

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

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

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

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the "738 Acetadote Patent") which is assigned to Cumberland. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, the Company became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

On February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the "065 Acetadote Patent") which is assigned to us. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in our favor in our lawsuit against Mylan for infringement of the 445 Acetadote Patent. The opinion upheld our 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to us for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On November 17, 2015, the District Court entered an order enjoining Mylan and its affiliates from selling or using its generic version of Acetadote until August 2025, the date of expiration of the 445 Acetadote Patent. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

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

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

Caldolor

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

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty obligations related to Caldolor. During 2014, we obtained additional patents for the brand.

On May 27, 2014, the USPTO issued U.S. Patent number 8,735,452 (the "452 Caldolor Patent") which is assigned to us. The claims of the 452 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 452 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

On October 28, 2014, the USPTO issued U.S. Patent number 8,871,810 (the "810 Caldolor Patent") which is assigned to us. The claims of the 810 Caldolor Patent encompass methods of treating pain using intravenous ibuprofen. Following its issuance, the 810 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029.

During the third quarter of 2015, we obtained three additional patents for Caldolor. On July 7, 2015, the USPTO issued U.S. Patent number's 9,072,710 (the "710 Caldolor Patent") and 9,072,661 (the "661 Caldolor Patent") which are assigned to us. The claims of the 710 Caldolor Patent and the 661 Caldolor Patent include composition and methods of treating pain, inflammation and fever using intravenous ibuprofen. These Caldolor Patents are scheduled to expire in March 2032.

On August 25, 2015, the USPTO issued U.S. Patent number 9,114,068 (the "068 Caldolor Patent") which is assigned to us. The claims of the 068 Caldolor Patent include methods of treating pain and inflammation using intravenous ibuprofen. Following its issuance, the 068 Caldolor Patent was listed in the FDA Orange Book and is scheduled to expire in September 2029. We also have additional patent applications related to Caldolor which are pending with the USPTO.

Vaprisol

We own numerous U.S. patents and related international patents for Vaprisol. These patents were acquired in our February 2014 acquisition of certain product rights, intellectual property and related assets of Vaprisol from Astellas. The primary patent is U.S. Patent No. 5,723,606 (the "606 Vaprisol Patent") which includes composition of matter claims that encompass the Vaprisol formulation as well as methods for the intravenous treatment of patients with euvolemic hyponatremia. The 606 Vaprisol Patent is listed in the FDA Orange Book and expires in December 2019.

Remaining Products

We have no issued patents for our Kristalose or Omeclamox-Pak products. We have patent applications relating to our Hepatoren and Boxaban products pending with the USPTO.

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, 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 Acetadote containing EDTA. In late 2012, we entered into the Settlement Agreement with Paddock and Perrigo that included the right to distribute our Authorized Generic Acetadote injection product. Our branded Acetadote now competes with both the EDTA free Authorized Generic Acetadote distributed by Paddock and Perrigo along with generic Acetadote products that contain EDTA.

Caldolor

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

- Morphine, the most commonly used product for the treatment of acute, post-operative pain, is manufactured and distributed by several generic pharmaceutical companies;
- Other generic injectable opioids, including fentanyl, meperidine and hydromorphone, address this market;
- Ketorolac (brand name Toradol®), an injectable NSAID, is also manufactured and distributed by several generic pharmaceutical companies;
- Ofirmev®, an injectable acetaminophen product is marketed by Mallinckrodt plc;
- Exparel®, a bupivacaine delivery platform marketed by Pacira Pharmaceuticals, Inc; and
- Dyloject, an injectable diclofenac product approved by the FDA during 2015.

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® , an oral product indicated for the treatment of chronic idiopathic constipation in adults, and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited.
- Movantik™, an oral product indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.
- Linzess®, an oral product indicated for the treatment of irritable bowel syndrome with constipation and chronic idiopathic constipation. It is marketed by Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc; and
- Liquid lactulose products are marketed by a number of pharmaceutical companies.

There are several hundred OTC products used to treat constipation marketed by numerous pharmaceutical and consumer health companies. MiraLax (polyethylene glycol 3350), previously a prescription product, was indicated for

the treatment of constipation and manufactured and marketed by Braintree Laboratories, Inc. Under an agreement with Braintree, Schering-Plough introduced MiraLax as an OTC product in February 2007.

