CUMBERLAND PHARMACEUTICALS INC
Form S-1/A
February 18, 2009

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As filed with the Securities and Exchange Commission on February 18, 2009
Registration No. 333-142535

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 15
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Cumberland Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Tennessee	**2834**	**62-1765329**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
(615) 255-0068
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

A.J. Kazimi
Chairman and CEO
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Nashville, Tennessee 37203
(615) 255-0068
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed offering to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION February 18, 2009

6,250,000 Shares

Common Stock

This is the initial public offering of our common stock. No public market currently exists for our common stock. We are offering all of the 6,250,000 shares of our common stock offered by this prospectus. We expect the public offering price to be between $14.00 and $16.00 per share.

We have applied to have our common stock included for quotation on The Nasdaq Global Market under the symbol CPIX .

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock in Risk factors beginning on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also purchase up to an additional 937,500 shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $, and our total proceeds, before expenses, will be $.

The underwriters are offering the common stock as set forth under Underwriting. Delivery of the shares will be made on or about , 2009.

UBS Investment Bank **Jefferies & Company** **Wachovia Securities**

Morgan Joseph

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock.

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Through and including , 2009 (the 25th day after the date of this prospectus), federal securities laws may require all dealers that effect transactions in our common stock, whether or not participating in this offering, to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Amelior®, Acetadote® and the Cumberland Pharmaceuticals logo are trademarks or service marks of Cumberland Pharmaceuticals Inc. All other trademarks or service marks appearing in this prospectus are the property of their respective holders.

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Prospectus summary

This summary highlights select contents of this prospectus, and may not contain all of the information that you should consider before investing in our common stock. This summary should be read together with the more detailed information found elsewhere in this prospectus, including Risk factors and our consolidated financial statements and related notes beginning on page F-1. References in this prospectus to Cumberland, we, us and our refer to Cumberland Pharmaceuticals Inc. and our consolidated subsidiaries, unless the context indicates otherwise.

OUR COMPANY

We are a profitable and growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology, which are characterized by relatively concentrated physician prescriber bases. Unlike many emerging pharmaceutical and biotechnology companies, we have established both product development and commercialization capabilities, and believe our organizational structure can be expanded efficiently to accommodate our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, clinical and regulatory affairs, and sales and marketing.

Since our inception in 1999, we have successfully funded the acquisition and development of our product portfolio with limited external investment, while maintaining profitable operations over the past four years. Our portfolio consists of two products approved by the U.S. Food and Drug Administration, or FDA, one late-stage product candidate and several pre-clinical development projects. We were directly responsible for the clinical development and regulatory approval of Acetadote, one of our marketed products, and are currently pursuing regulatory approval of Amelior, our lead product candidate. We promote Acetadote and our other FDA-approved product, Kristalose, through dedicated hospital and gastroenterology sales forces, which together are comprised of 64 sales representatives and district managers. We believe that our target markets are highly concentrated, and consequently can be penetrated effectively by small, dedicated sales forces without large-scale promotional activity. For the years 2006, 2007 and 2008, our net revenue was $17.8 million, $28.1 million and $35.1 million, respectively, and our net income was $4.4 million, $4.0 million and $4.8 million, respectively.

OUR PRODUCTS

Our key products and product candidates include:

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

Amelior, our lead pipeline candidate, is an intravenous formulation of ibuprofen. We completed our clinical program to support FDA approval of the product in 2008 and are pursuing regulatory approval. There currently are no injectable products approved for sale in the United States for the treatment of both pain and fever. If we receive FDA

approval for Amelior on our current projected timeline, we believe Amelior would be the first injectable product available for the treatment of both pain and fever in the United States. If approved, we plan to market Amelior in the United States through our existing hospital sales force and internationally through alliances with marketing partners. We believe Amelior currently represents our most significant product opportunity.

According to IMS Health, the U.S. market for injectable analgesics, or pain relievers, exceeded $302 million, or 471 million units, in 2007. This market consists primarily of generic opioids and the non-steroidal anti-inflammatory drug ketorolac. Despite having a poor safety profile, usage of ketorolac

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has grown from approximately 38 million units in 2003, or 7% of the market, to approximately 45 million units in 2007, or 10% of the market, according to IMS Health. Injectable opioids such as morphine and meperidine accounted for approximately 427 million units sold in 2007. While opioids are widely used for acute pain management, they are associated with a variety of side effects including sedation, nausea, vomiting, headache, cognitive impairment and respiratory depression. Based on the results of our clinical studies to date, we believe Amelior represents a potentially safer alternative to ketorolac, the only non-opioid injectable pain relief drug available in the U.S. There is currently no approved injectable treatment for fever in the U.S.

Acetadote is the only intravenous formulation of N-acetylcysteine, or NAC, approved in the U.S. for the treatment of acetaminophen poisoning. Though safe at recommended doses, acetaminophen can cause liver damage with excessive use. Acetaminophen overdose is the most common cause of acute liver failure in adults in the U.S. According to the American Association of Poison Control Centers National Poison Data System, acetaminophen was the leading cause of toxic drug ingestions reported to poison control centers in the U.S. in 2007.

NAC is accepted worldwide as the standard of care for treating acetaminophen overdose, which is well-documented and is supported by a 2005 article in volume 17 of *Current Opinion in Pediatrics*. Until our 2004 launch of Acetadote, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Medical literature suggests that, for a number of patients, IV treatment is the only reasonable route of administration due to nausea and vomiting associated with the administration of oral NAC for acetaminophen overdose. Sales of Acetadote have increased consistently since we launched the product in June 2004. According to Wolters Kluwer Health Source^{tm} Pharmaceutical Audit Suite, Acetadote sales to hospitals grew 42% from 2006 to 2007. Total sales to hospitals in 2007 were $18.3 million. We believe that we can continue to expand market share, and that our Acetadote sales and marketing platform should help facilitate the anticipated launch of Amelior.

Kristalose, a prescription laxative product, is a crystalline form of lactulose designed to enhance patient acceptance and compliance. Based on data from IMS Health, the U.S. prescription laxative market has grown rapidly over the past few years, increasing from approximately $206 million in 2003 to $372 million in 2007, representing a compound annual growth rate of 16%. Wholesaler sales of Kristalose to pharmacies were $10.5 million in 2007. During that year, we acquired exclusive U.S. commercialization rights to Kristalose, subsequently assembling a dedicated field sales force and re-launching the product in September 2006 under the Cumberland brand. We believe that we can increase market share for Kristalose given its many positive, competitive attributes including better taste, consistency, ease of use and cost relative to competing products.

Early-stage product candidates. Our pre-clinical product candidates are being developed by Cumberland Emerging Technologies, Inc., or CET, our 85%-owned subsidiary. CET collaborates with leading research institutions to identify and advance the development of promising pre-clinical product candidates within our target segments. Current CET projects include an improved treatment for fluid buildup in the lungs of cancer patients and an anti-infective for treating fungal infections in immuno-compromised patients.

OUR COMPETITIVE STRENGTHS

We believe our key competitive strengths include the following:

Ø A significant late-stage product opportunity in Amelior;

Ø Strong growth potential of our existing marketed products, Acetadote and Kristalose;

Ø Our focus on underserved niche markets, including hospital acute care and gastroenterology;

- A profitable business with a history of fiscal discipline; and
- Extensive management expertise in business development, clinical and regulatory affairs, and sales and marketing.

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OUR STRATEGY

Our objective is to develop, acquire and commercialize branded pharmaceutical products for specialty physician market segments. Our strategy to achieve this objective includes the following key elements:

- Successfully develop and commercialize Amelior, our lead product candidate for which we are pursuing regulatory approval;
- Maximize sales of our marketed products, Acetadote and Kristalose;
- Expand our dedicated hospital and gastroenterology sales forces;
- Expand our product portfolio by acquiring rights to additional marketed products and late-stage product candidates; and
- Develop a pipeline of early-stage products through CET, our majority-owned subsidiary.

RISKS AFFECTING US

Our business is subject to numerous risks that could prevent us from successfully implementing our business strategy. These and other risks are discussed further in the section entitled Risk factors immediately following this prospectus summary, and include the following:

- Our Amelior product candidate has not been approved for sale and may never be successfully commercialized;
- Sales of Acetadote and Kristalose currently generate almost all of our revenues. An adverse development regarding either of these products could have a material and adverse impact on our future revenues and profitability;
- If any manufacturer we rely upon fails to produce our products and product candidates in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of Amelior, or may be unable to meet demand for the product supplied by the manufacturer and may lose potential revenues;
- 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; and
- If we are unable to maintain and build an effective sales and marketing infrastructure, we will not be able to successfully commercialize and grow our products and product candidates.

CORPORATE INFORMATION

We were incorporated in Tennessee in 1999. Our principal executive offices are located at 2525 West End Avenue, Suite 950, Nashville, Tennessee 37203, and our telephone number is (615) 255-0068. Our website address is www.cumberlandpharma.com. The information on, or accessible through, our website is not part of this prospectus.

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The offering

Common stock we are offering	6,250,000 shares
Common stock to be outstanding after this offering	17,778,545 shares
Fully diluted common stock to be outstanding after this offering	24,862,456 shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $83.3 million, or approximately $96.4 million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of $15.00 per share, the midpoint of the price range on the cover of the prospectus. We expect to use the net proceeds from this offering primarily for potential acquisitions and product development. We may use the proceeds from this offering for additional development and potential commercial introduction of our lead product candidate, Amelior. We may also use the proceeds from this offering to expand operations, including expansion of our sales forces, and for general corporate purposes.
Proposed Nasdaq Global Market Symbol	CPIX

Common stock to be outstanding after this offering is based on 11,528,545 shares outstanding as of December 31, 2008 and excludes:

- 2,550 shares of unvested restricted common stock;
- 7,910,986 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of $1.65 per share;
- 68,958 shares of common stock issuable upon exercise of outstanding warrants at a weighted- average exercise price of $6.17 per share; and
- 2,505,389 shares of common stock reserved for future issuance under our current incentive plans.

Fully diluted common stock to be outstanding after this offering represents the sum of the 17,778,545 shares to be outstanding after this offering, 2,550 shares of unvested restricted stock and the 7,979,944 shares of common stock issuable upon exercise of options and warrants outstanding as of December 31, 2008. The number of outstanding options and warrants is reduced by the 898,583 shares of common stock that could theoretically be repurchased with the approximately $13.5 million in aggregate exercise price of such options and warrants at a repurchase price equal to the assumed initial public offering price of $15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus.

Unless otherwise indicated, the share information in this prospectus is as of December 31, 2008 and has been adjusted to reflect or assume the following:

- the conversion of all outstanding shares of our preferred stock into 1,625,498 shares of common stock;

- a 2-for-1 stock split of our common stock, which became effective on July 6, 2007; and
- no exercise of the underwriters over-allotment option.

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Summary consolidated financial data

The tables below summarize our financial data as of the dates and for the periods indicated. You should read the following information together with the more detailed information contained in Selected consolidated financial data, Management s discussion and analysis of financial condition and results of operations and our consolidated financial statements and the accompanying notes included elsewhere in this prospectus.

The pro forma statement of operations and balance sheet data below gives effect to the conversion of 812,749 shares of our preferred stock into 1,625,498 shares of common stock. The pro forma as adjusted balance sheet data below gives further effect to the sale of 6,250,000 shares of common stock that we are offering at an assumed initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

Statement of operations data:	**Years Ended December 31, 2006**	**2007**	**2008**
	(in thousands, except per share data)		
Net revenues:			
Acetadote	$ 10,722	$ 18,817	$ 25,439
Kristalose	6,511	9,013	9,469
Other[1]	582	234	167
Total net revenues[3]	$ 17,815	$ 28,064	$ 35,075
Operating income	2,224	6,725	7,282
Net income before income taxes	1,708	6,469	7,310
Net income	4,404	4,044	4,766
Earnings per share basic	$ 0.45	$ 0.40	$ 0.47
Earnings per share diluted	$ 0.27	$ 0.24	$ 0.29
Pro forma earnings per share basic (unaudited)			$ 0.41
Pro forma earnings per share diluted (unaudited)			$ 0.29
Weighted-average shares outstanding basic	9,797	10,032	10,143
Weighted-average shares outstanding diluted	16,454	16,582	16,540
Pro forma weighted-average shares outstanding basic (unaudited)			11,768
Pro forma weighted-average shares outstanding diluted (unaudited)			16,540

Balance sheet data:	**As of December 31, 2008**		
	Actual	**Pro Forma**	**Pro Forma as Adjusted[4]**
	(in thousands)		

		(unaudited)	
Cash and cash equivalents	$ 11,830	$ 11,830	$ 95,117
Working capital	10,104	10,104	93,392
Total assets	31,119	31,119	114,407
Total long-term debt and other long-term obligations (including current portion)	7,666	7,666	7,666
Convertible preferred stock	2,604		
Retained earnings	1,451	1,451	1,451
Total shareholders equity	17,555	17,555	100,842

(1) Includes revenue from products we are no longer selling, revenue reduction for promotional costs to a wholesaler, grant revenue and other miscellaneous revenue.

(2) Includes the revenue reduction for promotional costs owed to a wholesaler.

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

(4) Each $1.00 increase or decrease in the assumed initial public offering price of $15.00 per share would increase or decrease, as applicable, our cash and cash equivalents, working capital, total assets and total shareholders equity by approximately $5.8 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us.

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Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks, together with all of the information included in this prospectus, before investing in our common stock. If any of the following risks were to occur, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you might lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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

We anticipate that a substantial portion of our future growth will come from sales of our Amelior product candidate. However, Amelior has not been approved for marketing by the U.S. Food and Drug Administration, or FDA, and it is still subject to risks associated with its clinical development.

Amelior is undergoing a clinical program to test its efficacy and safety. Delays associated with this program, which can result from unforeseen issues, FDA interventions, problems with enrolling patients and other reasons, could significantly delay commercial launch and affect our product development costs. Moreover, results from these clinical studies may not be as favorable as the results we obtained in prior, completed studies.

We are pursuing FDA approval of Amelior. The FDA may decline to accept our application. If the FDA declines our application for approval, it may require that we conduct additional studies and submit additional data prior to resubmitting the application. If the FDA accepts and reviews the application, it may still require that we conduct additional studies or submit other data. Conducting studies and collecting, analyzing and submitting necessary data can be time-consuming and expensive. The FDA may not act on our application during the timeframe that we expect. Moreover, the FDA might not approve our application, in which event we would not be able to sell Amelior in the U.S., or it might approve Amelior for only limited uses, in which event the market for this product could be significantly reduced, adversely affecting our commercial opportunity. In addition, new government regulations could prevent or delay regulatory approval of Amelior.

Amelior, which is injectable ibuprofen, is a non-steroidal anti-inflammatory drug, or NSAID. The widespread use of NSAIDs has meant that the adverse effects of these relatively safe drugs have become increasingly prevalent. The two main adverse drug reactions associated with NSAIDs relate to the gastrointestinal tract and the kidneys. Recent studies suggest there may also be a risk of cardiovascular adverse effects associated with NSAIDs. While we have studied and continue to study the safety of Amelior in our clinical trials, the FDA may require additional safety data be collected prior to or after any approval of the product.

Even if Amelior is successfully developed and approved by the FDA, it may never gain significant acceptance in the marketplace and therefore never generate substantial revenue or profits for us. Physicians may determine that existing drugs are adequate to address patients needs. For example, oral non-narcotic pain and fever reducers, as well as narcotic IV pain relievers, are widely available and commonly prescribed. If physicians determine that Amelior is safe and effective, it will still compete, on a patient-by-patient and physician-by-physician basis, with other therapeutic alternatives. Additionally, we are aware of other companies developing products that would address the same market that we are targeting for Amelior. The extent to which Amelior will be reimbursed by the U.S. government or third-party payors is also currently unknown, and reimbursement levels of Amelior compared to those of other competitive drugs will also affect the level of market acceptance.

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Risk factors

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

Sales of Acetadote and Kristalose currently generate almost all of our revenues. An adverse development regarding either of these products could have a material and adverse impact on our future revenues and profitability.

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

Ø The prices of Acetadote and Kristalose relative to other drugs or competing treatments;

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

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

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

Ø The inability of the orphan drug designation of Acetadote (under which the FDA granted seven years marketing exclusivity for intravenous treatment of moderate to severe acetaminophen overdose) to prevent development and marketing of a different product that competes with Acetadote;

Ø Changes in intellectual property protection available for Acetadote or Kristalose or competing treatments;

Ø The availability and level of third-party reimbursement for sales of Acetadote and Kristalose; and

Ø The continued availability of adequate supplies of Acetadote and Kristalose to meet demand.

If demand for either Acetadote or Kristalose weakens, 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. No unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products. The most frequently reported adverse events attributed to Acetadote include rash, urticaria (hives) and pruritus (itching), and anaphylactoid reactions. The most frequently reported adverse events attributed to Kristalose, and reported to us, include flatulence and nausea.

If any manufacturer we rely upon fails to produce our products and product candidates in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of Amelior, or may be unable to meet demand for

the product supplied by the manufacturer and may lose potential revenues.

We do not manufacture any of our products or product candidates, 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. In either event, we may

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Risk factors

choose to or need to seek an alternative source of supply for, or abandon, a product line or sell a product line on unsatisfactory terms. We have agreements with Bioniche Teoranta, or Bioniche, and with Bayer Healthcare, LLC, or Bayer, for the manufacture and supply of Acetadote. Our agreement with Bioniche requires us to purchase minimum amounts of Acetadote.

We also have minimum purchase obligations under our Kristalose supply agreement with Inalco S.p.A. and Inalco Biochemicals, Inc., or collectively Inalco. If our purchase obligations exceed demand for our products, we may be forced to either breach our contract with that manufacturer or purchase a supply of the product that we may be unable to sell. Our contract with Bioniche extends until 2011, and our contract with Inalco extends until 2021.

On February 2, 2007, Mayne Pharma Pty. Ltd., our primary manufacturer of Amelior, was acquired by Hospira Australia Pty. Ltd., or Hospira. If Hospira encounters integration problems or if we have disagreements with Hospira, with whom we have not collaborated in the past, our supply of Amelior from Hospira could be interrupted. Our agreement with Bayer also provides for the manufacture and supply of Amelior.

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

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

Ø fines and civil penalties;

Ø suspension of production or distribution;

Ø suspension or delay in product approval;

Ø product seizure or recall; and

Ø withdrawal of product approval.

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

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

Ø Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which warehouses and ships both Kristalose and Acetadote;

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Risk factors

Ø Inventiv Commercial Services, LLC, which provides a field sales force that is the primary selling team for Kristalose; and

Ø Vanderbilt University and the Tennessee Technology Development Corporation, co-owners with us of Cumberland Emerging Technologies, Inc., or 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, delay completion of clinical trials, regulatory approval and market launch of Amelior or any future product candidate, increase our operating expenses and otherwise adversely affect our operating results.

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

Historically, we have relied on Cardinal to provide sales representatives to promote our products. In 2007, we exercised an option under our agreement with Cardinal to convert the hospital sales force for our products to Cumberland employees. This conversion was completed in January 2007. Our ability to maintain and increase our revenues and profitability, particularly in the near term, will depend on our ability to address any issues or inefficiencies that arise from transitioning this sales force from Cardinal employees to our employees.

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 acute care/emergency medicine and gastroenterology, since our sales forces specialize in these areas. If we are unable to expand our sales and marketing capability or any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. If we are unable to establish and maintain adequate sales and marketing capabilities:

Ø we may not be able to increase our product revenue;

Ø we may generate increased expenses; and

Ø we may not continue to be profitable.

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. For example, a new entrant into a smaller market could have a disproportionately large impact on others in the market. In addition, certain of our competitors do not aggressively promote their products in our markets. A relatively modest increase in promotional activity in our markets could result in large shifts in market share, adversely affecting us.

Kristalose competes in the U.S. with several other prescription laxative products, including Amitiza®, which is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. Acetadote competes

domestically with several orally administered prescription products for treating acetaminophen overdose. We are aware of products under development, including an intravenous acetaminophen product being developed by Cadence Pharmaceuticals Inc., which could compete with Amelior. We have limited patent protection against direct competition.

Our competitors may sell or develop drugs that are more effective and useful and less costly than ours, and they may be more successful in manufacturing and marketing their products. Many of our

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competitors have significantly greater financial and marketing resources than we do. Additional competitors may enter our markets.

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

Governmental and private health care payors have recently emphasized substitution of branded pharmaceuticals with less expensive generic equivalents. An increase in the sales of generic pharmaceutical products could result in a decrease in our revenues. While there are no generic equivalents competing with Amelior, Acetadote or Kristalose at this time, in the future we could face generic competition.

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

We acquired rights to Amelior, Acetadote and Kristalose. Our business strategy is to continue to acquire rights to FDA-approved products as well as pharmaceutical product candidates in the late stages of development. We do not plan to conduct basic research or pre-clinical product development, except to the extent of our investment in CET. 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. In addition, our bank credit agreement requires that we obtain the consent of the bank prior to making acquisitions unless the acquisitions meet certain criteria. See Management s discussion and analysis of financial condition and results of operations Liquidity and capital resources.

With future acquisitions, we may face financial and operational risks and uncertainties, including:

Ø not realizing the expected economic return or other benefits from an acquisition;

Ø incurring higher than expected acquisition and integration costs;

Ø assuming or otherwise being exposed to unknown liabilities;

Ø developing or integrating new products that could disrupt our business and divert our management s time and attention;

Ø not being able to preserve key suppliers or distributors of any acquired products;

Ø incurring substantial debt or issuing dilutive securities to pay for acquisitions; and

Ø acquiring products that could substantially increase our amortization expenses.