Omeclamox-Pak

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

- PrevPac®, an oral product marketed by Takeda Pharmaceutical Company. There are also approved generic versions of PrevPac;
- Pylera®, an oral product marketed by Actavis Pharma, Inc. and Forest Laboratories, Inc.; and
- Helidac®, an oral product marketed by Prometheus Therapeutics.

Vaprisol

Vaprisol is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia. The product was developed and registered by Astellas and then launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia, and the first and only intravenously administered branded treatment. The other competing product is Samsca, an oral product marketed by Otsuka Pharmaceutical Company.

GOVERNMENT REGULATION

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

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

FDA Approval Process

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

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

The progression to drug approval begins before FDA involvement. First, basic scientists work in the laboratory and with animals; second, a drug or biotechnology company develops a prototype drug. That company must seek and

receive FDA approval, by way of an IND application, to test the product with human subjects. Those tests, called clinical trials, are carried out sequentially in Phase I, II, and III studies, which involve increasing numbers of subjects. The manufacturer then compiles the resulting data and analysis in a NDA. The FDA reviews the NDA with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's identity, strength, quality, and purity.

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

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

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

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

Section 505(b) (2) New Drug Applications

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

18

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

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

Special protocol assessment process

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

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

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

Orphan drug designation

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

19

ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetadote was entitled to marketing exclusivity until January 2011 for the treatment of this approved indication.

Section 505(j) abbreviated new drug applications

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

Health care legislation

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

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

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

Medicaid Rebate Rate: We currently provide rebates for products sold to Medicaid beneficiaries.

Post Approval Activities

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

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

The FDA continuously gathers information about possible adverse reactions to the products it has approved for use. The FDA requires all manufacturers to report adverse events. It also provides a procedure for consumers and physicians to voluntarily report their concerns about drugs. The agency collects those reports through MedWatch and uses its Adverse Event Reporting System (AERS) to store and analyze them. Because some events may occur after the use of a drug for reasons unrelated to the product, the FDA reviews the events to assess which ones may indicate a problem with that particular drug. 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. A number of pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

ICH - International Committee on Harmonization

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

ENVIRONMENTAL MATTERS

We are subject to federal, state and local environmental laws and regulations and we believe that our operations comply with such regulations. We anticipate that the effects of compliance with federal, state and local laws and

21

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, 2015, we had 78 full-time employees. We believe that our future will depend in part on our continued ability to attract, hire, and retain qualified personnel, including hospital and field sales personnel in particular.

Item 1A. Risk Factors.

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

RISKS RELATED TO OUR BUSINESS

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

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

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

If demand for our products weaken, our revenues and profitability will likely decline. Known adverse effects of our marketed products are documented in product labeling, including the product package inserts, medical information disclosed

to medical professionals and all marketing-related materials. At this time, no unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products.

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

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

The FDA also requires manufacturers to appropriately label 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 continue to be administered primarily to hospital and surgery center 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 individuals hospital physicians to prescribe Caldolor repeatedly. The commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. As with our other products, if 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: Caldolor has historically been manufactured at Hospira Australia Pty. Ltd.'s facility in Australia and Bayer's facility in Kansas. We entered into agreements with three manufacturers for the commercial supply of Caldolor. We have successfully transferred the Caldolor manufacturing process to two of these manufacturers and these two suppliers have manufactured inventory under these agreements. During 2015, we began the process of obtaining a third supplier for the manufacture of commercial supply of Caldolor and expect to obtain commercial supply from this manufacturer during 2016. If the manufacturers of Caldolor are unable to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Acetadote: Acetadote was previously manufactured and packaged by two entities: at Bayer's facility in Kansas through January 2014 and in Ireland by Mylan through April 2014. During the fourth quarter of 2014, we entered into an agreement with a U.S. based manufacturer to supply our Acetadote product. We have transferred the Acetadote manufacturing process to this supplier and received and sold commercial units from them during 2015. If the manufacturer of Acetadote is unable

to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

Kristalose: The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy and we have manufacturing agreements with two Kristalose packagers. If these facilities are damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our product. 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.