We are not precluded from engaging in a large acquisition in the future, including an acquisition that entails the investment of substantially all of the proceeds from this offering. While large acquisitions potentially present large opportunities, they also could magnify the risks identified above. As of the date of this prospectus, we have no commitments or agreements regarding any potential acquisitions.

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.

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

We sell most of our products to large pharmaceutical wholesalers, who in turn sell to, thereby supplying, hospitals and retail pharmacies. The distribution network for pharmaceutical products has become increasingly consolidated in recent years. Today, three large wholesalers control most of the market. Further consolidation among, or any financial difficulties of, pharmaceutical wholesalers or retailers could result in the combination or elimination of warehouses, which could cause product returns to us. In addition, further consolidation or financial difficulties could also cause our customers to reduce the amounts of our products that they purchase, which would materially and adversely affect our business, financial condition and results of operations.

If governmental or third-party payors do not provide adequate reimbursement for our products, our revenue and prospects for continued profitability will 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. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare beneficiaries in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Under this program, drug prices for certain prescription drugs are negotiated by drug plans, with the goal to lower costs for Medicare beneficiaries. Future cost control initiatives could decrease the price that we would receive for any products, which would limit our revenue and profitability. In addition, legislation and regulations affecting the pricing of pharmaceuticals might change.

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

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

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

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

Our CET joint initiative with Vanderbilt University and Tennessee Technology Development Corporation is designed to help us investigate, in a cost-effective manner, early-stage products and

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technologies. However, we may never gain access to commercially viable products from CET for a variety of reasons, including:

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

The size of our organization and our activities are growing, and we may experience difficulties in managing growth.

As of December 31, 2008, we had 49 full-time employees, which includes 22 hospital sales force representatives and district managers. 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, rapid growth in the scope of our operations in connection with the commercial launch of new products. Our financial performance will depend, in part, on our ability to manage any such growth effectively. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth.

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

We are a relatively small company, and we depend to a great extent on principal members of our management and scientific staff. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, it could have a material adverse effect on our business prospects. We currently have a key man life insurance policy covering the life of Mr. Kazimi. We have entered into agreements with each of our employees that contain restrictive covenants relating to non-competition and non-solicitation of our customers and suppliers for one year after termination of employment. Nevertheless, each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason, and so as a practical matter these agreements do not guarantee the continued service of these employees. Our success depends on our ability to attract and retain highly qualified scientific, technical and managerial personnel and research partners. Competition among pharmaceutical companies for qualified employees is intense, and we may not be able to retain existing personnel or

attract and retain qualified staff in the future. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results.

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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:

Ø decreased demand for our products;

Ø injury to our reputation;

Ø withdrawal of clinical trial participants;

Ø significant litigation costs;

Ø substantial monetary awards to or costly settlement with patients;

Ø product recalls;

Ø loss of revenue; and

Ø the inability to commercialize our product candidates.

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

We have product liability insurance that covers our clinical trials and the marketing and sale of our products up to a $10 million annual aggregate limit, subject to specified deductibles. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

We have never paid cash dividends on our capital stock. We do not anticipate paying cash dividends to our shareholders in the foreseeable future. The availability of funds for distributions to shareholders will depend substantially on our earnings. Furthermore, our loan agreement places certain restrictions on payment of dividends. Even if we become able to pay dividends in the future, we expect that we would retain such earnings to enhance

capital and/or reduce long-term debt.

RISKS RELATING TO GOVERNMENT REGULATION

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

Virtually all aspects of our business activities are regulated by government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution, promotion and sampling, and advertising of

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our products, and disposal of waste products arising from such activities, are subject to governmental regulation. These activities are regulated by one or more of the FDA, the Federal Trade Commission, or the FTC, the Consumer Product Safety Commission, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency, or the EPA, as well as by comparable agencies in foreign countries. These activities are also regulated by various agencies of the states and localities in which our products are sold. For more information, see Business Government Regulation.

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

Pharmaceutical products must be distributed, sampled and promoted in accordance with FDA requirements. The FDA also regulates the advertising of prescription drugs. The FDA has the authority to request post-approval commitments that can be time-consuming and expensive to comply with.

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

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

We cannot determine what effect changes in regulations or statutes or legal interpretation, when and if promulgated or enacted, may have on our business in the future. Such changes could, among other things, require:

Ø changes to manufacturing methods;

Ø expanded or different labeling;

Ø recall, replacement or discontinuance of certain products;

Ø additional record keeping; and

Ø expanded documentation of the properties of certain products and scientific substantiation.

Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations.

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RISKS RELATING TO INTELLECTUAL PROPERTY

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

We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Acetadote has been designated as an orphan drug and is indicated to prevent or lessen hepatic (liver) injury when administered intravenously within eight to ten hours after ingesting quantities of acetaminophen that are potentially toxic to the liver. The FDA is authorized to grant orphan drug designation to drugs intended to treat a rare disease or condition. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market another drug using the same active ingredients for the same indication, except in very limited circumstances, for seven years. To this extent, Acetadote is protected until 2011 against competition from another drug using the same active ingredient to treat the same indication. Orphan drug marketing exclusivity does not, however, protect a drug from competition by a different drug marketed for the same indications.

We do not have composition of matter or use patents for our marketed products. We do have a U.S. patent, No. 6,727,286, and some related international patents, which are directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which are related to our formulation and manufacture of Amelior. We have applied for additional U.S. and international patent protection for our invention related to ibuprofen solution formulations, methods of making the same, and methods of using the same, but those applications may not result in issued patents. Additionally, the active ingredient in Amelior ibuprofen is in the public domain, and if a competitor were to develop a sufficiently distinct formulation, it could develop and seek FDA approval for an ibuprofen product that competes with Amelior. Following successful completion of our clinical studies, we also plan to seek three-year marketing exclusivity for Amelior.

Inalco manufactures Kristalose and owns two U.S. patents, Nos. 5,003,061 and 5,480,491, related to the manufacture of Kristalose. These patents are not directed to the composition or use of Kristalose and do not prevent a competitor from developing a formulation and developing and seeking FDA approval for a product that competes with Kristalose.

While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the U.S. Patent and Trademark Office nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products.

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

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

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

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

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

Third parties, including our competitors, could have or acquire patent rights that they could enforce against us. In addition, we may be subject to claims from others that we are misappropriating their trade secrets or confidential proprietary information. If our products conflict with the intellectual property rights of others, they could bring legal action against us or our licensors, licensees, manufacturers, customers or collaborators. If we were found to be infringing a patent or other intellectual property rights held by a third party, we could be forced to seek a license to use the patented or otherwise protected technology. We might not be able to obtain such a license on terms acceptable to us or at all. If an infringement or misappropriation legal action were to be brought against us or our licensors, we would incur substantial costs in defending the action. If such a dispute were to be resolved against us, we could be subject to significant damages, and the manufacturing or sale of one or more of our products could be enjoined.

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

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

may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse

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result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

Our agreement with Inalco appoints us as the exclusive marketer, seller and distributor of Kristalose in the U.S. Either we or Inalco may terminate this agreement upon the breach of any material provision of the agreement if the breach is not cured within 45 days following written notice. If our agreement with Inalco were terminated, we would lose our right to continue commercialization of Kristalose in the U.S.

Under an agreement between us and Vanderbilt University, we have received certain clinical data to support regulatory approval for Amelior. Either we or Vanderbilt may terminate this agreement upon the breach of any material provision of the agreement if the breach is not cured within 45 days following written notice. If our agreement with Vanderbilt were terminated, we would lose our right to use the data to support regulatory approval, and this loss might hinder our ability to commercialize Amelior in accordance with our plans.

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are a relatively new company seeking to capture significant growth. While our revenues and operating income have increased over time, we anticipate that there may be fluctuations in our future operating results. Potential causes of future fluctuations in our operating results may include:

- new product launches, which could increase revenues but also increase sales and marketing expenses;
- acquisition activity and other charges (such as for inventory expiration);
- increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional development;

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

Ø unexpected product liability or intellectual property claims and lawsuits.

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

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

Our total assets include intangible assets related to our acquisitions. As of December 31, 2008, intangible assets relating to product and data acquisitions represented approximately 27.4% of our total assets. We may never realize the value of these assets. Generally accepted accounting principles require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any determination requiring the write-off of a significant portion of unamortized intangible assets would adversely affect our results of operations.

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

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

We have a relatively short history of profitability and may not be able to sustain or increase our net income levels.

We were incorporated in 1999 and incurred operating losses until 2004. We recorded our first year of profitability in 2004 and have remained profitable in each of 2005, 2006, 2007 and 2008. As of December 31, 2008, we had retained earnings of $1.5 million, representing the amount by which our historical profits have exceeded our historical losses. We may not be able to maintain or improve our current levels of revenue or net income. In such event, investors are likely to lose confidence in our ability to grow, and our stock price would suffer.

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RISKS RELATED TO THIS OFFERING AND AN INVESTMENT IN OUR STOCK

As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your shares.

The initial public offering price of our common stock in this offering is considerably more than the net tangible book value per share of our outstanding common stock. Investors purchasing shares of common stock in this offering will pay a price that substantially exceeds the value of our tangible assets after subtracting liabilities. As a result, investors in this offering will:

Ø incur immediate dilution of $9.81 per share, based on an assumed initial public offering price of $15.00 per share;

Ø contribute 85.3% of the total amount invested to date to fund our company based on an assumed initial offering price to the public of $15.00 per share;

Ø but will own only 35.2% of the shares of common stock outstanding after the offering.

These percentages do not give effect to the exercise of options and warrants to purchase up to an aggregate of 7,979,944 shares of common stock or the vesting of 2,550 shares of restricted stock. See Dilution.

We may conduct substantial additional equity offerings or issue equity as consideration in an acquisition or otherwise. These future equity issuances, together with the exercise of outstanding options or warrants, could result in future dilution to investors.

The market price of our common stock may fluctuate substantially.

The initial public offering price for the shares of our common stock sold in this offering has been determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. The price of our common stock may decline. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially.

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.

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

We will incur increased costs as a result of operating as a public company, and our management will be required to devote additional time to new compliance initiatives. As a public company, we will incur legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq, have imposed various new

requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations will increase our legal and financial compliance costs and will render some activities more time-consuming and costly.

The Sarbanes-Oxley Act will require, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system

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and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2010, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses.

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

There may not be a viable public market for our common stock.

Prior to this offering, there has been no public market for our common stock, and a regular trading market might not develop or continue after this offering. Moreover, the market price of our common stock might decline below the initial public offering price.

We will have broad discretion in how we use the proceeds of this offering, and we may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have broad discretion over the use of proceeds from this offering. We expect that the net proceeds from this offering will be used to fund continued development for Amelior as well as other research, marketing and development activities, and to fund working capital, capital expenditures and other general corporate purposes. We may also use a portion of the net proceeds to acquire products. We have no present agreements with respect to any such product acquisitions. We will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that lose value.

Future sales of our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock in the public market after this offering or the perception that these sales may occur could cause the market price of our common stock to decline. In addition, the sale of these shares in the public market could impair our ability to raise capital through the sale of additional common or preferred stock. After this offering, we will have 17,778,545 shares of common stock outstanding. Of these shares, all shares sold in the offering, other than shares, if any, purchased by our affiliates, will be freely tradable.

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

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

- Ø the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval;
- Ø advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders;
- Ø limitations on persons authorized to call a special meeting of shareholders;
- Ø a staggered board of directors;
- Ø a 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
- Ø no cumulative voting.

These and other provisions contained in our second 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.

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

In addition, we are subject to control share acquisitions provisions and affiliated transaction provision of the Tennessee Business Corporation Act, the applications of which may have the effect of delaying or preventing a merger, takeover or other change of control of us and therefore could discourage attempts to acquire our company. For more information, see Description of capital stock Anti-takeover effects of Tennessee law and provisions of our charter and bylaws.

Some of our shareholders have registration rights, which could impair our ability to raise capital or involve us in disputes.

Holders of our preferred stock have rights to be included in registration statements we file with the U.S. SEC. These rights could interfere with our ability to raise capital. To the extent that these rights might have applied to this

offering, we have obtained waivers from preferred holders for all but approximately 1% of our shares to be outstanding after this offering. We do not believe that these rights apply to this offering, although the non-waiving parties might claim otherwise.

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Special note regarding forward-looking statements

Statements in this prospectus 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, sho anticipate and other comparable terms or the negative thereof. In addition, we, through our senior management, from time to time make forward-looking oral and written public statements concerning our expected future operations and other developments. While forward-looking statements reflect our good-faith beliefs and best judgment based upon current information, they are not guarantees of future performance and are subject to known and unknown risks and uncertainties, including those mentioned in Risk factors, Management s discussion and analysis of financial condition and results of operations and elsewhere in this prospectus. Actual results may differ materially from the expectations contained in the forward-looking statements as a result of various factors. Such factors include, without limitation:

- legislative, regulatory or other changes in the healthcare industry at the local, state or federal level which increase the costs of, or otherwise affect our operations;

- changes in reimbursement available to us by government or private payers, including changes in Medicare and Medicaid payment levels and availability of third-party insurance coverage;

- competition; and

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

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Use of proceeds

We estimate that the net proceeds to us from the sale of the 6,250,000 shares of common stock offered hereby will be approximately $83.3 million, assuming an initial public offering price of $15.00, which is the midpoint of the range listed on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately $96.4 million. Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $5.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus.

We plan to use the net proceeds from this offering principally for acquisitions of product candidates, new products, intellectual property rights to products or companies that complement our business. We actively seek out acquisitions in the markets in which we have developed our sales forces hospital acute care and gastroenterology. We concentrate our efforts on products that are in the late stages of development or that are currently marketed. We do not currently have a letter of intent or definitive purchase agreement for any potential target. We may undertake one large acquisition, utilizing substantially all of the net proceeds from this offering, or we may engage in one or more smaller acquisitions. It is also possible that we do not identify and complete any acquisitions. Our bank credit agreement requires that we obtain the consent of the bank prior to making acquisitions unless the acquisitions meet certain criteria. See Management s discussion and analysis of financial condition and results of operations Liquidity and capital resources.

Subject to the foregoing, we currently expect to use our net proceeds from this offering as follows:

Ø the majority for potential acquisition of rights to additional products or product candidates, as discussed above;

Ø approximately $4.0 million for ongoing clinical work, product development and other costs related to Amelior;

Ø approximately $12.0 million for expected commercial introduction of Amelior to the U.S. market;

Ø approximately $15.0 million for expansion of our hospital and field sales forces to a total of approximately 130 representatives and district managers;

Ø approximately $1.0 million for product development by CET, our 85%-owned subsidiary; and

Ø the remainder to fund working capital and for general corporate purposes.

The expected uses of net proceeds of this offering represent our current intentions based upon our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon completion of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and you will be relying on the judgment of our management regarding the application of the proceeds of this offering.

The amounts we actually expend for the above-specified purposes may vary depending on a number of factors, including the extent of our success in identifying and completing acquisitions, changes in our business strategy, the amount of our future revenues and expenses and our future cash flow. If our future revenues or cash flow are less than we currently anticipate, we may need to support our ongoing business operations with net proceeds from this offering

that we would otherwise use to support acquisitions and other methods of growth.

Until we use the net proceeds from this offering for the above purposes, we intend to invest the funds in short-term, investment-grade, interest-bearing securities as directed by our investment policy. Our goals with respect to the investment of these net proceeds are capital preservation and liquidity so that such funds are readily available.

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Dividend policy

We have not declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends on our common stock for the foreseeable future. We currently intend to retain any future earnings for use in the operation of our business and to fund future growth. The payment of dividends by us on our common or preferred stock is limited by our loan agreement with Bank of America. Any future decision to declare and pay dividends will be at the sole discretion of our board of directors.

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Capitalization

The following table sets forth our capitalization as of December 31, 2008:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of all of our outstanding preferred stock into 1,625,498 shares of common stock; and
- on a pro forma as adjusted basis to give further effect to the sale of 6,250,000 shares of common stock that we are offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

You should read the following table in conjunction with our consolidated financial statements and related notes and Management s discussion and analysis of financial condition and results of operations appearing elsewhere in this prospectus.

	As of December 31, 2008		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands)		
Cash and cash equivalents[1]	$ 11,830	$ 11,830	$ 95,117
Long-term debt and long-term obligations (less current portion)	$ 5,958	$ 5,958	$ 5,958
Shareholders equity:[1]			
Convertible preferred stock, no par value; 3,000,000 shares authorized, 812,749 shares issued and outstanding, actual; and 3,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted[2]	2,604		
Common stock, no par value; 100,000,000 shares authorized, 9,903,047 shares issued and outstanding, actual; 100,000,000 shares authorized, 11,528,545 shares issued and outstanding, pro forma; and 100,000,000 shares authorized, 17,778,545 shares issued and outstanding, pro forma as adjusted[4]	13,500	16,104	99,392
Retained earnings	1,451	1,451	1,451
Total shareholders equity[1][3]	17,555	17,555	100,842
Total capitalization[1][3]	$ 23,513	$ 23,513	$ 106,801

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $15.00 per share would increase or decrease, as applicable, the amount of cash and cash equivalents, additional paid-in capital, total shareholders

equity and total capitalization by approximately $5.8 million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions payable by us.

(2) Upon the completion of this offering, the outstanding shares of preferred stock will convert into an aggregate of 1,625,498 shares of common stock.

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

(4) Excludes:

- 2,550 shares of unvested restricted common stock;
- 7,910,986 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of $1.65 per share;
- 2,505,389 shares of common stock reserved for future issuance under our current incentive plans; and
- 68,958 shares of common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $6.17 per share.

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Dilution

Our net tangible book value as of December 31, 2008 was $9.0 million, or $0.91 per share. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding. Our pro forma net tangible book value per share as of December 31, 2008 was $0.78. Pro forma net tangible book value per share gives effect to the conversion of all of our preferred stock into 1,625,498 shares of our common stock, which will occur upon completion of this offering.

After giving further effect to the sale by us of 6,250,000 shares of common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, and after taking into account the automatic conversion of our preferred stock upon completion of this offering, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2008 would have been approximately $92.3 million, or approximately $5.19 per share. This amount represents an immediate increase in pro forma net tangible book value of $4.41 per share to our existing shareholders and an immediate dilution in pro forma net tangible book value of approximately $9.81 per share to new investors purchasing shares of common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$ 15.00
Net tangible book value per share as of December 31, 2008	$ 0.91	
Effect on net tangible book value per share on conversion of preferred stock into common stock	(0.13)	
Pro forma net tangible book value per share as of December 31, 2008	0.78	
Increase per share attributable to this offering	4.41	
Pro forma as adjusted net tangible book value per share after this offering		5.19
Dilution per share to new investors		$ 9.81

A $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share would increase (decrease) our pro forma as adjusted net tangible book value as of December 31, 2008 by approximately $5.8 million, the pro forma as adjusted net tangible book value per share after this offering by $0.32 and the dilution in pro forma as adjusted net tangible book value to new investors in this offering by $0.68 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

In addition, the above discussion and table do not account for the vesting of 2,550 shares of restricted stock or the exercise of stock options and warrants after December 31, 2008. As of December 31, 2008, we had outstanding options to purchase a total of 7,910,986 shares of common stock at a weighted-average exercise price of $1.65 per share and outstanding warrants to purchase a total of 68,958 shares of common stock at a weighted-average exercise price of $6.17 per share. If all such options and warrants had been exercised and the restricted stock had vested as of December 31, 2008, pro forma as adjusted net tangible book value per share would have been $4.11 per share, and

dilution to new investors would have been $10.89 per share.

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Dilution

The following table summarizes, as of December 31, 2008, the differences between the number of shares purchased from us, the total consideration paid to us and the average price per share that existing shareholders and new investors paid. The table gives effect to the conversion of all of our outstanding preferred stock into 1,625,498 shares of common stock, which will occur upon completion of this offering. The calculation below is based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, and before deducting underwriting discounts and commissions and estimated offering expenses that we must pay.

	Total Shares		Total Consideration		Average Price per Share
	Number	%	Number	%	
Existing shareholders	11,528,545	64.8%	$ 16,104,104	14.7%	$ 1.40
New investors	6,250,000	35.2%	93,750,000	85.3%	15.00
Total	17,778,545	100.0%	$ 109,854,104	100.0%	

Assuming that the 2,550 shares of restricted stock had vested, that all options and warrants outstanding as of December 31, 2008 had been exercised for 7,979,944 shares of common stock, and the aggregate exercise price of approximately $13.5 million had been applied to repurchase 898,583 shares of common stock (at a repurchase price equal to the assumed initial public offering price of $15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus), new investors would have purchased 25.1% of our shares of common stock outstanding after this offering.

A $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share would increase (decrease) total consideration paid to us by investors participating in this offering by approximately $5.8 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The discussion and tables above assume no exercise of the underwriters over-allotment option. If the underwriters over-allotment option is exercised in full (but assuming no exercise of outstanding options or warrants or vesting of restricted stock), the number of shares of common stock held by existing shareholders would be reduced to 61.6% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering would be 38.4% of the total number of shares of common stock to be outstanding after this offering.

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Selected consolidated financial data

The selected consolidated financial data set forth below should be read in conjunction with the consolidated financial statements and related notes and Management s discussion and analysis of financial condition and results of operation and other financial information appearing elsewhere in this prospectus. The consolidated statement of operations data for the years ended December 31, 2006, 2007 and 2008 and consolidated balance sheet data as of December 31, 2007 and 2008 are derived from consolidated financial statements audited by KPMG LLP and are included elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 2004 and 2005 and the consolidated balance sheet data as of December 31, 2004, 2005 and 2006 have been derived from our audited consolidated financial statements that do not appear in this prospectus. The historical results are not necessarily indicative of the results to be expected for any future periods.