Omeclamox-Pak: Under the agreement we signed with Pernix, they were responsible for providing Omeclamox-Pak inventory. Effective with the November 2015 agreement with GEL, Cumberland assumes supply chain responsibilities and will now work directly with GEL to ensure availability of Omeclamox-Pak. If we are unable to obtain marketable inventory in the future we could suffer an inability to meet demand for our product.

Vaprisol: As part of the acquisition of Vaprisol, we purchased an existing supply of raw material inventory. In addition, as part of this transaction, we were assigned a commercial supply agreement with the manufacturer Astellas used to prepare, package, inspect and label Vaprisol. The manufacturer continues to supply commercial inventory to Cumberland under this agreement. If the manufacturer of Vaprisol is unable to produce additional marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for our product.

In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practices, ("GMPs"), enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with GMP requirements and with other FDA, state and foreign regulatory requirements. We have no control over our manufacturers' compliance with these regulations and standards. If our third-party manufacturers do not comply with these requirements, we could be subject to:

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

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

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

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

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

Competitive pressures could reduce our revenues and profits.

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

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

24

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

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

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

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

In addition, we have only obtained regulatory approval to market our products in the United States. Not all foreign jurisdictions may represent attractive opportunities for our products due to pricing, competitive, regulatory or other factors. In certain foreign jurisdictions, we have licensed the right to market some of our products to third parties. These third parties are responsible for seeking regulatory approval for the products in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for our products will be obtained outside the United States.

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

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

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

We added two marketed products to our portfolio of brands: Omeclamox-Pak in the fourth quarter of 2013 and Vaprisol during the first quarter of 2014. We successfully launched our promotional efforts to support both brands during 2014. If we are unable to continue to build on our initial success with these brands or we are unable to successfully integrate the marketing, sale and distribution of any other potential products into our current infrastructure or if they require significantly greater resources than originally anticipated, we may face financial and operational risks and uncertainties. If we are unable to successfully integrate any acquired brands, both current and future, these product acquisitions may not be beneficial to us in the long term.

Our Hepatoren and Boxaban product candidates have 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 and Boxaban product candidates. Hepatoren (intravenous ifetroban) and Boxaban (oral ifetroban) are candidates used to treat hepatorenal syndrome ("HRS") and aspirin exacerbated respiratory disease ("AERD"), respectively. However, ifetroban has not been approved by the FDA for marketing, and these product candidates are still subject to risks associated with their development.

The FDA has cleared our IND's for these product candidates as we evaluate them as treatments for these conditions. Delays in the enrollment and completion of the clinical studies could significantly delay commercial launch and affect our product development costs. Moreover, results from the clinical studies may not be favorable.

Even if they are eventually developed and approved by the FDA, they 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 these product candidates 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 and Boxaban will contribute to our future growth.

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

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

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

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

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

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

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

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

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

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

We sell most of our products to large pharmaceutical wholesalers, who in turn sell to hospitals, surgery centers and retail pharmacies. The distribution network for pharmaceutical products has become increasingly consolidated in

recent years. Further consolidation or financial difficulties could also cause our customers to reduce the amounts of our products that they purchase, which would materially and adversely impact our business, financial condition and results of operations.

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

Our CET joint initiative with Vanderbilt University, Gloria 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, scientific staff, and sales representatives and managers. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, or other members of senior management it could have a material adverse effect on our business prospects. Mr. Kazimi, plays a key role in several operational and strategic decisions such that any loss of his services due to death or disability would adversely impact our day-to-day operations. We have a 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, sales 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, 2015, we had 78 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;

27

- Significant litigation costs;
- Substantial monetary awards to or costly settlement with patients;
- Product recalls;
- Loss of revenue; and
- The inability to commercialize our product candidates.

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

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

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

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

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

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or payment of 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, security breaches, adverse events or other disruptions within our information technology infrastructure 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 ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information and that of our customers. We also maintain personally identifiable information of our employees in our data centers and on our networks. The secure processing and maintenance of this information is critical to our operations. 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. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. 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.

28

RISKS RELATING TO GOVERNMENT REGULATION

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

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

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

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

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

We must comply with the Foreign Corrupt Practices Act.

We are required to comply with the United States Foreign Corrupt Practices Act, which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some of our competitors, are not subject to these prohibitions. If our competitors engage in these practices, they may receive preferential treatment from personnel of some companies, giving our competitors an advantage in securing business from government officials who might give them priority in obtaining new licenses, which would put us at a disadvantage. We have established formal policies or procedures for prohibiting or monitoring this conduct, but we cannot assure you that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties.