	Years Ended December 31,				
Statement of operations data[1]:	**2004**	**2005**	**2006**	**2007**	**2008**
			(in thousands, except per share data)		
Net revenues	$ 12,032	$ 10,690	$ 17,815	$ 28,064	35,075
Operating costs and expenses:					
Cost of products sold	816	533	2,399	2,670	3,046
Selling and marketing	6,802	5,647	7,349	10,053	14,387
Research and development	746	1,158	2,233	3,694	4,429
General and administrative	2,358	2,588	2,999	4,138	5,140
Amortization of product license rights			515	687	687
Other	6	13	96	97	104
Total operating costs and expenses	10,729	9,940	15,592	21,338	27,793
Gain on insurance recovery	266				
Operating income	1,569	750	2,224	6,725	7,282
Interest income	1	89	209	383	241
Interest expense	(1,012)	(63)	(722)	(640)	(213)
Other expense		(6)	(3)		
Net income before income taxes	558	770	1,708	6,469	7,310
Income tax benefit (expense)		1,184	2,697	(2,424)	(2,544)
Net income	$ 558	$ 1,954	$ 4,404	$ 4,044	$ 4,766
Earnings per share basic	$ 0.06	$ 0.21	$ 0.45	$ 0.40	$ 0.47
Earnings per share diluted	$ 0.04	$ 0.12	$ 0.27	$ 0.24	$ 0.29
Weighted-average shares outstanding basic	9,082	9,496	9,797	10,032	10,143
Weighted-average shares outstanding diluted	15,482	16,306	16,454	16,582	16,540

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

Balance sheet data:	As of December 31, 2004	2005	2006	2007	2008
			(in thousands)		
Cash and cash equivalents	$ 516	$ 5,536	$ 6,255	$ 10,815	11,830
Working capital	262	5,640	3,945	6,669	10,104
Total assets	4,507	10,173	26,481	28,919	31,119
Total long-term debt and other long-term obligations (including current portion)	2,436	2,398	10,543	7,623	7,666
Convertible preferred stock	2,743	2,743	2,743	2,743	2,604
Retained earnings (accumulated deficit)	(13,719)	(11,764)	(7,360)	(3,316)	1,451
Total shareholders equity (deficit)	(22)	6,234	11,126	16,746	17,555

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Management s discussion and analysis of financial condition and results of operations

The following discussion and analysis of our financial position and results of operations should be read together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. This discussion and analysis may contain forward-looking statements that involve risks and uncertainties. You should review the Risk factors section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

OVERVIEW

We are a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded, prescription products. We are building our product portfolio primarily by acquiring rights to FDA-approved and late-stage development products and marketing them to specialty physician segments. Our primary target markets are hospital acute care and gastroenterology. Our current portfolio consists of two marketed products and one late-stage development product for which we are pursuing regulatory approval.

We pursued the development of Acetadote for the treatment of acetaminophen poisoning and acquired rights to clinical data to support its approval. Approval of the product was obtained in January 2004 and we began to market Acetadote in the second quarter of 2004 and launched the product with a dedicated hospital sales force. In March 2006, we received approval from the FDA for the use of Acetadote in pediatric patients.

We gained access to marketed gastroenterology products by negotiating co-promotion agreements with the original developers of these products. These agreements allowed us to enter the gastroenterology market with minimal up-front costs and limited ongoing operating risk. In 2005, we made a strategic decision to de-emphasize our reliance on co-promotion agreements as a primary growth driver. In April 2006, we acquired exclusive commercial rights in the U.S. to Kristalose, a gastroenterology product we had previously co-promoted under an arrangement with Bertek Pharmaceuticals Inc., a subsidiary of Mylan Laboratories Inc. In September 2006, we re-launched Kristalose under the Cumberland brand with a dedicated field sales force targeting gastroenterologists and other high prescribers of laxative products.

Our research and development expenses have continued to grow because of our program to develop Amelior. We completed the clinical program for Amelior intended to support regulatory approval in 2008. We expect research and development expenses to continue to be significant as we continue clinical work related to Amelior and other products.

We have funded our operations with private equity capital of approximately $14 million since our inception in 1999. We have supplemented this equity funding by re-investing our profits and utilizing our credit facilities in order to support our operations.

Prior to 2007, our sales forces were contracted to us by a third party. In January 2007, we brought the hospital sales force in-house via our newly-formed, wholly-owned subsidiary, Cumberland Pharma Sales Corp. We continue to outsource the dedicated gastroenterology sales force. All expenses associated with the sales forces are included in selling and marketing expense.

In 2000, we formed CET with Vanderbilt University and Tennessee Technology Development Corporation to identify early-stage drug development activities. CET partners with universities and other research organizations to advance promising, early-stage product candidates through the development process and on to commercialization.

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Management s discussion and analysis of financial condition and results of operations

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

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Accounting Estimates and Judgments

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. We base our estimates on past experience and on other factors we deem reasonable given the circumstances. Past results help form the basis of our judgments about the carrying value of assets and liabilities that are not determined from other sources. Actual results could differ from these estimates. These estimates, judgments and assumptions are most critical with respect to our accounting for revenue recognition, provision for income taxes, stock-based compensation, research and development accounting, and intangible assets.

As of December 31, 2008, we have capitalized $3.3 million of costs associated with our initial public offering in accordance with SEC Staff Accounting Bulletin Topic 5A. If events or circumstances were to change, we may be required to expense these costs in a future period.

Revenue Recognition

We recognize revenue in accordance with the SEC s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104 (together, SAB 101), and Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48).

Our revenue is derived primarily from the product sales of Acetadote and Kristalose. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our wholesalers for a particular product.

Our net product revenue reflects the reduction of gross product revenue at the time of initial sales recognition for estimated accounts receivable allowances for chargebacks, discounts and damaged product as well as provisions for sales related accruals of rebates, product returns and administrative fees and fee for services. Our financial statements reflect accounts receivable allowances of $0.3 million, $0.1 million and $0.1 million as of December 31, 2006, 2007 and 2008, respectively, for chargebacks, discounts and allowances for product damaged in shipment. We had accrued liabilities of $0.7 million, $0.7 million and $1.0 million as of December 31, 2006, 2007 and 2008, respectively, for rebates, product returns, service fees, and administrative fees.

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Management s discussion and analysis of financial condition and results of operations

The following table reflects our sales-related accrual activity:

	Sales Related Accruals
Balance as of December 31, 2005	$ 83,056
Current Provision	892,518
Current Provision for Prior Period Sales	30,999
Actual Returns/Credits	(263,895)
Balance as of December 31, 2006	742,678
Current Provision	1,194,869
Current Provision for Prior Period Sales	(44,252)
Actual Returns/Credits	(1,154,933)
Balance as of December 31, 2007	738,362
Current Provision	1,690,134
Current Provision for Prior Period Sales	(73,960)
Actual Returns/Credits	(1,314,333)
Balance as of December 31, 2008	$ 1,040,203

The allowances for chargebacks, discounts, and damaged products and sales related accruals for rebates and product returns are determined on a product-by-product analysis and are established by management as our best estimate at the time of sale based on each product s historical experience, adjusted to reflect known changes in the factors that impact such allowances and accruals. Additionally, these allowances and accruals are established based on the contractual terms with customers; analysis of historical levels of discounts, returns, chargebacks and rebates; communication with customers, and purchased information about the rate of prescriptions being written and the level of inventory remaining in the distribution channel, if known; as well as expectations about the market for each product, including any anticipated introduction of competitive products.

The allowances for chargebacks and accruals for rebates and product returns are the most significant estimates used in the recognition of our revenue from product sales. Of the accounts receivable allowances and our sales related accruals, our accrual for rebates and product returns represent the majority of the balance. Sales related accrued liabilities totaled $0.7 million, $0.7 million and $1.0 million as of December 31, 2006, 2007 and 2008, respectively. Of these amounts, our estimated liability for rebates represented $598,000, $261,000 and $129,000, respectively, while our accrual for product returns totaled $51,000, $324,000 and $638,000, respectively. If the actual amount of cash discounts, chargebacks, rebates, and product returns differ from the amounts estimated by management, material differences may result from the amount of our revenue recognized from product sales. A change in our rebate estimate of one percentage point would have impacted net sales by approximately $96,000 and $102,000 for the years ended December 31, 2007 and 2008, respectively. A change in our product return estimate of one percentage point would have impacted net sales by $302,000 and $377,000 for the years ended December 31, 2007 and 2008, respectively. Our product returns for expired product are not tracked against specific periods. Any expired product return would be

from a prior period, given the shelf-life of the products.

From January 2006 through part of April 2006, we recorded contract sales revenue which was based on co-promotion agreements primarily with Bertek Pharmaceuticals Inc., for the sales of Kristalose. Co-promotion fees were calculated based on a percent of gross sales or similar calculation. Contract sales revenue is included in net revenues.

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Management s discussion and analysis of financial condition and results of operations

In 2005, we allowed customers to purchase additional product prior to a scheduled price increase. Revenue for shipments of these purchases was recognized in accordance with our stated revenue recognition policy. As a general rule, effective January 1, 2006, we no longer offer these or any other type of incentive purchases to our customers. We occasionally make an exception to this policy, when we offer odd-lot quantities at a slightly reduced price or when a customer opens a new facility and requests special terms on their initial purchase. To date, we believe these types of transactions have not been material. Moreover, when we offer special terms, we review the transaction against our revenue recognition policy for proper treatment. If we determine such transactions become material, we will disclose the impact in the notes to our financial statements.

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

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

Income Taxes

We provide for deferred taxes using the asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to operating loss and tax credit carry-forwards and differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Our principal differences are related to the timing of deductibility of certain items such as depreciation, amortization, and expense for options issued to nonemployees. Deferred tax assets and liabilities are measured using management s estimate of tax rates expected to apply to taxable income in the years in which management believes those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. In order to fully utilize the deferred tax asset of $1.5 million as of December 31, 2008, we will need to generate future taxable income of approximately $7.2 million prior to the expiration of the net operating loss carry-forwards in 2023.

Stock-Based Compensation

We determine our share value on a contemporaneous basis when we issue shares of common stock and options to purchase shares of our common stock. Our board of directors establishes a share value of the common stock based on a recommendation by management and its assessment of several factors, including:

Ø the fact that, prior to this offering, our common stock has not traded on a public market;

Ø reports by management of arms length negotiations with third parties who accept our common stock as consideration for services rendered;

- our performance and the status of our research and product development efforts;

- review of third-party valuation analysis secured from time to time by management, such as those secured from Morgan Joseph & Co. Inc. most recently in December 2008; and

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Management s discussion and analysis of financial condition and results of operations

Ø the board s consideration of the timing of a liquidity event (such as an initial public offering, merger, or sale of our company), given our board s consideration of existing market conditions.

In preparing its recommendation for our board, our management analyzes our revenue and expense projections, along with financial assumptions (including anticipation of future events). We have historically estimated a range for the value of our company as an enterprise, based on multiples of revenues, EBITDA, and earnings. We then adjust the range of enterprise values for cash and debt in order to determine the range of equity values of our company. We divide the equity values by the total number of common shares outstanding or subject to issuance upon the exercise or conversion of all outstanding options, warrants, and shares of preferred stock to establish the per share price range. In allocating equity value to preferred and common shares, we consider the features of common and preferred shares, recognizing that dividend and voting rights are the same for each and that the primary difference is a liquidation preference of $3.25 per share for preferred shares. After considering the range of values in December 2008, we determined that the equity value of our company was approximately $254 million. In the event of liquidation, aggregate preferential payments to holders of our preferred stock would be less than $2.7 million. We have evaluated the preference related to these potential payments and determined that its value is not material in relation to our company s overall equity value or on a per share basis. In recommending a specific price within the range of values, management makes subjective judgments based upon its current assessment of our historical and projected performance, general market conditions, and similar subjective criteria that management deems appropriate. All valuation analyses are performed contemporaneously. Most recently in December 2008, Morgan Joseph & Co. Inc., acting in connection with its role as our financial advisor, assisted management in preparing its valuation analysis for board review.

Prior to January 1, 2006, we applied the intrinsic-value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations including FIN No. 44, *Accounting for Certain Transactions Involving Stock Compensation an interpretation of APB Opinion No. 25*, to account for our stock options issued under the 1999 Stock Option Plan. Under this method, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation,* and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure, an amendment of FASB Statement No. 123*, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based compensation plans. As permitted by then-existing accounting standards, we elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS No. 123, as amended for options issued to employees. We applied the fair-value method prescribed by SFAS 123 for options issued to nonemployees.

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payments*, which revises SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123(R) requires that all share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. We adopted SFAS 123(R) effective January 1, 2006, prospectively for new equity awards issued subsequent to December 31, 2005, or existing awards that were modified, repurchased, or cancelled subsequent to the adoption of SFAS 123(R).

The 1999 Stock Option Plan was superseded and replaced by the 2007 Long-Term Incentive Compensation Plan (the 2007 Plan) and 2007 Directors Incentive Plan (the Directors Plan). The terms

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of the awards granted under the 1999 Stock Option Plan were not impacted by the implementation of the new plans.

Information on employee and non-employee stock options granted in 2006, 2007 and 2008 is summarized as follows:

Grants made during quarter ended	Number of Stock Options Granted	Weighted-Average Exercise Price	Average Intrinsic Value per Share[1]	Weighted-Average Fair Value of Option (per Share)
March 31, 2006	24,000	$ 9.00	$ 4.00	$ 4.18
June 30, 2006	48,600	$ 9.37	$ 3.63	$ 4.95
September 30, 2006	18,150	$ 9.00	$ 4.00	$ 5.58
December 31, 2006	5,200	$ 9.00	$ 4.00	$ 5.50
March 31, 2007	90,920	$ 11.00	$ 2.00	$ 7.21
June 30, 2007				
September 30, 2007				
December 31, 2007				
March 31, 2008				
June 30, 2008				
September 30, 2008	134,100	$ 13.29		$ 6.27
December 31, 2008				

(1) Calculated as of December 31, 2008

The fair value of employee options granted during 2006, 2007 and 2008 were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2006	2007	2008
Dividend yield	%	%	%
Expected term (years)	3 - 7	5.5 - 6.4	3.5 - 6.0
Expected volatility	47% - 54%	58% - 64%	49% - 51%
Risk-free interest rate	4.68% - 5.08%	4.6% - 4.8%	3.1%

The fair value of non-employee options granted during 2006, 2007 and 2008, were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2006	2007	2008

Dividend yield	%	%	%
Expected term (years)	.17-10	10	10
Expected volatility	37% - 63%	74%	68%
Risk-free interest rate	4.34% - 4.42%	4.83%	3.7%

For employee stock option grants, the weighted-average expected option terms for 2006, 2007 and 2008 represent the application of the simplified method as defined in SEC Staff Accounting Bulletin (SAB) No. 107 issued in March 2005, as amended by SAB 110 issued in December 2007. The simplified method defines the expected life as the average of the contractual term of the option and the weighted-average vesting period for the option. For non-employee stock option grants, the expected option terms for 2006, 2007 and 2008 represent the contractual term.

We estimated volatility for 2006, 2007 and 2008 in accordance with SAB No. 107. As there has been no public market for our common stock prior to this offering, and therefore, a lack of company-specific historical or implied volatility data, we have determined the share-price volatility based on an analysis

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of certain publicly-traded companies that we consider to be our peers. The comparable peer companies used for our estimated volatility are publicly-traded companies with operations which we believe to be similar to ours. When identifying companies as peers, we consider such characteristics as the type of industry, size and/or type of product(s), research and/or product development capabilities, and stock-based transactions. We intend to continue to consistently estimate our volatility in this manner until sufficient historical information regarding the volatility of our own shares becomes available, or circumstances change such that the identified entities are no longer similar to us. In this latter case, we would utilize other similar entities whose share prices are publicly available.

As of December 31, 2008, we had approximately $0.9 million of unrecognized share-based compensation expense related to unvested option awards. Additionally, as of December 31, 2008, we had outstanding vested options to purchase 7,673,031 shares of our common stock and unvested options to purchase 237,955 shares of our common stock. Furthermore, as of December 31, 2008, we had 68,958 warrants outstanding to purchase shares of our common stock.

Research and Development

We account for research and development costs and accrue expenses based on estimates of work performed, patient enrollment, or fixed-fee-for-services. As work is performed and/or invoices are received, we adjust our estimates and accruals. To date, our accruals have been within our estimates.

Total research and development costs are a function of studies being conducted and will increase or decrease, depending on the level of activity in any particular year.

Intangible Assets

Intangible assets include license agreements, product rights, and other identifiable intangible assets. We assess the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. In determining the recoverability of our intangible assets, we must make assumptions regarding estimated future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets, we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than the carrying value, an impairment loss will be recognized in an amount equal to the difference.

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RESULTS OF OPERATIONS

The following table sets forth, for the periods indicated, certain items from our statement of operations expressed as a percentage of net revenues, as well as the period-to-period change in these items.

	Years Ended December 31,			% Change	
	2006	2007	2008	2006-2007	2007-2008
Net revenues	100.0%	100.0%	100.0%	57.5%	25.0%
Operating costs and expenses:					
Cost of products sold	13.5	9.5	8.7	11.3	14.1
Selling and marketing	41.2	35.8	41.0	36.8	43.1
Research and development	12.5	13.2	12.6	65.4	19.9
General and administrative	16.8	14.7	14.7	38.0	24.2
Amortization of product license rights	2.9	2.4	2.0	33.3	0.0
Other	0.5	0.3	0.3	0.1	8.0
Total operating costs and expenses[1]	87.5	76.0	79.2	36.9	30.2
Operating income	12.5	24.0	20.8	202.4	8.3
Interest income	1.2	1.4	0.7	83.5	(37.0)
Interest expense	(4.1)	(2.3)	(0.6)	(11.4)	(66.7)
Net income before income taxes[1]	9.6	23.0	20.8	278.7	13.0
Income tax benefit (expense)	15.1	(8.6)	(7.3)	(189.9)	4.9
Net income[1]	24.7	14.4	13.6	(8.2)	17.8

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

Description of operating accounts

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

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

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

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

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

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

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

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

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Income tax benefit in 2006 consists primarily of the realization of our deferred tax assets less taxes incurred on income. *Income tax expense* in 2007 and 2008 consists primarily of current and deferred income taxes on our taxable income for financial reporting purposes.

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

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

Gross product sales were reduced by $2.8 million and $2.4 million in 2008 and 2007, respectively. In 2008, this reduction included $1.1 million for damaged and expired product returns, $0.7 million for cash discounts, $0.7 million related to fee-for-service costs and $0.3 million for estimated rebates, chargebacks and discounts related to Kristalose. For 2007 this reduction included $1.1 million for damaged and expired product returns, $0.6 million for cash discounts, $0.4 million related to fee-for-service costs and $0.2 million for estimated rebates, chargebacks and discounts related to Kristalose.

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

Selling and marketing. Selling and marketing expense for 2008 totaled $14.4 million, representing an increase of $4.3 million, or 43%, over 2007. Selling and marketing expense as a percentage of net revenue was 41.0% and 35.8% in 2008 and 2007, respectively. The increase was primarily due to $3.1 million for the expansion and ongoing costs of our sales forces as we continue to grow our products in our target markets and expand our territories. We also incurred an increase of $0.4 million in advertising expense primarily associated with a new marketing campaign for Kristalose and $0.4 million of additional royalty expense. We anticipate selling and marketing expenses to continue to increase as we expand both sales forces as well as our product lines.

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

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

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

Interest expense. Interest expense totaled $0.2 million for 2008, representing a decrease of $0.4 million, or 67%, over 2007. The decrease was primarily due to lower outstanding debt during

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2008 as compared to 2007. In April 2008, we amended our agreement to pay the remaining obligation related to the purchase of the product license right, resulting in lower interest expense in 2008 associated with this obligation.

Income tax expense. Income tax expense for 2008 totaled $2.5 million, representing a decrease of $0.1 million, or 5%, over 2007. As a percentage of net income before income taxes, income tax expense decreased from 37.5% for 2007 to 34.8% for 2008. The decrease in the tax rate was primarily due to the recognition in 2008 of previously unrecognized tax benefits associated with the reversal of the Company s FIN 48 reserve.

Year ended December 31, 2007 compared to year ended December 31, 2006

Net revenues. Net revenues in 2007 totaled $28.1 million, representing an increase of $10.2 million, or 57.5%, over 2006. Of this increase, $8.1 million was attributable to increased sales of Acetadote, and $2.8 million was attributable to increased sales of Kristalose. These increases were partially offset by a $0.6 million decrease in co-promotion and other revenue. In April 2006, we entered into an agreement to acquire the exclusive U.S. commercial rights to Kristalose and began recording revenue based on shipments of the product. Prior to April 2006, we co-promoted Kristalose and recorded a co-promotion fee based on a percentage of the product s sales. The increase in sales of Acetadote was primarily due to increased market share in our target area for the treatment of acetaminophen toxicity, a one-time sale to an international customer for $0.9 million and the impact of additional sales representatives. Other income in 2006 was primarily comprised of co-promotion fees related to Kristalose and grant related activity.

Gross product sales were reduced by $2.4 million and $2.1 million in 2007 and 2006, respectively. In 2007, this reduction included $1.1 million for damaged and expired product returns, $0.6 million for cash discounts, $0.4 million related to fee-for-service costs and $0.2 million for estimated rebates, chargebacks, and discounts related to Kristalose. For 2006, this reduction included $0.7 million related to damaged and expired product returns, $0.3 million related to cash discounts, $0.2 million related to fee-for-service costs and $1.0 million related to estimated rebates, chargebacks, and discounts related to Kristalose.