We must comply with the Physician Payment Sunshine Act.

We are required to comply with the United States Physician Payment Sunshine Act, which requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals. Manufacturers are required to report this information annually to The Centers for Medicare & Medicaid Services (CMS). Cumberland has implemented a series of policies and procedures for every employee involved in the data collection process, and has systems in place to capture the data, which is verified by an outside firm that specializes in reporting the payments. Cumberland has also established a redundant system to ensure that data was reported completely, in the correct format, and on time. Despite these policies, procedures and systems, we cannot assure you that we will collect and report all data accurately. If we fail to accurately report this information, we could suffer severe penalties.

RISKS RELATING TO INTELLECTUAL PROPERTY

Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited or no protection from competition.

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product formulation. Acetadote is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. As discussed in Part I, Item 1, Business - Trademarks, Patents and Proprietary Rights, of this Form 10-K, during April 2012, the United States Patent and Trademark Office (the “USPTO”) issued U.S. Patent number 8,148,356 (the “356 Acetadote Patent”) which is assigned to us. The claims of the 356 Acetadote Patent encompass the new Acetadote formulation and include composition of matter claims. Following its issuance, the 356 Acetadote Patent was listed in the FDA Orange Book. The 356 Acetadote Patent is scheduled to expire in May 2026, which time period includes a 270-day patent term adjustment granted by the USPTO.

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

30

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

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

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

On January 7, 2013, Perrigo announced initial distribution of our Authorized Generic acetylcysteine injection product.

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

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

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

On September 30, 2013, the United States District Court for the District of Columbia filed an opinion granting a Summary Judgment in favor of the FDA regarding Cumberland’s November 13, 2012 suit. On November 1, 2013, the United States District Court for the District of Delaware filed opinions granting Sagent’s and InnoPharma’s motions to dismiss our May 2012 and June 2012 suits.

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

31

On May 13, 2014, the USPTO issued U.S. Patent number 8,722,738 (the “738 Acetadote Patent”) which is assigned to us. The claims of the 738 Acetadote Patent encompass administration methods of acetylcysteine injection, without specification of the presence or lack of EDTA in the injection. Following its issuance, the 738 Acetadote Patent was listed in the FDA Orange Book and it is scheduled to expire in April 2032.

On December 11, 2014 and March 3, 2015, we became aware of Paragraph IV certification notices from Aurobindo Pharma Limited and Zydus Pharmaceuticals (USA) Inc., respectively, challenging the 356, 445, 061, and 738 Acetadote Patents on the basis of non-infringement.

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

On February 10, 2015, the USPTO issued U.S. Patent number 8,952,065 (the “065 Acetadote Patent”) which is assigned to us. The claims of the 065 Acetadote Patent encompass the use of the 200 mg/ml Acetadote formulation to treat patients with acute liver failure. The 065 Acetadote Patent is scheduled to expire in August 2025.

On September 30, 2015, the United States District Court for the Northern District of Illinois, Eastern Division ("District Court") ruled in our favor in our lawsuit against Mylan for infringement of the 445 Acetadote Patent. The opinion upheld our 445 Acetadote Patent and expressly rejected Mylan's validity challenge. The District Court ruled that Mylan is liable to us for infringement of the 445 Acetadote patent in light of Mylan's Abbreviated New Drug Application in which Mylan sought to market a generic version of Acetadote. On November 17, 2015, the District Court entered an order enjoining Mylan and its affiliates from selling or using its generic version of Acetadote until August 2025, the date of expiration of the 445 Acetadote Patent. On October 30, 2015, Mylan filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

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

We have U.S. patents and related international patents which include composition of matter claims that encompass the Caldolor formulation, including methods of treating pain using intravenous ibuprofen and claims directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Caldolor. Additionally, the active ingredient in Caldolor, ibuprofen, is in the public domain, and a competitor could try to develop, test and seek FDA approval for a sufficiently distinct formulation for another ibuprofen product that competes with Caldolor. The U.S. patents are listed in the FDA Orange Book, with one expiring in November 2021, four others expiring in September 2029 and one other expiring in September 2030.