Cost of products sold. Cost of products sold totaled approximately $2.7 million in 2007, representing an increase of approximately $0.3 million, or 11%, over cost of products sold in 2006 of approximately $2.4 million. Of the increase, approximately 52% related to Acetadote and 48% related to Kristalose. Cost of products sold as a percentage of net revenues decreased from 13.5% in 2006 to 9.5% in 2007. The decrease in the cost of products sold as a percentage of net revenue was due to the shift in the sales mix. Acetadote cost of products sold as a percentage of Acetadote net revenue was not materially different between 2007 and 2006.

Selling and marketing. Selling and marketing expense totaled approximately $10.1 million in 2007, representing an increase of approximately $2.7 million, or 37%, over selling and marketing expense in 2006. Selling and marketing expense as a percentage of net revenue was 35.8% and 41.2% in 2007 and 2006, respectively. The dollar increase was primarily due to $2.0 million in additional costs related to the new sales force created to promote Kristalose. Additionally, we incurred approximately $0.7 million of increased royalty expense, of which $0.4 million related to Acetadote and $0.3 million related to Kristalose. We anticipate selling and marketing expense will grow as we expand both sales forces as well as our product lines.

Research and development. Research and development expense for 2007 totaled approximately $3.7 million, representing an approximate $1.5 million, or 65%, increase over research and development expense in 2006 of approximately $2.2 million. The increase was primarily due to the increased clinical studies in 2007 as we worked

towards completing the studies of Amelior. We expect

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research and development expense in 2008 to remain consistent with 2007 expense, and expect to include the NDA filing fee for Amelior.

General and administrative. General and administrative expense totaled $4.1 million in 2007, representing a $1.1 million, or 38%, increase over general and administrative expense in 2006 of $3.0 million. General and administrative expense as a percentage of net revenue was 14.7% and 16.8% in 2007 and 2006, respectively. The dollar increase was primarily due to increased personnel expense of $0.5 million, increased stock compensation expense of $0.3 million, increased audit fees of $0.2 million, and increased rent of $0.1 million. We expect general and administrative expense to increase in future periods as we continue to add staff, expand our infrastructure, and support the requirements of a public company.

Amortization of product license rights. Amortization of product licensing rights increased $0.2 million in 2007 as compared to 2006. The increase was due to recording twelve months of expense in 2007 compared to recording nine months in 2006 as the licensing rights were not acquired until April 2006. We expect to incur annual amortization expense relating to these product license rights through March 2021.

Interest income. Interest income in 2007 totaled $0.4 million, representing a $0.2 million, or 84%, increase over interest income in 2006 of $0.2 million. The increase in interest income was due to larger cash equivalent balances in 2007 as compared to 2006.

Interest expense. Interest expense totaled $0.6 million in 2007 as compared to $0.7 million in 2006. The decrease in interest expense in 2007 was due to lower outstanding term debt balances during 2007 as compared to 2006.

Income tax expense. Income tax expense totaled $2.4 million in 2007 as compared to an income tax benefit of $2.7 million in 2006. The income tax expense in 2007 was primarily due to current and deferred income taxes on our taxable income for financial reporting purposes. In 2006, the income tax benefit was primarily due to the reversal of our deferred tax asset valuation allowance after determining that it was more likely than not that we would realize the benefits of the deferred tax asset.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity are cash flows provided by our operations and our borrowings. We believe that our internally generated cash flows and amounts available under our debt agreements will be adequate to service existing debt, finance internal growth and fund capital expenditures.

As of December 31, 2008, cash and cash equivalents was $11.8 million, working capital was $10.1 million and our current ratio (current assets to current liabilities) was 2.33 to 1. Management expects funds for our operating and capital requirements will be provided by continuing operations and existing cash balances, as well as from collaborative agreements and other financing arrangements. As of December 31, 2008, we also had the ability to make additional draws of up to approximately $0.2 million on our line of credit. Our borrowing capacity on this line of credit increased to a total of $7.5 million on January 7, 2009. We will also have substantial proceeds from this offering.

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The following table summarizes our net changes in cash and cash equivalents for the years ended December 31, 2006, 2007 and 2008:

	Years Ended December 31,		
	2006	2007	2008
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ 2,163	$ 8,627	$ 6,397
Investing activities	(6,553)	(163)	(134)
Financing activities	5,109	(3,904)	(5,248)
Net increase in cash and cash equivalents[(1)]	$ 719	$ 4,559	$ 1,015

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

Net cash provided by operating activities was approximately $6.4 million for the year ended December 31, 2008, which was impacted by net income of approximately $4.8 million, adjustments for non-cash charges of approximately $1.7 million, the timing of the collection of accounts receivable of ($0.8) million and the timing of cash payments of accounts payable and accrued liabilities of approximately $1.7 million.

Net cash used in investing activities was approximately $0.1 million for the year ended December 31, 2008, and was used for additions of property, equipment and patents.

Net cash used in financing activities was approximately $5.2 million for the year ended December 31, 2008. This amount consisted of approximately $1.8 million related to principal payments on an outstanding note payable, payment of approximately $2.8 million of our other long-term obligation related to the purchase of our product license right, approximately $5.0 million of payments made to repurchase 384,615 shares of common stock and approximately $0.7 million in payments related to our initial public offering. In addition to these payments, we borrowed $0.5 million on our line of credit and $4.1 million on a term debt agreement.

In April 2006, we entered into an agreement with Inalco to acquire exclusive U.S. commercial rights for Kristalose. In order to complete this transaction, we obtained funding from Bank of America in the form of a three-year term loan for $5.5 million and a two-year revolving line of credit agreement, both with an interest rate of LIBOR plus 2.5% (7.4% as of December 31, 2007). The borrowings were collateralized by a first lien against all of our assets. We were paying off the term loan in quarterly installments, with the final payment due in 2009. This agreement contained various covenants, all of which we were in compliance with as of December 31, 2007. One covenant under this agreement required that we obtain the bank s consent to acquire or purchase a business or its assets unless: (a) we acquired a business or assets related to a product that has already received FDA approval and the product was currently available for purchase, or (b) we acquired a business or assets related to a product that the bank determined was in the final stages of development and we had at least $10 million in cash available following the acquisition. In

order to have made an acquisition without obtaining the bank s consent, we could not rely on the proceeds of any bank debt to fund the acquisition, and we must have been be in compliance with certain financial covenants. In addition to the three-year term loan, we deferred $4.5 million of the purchase price, of which $1.5 million was paid in April 2007 and $3.0 million was originally due in 2009. In April 2008, the Company paid the remaining obligation for an 8% discount on the $3.0 million face value of the obligation.

In conjunction with the original line of credit agreement and term loan agreement, we issued to the lender warrants to purchase up to 3,958 shares of common stock at $9.00 per share. The warrants

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expire in April 2016. The estimated fair value of these warrants of $25,680, as determined using the Black- Scholes model, has been recorded in the accompanying financial statements as permanent equity in accordance with Emerging Issues Task Force (EITF), No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.*

In December 2008, we refinanced the remaining term loan balance of $917,000 and borrowed an additional $4,083,000 as well as establishing a new $7.5 million line of credit via the Third Amendment to the Loan Agreement. Both the line of credit and the term loan carry an interest rate of LIBOR plus an applicable margin, as defined in the agreement (4.42% as of December 31, 2008). The borrowings are collateralized by a first lien against all our assets. We are paying off the term loan in quarterly installments, with the final payment due in 2011. The line of credit is also due in 2011. This agreement contains various covenants, all of which we were in compliance with as of December 31, 2008.

Under our agreements with Inalco and Bioniche for the manufacturing of Kristalose and Acetadote, we are obligated to purchase minimum amounts of inventory each year. These obligations require us to purchase approximately $2.6 million of Kristalose and $0.1 million of Acetadote during 2009, $3.0 million of Kristalose and $0.1 million of Acetadote during 2010, and $2.4 million of Kristalose during 2011. Beginning in October 2011 and continuing through the life of the Kristalose agreement, our minimum purchase requirements will be based on not less than 65% of the average purchases in each of the three immediately preceding annual periods. We expect our normal inventory purchasing levels to be above the required minimum amounts. As of December 31, 2008, we had met our purchase obligations for 2008 under these agreements.

In the second quarter of 2005, we received approximately $2.0 million from various investors in exchange for convertible promissory notes with a maturity date six months from the date of issuance. The notes bore interest at a fixed annual rate of 3.5%. In the fourth quarter of 2005, and pursuant to the terms of the notes, the principal value plus all elected accrued interest was converted into shares of our common stock.

In April 2005, we conducted a private placement of our common stock in which we issued 200,000 shares of common stock for total gross proceeds of $1.8 million, with net proceeds of $1.7 million. The purpose of this offering was to provide funding to advance product agreements, to complete product development and for general corporate purposes.

During 2001, we signed an agreement with Cato Research Ltd., or Cato, to cover a variety of development efforts related to Amelior, including preparation of submissions to the FDA. Under the terms of the agreement, we deferred a portion of each bill from Cato. One-third of the deferred amount accrued interest at an annual rate of 12.5% and was due after eighteen months. The remaining two-thirds will be due upon specific milestone events. Upon meeting the first milestone, an amount equal to one-third of the original deferred amount, or approximately $0.2 million, will become due and payable. Upon completion of the final milestone event, an amount equal to five times one-third of the original deferred amount, or approximately $1.0 million, will become due and payable to Cato. Since the application of these factors is contingent upon specific events which may or may not occur in the future and which did not occur as of December 31, 2006, the expense for these factors was not recognized in the 2006 consolidated financial statements. During the third quarter of 2007, we progressed our studies and NDA application to the extent that we determined it is probable the first milestone will be met. As such, we recorded the obligation related to the first milestone of approximately $0.2 million as a current liability as of December 31, 2007. As of December 31, 2008, the total liability recorded related to Cato was approximately $0.6 million. Should the remaining potential milestone be accomplished, the total remaining value we would be required to pay under this agreement would be approximately

$1.6 million. Additionally, if the FDA approves the product within eighteen months of acceptance of the

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NDA, Cato will vest in options to acquire up to 60,000 shares of our common stock depending on the timing of the approval.

The following table sets forth a summary of our contractual cash obligations as of December 31, 2008:

		Payments Due by Year				
Contractual obligations[1]	**Total**	**2009**	**2010**	**2011**	**2012**	**2013+**
			(in thousands)			
Amounts reflected in the balance sheet:						
Term loan	$ 5,000	$ 1,250	$ 1,667	$ 2,083		
Line of credit	1,826			1,826		
Estimated interest on debt/obligations[2]	630	244	217	169		
Other contractual obligations[3]	616	410	205			
Other cash obligations not reflected in the balance sheet						
Operating leases	1,678	590	559	138	93	298
Purchase obligations[4]	8,343	2,143	2,999	3,200		
Total	$ 18,093	$ 4,638	$ 5,648	$ 7,416	$ 93	$ 298

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

(2) Represents estimated interest payments on our company s line of credit and term loan based on the December 31, 2008 interest rate of LIBOR plus an applicable margin, as defined in the agreement (4.42%). Interest payments are due and payable quarterly in arrears. The line of credit becomes due and payable in December 2011. Estimated interest for the line of credit is based on the assumption of a consistent outstanding balance. The term loan matures in April 2012 with principal payments due and payable quarterly.

(3) Includes undiscounted cash flows as the imputed interest is included in these amounts.

(4) Represents minimum purchase obligations under Kristalose and Acetadote manufacturing agreements. Beginning in October 2011 and continuing through the life of the agreement, which expires in 2021, one of the manufacturing and supply agreements requires minimum purchases of not less than 65% of the average purchases in each of the three immediately preceding annual periods. Using minimum purchase requirements and the current pricing structure, these obligations would be approximately $1.9 million in 2012 and approximately $8.1 million in years 2013 - 2021.

OFF-BALANCE SHEET ARRANGEMENTS

During 2006, 2007 and 2008, we did not engage in any off-balance sheet arrangements.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2007, the FASB issued SFAS No. 141 (revised), *Business Combinations* (SFAS 141(R)). SFAS 141(R) relates to business combinations and requires the acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date measured at fair values on the acquisition date. This statement must be adopted prospectively by our company for all business combinations occurring on or after January 1, 2009. Early adoption is not allowed. The impact of adoption of SFAS 141(R) will depend on future acquisitions.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment to ARB No. 51* (SFAS 160). This statement establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. It also requires consolidated results of operations to include amounts attributable to both the parent and noncontrolling interest, with disclosure on the consolidated statement of operations of the amounts attributable to the parent and noncontrolling interest. The statement also requires that equity transactions by and between each part be accounted for as equity transactions unless the parent company loses its controlling interest in the subsidiary. In the event the parent company loses its

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controlling interest, the investment in the subsidiary will be adjusted to fair value, and a gain or loss on investment will be recognized in the statement of operations. The adoption of SFAS 160 will result in the allocation of future operating results of CET, including losses, to the noncontrolling interest of CET. In addition, the Company s balance sheet and statement of shareholders equity will reflect amounts attributable to the noncontrolling interest.

In December 2007, the FASB issued EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1), that prohibits companies from applying the equity method of accounting to activities performed outside a separate legal entity by a virtual joint venture. Instead, revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other applicable accounting literature. EITF 07-1 should be applied to collaborative arrangements in existence at the date of adoption using a modified retrospective method that requires reclassification in all periods presented for those arrangements still in effect at the transition date, unless that application is impracticable. EITF 07-1 is effective for our company beginning on January 1, 2009. Our company currently collaborates with certain research institutions to identify and pursue promising pre-clinical programs. We have negotiated rights to develop and commercialize these product candidates. The adoption of EITF 07-1 is not expected to have a material impact on our financial position or results of operations.

RECENTLY ADOPTED ACCOUNTING STANDARDS

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. More specifically, this statement clarifies the definition of fair value, establishes a fair valuation hierarchy based upon observable (e.g. quoted prices, interest rates, yield curves) and unobservable market inputs, and expands disclosure requirements to include the inputs used to develop estimates of fair value and the effects of the estimates on income for the period. This statement does not require any new fair value measurements. This pronouncement was effective for us on January 1, 2008. The adoption of SFAS 157 did not have a material impact on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), which permits entities to measure many financial instruments and certain other items at fair value. The objective of the statement is to improve financial reporting by allowing entities to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without applying complex hedge accounting provisions. The fair value option provided by this statement may be applied on an instrument by instrument basis, is irrevocable, and may be applied only to entire instruments and not portions of instruments. This statement was effective for us beginning in 2008. As of the date of adoption, we elected to recognize our financial assets and liabilities at historical cost. We may elect, on a case-by-case basis, to recognize new assets acquired or liabilities assumed at fair value.

In June 2007, the FASB issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). The scope of this issue is limited to nonrefundable advance payments for goods and services related to research and development activities. EITF 07-3 addresses whether such advanced payments should be expensed as incurred or capitalized. Our company was required to adopt EITF 07-3 effective January 1, 2008. The adoption of EITF 07-3 did not have a material impact on our results of operations or financial position.

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Management s discussion and analysis of financial condition and results of operations

QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISKS

Interest Rate Risk

We are exposed to market risk related to changes in interest rates on our cash on deposit in highly liquid money market accounts, our revolving credit facility, and our term note payable. We do not utilize derivative financial instruments or other market risk-sensitive instruments to manage exposure to interest rate changes. The main objective of our cash investment activities is to preserve principal while maximizing interest income through low-risk investments. Our investment policy focuses on principal preservation and liquidity.

We believe that our interest rate risk related to our portfolio of money market accounts is not material. Additionally, we have immediate access to these funds and could shift these funds to certificates of deposits with guaranteed rates. The risk related to interest rates for our money market accounts is that these accounts would produce less income than expected if market interest rates fall. If interest rates decreased by 1.0%, our annual interest income on cash and equivalents balance would decrease by approximately $118,000 based on the cash and equivalents balance at December 31, 2008.

The interest rate risk related to borrowings under our credit facility and term debt is a variable rate of the LIBOR rate plus an applicable margin, as defined in the loan agreement (4.42% at December 31, 2008). As of December 31, 2008, we had outstanding borrowings of $6.8 million under our Credit Facility and Term Debt combined. If interest rates increased by 1.0%, our annual interest expense on our borrowings would increase by approximately $68,000.

Exchange Rate Risk

While we operate primarily in the U.S., we are exposed to foreign currency risk. Acetadote is manufactured largely by a supplier that denominates supply prices in Canadian dollars. Additionally, much of our research and development is performed abroad. Our foreign currency transactions in U.S. dollars totaled approximately $0.8 million, $1.1 million and $1.5 million in 2006, 2007 and 2008, respectively.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange losses were immaterial for 2006 and 2007. Neither a 5% increase nor decrease from current exchange rates would have a material effect on our operating results or financial condition.

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OVERVIEW

We are a profitable and growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology, which are characterized by relatively concentrated physician prescriber bases. Unlike many emerging pharmaceutical and biotechnology companies, we have established both product development and commercialization capabilities, and believe our organizational structure can be efficiently expanded to accommodate our expected growth. Our management team consists of pharmaceutical industry veterans with significant experience in business development, clinical and regulatory affairs, and sales and marketing.

Since our inception in 1999, we have successfully funded the acquisition and development of our product portfolio with limited external investment and maintained profitable operations over the past four years. Our portfolio consists of two products approved by the U.S. Food and Drug Administration, or FDA, one late-stage product candidate and several pre-clinical development projects. We were directly responsible for the clinical development and regulatory approval of Acetadote, one of our marketed products, and are currently pursuing regulatory approval of Amelior, our lead product candidate. We promote Acetadote and our other FDA-approved product, Kristalose, through dedicated hospital and gastroenterology sales forces, which are comprised of 64 sales representatives and district managers.

Our key products and product candidates include:

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

Amelior, our lead pipeline candidate, is an intravenous formulation of ibuprofen. We completed our clinical program to support FDA approval of Amelior in 2008 and are pursuing regulatory approval of the product. There currently are no injectable products approved for sale in the United States for the treatment of both pain and fever. If we receive FDA approval for Amelior on our current projected timeline, we believe Amelior would be the first injectable product available for the treatment of both pain and fever. If approved, we plan to market Amelior in the United States through our hospital sales force and internationally through alliances with marketing partners. We believe Amelior currently represents our most significant product opportunity.

Injectable analgesics, or pain relievers, currently available in the U.S. include opioids, such as morphine and meperdine, and ketorolac, a non-steroidal anti-inflammatory drug, or NSAID. According to IMS Health Inc., or IMS Health, opioids accounted for over 90% of injectable analgesic market volume in 2007 with approximately 427 million units sold. Opioids are, however, known to cause undesirable side effects, including nausea, vomiting and cognitive impairment. Ketorolac, the only non-opioid injectable analgesic approved for sale in the United States, is also known to cause unwanted side effects, including an increased risk of bleeding. Despite strong safety warnings from the FDA, use of ketorolac in the United States has grown from approximately 38.0 million units sold in 2003 (7% of the market) to approximately 45.1 million units sold in 2007 (10% of the market) according to IMS Health.

Based on the results of our clinical studies to date, we believe Amelior represents a potentially safer alternative therapy to ketorolac. There is currently no approved injectable treatment for fever in the U.S.

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Acetadote is an intravenous formulation of N-acetylcysteine, or NAC, indicated for the treatment of acetaminophen poisoning. According to the American Association of Poison Control Centers National Poison Data System, acetaminophen was the leading cause of toxic drug ingestions reported to poison control centers in the U.S. in 2007. In January 2004, Acetadote received FDA approval as an orphan drug, a designation which provides for seven years of marketing exclusivity from date of approval. Since its launch in June 2004, we have consistently grown product sales for Acetadote. According to Wolters Kluwer Health Source[tm] Pharmaceutical Audit Suite, or Wolters Kluwer, Acetadote sales to hospitals grew 42% from 2006 to 2007. Total sales to hospitals in 2007 were $18.3 million. We believe that we can continue to expand market share, and that our Acetadote sales and marketing platform should help facilitate the commercial launch of Amelior.

Kristalose, a prescription laxative product, is a crystalline form of lactulose designed to enhance patient acceptance and compliance. Based on data from IMS Health, the market for prescription laxatives in the U.S. grew from approximately $206 million in 2003 to $372 million in 2007, driven largely by new product introductions and increased promotional activity by our competitors. We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a new dedicated field sales force and re-launched the product in September 2006 under the Cumberland brand. Wholesaler sales of Kristalose to pharmacies were $10.5 million in 2007. We believe that Kristalose has competitive advantages over competing prescription laxatives, such as fewer potential side effects and contraindications, as well as lower cost, and that the potential for growth of this product is significant.

Early-stage product candidates. Our pre-clinical product candidates are being developed through Cumberland Emerging Technologies, Inc., or CET, our 85%-owned subsidiary. CET collaborates with leading research institutions to identify and pursue promising pre-clinical programs within our target market segments. We have negotiated rights to develop and commercialize these product candidates. Current CET projects include an improved treatment for fluid buildup in the lungs of cancer patients and an anti-infective for treating fungal infections in immuno-compromised patients. In conjunction with these research institutions, we have obtained nearly $1 million in grant funding from the National Institutes of Health to support the development of these programs.

OUR COMPETITIVE STRENGTHS

Significant late-stage product opportunity in Amelior

We believe Amelior currently represents our most significant product opportunity based on the large potential markets for intravenous treatment of pain and fever, as well as clinical results for the product to date. We have conducted several clinical trials to support regulatory approval of this product. We completed this clinical program in 2008 and are pursuing regulatory approval of the product. Based on our clinical results to date, we believe Amelior represents a potentially safer alternative to ketorolac, which is the only injectable non-opioid analgesic currently on the U.S. market, with approximately 45 million units sold in 2007. We have retained exclusive commercialization rights for Amelior in the U.S. and plan to market the product through our existing hospital sales force.

Strong growth potential of our existing marketed products, Acetadote and Kristalose

We believe that there is significant opportunity to increase sales of our two currently approved products, Acetadote and Kristalose. Since its launch in June 2004, we have consistently grown product sales for Acetadote. During 2007, hospital purchases of Acetadote grew 42% to approximately $18 million. Kristalose competes in the high growth

U.S. prescription laxatives market which, based on data from IMS Health, grew from approximately $206 million in 2003 to $372 million in 2007, or a compound annual growth rate of approximately 16%. After acquiring exclusive U.S. rights to Kristalose

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in April 2006, we assembled an experienced, dedicated sales force and designed a new marketing program, re-launching the product in September 2006. We believe both Kristalose and Acetadote have favorable competitive profiles, and that we can increase market share for each.

Focus on underserved niche markets

We focus our efforts on specialty physician segments where we believe we can leverage our industry expertise and sales capability to deliver products that address unmet medical needs. Currently, our primary target markets are hospital acute care and gastroenterology. We consider these markets attractive because of their relatively concentrated physician prescriber bases, which allow us to reach target prescribers with a small number of sales representatives. Moreover, we believe these markets are less prone to competition from larger pharmaceutical companies than other pharmaceutical sectors.

Profitable business with a history of fiscal discipline

We have been profitable since 2004, during which time we have generated sufficient cash flows to fund our development and marketing programs without the need for significant external financing. As an emerging pharmaceutical company with limited resources, we have historically focused on product opportunities with relatively low acquisition, development, and commercialization costs. Further, we believe that our third-party manufacturing and distribution relationships allow us to outsource these functions efficiently while directing most of our resources to our core competencies of business development, clinical and regulatory affairs, and sales and marketing.

Integrated specialty pharmaceutical company with extensive management expertise

Our executives have significant pharmaceutical industry experience in business development, clinical and regulatory affairs, and sales and marketing. This team is augmented by our Pharmaceutical and Medical Advisory Boards, which consist of highly experienced healthcare professionals.

Ø Our business development team is led by our CEO and our Senior Vice President of Commercial Development and is comprised of a multi-disciplinary group of executives. This team sources product opportunities independently as well as through our international network of pharmaceutical and medical industry insiders. Their efforts have resulted in acquisition, license, co-promotion and strategic alliance agreements, and have provided us with rights to our current portfolio. This group is also responsible for acquiring rights to early-stage product candidates through CET.

Ø Our clinical, regulatory affairs and product development team is led by three professionals with substantial experience advancing late-stage clinical candidates successfully through the FDA approval process. This team was directly responsible for obtaining FDA approval for Acetadote and is responsible for our development of Amelior. We have established internal capabilities to develop proprietary product formulations, design and manage our clinical trials, prepare all regulatory submissions and manage our medical call center.

Ø Our sales and marketing team is led by four executives who have broad experience marketing branded pharmaceuticals. They manage the dedicated hospital and gastroenterology sales forces that promote our products and that together are comprised of 64 sales representatives and district managers. Our executives also direct our national marketing campaigns and manage relationships with key accounts.

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OUR STRATEGY

Our objective is to develop, acquire and commercialize branded pharmaceutical products for specialty physician market segments. Specifically, we plan to:

Successfully develop and commercialize Amelior, our lead product candidate

We have completed Phase III clinical development intended to support regulatory approval of Amelior for the treatment of pain and fever. We have gathered positive data regarding the safety and efficacy of this product, and are pursuing regulatory approval. We believe that there is significant market potential for Amelior in both pain and fever. We intend to penetrate the U.S. hospital market with our existing hospital sales force and to commercialize the product internationally through alliances with marketing partners.

Maximize sales of our marketed products

Over the past three years, we have employed an effective marketing campaign resulting in consistent sales growth for our product Acetadote. We intend to expand our hospital sales force in anticipation of a potential launch of Amelior and believe we can leverage this expanded sales force to increase Acetadote sales. We are also supporting several studies to explore other potential indications for Acetadote. In September 2006, we re-launched Kristalose under the Cumberland brand with a new marketing program and dedicated sales force, which we recently expanded. This marketing program is designed to enhance brand awareness through increased promotional activity and highlights Kristalose s many positive, competitive attributes. In addition to our sales efforts, we may also pursue co-promotion arrangements with third parties to support growth of our products.

Expand sales force operations

We believe that continuing to build our sales and marketing infrastructure will help drive prescription volume and product sales. We currently utilize two distinct sales teams:

Ø We promote Acetadote, and plan to promote Amelior, through our dedicated hospital sales team consisting of 22 representatives and district managers. This team currently covers approximately 1,630, or 30%, of all U.S. hospitals. We expect to significantly increase this sales force in order to fully capitalize on the market potential of Acetadote and Amelior.

Ø We promote Kristalose through a dedicated contract field sales force which we recently expanded to 42 sales representatives and district managers. These representatives are now covering approximately 7,600 gastroenterologists and other high prescribers of laxatives in territories that account for approximately 86% of total retail Kristalose prescriptions nationally. By investing in our marketing program and significantly expanding this sales force, we believe that we will be able to increase market share for Kristalose.

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

We intend to build a portfolio of complementary, niche products largely through product acquisitions. We focus on under-promoted, FDA-approved drugs with existing brand recognition as well as late-stage development products which address unmet medical needs, a strategy which we believe helps minimize our exposure to the significant risk,

cost and time associated with drug discovery and research. We plan to continue to target products that are competitively differentiated, have valuable trademarks or other intellectual property, and allow us to leverage our existing infrastructure. We also plan to explore opportunities to seek approval for new uses of existing pharmaceutical products.

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Develop a pipeline of early-stage products through CET

In order to build our product pipeline, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities of CET, our majority-owned subsidiary. CET partners with universities and other research organizations to cost-effectively develop promising, early-stage product candidates. Current pre-clinical projects nearing clinical-stage development include:

Ø a palliative treatment for fluid buildup in the lungs of cancer patients, in collaboration with Vanderbilt University, and

Ø a highly purified anti-infective for treating fungal infections in immuno-compromised patients, in collaboration with the University of Mississippi.

INDUSTRY

The hospital market

According to IMS Health, U.S. hospitals accounted for approximately $32 billion, or 9%, of U.S. pharmaceutical sales in 2007. IMS Health also reports that in 2007, marketing and promotional efforts focused on hospital-use drugs represented only about $590 million, or 2%, of approximately $22 billion total pharmaceutical industry spending on promotional activity. The majority of promotional spending is directed towards large outpatient markets promoting drugs intended for chronic use rather than short-term use in the hospital setting. We believe the lack of promotional emphasis on the hospital marketplace indicates that the hospital market is underserved. We also believe that the hospital market is highly concentrated, with a small number of large institutions responsible for a majority of pharmaceutical spending, and consequently that it can be penetrated effectively without large-scale promotional activity by a small, dedicated sales force.

Market for injectable analgesics

Therapeutic agents used to treat pain are collectively known as analgesics. Physicians prescribe injectable analgesics for hospitalized patients who have high levels of acute pain, require rapid pain relief or cannot take oral analgesics.

According to IMS Health, the U.S. market for injectable analgesics exceeded $302 million, or 472 million units, in 2007. This market is comprised principally of generic opioids and the NSAID ketorolac. Injectable opioids such as morphine, meperidine, hydromorphone and fentanyl accounted for approximately 427 million units sold in 2007. While opioids are widely used for acute pain management, they are associated with a variety of unwanted side effects including sedation, nausea, vomiting, constipation, headache, cognitive impairment and respiratory depression. Respiratory depression, if not monitored closely, can be deadly. Opioid-related side effects can warrant dosing limitations, which may reduce overall effectiveness of pain relief. Side effects from opioids can cause a need for further medication or treatment, and can increase lengths of stay in post-anesthesia care units as well as overall hospital stay, which can lead to increased costs for hospitals and patients.

Despite having a poor safety profile, usage of ketorolac, the only non-opioid injectable analgesic available in the U.S., has grown from approximately 38 million units in 2003, or 7% of the market, to approximately 45 million units in

2007, representing 10% of the market, according to IMS Health. The FDA specifically warns that ketorolac should not be used in various patient populations that are at-risk for bleeding, as a prophylactic analgesic prior to major surgery or for intraoperative administration when stoppage of bleeding is critical.

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Fever

Significant fever is generally defined as a temperature of greater than 102 degrees Fahrenheit. High fevers can cause hallucinations, confusion, convulsions and death. Hospitalized patients are subject to increased risk for developing fever, especially from exposure to infectious agents. Patients with endotracheal intubation, sedation, reduced gastric motility, nausea or recent surgery are frequently unable to ingest, digest, absorb, or tolerate oral products to reduce fever. Treatment for these patients ranges from rectal delivery of medication to physical cooling measures such as tepid baths, ice packs and cooling blankets. In the U.S., there is currently no FDA-approved intravenous medication for the treatment of fever.

Acetaminophen poisoning

Acetaminophen is one of the most widely used drugs for oral treatment of pain and fever in the U.S. and can be found in many common over-the-counter, or OTC products and prescription narcotics. Though safe at recommended doses, the drug can cause liver damage with excessive use. According to the American Association of Poison Control Centers National Poison Data System, acetaminophen poisoning was the leading cause of toxic drug ingestions reported to poison control centers in 2007 in the U.S.

In a study published in 2005 that examined acute liver failure, researchers concluded that acetaminophen poisoning was responsible for acute liver failure in over half the patients examined in 2003, up from 28% in 1998. While an estimated 48% of cases were due to the accidental use of acetaminophen over several days, causing chronic liver failure, an estimated 44% of the cases were intentional overdoses, causing acute liver failure.

According to the FDA, four grams of acetaminophen is the daily maximum dosage recommended for adults. Ingesting eight grams of acetaminophen in a single day causes a significant number of people, whose livers have been previously stressed by a virus, medication or alcohol, to experience more serious complications. When used in conjunction with opiates, acetaminophen can be effective in relieving pain after surgery or injury; however, some patients who take acetaminophen/opiate combination drugs on a chronic basis eventually require increasing amounts to achieve the same level of pain relief, which can also lead to liver failure.

Market for the treatment of Acetaminophen overdose

NAC is widely accepted as the standard of care for acetaminophen overdose. Throughout Europe and much of the rest of the world, NAC has been available in an injectable formulation for over 25 years. Until the 2004 approval of Acetadote, however, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Prior to the approval of Acetadote, many U.S. hospitals prepared an off-label, IV form of NAC from the oral solution to treat patients suffering from acetaminophen poisoning. For a number of these patients, an IV product is the only reasonable route of administration due to nausea and vomiting associated with the administration of oral NAC for the overdose. Moreover, IV treatment requires fewer doses and a shorter treatment protocol, reducing treatment from three days to one day.

Acetaminophen poisoning treatment is typically initiated in the emergency department and continued in the intensive care unit. NAC is marketed to emergency physicians and nurses, critical care physicians, clinical and medical toxicologists and poison control centers. According to *The Medical Letter on Drugs and Therapeutics,* NAC is

virtually 100% effective in preventing severe liver damage, renal failure and death if administered within eight to ten hours of the overdose.

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The gastrointestinal market

According to the National Institute of Diabetes, Digestive and Kidney Diseases, gastrointestinal diseases result in approximately 50 million physician visits and 14 million hospitalizations annually. Many of these physician visits are to one of the only 11,700 gastroenterologists in the U.S.

There are over 40 common, well-defined gastrointestinal conditions recognized in the U.S., including constipation, chronic liver disease and cirrhosis, gastroesophageal reflux disease, infectious diarrhea, irritable bowel syndrome, lactose intolerance, pancreatitis and peptic ulcers. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe that it is an attractive specialty focus which can provide a wide variety of product opportunities but can be penetrated with a modest sales force.

Prescription laxative market

Constipation is a common condition in the U.S., affecting approximately 20% of the population each year. While many occurrences are non-recurring, a significant number are chronic in nature and require some treatment to control or resolve.

Constipation treatments are sold in both the OTC, and prescription segments. We believe that the prescription laxative market in which Kristalose competes has historically consisted of a few highly promoted brands including MiraLax® (polyethylene glycol 3350), which is now being sold as an OTC product, and Amitiza®, as well as several generic forms of liquid lactulose. In addition, Novartis AG marketed Zelnorm® as a prescription laxative until the company announced its withdrawal from the U.S. market in April 2008 following the announcement of adverse safety findings in 2007. According to data from IMS Health, the prescription laxative market grew from approximately $206 million in 2003 to $372 million in 2007, a compound annual growth rate of approximately 16%. This increase in sales resulted primarily from new product introductions and increased promotion of branded products.

PRODUCTS

Our key products and product candidates include:

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

Amelior

Amelior, our lead pipeline candidate, is an intravenous formulation of ibuprofen. We completed clinical development for Amelior in 2008 and are pursuing regulatory approval of the product. There currently are no injectable products approved for sale in the U.S. for the treatment of both pain and fever. If we receive FDA approval for Amelior on our current projected timeline, we believe Amelior would be the first injectable product available for the treatment of both pain and fever. If approved, we plan to market Amelior in the U.S. through our hospital sales force and internationally through alliances with marketing partners. We believe Amelior currently represents our most significant product opportunity.

Ibuprofen, an NSAID, is a widely-used product now taken orally for pain relief and fever reduction, but is currently unavailable in an injectable formulation for this use. In May 1999, we acquired from Vanderbilt University an exclusive, worldwide license to clinical trial data on the use of intravenous

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ibuprofen for treatment of sepsis. Published in the *New England Journal of Medicine* in March 1997, this data indicated that intravenous ibuprofen was effective in reducing high fever in critically ill patients who were largely unable to receive oral medication. We issued 50,000 shares of our common stock to Vanderbilt upon entering into the agreement and if we receive regulatory approval for any product developed based entirely or in part on this data, such as Amelior, we are required to issue Vanderbilt shares of our common stock valued at $150,000 within thirty days of receiving regulatory approval. We are also required to pay Vanderbilt a two percent royalty on sales of any product developed based on the data. We and Vanderbilt each have the right to terminate this agreement upon breach by the other party, subject to providing 45 days prior written notice and an opportunity to cure. If not terminated, the agreement shall continue until we cease distribution of Amelior in all countries for which we have obtained regulatory approval.

Following discussion with and recommendation by the FDA, we implemented a development program for Amelior designed to obtain approval for a dual indication for the product reduction of pain and treatment of fever.

Development history

We have actively managed the development of Amelior by implementing the following steps:

Ø We obtained exclusive rights to an investigator IND which contains supportive safety and efficacy data in which hospitalized adult patients with sepsis received intravenous ibuprofen.

Ø We developed a patented formulation for Amelior as well as a proprietary manufacturing process.

Ø We completed a clinical study to establish the pharmacokinetic equivalence of oral and intravenous ibuprofen in February 2001, a study to establish safe administration of the optimized dilution of Amelior s IV preparation in March 2002, and a study to demonstrate that the product is effective in reducing fever in hospitalized adult malaria patients in July 2002.

Ø We completed a dose-ranging study to determine the optimum dose to treat fever in hospitalized adult patients in August 2005.

Ø We completed enrollment for a dose-ranging study to determine the product s effectiveness in controlling pain in post-surgical adult patients in October 2006.

Ø In January 2007, we initiated a pivotal study to demonstrate the product s effectiveness in controlling pain in post-surgical adult patients. In April 2007, a subsequent study was initiated to support the product s use in additional surgical populations.

Ø Over four years of stability studies for Amelior have been successfully completed.

Ø A study to obtain data to support pediatric use is ongoing.

An integrated safety database is being built, combining both previously published data with data from our new studies. In the Phase II and Phase III clinical trials to date, no serious adverse events have been directly attributed to Amelior. Further, in the Phase II and Phase III clinical trials to date, there have been no statistical differences in the incidence of

any adverse events associated with Amelior compared to placebo treatment, with the exception of bacteremia in one study, which in the opinion of the investigator and medical monitor, was not attributable to study medication. Additionally, there have been no differences between Amelior and placebo treatment groups relating to safety concerns associated with oral non-steroidal medications, such as changes in renal function, bleeding events, or gastrointestinal disorders.

In March 2007, *Pediatrics,* the official journal of the American Academy of Pediatrics, published the results of a clinical study comparing orally administered ibuprofen, acetaminophen and codeine for the

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treatment of pain from acute musculoskeletal injuries in children. Three hundred patients were evaluated and investigators reported that ibuprofen provided the best pain relief of the three study drugs.

We expect Amelior will be administered primarily to hospitalized patients who are unable to receive analgesics or antipyretics orally. We believe Amelior represents our most significant product opportunity to date.

Commercialization strategy

We intend to expand our existing U.S. hospital sales force to promote Amelior to physicians, nurses and pharmacy directors, principally in the hospital setting. We believe that we can achieve our commercial goals by utilizing our experienced sales organization, and supporting them with an internal marketing infrastructure that targets high-use institutions. We have an international strategic alliance with Hospira Australia Pty. Ltd., formerly known as Mayne Pharma Pty. Ltd., which will manufacture commercial supplies of Amelior. We also have an agreement with Bayer Healthcare, LLC, which will serve as an alternate manufacturer for Amelior. We intend to partner with third-parties to reach markets outside the U.S. or to expand our reach to physician groups outside the hospital where applicable.

Acetadote

Acetadote is N-acetylcysteine, or NAC, for the intravenous treatment of acetaminophen overdose. Until we obtained FDA approval for Acetadote in 2004, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Medical literature suggested that many hospitals prepared an off-label, IV form of NAC from the oral solution for easier administration and accuracy in dosing. Given this market dynamic, we concluded that a medical need existed for an FDA-approved, injectable formulation of NAC for the U.S. market.

We actively managed the development and regulatory approval of Acetadote by implementing the following steps:

- Ø We held initial discussions with the FDA to design a development plan.
- Ø Acetadote was granted orphan drug status in October 2001, which provides for seven years of marketing exclusivity from date of marketing approval.
- Ø We submitted our NDA in July 2002.
- Ø We submitted a complete response to FDA initial review questions in July 2003.
- Ø We received FDA marketing approval for Acetadote in January 2004 for the treatment of acetaminophen overdose.
- Ø Acetadote was launched in June 2004.
- Ø Early in 2006, the FDA-approved revised labeling for the product, which included an expanded indication for dosing in pediatric patients.

In connection with the FDA s approval of Acetadote, we committed to certain post-marketing activities for the product. Our first phase IV commitment (pediatric) was completed and accepted by the FDA in December 2004. Our

second phase IV commitment (clinical) was completed and accepted by the FDA in August 2006. We completed our third and final phase IV commitment (manufacturing) for Acetadote in 2007 and have submitted the appropriate documentation to the FDA for review. We are also supporting a number of studies to explore other potential indications for the product.

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We believe Acetadote has clinical and financial benefits relative to oral NAC, including ease of administration, minimizing nausea and vomiting associated with oral NAC, accurate dosage control, shorter treatment protocol and reduction in overall cost of acetaminophen overdose management. Acetadote makes NAC administration easier to tolerate for patients and easier to administer for medical providers. We believe Acetadote also offers a significant cost benefit to both patient and hospital by reducing the treatment regimen, usually from three days to one day.

Acetadote is manufactured for us by Bioniche Teoranta at its FDA-approved manufacturing facility in Ireland, and by Bayer Healthcare, LLC at its FDA-approved facility in Kansas.

Kristalose

Kristalose is a prescription laxative administered orally for the treatment of constipation. In patients with a history of chronic constipation, lactulose therapy increases the number of bowel movements per day and the number of days on which they occur. Lactulose is a product with a long history of use as a laxative, and as a treatment for hepatic encephalopathy, which is a deterioration of the liver resulting in a build-up of ammonia. Kristalose is an innovative, dry powder crystalline formulation of lactulose which is designed to enhance patient compliance and acceptance.

We co-promoted Kristalose from 2002 until April 2006 under an agreement with Bertek Pharmaceuticals, Inc., the branded division of Mylan Laboratories, Inc. Following Mylan s discontinuance of Bertek operations in 2006, Inalco assumed exclusive rights to commercialize Kristalose and in turn transferred exclusive U.S. commercialization rights to Kristalose to us. In April 2006, we and Mylan Bertek Pharmaceuticals, Inc. entered into a mutual release of all claims against each other. We re-launched Kristalose under the Cumberland brand in September 2006 with a dedicated, contract sales force which is now comprised of 42 sales representatives and district managers. We direct our sales efforts to physicians who are the most prolific writers of prescription laxatives. These physicians include gastroenterologists, pediatricians, internists and colon and rectal surgeons.

We believe Kristalose offers competitive advantages over other laxative products. Packaged in single dose packets, Kristalose is very portable, is reconstituted in as little as four ounces of water, is clear, virtually tasteless, does not change the viscosity of the water and contains almost no calories, all of which we believe cause Kristalose to compare favorably to liquid lactulose products. Compared to polyethylene glycol 3350 products, we believe Kristalose has a fast onset of action and a better pregnancy category rating. Compared with Amitiza®, Kristalose has fewer potential side effects or contraindications and is less expensive.

Kristalose is manufactured for us by Inalco S.p.A. at an FDA-approved facility in Italy.