We have numerous U.S. patents and related international patents for Vaprisol. These patents were acquired in our February 2014 acquisition of certain product rights, intellectual property and related assets of Vaprisol from Astellas. The primary patent is U.S. Patent No. 5,723,606 (the “606 Vaprisol Patent”) which includes composition of matter claims that encompass the Vaprisol formulation as well as methods for the intravenous treatment of patients with euvolemic hyponatremia. The 606 Vaprisol Patent is listed in the FDA Orange Book and expires in December 2019.

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months

32

following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patents, we rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation where we do not believe patent protection is appropriate or attainable. For example, the manufacturing process for Kristalose involves substantial trade secrets and proprietary know-how. We have entered into confidentiality agreements with certain key employees and consultants pursuant to which such employees and consultants must assign to us any inventions relating to our business if made by them while they are our employees, as well as certain confidentiality agreements relating to the acquisition of rights to products. Confidentiality agreements can be breached, though, and we might not have adequate remedies for any breach. Also, others could acquire or independently develop similar technology.

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

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

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

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

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

We have been involved in lawsuits for infringement of the Acetadote Patents as previously described. Because of their nature, these lawsuits can be costly and time-consuming, and we only experience limited benefits and patent protection. A significant adverse ruling in any such lawsuit could put the Acetadote Patents at risk of being invalidated or interpreted narrowly and could compromise the issuance of our existing patent applications.

Competitors may infringe on our other patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is

33

unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

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

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

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

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

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

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

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

Our total assets include intangible assets related to our acquisitions. As of December 31, 2015, intangible assets relating to products represented approximately 23% of our total assets. We may never realize the value of these assets. U.S. Generally Accepted Accounting Principles ("GAAP") require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any determination requiring the write-off of a significant portion of unamortized intangible assets would adversely affect our results of operations.

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

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

If we are unable to maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock.

Effective internal controls are necessary for us to provide reliable financial reports and mitigate the risk of fraud. We maintain a system of internal control over financial reporting, which is defined as a process designed by, or under the supervision of, our principal executive officer and principal financial officer, and affected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

We cannot assure you that we will not, in the future, identify areas requiring improvement in our internal control over financial reporting. We cannot assure you that the measures we will take to improve these controls will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue to expand. If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock.

In addition, we maintain a system of internal controls and provide training to employees designed to provide reasonable assurance that unlawful and fraudulent activity, including misappropriation of assets, fraudulent financial reporting, and unauthorized access to sensitive or confidential data is either prevented or timely detected. However, in the event that our employees engage in such fraudulent behavior, we could suffer material adverse consequences.

Changes in, or interpretations of, accounting principles and tax laws could have a significant impact on our financial position and results of operations.

We prepare our consolidated financial statements in accordance with GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. A change

35

in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions.

For example, in recent years, the U.S.-based Financial Accounting Standards Board, ("FASB"), has worked together with the International Accounting Standards Board, ("IASB"), on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards, ("IFRS"), outside of the U.S. These efforts by the FASB and IASB may result in different accounting principles under GAAP that may result in materially different financial results for us in areas including, but not limited to, principles for revenue recognition and lease accounting.

RISKS RELATED TO OWNING OUR STOCK

The market price of our common stock may fluctuate substantially.

The price for the shares of our common stock sold in our initial public offering was determined by negotiation between the representatives of the underwriters and us. This price may not have reflected the market price of our common stock following our initial public offering. Through March 1, 2016, the closing price of our common stock since our initial public offering has ranged from a low of $4.03 to a high of $17.05 per share. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline.

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

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

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

We are experiencing increased costs and regulatory risk as a result of operating as a public company, and our management will be required to devote additional time to new compliance initiatives.

We have and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote additional time to new compliance initiatives. As a public company, we have and will continue to incur legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and other rules and regulations subsequently implemented by the SEC and NASDAQ, have imposed various requirements on public companies, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have and will continue to increase our legal and financial compliance costs and will render some activities more time-consuming and costly. Despite the internal controls and procedures put in place to maintain compliance with securities laws and regulations, our employees may still fail to comply with all SEC disclosure and reporting requirements. Such failure could lead to administrative and civil penalties, criminal penalties, and private litigation with shareholders. The consequences could have a material effect on our ability to effectively market our products and operate our business.