Early-stage product candidates

Our pre-clinical product candidates are being developed by CET, which collaborates with leading research institutions to identify and pursue promising pre-clinical programs. Two of the more advanced CET development programs are:

Ø In collaboration with Vanderbilt University, we are currently developing a new palliative treatment for fluid buildup in the lungs of cancer patients. The product candidate is a protein therapeutic being designed to treat pleural effusion, a condition which occurs when cancer spreads to the surface of the lung and chest cavity, causing fluid to accumulate and patients to suffer shortness of breath and chest pain. An estimated 100,000 patients are

affected by this condition each year. Currently, the substances used in treating this cause pain and have only a 60-90% success rate. Vanderbilt

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University researchers believe they have found a method of treating this condition which may involve less pain, a higher success rate and faster healing time, resulting in significantly shorter hospital stays.

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

BUSINESS DEVELOPMENT

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

We intend to continue to build a portfolio of complementary, niche products largely through product acquisitions. Our primary targets are under-promoted, FDA-approved drugs with existing brand recognition and late-stage development products that address unmet medical needs in the hospital acute care and gastroenterology markets. We also plan to explore opportunities to acquire rights to and seek approval for new uses of pharmaceutical products. We believe that by focusing mainly on approved or late-stage products, we can minimize the significant risk, cost and time associated with drug development. We have completed three material acquisitions including:

Ø exclusive, worldwide rights from Vanderbilt University to data for intravenous ibuprofen to support our FDA submission for Amelior;

Ø exclusive, worldwide rights to clinical data supporting the safety and efficacy of Acetadote, which served as a key component of our FDA submission and approval; and

Ø exclusive U.S. commercial rights to Kristalose.

Our business development team is also responsible for identifying appropriate CET product candidates and negotiating with our university partners to secure rights to these candidates. Through CET, we are collaborating with a growing list of research institutions including:

Ø Vanderbilt University;

Ø University of Mississippi, School of Pharmacy; and

Ø University of Tennessee Research Foundation.

Since 2004, these collaborations secured nearly $1 million in National Institutes of Health grant funding for the development of promising new products and several additional proposals have been submitted or are awaiting review. Although we believe that these collaborations may be important to our business in the future, these collaborations are not material to our business at this time.

CLINICAL AND REGULATORY AFFAIRS

We have established in-house capabilities for the management of our clinical, professional and regulatory affairs. Our team develops and manages our clinical trials, prepares regulatory submissions,

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manages ongoing product-related regulatory responsibilities and manages our medical information call center. They were responsible for devising the regulatory and clinical strategy and obtaining FDA approval for Acetadote and are responsible for ongoing development of Amelior.

Clinical development

Our in-house clinical development personnel are responsible for:

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

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

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

Professional and medical affairs

Our clinical and regulatory team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. Our call center was previously operated by the Rocky Mountain Poison and Drug Center, or RMPDC. In 2006, we expanded our clinical and regulatory capabilities and brought our call center in-house

in an effort to ensure the highest level of quality and service. The RMPDC continues to supplement our efforts by providing after-hours support for our call center and assisting us with our adverse event collection/reporting and global pharmacovigilance activities. In addition to coordinating the call center, our clinical/regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. They manage the dedicated hospital and gastroenterology sales forces, which are comprised of 64 sales representatives and district managers, direct our national marketing campaigns and maintain key

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national account relationships. We promote our products to hospitals and office-based physicians across the U.S. and plan to commercialize our products internationally through marketing alliances.

In January 2007, we converted our hospital sales force, which had previously been contracted to us by Cardinal Health Inc., or Cardinal, to Cumberland employees through our newly-formed, wholly-owned subsidiary, Cumberland Pharma Sales Corp. The hospital sales team is comprised of 22 sales representatives and district managers, covering approximately 1,630 hospitals across the U.S. The gastroenterology-focused team, formed in September 2006 with our re-launch of Kristalose, is a field sales force comprised of 42 representatives and district managers and covering approximately 7,600 high prescribers of laxatives. This gastroenterology sales force is contracted to us by Inventiv Commercial Services, LLC, or Inventiv. Under our agreement, we pay Inventiv a monthly fee of $442,484, a portion of which is used to compensate the sales force. In addition to this monthly fee, as of December 31, 2008, we have paid Inventiv an aggregate of approximately $1.6 million for bonuses and expenses during the existence of this agreement. This agreement terminates in March 2010. We have the option, with Inventiv s consent, to extend the contract for one additional year. We also have the option to bring this sales force in-house. We recently expanded our gastroenterology sales force, and expect to significantly expand our hospital sales force over the next several years in anticipation of the launch of Amelior.

Our sales and marketing executives conduct ongoing market analyses to evaluate marketing campaigns and promotional programs. The evaluations include development of product profiles, testing of the profiles against the needs of the market, determining what additional product information or development work is needed to effectively market the products and preparing financial forecasts. We utilize professional branding and packaging as well as promotional items to support our products, including direct mail, sales brochures, journal advertising, educational and reminder leave-behinds, patient educational pieces and product sampling. We also regularly attend targeted trade shows to promote broad awareness of our products.

Our National Accounts group is responsible for key large buyers and related marketing programs. This group supports sales and marketing efforts by maintaining relationships with our wholesaler customers as well as with third-party payors such as Group Purchasing Organizations, Pharmacy Benefit Managers, Hospital Buying Groups, state and federal government purchasers and influencers and health insurance companies.

International Sales and Marketing

Consistent with our strategy to outsource non-core functions, we have licensed to third parties the right to distribute certain products outside the U.S. We have granted Alveda Pharmaceuticals Inc., or Alveda, an exclusive license to distribute Amelior in Canada subject to receipt of regulatory approval. Alveda is obligated to make payments to us of up to $1,000,000 Canadian upon Amelior s achieving specified regulatory milestones in Canada and to pay us a royalty based on Canadian sales of Amelior. This license terminates five years after regulatory approval is obtained in Canada for the later of the fever or pain indications. We have granted Hospira Singapore Pte. Ltd. an exclusive license to market and distribute Amelior in Southeast Asia subject to the receipt of regulatory approval. Hospira Singapore Pte. Ltd. is obligated to make payments to us of up to $500,000 upon Amelior s achieving specified regulatory milestones in Southeast Asia as well as royalty payments. The initial term of the agreement expires on the fifth anniversary of Amelior obtaining regulatory approval in Southeast Asia. We have granted Phebra Pty. Limited, or Phebra, an exclusive license to market and distribute Acetadote in Australia, New Zealand, and Southeast Asia, subject to the receipt of regulatory approval. Phebra is obligated to make payments to us of up to $325,000 upon Phebra s achieving specified milestones as

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well as royalty payments. This license terminates seven years after sales of Acetadote are recorded in Australia.

MANUFACTURING AND DISTRIBUTION

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

Manufacturing

Our key manufacturing relationships include:

Ø In July 2000, we established an international manufacturing alliance with a predecessor to Hospira Australia Pty. Ltd., or Hospira. Hospira sources active pharmaceutical ingredients, or APIs, and manufactures Amelior for us under an agreement that expires on the fifth anniversary of FDA approval of Amelior, subject to early termination upon 45 days prior notice in the event of uncured material breach by us or Hospira. The agreement will automatically renew for successive three-year terms unless Hospira or we provide at least 12 months prior written notice of non-renewal. Under the agreement, we pay Hospira a transfer price per unit of Amelior supplied. In addition, we reimburse Hospira for agreed-upon development, regulatory and inspection and audit costs. As of December 31, 2008, we have made payments to Hospira for validation batches of commercial supplies of Amelior pursuant to this agreement. We have paid approximately $1.1 million in the aggregate for validation batches, supplies, development, regulatory, inspection, audit and all other costs for Amelior to Hospira and its predecessors, Mayne Pharma Pty. Ltd. and F.H. Faulding & Co. Limited, as of December 31, 2008. We have also granted Hospira a right of first negotiation with respect to the manufacture of all future pharmaceutical products we intend to sell and the distribution of these products in Australia, New Zealand, Canada and mutually agreed Southeast Asian and Latin American countries.

Ø Bioniche Teoranta, or Bioniche, sources APIs and manufactures Acetadote for us for sale in the U.S. at its FDA-approved manufacturing facility in Ireland. Our relationship with Bioniche began in January 2002. Bioniche manufactures and packages Acetadote for us, and we purchase Acetadote from Bioniche pursuant to an agreement expiring in January 2011. This agreement is subject to early termination upon prior written notice in the event of an uncured material default by us or Bioniche. We have an option to renew the agreement for a five-year term upon expiration. Under the agreement, we pay Bioniche a transfer price per unit of Acetadote supplied, which transfer price is subject to annual adjustment, and a percentage royalty in the mid-single-digits throughout the term of the agreement based on our net sales of the product. In addition, we are required to purchase minimum quantities of Acetadote.

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

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

Distribution

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

INTELLECTUAL PROPERTY

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

Amelior

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 applied for additional protection for our invention related to ibuprofen solution formulations, methods of making the same and methods of using the same through U.S. application No. 10/739,050 and international application No. PCT/US04/39770, both of which remain pending.

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty and other payment obligations that are conditioned upon approval by the FDA of Amelior.

If Amelior is approved by the FDA, we intend to seek three years marketing exclusivity from the FDA based on the clinical studies we have sponsored to pursue approval of the product.

Acetadote

Acetadote was approved by the FDA in January 2004 as an orphan drug for the intravenous treatment of acetaminophen overdose. As an orphan drug, Acetadote is entitled to seven years of marketing

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exclusivity for the treatment of this approved indication. We have applied for patent protection for a new formulation of Acetadote through U.S. patent application No. 11/209,804, as well as through international application No. PCT/US06/20691, both of which are directed to acetylcysteine compositions, methods of making the same and methods of using the same. In addition, we have an exclusive, worldwide license to NAC clinical data from Newcastle Master Misercordiae Hospital in Australia. We have no expected outstanding payment obligations pursuant to this contract.

Kristalose

We are the exclusive licensee of two U.S. patents owned by Inalco relating to Kristalose. The first, U.S. Patent No. 5,003,061, is directed to a method for preparing high-purity crystalline lactulose. The second, U.S. Patent No. 5,480,491, is directed to a process for preparation of crystalline lactulose. Our license rights include an exclusive license to use related Inalco know-how and the Kristalose trademark to manufacture, market and distribute Kristalose in the U.S. Under our agreement with Inalco, Inalco is solely responsible for prosecuting and maintaining both the patents and know-how that we license from them. Our license expires in 2021 and is subject to earlier termination for material breach. Our payment obligations under this agreement are described under Manufacturing and Distribution Manufacturing.

COMPETITION

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

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

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

Amelior

We are developing Amelior for the treatment of pain and fever, primarily in a hospital setting. A variety of products already address the acute pain market.

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

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

Ø Other generic injectable opioids, including fentanyl, meperidine and hydromorphone.

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Ø Ketorolac (brand name Toradol®), an injectable NSAID, is also manufactured and distributed by several generic pharmaceutical companies.

We are aware of other product candidates in development to treat acute pain including injectable NSAIDs, novel opioids, new formulations of existing therapies and extended release anesthetics. We believe the companies developing injectable, non-narcotic analgesics for the treatment of post-surgical pain are the primary potential competitors to Amelior. Cadence Pharmaceuticals Inc. is developing an injectable formulation of acetaminophen for the treatment of pain and fever, and Javelin Pharmaceuticals Inc. is developing an injectable form of an NSAID, diclofenac.

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. There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including acetaminophen, ibuprofen and aspirin. These drugs are manufactured by numerous pharmaceutical companies.

Acetadote

Acetadote is our injectable formulation of NAC for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Despite the availability of injectable NAC outside the United States, Acetadote, to our knowledge, is the only injectable NAC product approved in the U.S. to treat acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC including, but not limited to, Geneva Pharmaceuticals, Inc., Bedford Laboratories division of Ben Venue Laboratories, Inc., Roxane Laboratories, Inc. and Hospira Inc.

Kristalose

Kristalose is a dry powder crystalline prescription formulation of lactulose indicated for the treatment of constipation. The U.S. constipation therapy market includes various prescription and OTC products. The prescription products which we believe are our primary competitors are Amitiza® and liquid lactuloses:

Ø Amitiza is indicated for the treatment of chronic idiopathic constipation in adults and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited; and

Ø Liquid lactulose products are marketed by a number of pharmaceutical companies.

In addition, Kristalose competed with Novartis Pharma AG s prescription product Zelnorm® until the company announced its withdrawal from the U.S. market in April 2008 after adverse safety findings led to U.S. marketing suspension in 2007.

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.

EMPLOYEES

As of December 31, 2008, we had 49 full-time employees, which includes 22 hospital sales force representatives and district managers. We also have a dedicated gastroenterology field sales force under contract that is comprised of 42 dedicated sales representatives and district managers. We believe that

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employing experienced, independent contractors and consultants is a cost-efficient and effective way to accomplish our goals. A number of additional individuals have provided or are currently providing services to us pursuant to agreements between the individuals or their employers and us. None of our employees are represented by a collective bargaining unit. We believe that we have positive relationships with our employees.

FACILITIES

We currently lease approximately 9,300 square feet of office space in Nashville, Tennessee for our headquarters. This lease expires in December 2010 for approximately 6,300 square feet and in December 2015 for approximately 3,000 square feet. We also entered into a sublease agreement for approximately 9,000 square feet of additional office space adjoining our headquarters, effective June 1, 2007. The sublease expires in October 2010. We believe that these facilities are adequate to meet our current needs for office space. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us by third-party contract groups.

Under an agreement expiring in July 2011, CET leases approximately 6,900 square feet of office and wet laboratory space in Nashville, Tennessee. CET uses this space to operate the CET Life Sciences Center for product development work to be carried out in collaboration with universities, research institutions and entrepreneurs. CET has an option to lease up to 20,000 square feet at the Life Sciences Center should it need additional space. The CET Life Sciences Center provides laboratory and office space, equipment and infrastructure to early-stage life sciences companies and university spin-outs.

GOVERNMENT REGULATION

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

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

FDA Approval Process

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

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

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

- Ø submission and approval of a NDA.

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

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

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

The time and cost of completing these steps and obtaining FDA approval can vary dramatically depending on the drug. However, to complete these steps for a novel drug can take many years and cost millions of dollars.

Section 505(b)(2) New Drug Applications

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a stand-alone or full NDA. Section 505(b)(2) of the FDC Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs which have a new dosage form, strength, route of administration, formulation or indication.

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We successfully secured FDA approval of a 505(b)(2) NDA for Acetadote in January 2004. We also plan to pursue marketing approval for Amelior pursuant to the 505(b)(2) pathway.

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

Special Protocol Assessment Process

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

On June 14, 2004, we submitted a request for SPA of our Amelior 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 will be considered sufficient to support a 505(b)(2) application for the pain indication. Final determinations by the FDA with respect to a product candidate, including as to the scope of its labeling , are made after a complete review of the applicable NDA and are based on the entire data in the application. Moreover, notwithstanding any SPA, FDA approval of an NDA is subject to future public health concerns unrecognized at the time of protocol assessment.

Orphan Drug Designation

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

The Hatch-Waxman Act

The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored

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by the applicant are essential to the approval of the application. It is under this provision that we expect to receive three years marketing exclusivity for Amelior.

Other regulatory requirements

Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

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

LEGAL PROCEEDINGS

We are not currently engaged in any legal proceedings.

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OFFICERS AND DIRECTORS

The following table sets forth the names and ages of our directors, executive officers and key managers as of January 31, 2008:

Name	Age	Position
Directors and executive officers:		
A.J. Kazimi	50	Chairman and Chief Executive Officer
Martin E. Cearnal[1]	64	Director and Senior Vice President, Commercial Development
Dr. Robert G. Edwards[2]	81	Director
Dr. Lawrence W. Greer[1],[2]	64	Director
Thomas R. Lawrence[1],[2]	69	Director
Jean W. Marstiller	58	Senior Vice President and Corporate Secretary
Dr. Gordon R. Bernard	57	Senior Vice President and Medical Director
Leo Pavliv	48	Vice President, Operations
J. William Hix	61	Vice President, Sales & Marketing
David L. Lowrance	41	Vice President and Chief Financial Officer
Key managers:		
James L. Herman	53	Senior Director, National Accounts and Corporate Compliance Officer
Dr. Arthur P. Wheeler	51	Director, Medical Affairs
Barry L. Lee	50	Product Director
Cindy Patton	54	Director, National Sales
Amy D. Rock	37	Senior Manager, Regulatory Affairs
Doug Jack	38	Senior Manager, SEC Reporting

(1) Member of Audit Committee

(2) Member of Compensation Committee

A.J. Kazimi, Chairman and Chief Executive Officer. Mr. Kazimi founded our company in 1999 and has served as our Chief Executive Officer and Chairman of our Board of Directors since inception. His career includes 20 years in the biopharmaceutical industry. Prior to joining our company, he spent eleven years from 1987 to 1998 helping to build Therapeutic Antibodies Inc., a biopharmaceutical company, where as President and Chief Operating Officer he made key contributions to the company s growth from its start-up phase through its initial public offering and product launches. Mr. Kazimi oversaw operations in three countries and was personally involved with the company s product development strategies, licensing and distribution agreements, and the raising of more than $100 million through equity and debt financings. From 1984-1987, Mr. Kazimi worked at Brown-Forman Corporation, rising through a series of management positions and helping to launch several new products. Mr. Kazimi currently serves on the board of directors for the Nashville Health Care Council; Aegis Sciences Corporation, a federally certified forensic toxicology laboratory; the Tennessee Biotechnology Association; and Aetos Technologies Inc., a technology

development company associated with Auburn University. He also serves as Chairman and Chief Executive Officer of Cumberland Emerging Technologies, Inc., or CET. He holds a B.S. from the University of Notre Dame and an M.B.A. from the Vanderbilt Owen Graduate School of Management.

Martin E. Cearnal, Director and Senior Vice President, Commercial Development. Mr. Cearnal has served as a member of our board of directors since 2004, and in 2008 was named Senior Vice President

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of Commercial Development. Mr. Cearnal is the former President and Chief Executive Officer of Physicians World, which became the largest provider of continuing medical education during his tenure from 1985 to 2000. Physicians World was acquired by Thomson Healthcare in 2000, and Mr. Cearnal served as President of Thomson Physicians World from 2000 to 2003 and Executive Vice President-Chief Strategy Officer for Thomson Medical Education from 2003 through 2005. Since 2006, he has been Executive Vice President-Chief Strategy Officer for Jobson Medical Information. Mr. Cearnal has 40 years experience in the healthcare industry and has been involved with the launches of such noteworthy pharmaceutical products as Lipitor®, Actos®, Intron-A®, Straterra®, Botox® and Humira®. He spent 17 years at Revlon Healthcare in a variety of domestic and international pharmaceutical marketing roles culminating in his position as Vice President, Marketing for International Operations. He serves the industry through several organizations, including the Healthcare Marketing & Communications Council and the Alliance for Continuing Medical Education. Mr. Cearnal also serves as a member of our Audit Committee. He has a B.S. degree from Southeast Missouri State University.

Dr. Robert G. Edwards, Director. Dr. Edwards has served as a member of our board of directors since 1999. From 1991 to 1999, he was Chairman and Managing Director of the Australasian subsidiary of Therapeutic Antibodies Inc., overseeing operations in Australia, New Zealand and Southeast Asia. Dr. Edwards also served as Deputy Director of the Institute for Medical & Veterinary Science in South Australia, President of the Royal College of Pathologists of Australasia, and member of the Australian National Health & Medical Research Council. Dr. Edwards currently serves as a member of our Compensation Committee. He also serves as a director for CET, and is chairman of the CET Scientific Advisory Board. Dr. Edwards holds a Primary Degree from London University, Master of Human Physiology from London University and an M.D. from the University of Adelaide.

Dr. Lawrence W. Greer, Director. Dr. Greer has served as a member of our board of directors since 1999. Since 2002, he has been Senior Managing Partner of Greer Capital Advisors of Birmingham, Alabama. Dr. Greer serves as investment advisor to two private equity funds and general partner for two additional private equity funds, including the S.C.O.U.T. Healthcare Fund from which we have received equity financing. Dr. Greer and his firm are established leaders in private healthcare investments in the mid-south. Previously, he served as Vice President-Investments of Dunn Investment Company, where he was responsible for management of a marketable securities portfolio plus personal management of a portfolio of 15 private equity investments. He is the former Chairman of Southern BioSystems which was acquired by DURECT Corporation in 2001. Dr. Greer has also worked as an independent consultant in healthcare administration and finance. Dr. Greer serves as the chairman of the Audit Committee of our board of directors, as a member of our Compensation Committee, and is an Audit Committee financial expert. He also served as the chairman of the Audit Committee for the Southtrust (Bank) Funds Board of Trustees for several years. Dr. Greer holds a B.S. from Tulane University, D.D.S. from Emory University and an M.B.A. from Emory University.

Thomas R. Lawrence, Director. Mr. Lawrence has served as a member of our board of directors since 1999. Since 2003 he has been Chairman and Chief Executive Officer of Aetos Technologies Inc., a corporation formed in 2003 by Auburn University to market technological breakthroughs by its faculty. From 1998 to 2003, Mr. Lawrence advised business clients on matters of marketing and corporate governance through his firm Capital Consultants. He previously served as Co-Founder and Managing Partner of Delta Capital Partners in Memphis from 1989 to 1998. The partnership made investments in ten early-stage companies which, by 1998, were valued at more than $30 million. Prior to the formation of Delta, Mr. Lawrence founded several companies in the areas of commercial leasing and venture capital financing. He also worked for most of the 1980s as an Institutional Sales Representative and Commercial Leasing Specialist with the Investment Banking Group of Union Planters Bank in Memphis, where he

was responsible for the structure and sale of over $1 billion in securities.

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Mr. Lawrence serves as the chairman of our Compensation Committee, as a member of our Audit Committee and as a director for CET. He holds a B.S. from Mississippi State University.

Jean W. Marstiller, Senior Vice President and Corporate Secretary. Ms. Marstiller joined our company in 1999. She oversees our administrative operations, human resources, site services and information systems, and became our Corporate Secretary in 2007. She has 18 years biopharmaceutical industry experience and was formerly Director of Administrative Operations at Therapeutic Antibodies Inc., where she worked from 1989 until 1998. In that capacity, she oversaw administrative services, information systems, and human resources. Ms. Marstiller was employed by Brown-Forman Corporation from 1982 until 1987, where she held management level positions in the areas of finance and operations. She holds a B.E. from Vanderbilt University and attended the Vanderbilt Owen Graduate School of Management.

Dr. Gordon R. Bernard, Senior Vice President and Medical Director. Dr. Bernard has served as our medical director since 1999. Dr. Bernard is the Assistant Vice-Chancellor for Research at Vanderbilt University, and also the Melinda Owen Bass Professor of Medicine and former Chief of the Division of Allergy, Pulmonary and Critical Care Medicine at Vanderbilt. In addition, he is the Medical Director of the Vanderbilt Institutional Review Board and Chairman of Vanderbilt s Pharmacy and Therapeutics Committee, which is responsible for approving the Vanderbilt Medical Center Formulary of approved drugs and therapeutics. Dr. Bernard also chairs the National Institutes of Health, Acute Respiratory Distress Syndrome Clinical Trials Network. He holds a B.S. from the University of Southwestern Louisiana and an M.D. from Louisiana State University.

Leo Pavliv, Vice President, Operations. Mr. Pavliv has served as our Vice President, Operations since 2003, and is responsible for Cumberland s overall drug development, including manufacturing and quality operations. He has 24 years of experience developing pharmaceutical and biological products. From 1997 to 2003 he worked at Cato Research, a contract research organization, most recently as Vice President of Pharmaceutical Development where he oversaw development of a wide variety of products throughout the development cycle. Prior to 1997, he held various scientific and management positions at both large pharmaceutical and smaller biopharmaceutical firms including Parke-Davis from 1984 to 1986, Agouron Pharmaceuticals from 1992 to 1997, ProCyte from 1989 to 1992, and Interferon Sciences from 1986 to 1989. He is a registered pharmacist (R.Ph.) and is regulatory affairs certified (RAC). Mr. Pavliv holds a B.S., Pharmacy, and an M.B.A. from Rutgers University.

J. William Hix, Vice President, Sales and Marketing. Mr. Hix is responsible for all our sales and marketing efforts. He joined us in 2004 to form and manage our national sales force promoting our acute care product line to hospitals, poison control centers and physicians. He was also instrumental in the design and implementation of our field sales force which is responsible for promoting our products in the gastroenterology market. Mr. Hix brings significant industry experience to our company having spent 30 years at Novartis/CIBA-GEIGY Pharmaceutical Corporation from 1974 to 2004. There, his responsibilities ranged from field sales, sales management, sales operations, planning and promotion to marketing support and operations. He holds a B.S. from the University of Memphis and an M.B.A. from Our Lady of the Lake University.

David L. Lowrance, Vice President and Chief Financial Officer. Mr. Lowrance is responsible for overseeing all our accounting and financial activities, including financial reporting and planning. He has been with us since 2003 and has 18 years of accounting and financial experience in both international business and manufacturing. From 1994 to 2003, he spent eight years with two global conglomerates, including four years as Senior Vice President for Icore International, a division of Smiths Group, PLC. Prior to that, Mr. Lowrance worked as a senior accountant for Ernst &

Young, LLP from 1990 to 1994. He is a Certified Public Accountant, or CPA, and holds a B.B.A. from the University of Georgia.

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James L. Herman, Senior Director, National Accounts and Corporate Compliance Officer. Mr. Herman handles all national accounts sales, including wholesalers and retail chain buying offices, managed care home offices and federal government accounts. He is also charged with overseeing our corporate compliance efforts. He has been with us since 2003 and has 18 years pharmaceutical industry experience. From 1998 to 2003, he was with Solvay Pharmaceuticals and served as Director of Managed Care as well as Director of Trade Affairs and Customer Service. From 1990 to 1998, Mr. Herman was with Schwarz Pharma, where he held national sales leadership positions in National Accounts and Managed Care. He holds a B.S. from Indiana University and an M.B.A. from Cardinal Stritch University.

Dr. Arthur P. Wheeler, Director, Medical Affairs. Dr. Wheeler joined our company as Director of Medical Affairs in 2007 and has served on our Medical Advisory Board since 2005. He is Associate Professor of Allergy, Pulmonary and Critical Care Medicine as well as Associate Professor of Medicine at Vanderbilt University. Dr. Wheeler also serves as Director of the Medical Intensive Care Unit at Vanderbilt University Medical Center. He is the vice chairman of the Vanderbilt Pharmacy and Therapeutics committee, and Director of the Vanderbilt Clinical Coordinating Center. He holds B.A. and M.D. degrees from the University of Maryland.

Barry L. Lee, Product Director. Mr. Lee joined our company as Product Director for Amelior in 2008. He is responsible for all marketing activities associated with the launch and ongoing commercialization of Amelior, our lead product candidate. Beginning his career with Berlex Laboratories, Inc. in 1984, Mr. Lee spent 24 years at the company, which is now known as Bayer Healthcare Pharmaceuticals Inc. following its acquisition of Berlex in 2006. There he served in a variety of pharmaceutical sales and marketing positions, and most notably was responsible for the launch of Yasmin® in 2001 one of the most successful industry product launches at that time. He has a B.S. degree from Texas A&M University.

Cindy Patton, National Sales Director. Ms. Patton joined our company in 2009 as National Sales Director. She is responsible for the development and management of Cumberland s hospital and field sales forces, and the successful execution of sales plans for our current and future products. Ms. Patton joined us from Novartis/CIBA-GEIGY Pharmaceutical Corporation where she acquired 25 years of pharmaceutical sales and marketing experience from 1983 to 2008. Her responsibilities there ranged from field and hospital sales to customer and product marketing, including serving as product director for the successful Novartis brand Lotensin®. Most recently, she served as Regional Sales Director of the Ciba Novartis Field Force, leading a team of managers and representatives in six states. Ms. Patton received her B.A. from Lambuth College.

Amy Dix Rock, Ph.D., Senior Manager, Regulatory Affairs. Dr. Rock joined our company in 2001 and built our Regulatory Affairs Department and infrastructure. In addition to managing all interactions between our company and the FDA, Dr. Rock oversees the preparation of pre-approval and post-approval regulatory submissions. Her additional responsibilities include involvement in protocol development and clinical trials management, overseeing our medical call center and supporting our corporate compliance initiatives. She holds a B.A. from Washington University, a Ph.D. in Immunology from the University of Kentucky, and an M.B.A. from the Vanderbilt Owen Graduate School of Management.

Doug Jack, Senior Manager, SEC Reporting. Mr. Jack is responsible for the preparation of all SEC required financial reports, including quarterly reports on Form 10-Q and annual reports on Form 10-K. Joining us in 2007, he has over 14 years of accounting and financial experience. Mr. Jack spent a combined eight years in the public accounting arena, most recently as an audit manager with Ernst & Young LLP from 2006 to 2007, and previously with

PricewaterhouseCoopers from 1993 to 2000. He

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has worked with manufacturing, wholesale and retail clients, including SEC registrants. Mr. Jack also served as Chief Financial Officer and Controller at Southern Specialty Brands from 2001 to 2006. He is a Certified Public Accountant and holds a B.B.A. from the University of Georgia.

ADVISORY BOARDS

In order to augment the efforts of our management and directors, we have established two key advisory boards to support our management and directors.

Pharmaceutical Advisory Board

Our Board of Pharmaceutical Advisors is comprised of eight individuals who have spent their careers in the pharmaceutical industry. These advisors help to build our company by actively contributing to many areas of our business such as strategy, business development, human resources, marketing, international activities, accounting and logistics. The members of our Board of Pharmaceutical Advisors are:

Joseph D. Williams	Former Chairman and CEO Warner Lambert Company
Joseph Carpino	Former VP, Business Development Warner Lambert Company
Jonathan Griggs	Former VP, Human Resources Warner Lambert Company
Robert Anderson	Former Chief Marketing Officer Thomson Medical Education Former Marketing Positions at Pfizer Pharmaceutical Company, Ciba Corp., Parke-Davis Company
Timothy Meakin	Former CEO Faulding Hospital Pharmaceuticals Division of F H Faulding & Co. Limited Former President Bristol-Myers Squibb Canada Co.
Neil M. Richie, Jr.	Former Director of Logistics Parke-Davis Company
James D. Aderhold, Jr.	Former VP, Sales and Marketing Cumberland Pharmaceuticals Inc. Former Sales and Marketing Positions at Parke-Davis Company, Ciba Corp.

Medical Advisory Board

We have also established a Board of Medical Advisors to support our product development efforts. This board includes five physicians from the U.S. and international medical communities who are leaders in the fields of emergency, critical care and infectious disease medicine as well as toxicology and cardiology. These individuals meet as a group with our management to help us identify unmet medical

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needs and underserved patient populations in our target areas. They also help us identify and evaluate relevant product opportunities. The members of our Board of Medical Advisors are:

Dr. Art Wheeler	Associate Professor of Medicine Vanderbilt University
Dr. Ben deBoisblanc	Professor of Medicine and Physiology Louisiana State University Medical School
Dr. Richard Dart	Director Rocky Mountain Poison and Drug Center
Dr. Robert Roberts	President and CEO University of Ottawa Heart Institute
Dr. David Warrell	Head, Nuffield Department of Clinical Medicine Professor Emeritus Tropical Medicine and Infectious Disease Oxford University

BOARD COMPOSITION

Our board of directors currently consists of five directors who are divided into three classes serving staggered three-year terms. Dr. Robert G. Edwards is a Class I director who will serve until our 2011 annual meeting of shareholders. Dr. Lawrence W. Greer and Thomas R. Lawrence are Class II directors who will serve until our 2009 annual meeting. A.J. Kazimi and Martin E. Cearnal are Class III directors who will serve until our 2010 annual meeting. Upon expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of shareholders in the year in which their term expires. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of directors could have the effect of increasing the length of time necessary to change the composition of a majority of our board of directors. In general, at least two annual meetings of shareholders will be necessary for shareholders to effect a change in a majority of the members of our board of directors.

DIRECTOR INDEPENDENCE

In December 2006 and in February 2007, our board of directors undertook reviews of the independence of the directors and considered whether any director had a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that Dr. Lawrence W. Greer and Martin E. Cearnal were independent as defined under applicable National Association of Securities Dealers Automated Quotation System, or NASDAQ, rules and SEC rules and regulations. Effective July 2008, we appointed Martin E. Cearnal as our Senior Vice President, Commercial Development. Our board of directors will reassess the independence of our directors as a result of this change. Thomas R. Lawrence is eligible to be considered independent subject to the board s review. We expect that a majority of our board will be independent within a year following this offering as required by the Sarbanes-Oxley Act of 2002, SEC rules and

regulations and NASDAQ rules.

BOARD COMMITTEES

The standing committees of our board consist of an audit committee and a compensation committee. Both committees will have three members following this offering, two of whom will be independent. We

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expect that all directors on our audit and compensation committees will be independent within a year following this offering.

Audit committee

The members of our audit committee are Dr. Lawrence W. Greer, Martin E. Cearnal and Thomas R. Lawrence. The Chair of the audit committee is Dr. Greer, who has been affirmatively determined by our board of directors to be independent in accordance with applicable rules. In addition, the board of directors has determined that Dr. Greer is an audit committee financial expert, as such term is described in Item 407 of Regulation S-K.

The primary function of the audit committee is to assist our board of directors in fulfilling its oversight responsibilities by reviewing the financial reports and certain financial information provided by us to any governmental body or the public, reviewing our systems of internal controls regarding finance, accounting, legal compliance and ethics that we have established and overseeing our auditing, accounting and financial reporting processes generally. Consistent with this function, we expect the audit committee to encourage continuous improvement of, and to foster adherence to, our policies, procedures and practices at all levels, to be responsible for managing the relationship with our independent registered public accountants, and to provide a forum for discussion with the independent registered public accountants and our board.

Some of the audit committee s responsibilities include:

- Ø appointing, determining the compensation for and overseeing our relationship with our independent registered public accountants;
- Ø overseeing, reviewing and evaluating our financial statements, the audits of our financial statements, our accounting and financial reporting processes, the integrity of our financial statements, our disclosure controls and procedures and our internal audit functions;
- Ø reviewing and approving the services provided by our independent registered public accountants, including the scope and results of their audits and pre-approving permissible non-audit services to be performed by them;
- Ø resolving disagreements between management and our independent registered public accountants;
- Ø overseeing our compliance with legal and regulatory requirements and compliance with ethical standards adopted by us;
- Ø establishing and maintaining whistleblower procedures; and
- Ø evaluating periodically our Standards of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers and Procedures for Complaints and Concerns Regarding Accounting, Internal Accounting Controls and Auditing Matters.

Compensation committee

The members of our compensation committee are Dr. Lawrence W. Greer, Dr. Robert G. Edwards, and Thomas R. Lawrence. The Chair of the compensation committee is Thomas R. Lawrence. The responsibilities of the compensation committee include:

- reviewing and recommending to the board of directors the compensation and benefits of all of our executive officers and directors;
- evaluating the performance of the principal executive officer;
- administering our equity incentive plans;

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Ø establishing and reviewing general policies relating to compensation and benefits of our employees;

Ø reviewing and evaluating the compensation discussion and analysis prepared by management; and

Ø preparing an executive compensation report for publication in our annual proxy statement.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Thomas R. Lawrence, the Chair of our compensation committee, is the Chairman of Aetos Technologies, Inc., a corporation formed in 2003 by Auburn University to market technological breakthroughs by its faculty. Mr. Kazimi, our Chairman and Chief Executive Officer, serves on the board of directors of Aetos Technologies. Other than this relationship, none of our executive officers serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers who serve on our board of directors or compensation committee.

CODES OF CONDUCT AND CORPORATE GOVERNANCE

We have implemented and continue to develop a Corporate Compliance Program. Within this program, we plan to maintain internal processes and review procedures that ensure our business activities are conducted in compliance with applicable federal and state laws, statutes, regulations or program requirements, including guidance documents drafted specifically by governing entities for the healthcare and pharmaceutical industries, consistent with advancing, preserving and protecting public health.

To help ensure compliance, we plan to conduct regular, periodic compliance audits by internal and external auditors and compliance staff, who have expertise in federal and state healthcare laws and regulations.

Our codes of conduct consist of a Standards of Business Conduct and Ethics, a Code of Ethics for Senior Financial Officers, an Insider Information, Trading or Dealing and Stock Tipping Policy and Procedures for Complaints and Concerns Regarding Accounting, Internal Accounting Controls, and Auditing Matters. As part of our corporate compliance program, in 2006 we established a compliance hotline to enable employees, directors and other representatives to report compliance violations, including violations of our codes of conduct.

Standards of Business Conduct and Ethics

Our board of directors has adopted a Standards of Business Conduct and Ethics which establish the standards of ethical conduct applicable to all of our directors, officers, employees, key advisors, consultants and contract organizations. The code of ethics addresses, among other things, compliance with laws and regulations, business practices, conflicts of interest, employment policies and reporting procedures. Suspected violations of this code may be reported on a confidential, anonymous basis through the compliance hotline. The audit committee oversees this process, tracks the complaints and resolutions and reports the significant results to the full board of directors. The code is distributed to all employees and directors. All employees and directors must sign, date and return a certification stating that they received, understand and will comply with the code.

Code of Ethics for Senior Financial Officers

In 2006, we adopted a Code of Ethics for Senior Financial Officers. The code is designed to deter wrongdoing and to promote honest and ethical conduct, full and accurate disclosure in periodic reports, and compliance with laws and regulations by our senior management who has financial responsibility. We expect that any suspected violations of this code will be reported to the audit committee. Any waiver of this code may only be authorized by our audit committee and will be disclosed as required by applicable law.

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Insider Information, Trading or Dealing and Stock Tipping Policy

We are committed to fair trading for publicly traded securities and have established standards of conduct for directors, employees and others who obtain material or price-sensitive, non-public information through their work with us. The policy is distributed to all employees. Non-compliance with the policy may be submitted on a confidential, anonymous basis through the compliance hotline.

Procedures for Complaints and Concerns Regarding Accounting, Internal Accounting Controls, and Auditing Matters

In 2006, we established Procedures for Complaints and Concerns Regarding Accounting, Internal Accounting Controls and Auditing Matters to encourage any person who has a reasonable basis for a complaint or concern regarding our financial statement disclosures, accounting matters, internal accounting controls or auditing matters to promptly submit a complaint or concern. Complaints may be submitted on a confidential, anonymous basis through the compliance hotline. The audit committee oversees this process, immediately reviews the complaints and oversees all necessary investigations. The audit committee tracks the complaints and resolutions and reports the significant results to the full board of directors.

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COMPENSATION DISCUSSION AND ANALYSIS

We provide what we believe is a competitive total compensation package to our executive management team through a combination of base salary, long-term equity incentive compensation plan and broad-based benefits programs.

We place significant emphasis on performance-based incentive compensation programs. This Compensation Discussion and Analysis explains our compensation philosophy, policies and practices with respect to our chief executive officer, chief financial officer, and the other three most highly-compensated executive officers or the named executive officers.

The objectives of our executive compensation program

Our compensation committee is responsible for establishing and administering the policies governing the compensation for our executive officers. Our executive officers are appointed by our board of directors.

Our executive compensation programs are designed to achieve the following objectives:

- attract and retain talented and experienced executives;
- motivate and reward executives whose knowledge, skills and performance are critical to our success;
- align the interests of our executive officers and shareholders by motivating executive officers to increase shareholder value and rewarding executive officers when shareholder value increases;
- provide a competitive compensation package in which total compensation is primarily determined by company and individual results and the creation of shareholder value;
- ensure fairness among the executive management team by recognizing the contributions each executive makes to our success; and
- compensate our executives to manage our business to meet our long-range objectives.

The compensation committee meets outside the presence of all of our executive officers, including the named executive officers, to consider appropriate compensation for our CEO. For all other named executive officers, the committee meets outside the presence of all executive officers except our CEO. Mr. Kazimi annually reviews each other named executive officer s performance with the committee and makes recommendations to the compensation committee with respect to the appropriate base salary and the grants of long-term equity incentive awards for all executive officers. Based in part on these recommendations from our CEO, the compensation committee approves the annual compensation package of our executive officers other than our CEO. The compensation committee also annually analyzes Mr. Kazimi s performance and determines his base salary and grants of long-term equity incentive awards based on its assessment of his performance.

When making decisions on setting base salary and initial grants of long-term equity incentive awards for new executive officers, the compensation committee considers the importance of the position to us, the past salary history of the executive officer and the contributions to be made by the executive officer to us.

We use the following principles to guide our decisions regarding executive compensation:

Ø provide compensation opportunities targeted at market median levels;

Ø require performance goals to be achieved or common stock price to increase in order for the majority of the target pay levels to be earned;

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Ø offer a comprehensive benefits package to all full-time employees; and

Ø provide fair and equitable compensation.

Our executive compensation programs

Overall, our executive compensation programs are designed to be consistent with the objectives and principles set forth above. The basic elements of our executive compensation programs are base salary, long-term equity incentive plan awards, retirement savings opportunities and health and welfare benefits. Each of these elements is summarized below.

Base salary

Annually we review salary ranges and individual salaries for our executive officers. We establish the base salary for each executive officer based on consideration of median pay levels in the market and internal factors, such as the individual s performance and experience, and the pay of others on the executive team.

The base salaries paid to our named executive officers are set forth below in the Summary Compensation Table. For the fiscal year ended December 31, 2008, base cash compensation to our named executive officers was approximately $1,120,600, with our CEO receiving approximately $333,000 of that amount. We believe that the base salary paid to our executive officers during 2008 achieves our executive compensation objectives, compares favorably to market pay levels and is within our target of providing a base salary at the market median.

In 2009, adjustments to our executive officers total compensation were made based on an analysis of current market pay levels of peer companies and in published surveys. In addition to the market pay levels, factors taken into account in making any changes for 2009 included the contributions made by the executive officer, the performance of the executive officer, the role and responsibilities of the executive officer and the relationship of the executive officer s base pay to the base salary of our other executives.

Long-term equity incentive compensation

We award long-term equity incentive grants to executive officers, including the named executive officers, as part of our total compensation package. These awards are consistent with our pay for performance principles and align the interests of the executive officers to the interests of our shareholders. The compensation committee reviews and recommends to the board of directors the amount of each award to be granted to each named executive officer and the board of directors approves each award. Long-term equity incentive awards to our executives were made pursuant to our 1999 Stock Option Plan, or the 1999 Plan, until April 2007, and thereafter, pursuant to our Long-Term Incentive Compensation Plan.

1999 Stock Option Plan

Our 1999 Plan provides for the grant of incentive stock options and nonqualified stock options. Grants can be made under the 1999 Plan to any of our employees, directors and consultants. The 1999 Plan is administered by a committee designated by our board of directors. The committee, in its sole discretion, granted options under the 1999 Plan to certain persons rendering services to us. Except as otherwise determined by the committee and stated in the applicable

option agreement, the exercise price per share of each option granted under the 1999 Plan will be the fair market value per share, as defined in the 1999 Plan. In general, the fair market value per share is determined by our board of directors.