36

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Some provisions of our third amended and restated charter, bylaws and Tennessee law may inhibit potential acquisition bids that you may consider favorable.

Our corporate documents contain provisions that may enable our board of directors to resist a change in control of our company even if a change in control were to be considered favorable by you and other shareholders. These provisions include:

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

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

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

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

We have never paid cash dividends on our capital stock. We do not anticipate paying cash dividends to our shareholders in the foreseeable future. The availability of funds for distributions to shareholders will depend substantially on our earnings.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

"plan," "estimate," "should," "seek," "anticipate" and other comparable terms or the negative thereof. In addition, we, through our senior management, from time to time make forward-looking oral and written public statements concerning our expected future operations and other developments. While forward-looking statements reflect our good-faith beliefs and best judgment based upon current information, they are not guarantees of future performance and are subject to known and unknown risks and uncertainties, including those mentioned in Item 1A, "Risk Factors," Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 10-K. Actual results may differ materially from the expectations contained in the forward-looking statements as a result of various factors. Such factors include, but are not limited to:

- The possible or assumed future results of operations, including the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- Changes in national or regional economic conditions, including changes in interest rates and the availability and the cost of capital to us;
- Our competitive position and competitors, including the size and growth potential of the markets for our products and product candidates;
- The success, cost and timing of our product development activities and clinical trials; and our ability to successfully commercialize our product candidates;
- The performance of our third-party suppliers and manufacturers; and the retention of key scientific and management personnel;
- Our expectations regarding our ability to provide intellectual property protection for our product candidates; and
- Changes in reimbursement available to us, including changes in Medicare and Medicaid payment levels and availability of third-party insurance coverage and the effects of future legislation or regulations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of December 31, 2015, we leased approximately 25,500 square feet of office space in Nashville, Tennessee for our corporate headquarters. The lease expires in October 2022. We believe these facilities are adequate to meet our current needs for office space. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us by third-party contract groups.

Under an agreement amended in July 2012 and expiring in April 2018, CET leases approximately14,200 square feet of office and wet laboratory space in Nashville, Tennessee. CET uses this space to operate the CET Life Sciences Center for product development work to be carried out in collaboration with universities, research institutions and entrepreneurs. The CET Life Sciences Center provides laboratory and office space, equipment and infrastructure to early-stage life sciences companies and university spin-outs.

Item 3. Legal Proceedings.

On April 14, 2014, we filed with the American Arbitration Association a request for arbitration with Mylan Inc., Mylan Institutional LLC, Mylan Pharma Group Limited, and Mylan Teoranta (collectively, “Mylan”). We are seeking to arbitrate claims against Mylan in connection with our Alliance Agreement dated January 15, 2002, and Manufacturing and Supply Agreement as amended April 25, 2011, which require that Mylan and its affiliates manufacture and supply acetylcysteine drug product, including Acetadote, for us exclusively until April 2016. We have asserted in the request for arbitration claims against Mylan for breach of contract, breach of implied covenant of good faith and fair dealing, and unjust enrichment and seek monetary damages or to enjoin Mylan and its affiliates from selling or supplying acetylcysteine drug product to another entity or person until April 2016.

On September 14, 2015, the arbitrator issued a final award in our favor, enjoining Mylan Pharma Group Limited and Mylan Teoranta, together with all their affiliates, from selling, delivering, or giving away any acetylcysteine injectable drug product to another entity or person until April 30, 2018. The award notes that as the prevailing party, we are entitled to reimbursement of our attorney’s fees and related costs associated with the arbitration.

Also see the discussion of our Acetadote patent defense legal proceedings contained in Part 1, Item 1, Business -Trademarks and Patents, of this Form 10-K, which is incorporated by reference herein.

PART II

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

Market Information

Our common stock, no par value, has been traded on the Nasdaq Global Select Market since August 11, 2009 under the symbol "CPIX." As of March 4, 2016, we had 79 shareholders of record of our common stock. This excludes shareholders whose shares are held by brokers and other institutions on behalf of shareholders. The closing price of our common stock on the Nasdaq Global Select Market on March 4, 2016 was $4.81 per share. The following table sets forth the high and low trading sales prices for our common stock as reported on the Nasdaq Global Select Market for the full quarterly periods during 2015 and 2014:

	High	Low
Fiscal year ended December 31, 2015:		