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An option may generally be exercised until the tenth anniversary of the date that we granted the option. Option holders who exercise their options may pay for their shares in cash, check or such other consideration as is deemed acceptable by us.

As of December 31, 2008, there were outstanding options to purchase a total of 7,577,454 shares of common stock pursuant to the 1999 Plan. The exercise price per share under such options ranges from $0.10 to $11.00.

Under the 1999 Plan, all executive officers were granted incentive option agreements for common stock at exercise prices equal to fair market value at time of issuance, except Mr. Kazimi s, whose exercise price is 110% of fair market value at time of issuance. Each option agreement has a term of ten years, except for Mr. Kazimi s option agreements, which have five-year terms. All agreements have defined vesting schedules.

2007 Long-Term Incentive Compensation Plan

The purposes of the 2007 Long-Term Incentive Compensation Plan, or the 2007 Plan, are:

Ø to encourage our employees and consultants to acquire stock and other equity-based interests; and

Ø to replace the 1999 Plan without impairing the vesting or exercise of any option granted thereunder.

The 2007 Plan authorizes the issuance of each of the following incentives:

Ø incentive stock options (options that meet Internal Revenue Service requirements for special tax treatment);

Ø non-statutory stock options (all stock options other than Incentive Stock Options);

Ø stock appreciation rights (right to receive any excess in fair market values of shares over a specified exercise price);

Ø restricted stock (shares subject to vesting, transfer and forfeiture limitations); and

Ø performance shares (contingent awards comprised of stock and/or cash and paid only if specified performance goals are met).

The compensation committee administers the 2007 Plan. The compensation committee is authorized to select participants, determine the type and number of awards to be granted, determine and later amend, subject to certain limitations, the terms of any award, interpret and specify the rules and regulations relating to the 2007 Plan and make all other necessary determinations.

Employees and consultants other than non-employee directors are eligible to participate. We may cancel unvested or unpaid incentives for terminated employees and consultants to the extent permitted by law.

Upon the occurrence of a change of control event, as defined in the 2007 Plan, all outstanding options will automatically become exercisable in full, and restrictions and conditions for other issued incentives will generally be

deemed terminated or satisfied. In addition, our board of directors may amend or terminate the 2007 Plan, subject to shareholder approval, to comply with tax or regulatory requirements.

As of December 31, 2008, there were outstanding options to purchase a total of 134,100 shares of common stock pursuant to the 2007 Plan. The exercise price per share of these options ranges from $13.00 to $14.30.

Under the 2007 Plan, all executive officers were granted incentive option agreements for common stock at exercise prices equal to fair market value at time of issuance, except Mr. Kazimi, whose exercise price is 110% of fair market value at time of issuance. Each option agreement has a term of ten years, except for Mr. Kazimi s option agreements which have five-year terms. All agreements have defined vesting schedules.

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Compensation

As of December 31, 2008, there were 2,550 shares of unvested restricted stock issued pursuant to the 2007 Plan, which have defined vesting schedules. There were also 7,961 shares of common stock outstanding as of that date which were issued pursuant to the 2007 Plan.

Retirement savings opportunity

Effective January 1, 2006, we established a 401(k) plan covering all employees meeting certain minimum service and age requirements. The plan allows all qualifying employees to contribute the maximum tax-deferred contribution allowed by the Internal Revenue Code. The non-Highly Compensated Employees, or non-HCEs, do not have a minimum or maximum percentage limit that they can defer. The HCEs, however, are limited to what they can defer based on prior year s testing. Hardship distributions are permitted under well-defined circumstances. Beginning January 2008, our Board approved matching employee contributions. We intend to match a portion of the employee contributions on an annual basis. We do not provide profit sharing at this time; however, the plan is designed so that profit sharing can be arranged at any time.

Health and welfare benefits

All full-time employees, including our named executive officers, may participate in our health and welfare benefits programs, including medical, dental and vision care coverage, disability insurance and life insurance.

Employment agreements, severance benefits and change in control provisions

We have entered into employment agreements in 2009 with A.J. Kazimi, our Chairman and CEO; Jean W. Marstiller, our Senior Vice President, Administrative Services and Corporate Secretary; Leo Pavliv, our Vice President, Operations; J. William Hix, our Vice President, Sales and Marketing; and David L. Lowrance, our Vice President and CFO. The following is a summary of the material provisions of those employment agreements.

The employment agreements provide for an annual base salary of $366,000 for Mr. Kazimi, $204,500 for Ms. Marstiller, $246,000 for Mr. Pavliv, $212,000 for Mr. Hix, and $186,400 for Mr. Lowrance. In addition, the employment agreements provide that the individuals may be eligible for any bonus program which has been approved by our board of directors. Any such bonus is discretionary and will be subject to the terms of the bonus program, the terms of which may be modified from year-to-year in the sole discretion of our board of directors. During the period of employment under these agreements, each of our executives will be entitled to additional benefits, including eligibility to participate in any company-wide employee benefits programs approved by our board of directors and reimbursement of reasonable expenses.

Each executive s employment is at-will and may be terminated by us at any time, with or without notice and with or without cause. Similarly, each executive may terminate his or her employment with us at any time, with or without notice. The employment agreements do not provide for any severance payments in the event the employment is terminated for cause nor any severance benefits in the event the employment is terminated as a result of his or her death or permanent disability.

The employment agreements also include non-competition, non-solicitation and nondisclosure covenants on the part of the executives. During the term of each executive s employment with us and for one year after the executive ceases to be employed by us, the employment agreements provide that he or she may not compete with our business in any

manner, unless the executive discloses all facts to our board of directors and receives a release allowing him or her to engage in a specific activity. Pursuant to the employment agreements, the executives also agree for a period of one year after the executive ceases to

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be employed by us, he or she will not solicit business related to the development or sales of pharmaceuticals products from any entity, organization or person which is contracted with us, which has been doing business with us, or a firm which the executive knew we were going to solicit business from at the time the executive ceased to be employed. Also, the executives may not solicit our employees. The employment agreements also impose obligations regarding confidential information and state that any discoveries or improvements that are conceived, developed or otherwise made by the executives, or with others, are deemed our sole property. The employment agreements do not contain any termination or change in control provisions.

SUMMARY COMPENSATION TABLE

The following table sets forth information, for the fiscal years ended December 31, 2006, 2007 and 2008, regarding the aggregate compensation we paid to our named executive officers:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
A.J. Kazimi	2008	333,000	125,000		55,425			513,425
Chairman and CEO	2007	303,390	106,000		20,825			430,215
	2006	293,130	96,255		20,825			410,210
Leo Pavliv	2008	230,000	55,000		35,745			320,745
V.P., Operations	2007	211,000	50,000		20,670			281,670
	2006	192,500	42,000					234,500
J. William Hix	2008	198,000	55,000		32,300			285,300
V.P., Sales & Marketing	2007	176,483	50,000		17,225			243,708
	2006	137,800	25,000					162,800
Jean W. Marstiller	2008	187,000	55,000		50,925			292,925
Senior V.P. and	2007	170,000	50,000		35,850			255,850
Corporate Secretary	2006	135,160	40,000		15,180			190,340
David L. Lowrance	2008	172,600	45,000		30,625			248,225
V.P. and CFO	2007	158,400	40,000		17,225			215,625
	2006	126,500	28,500					155,000

GRANTS OF PLAN-BASED AWARDS TABLE

The following table sets forth information regarding grants of compensatory awards we paid to our named executive officers during the fiscal year ended December 31, 2008:

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
A.J. Kazimi	7/31/2008		30,000	14.30	138,300
Leo Pavliv	7/22/2008		9,000	13.00	60,300
J. William Hix	7/31/2008		9,000	13.00	60,300
Jean W. Marstiller	7/31/2008		9,000	13.00	60,300
David L. Lowrance	7/31/2008		8,000	13.00	53,600

Our executive compensation policies and practices, pursuant to which the compensation set forth in the Summary Compensation Table and the Grants of Plan-Based Awards Table was paid or awarded, are described above under, Compensation Discussion and Analysis. A summary of certain material terms

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Compensation

of our compensation plans and arrangements is set forth above under Compensation Discussion and Analysis Employment Agreements, Severance Benefits and Change in Control Provisions.

OUTSTANDING EQUITY AWARDS TABLE

The following table sets forth information regarding unvested stock and unexercised option awards held by our named executive officers as of December 31, 2008:

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options(#) Exercisable	Number of Securities Underlying Unexercised Options(#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options(#)	Option Exercise Price($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested(#)	Market Value of Shares or Units of Stock That Have Not Vested($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested(#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested($)
A.J. Kazimi[1]	585,000			0.11	01/23/09				
	4,097,090			0.55	09/15/09				
	6,930			1.63	12/18/11				
	3,400			6.60	04/01/09				
	53,000			6.60	01/15/10				
	15,000	5,000		9.90	06/30/11				
	7,500	22,500		14.30	07/31/13				
Leo Pavliv[2]	5,000			0.50	12/27/09				
	18,000			0.93	05/15/10				
	3,000			1.63	09/30/11				
	160,000			3.50	04/14/13				
		40,000		6.00	01/15/15				
	6,000	6,000		11.00	02/02/17				

	2,250	6,750	13.00	07/22/18
J. William Hix[3]	58,000		6.00	05/03/14
	5,000	5,000	11.00	02/02/17
	2,250	6,750	13.00	07/31/18
Jean W. Marstiller[4]	145,680		0.10	01/23/09
	280,000		0.50	09/15/09
	9,230		1.63	01/04/12
	400		3.50	01/31/13
	10,000		6.00	04/01/14
	15,000		6.00	01/15/15
	8,250	2,750	9.00	06/30/16
	6,000	6,000	11.00	02/02/17
	2,250	6,750	13.00	07/31/18
David L. Lowrance[5]	90,000		3.50	01/30/13
	4,000		6.00	04/01/14
		25,000	6.00	01/15/15
	5,000	5,000	11.00	02/02/17
	2,000	6,000	13.00	07/31/08

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(1) A.J. Kazimi:
585,000 Options granted on January 23, 1999; vested immediately.
4,097,090 Option granted on September 15, 1999; vested 20% equally each December 31 over 5 year period 1999-2003.
6,930 Options granted on December 18, 2001; vested immediately.
3,400 Options granted on April 1, 2004; vested immediately.
53,000 Options granted on January 15, 2005; 10,600 options or 20% vested immediately; 20% more vested equally each December 31 over 4 year period 2005-2008 .
20,000 Options granted on June 30, 2006; 25% vested each December 31, 2006, 2007 and 2008; the remaining 25% vests December 31, 2009
30,000 Options granted on July 31, 2008; 25% vested December 31, 2008; the remainder will vest 25% equally each December 31 over 3 year period 2009-2011.

(2) Leo Pavliv:
5,000 Options granted on December 27, 1999; vested immediately.
18,000 Options granted on May 15, 2000; vested immediately.
3,000 Options granted on September 30, 2001; vested immediately.
160,000 Options granted on April 14, 2003; 25% vested each December 31 over the 4 year period 2003-2006.
40,000 Options granted on January 15, 2005; all options will vest on December 31, 2009.
12,000 Options granted on February 2, 2007; 3,000 vested December 31, 2007 and 2008; 3,000 will vest each December 31, 2009 and 2010.
9,000 Options granted on July 22, 2008; 25% vested December 31, 2008; remainder vests 25% equally each December 31 over 3 year period 2009-2011.

(3) J. William Hix:
58,000 Options granted on May 3, 2004; 10,000 vested immediately; 16,000 options vested each December 31, 2004, 2005 and 2006.
10,000 Options granted on February 2, 2007; 2,500 vested on December 31, 2007 and 2008; 2,500 will vest each December 31, 2009 and 2010.
9,000 Options granted July 31, 2008; 25% vested December 31, 2008; remainder vests 25% equally each December 31 over 3 year period 2009-2011.

(4) Jean W. Marstiller:
145,680 Options granted on January 23, 1999; vested immediately.
280,000 Options granted on September 15, 1999; 50,000 vested immediately; 46,000 vested each December 31, 1999-2003.
9,230 Options granted on January 4, 2002; vested immediately.
400 Options granted on January 31, 2003; vested immediately.
10,000 Options granted on April 1, 2004; vested immediately.
15,000 Options granted on January 15, 2005; 3,000 vested immediately; 3,000 vested each December 31, 2005, 2006, 2007 and 2008.
11,000 Options granted on June 30, 2006; 2,750 vested each December 31, 2006, 2007 and 2008; 2,750 will vest

December 31, 2009.
12,000 Options granted on February 2, 2007; 3,000 vested December 31, 2007 and 2008; 3,000 will vest each December 31, 2009 and 2010.
9,000 Options granted July 31, 2008; 25% vested December 31, 2008; remainder vests 25% equally each December 31 over 3 year period 2009-2011.

(5) David L. Lowrance:
90,000 Options granted on January 30, 2003; 10,000 vested immediately; 20,000 options vested each December 31, 2003-2006.
4,000 Options granted on April 1, 2004; vested immediately.
25,000 Options granted on January 15, 2005; all options will vest on December 31, 2009.
10,000 Options granted on February 2, 2007; 2,500 vested on December 31, 2007 and 2008; 2,500 will vest each December 31, 2009 and 2010.
8,000 Options granted July 31, 2008; 25% vested December 31, 2008; remainder vests 25% equally each December 31 over 3 year period 2009-2011.

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OPTION EXERCISES AND STOCK VESTED

The following table sets forth information regarding the exercise and vesting of stock and option awards held by our named executive officers during the fiscal year ended December 31, 2008:

	Option Awards		Stock Awards	
Name	**Number of Shares Acquired on Exercise(#)**	**Value Realized on Exercise($)**	**Number of Shares Acquired on Vesting(#)**	**Value Realized on Vesting($)**
A.J. Kazimi	6,000	42,900		
Leo Pavliv				
J. William Hix				
Jean W. Marstiller				
David L. Lowrance				

PENSION BENEFITS TABLE

We do not have any plan that provides for payments or other benefits at, following, or in connection with retirement.

NONQUALIFIED DEFERRED COMPENSATION TABLE

We do not have any plan that provides for the deferral of compensation on a basis that is not tax qualified.

DIRECTOR COMPENSATION TABLE

The following table sets forth information regarding the aggregate compensation we paid to the members of our board of directors during the fiscal year ended December 31, 2008:

Fees Earned or Paid in Cash	**Stock Awards**	**Option Awards**	**Non-Equity Incentive Plan Compensation**	**Change in Pension Value and Nonqualified Deferred Compensation**	**All Other Compensation**	**Total**

Name	($)	($)	($)	($)	Earnings	($)	($)
Martin E. Cearnal[1]	80,000						80,000
Dr. Robert G. Edwards[2]	80,000						80,000
Dr. Lawrence W. Greer[3]	35,007	44,993					80,000
Thomas R. Lawrence[4]	80,000						80,000

(1) For service as a director in 2008, Mr. Cearnal received fees equal to $80,000, paid fully in cash.

(2) For service as a director in 2008, Mr. Edwards received fees equal to $80,000, paid fully in cash.

(3) For service as a director in 2008, Mr. Greer received fees equal to $80,000, paid as follows: $35,007 cash, and shares of our common stock valued at $44,993.

(4) For service as a director in 2008, Mr. Lawrence received fees equal to $80,000, paid fully in cash.

Director compensation

Compensation to each outside director for service on the board of directors including board committee responsibilities for 2009 will consist of a total fee in the amount of $83,500. All fees will be paid in a combination of cash and equity, as we and each director shall agree. Cash fees will be accrued and paid on either a monthly or quarterly basis. Directors will not receive separate compensation for attendance at board meetings, board committee meetings or other company board-related activities. Outside directors will be reimbursed for all reasonable and necessary business expenses incurred in the performance of their service on the board of directors.

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Long-term equity incentive awards to our directors were made pursuant to the 1999 Plan until April 2007, and thereafter, pursuant to the 2007 Directors Compensation Plan, or the Directors Plan.

The purposes of the Directors Plan are:

Ø to strengthen our ability to attract, motivate, and retain qualified independent directors; and

Ø to replace the 1999 Plan without impairing the vesting or exercise of any option granted to any director thereunder.

The Directors Plan authorizes the issuance to non-employee directors of each of the following types of awards:

Ø options (all options to be issued under the Directors Plan will not meet IRS requirements for special tax treatment and therefore are non-qualified options);

Ø restricted stock grants (shares subject to various restrictions and conditions as determined by our compensation committee); and

Ø stock grants (award of shares or our common stock with full and unrestricted ownership rights).

The compensation committee of our board of directors will administer the Directors Plan, if it is adopted. In the event of a change of control of our company (as defined in the Directors Plan), all outstanding options would automatically become exercisable in full, and restrictions and conditions for other issued awards shall generally be deemed terminated or satisfied. Our board of directors may amend or terminate the Directors Plan, subject to shareholder approval if necessary, to comply with tax or regulatory requirements.

As of December 31, 2008, there were 3,461 shares of common stock outstanding which were issued pursuant to the Directors Plan.

INDEMNIFICATION OF DIRECTORS AND EXECUTIVE OFFICERS AND LIMITATION OF LIABILITY

Our charter and bylaws provide for indemnification of our directors to the fullest extent permitted by the Tennessee Business Corporation Act, as amended from time to time. Our directors shall not be liable to us or our shareholders for monetary damages for breach of their fiduciary duty of care. The Tennessee Business Corporation Act provides that a Tennessee corporation may indemnify its directors and officers against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by them in connection with any proceeding, whether criminal or civil, administrative or investigative if, in connection with the matter in issue, the individual s conduct was in good faith, and the individual reasonably believed: in the case of conduct in the individual s official capacity with the corporation, that the individual s conduct was in its best interest; and in all other cases, that the individual s behavior was at least not opposed to its best interest; and in the case of a criminal proceeding, the individual had no reason to believe the individual s conduct was unlawful. In addition, we have entered into indemnification agreements with our directors. These provisions and agreements may have the practical effect in certain cases of eliminating the ability of our shareholders to collect monetary damages from directors. We believe that these contractual agreements and the provisions in our charter and bylaws are necessary to attract and retain qualified persons as directors.

DIRECTORS AND OFFICERS INSURANCE

We maintain a directors and officers insurance policy that provides coverage to our directors and officers relating to certain potential liabilities. The directors and officers insurance policy, provided by The Hartford with a coverage amount of up to $3,000,000, covers wrongful act or securities claims.

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Certain relationships and related party transactions

Other than compensation agreements and other arrangements which are described in Compensation and the transactions described below, since January 1, 2006, there has not been, and there is not currently proposed, any transaction or series of similar transactions to which we were or will be a party in which the amount involved exceeded or will exceed $120,000 and in which any related party, including any director, executive officer, holder of five percent or more of any class of our capital stock or any member of their immediate families had or will have a direct or indirect material interest.

All of the transactions set forth below were approved by a majority of the board of directors, including a majority of any independent and disinterested members of the board of directors. We believe that all of the transactions set forth below had terms no less favorable to us than we could have obtained from unaffiliated third parties. In connection with this offering, we have adopted a written policy which requires all future transactions between us and any related persons (as defined in Item 404 of Regulation S-K) be approved in advance by our audit committee.

Board members were granted a total of 3,461, 11,036 and 24,818 shares of common stock in 2008, 2007 and 2006, respectively, for services rendered as directors and consultants. The amounts recorded for such services were approximately $45,000, $121,000, and $249,000, in 2008, 2007 and 2006, respectively. In 2008, a board member was granted an option to purchase 18,000 shares of common stock at an exercise price of $13.00 per share. No options were issued to board members in 2007 or 2006.

In connection with our $5 million Share Repurchase Program offered in December 2008 to all of our shareholders and allocated on a pro rata basis to participating shareholders, certain executive officers, directors and holders of five percent or more of any class of our capital stock received an aggregate of $1,733,485 in payment for the redemption of some of their shares, including payments of $547,248 to Mr. and Mrs. J. Kenneth Hazen, $634,296 to A.J. Kazimi and $161,876 to Jean W. Marstiller.

In connection with this offering, we have adopted a written policy, the Policy and Procedures with Respect to Related Person Transactions. Our board of directors has determined that our audit committee is best suited to review and approve all future related person transactions. The Policy and Procedures with Respect to Related Person Transactions covers a transaction, arrangement, or relationship in which we or any of our subsidiaries is or will be a participant and the amount involved exceeds $120,000 per year, and in which any related person has or will have a direct or indirect interest. The Policy and Procedures with Respect to Related Person Transactions defines a related person as:

- any person who is, or at any time since the beginning of our last fiscal year was, a director or executive officer of ours or a nominee to become a director of ours;
- any person who is known to be the beneficial owner of more than 5% of any class of our voting securities;
- any immediate family member of any of the foregoing persons; and
- any firm, corporation or other entity in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest.

No member of our audit committee shall review or approve a related person transaction in which he or an immediate family member of his is the related person. The audit committee shall approve only those related person transactions that are in, or are not inconsistent with, the best interests of us and our shareholders.ft

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Principal shareholders

The following table sets forth information known to us with respect to beneficial ownership of shares of our common stock as of December 31, 2008 by (i) each of our directors, (ii) each of our named executive officers; (iii) all of our directors and executive officers as a group; and (iv) each person or group of affiliated persons known to us to be the beneficial owner of 5% or more of our outstanding common stock.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock underlying options or warrants held by that person that are currently exercisable or will become exercisable within 60 days of December 31, 2008 are deemed outstanding and are included in the number of shares beneficially owned, while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. To our knowledge, except as indicated in the footnotes to this table and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

As of December 31, 2008, there were 245 holders of record of our common stock and 42 holders of record of preferred stock, which will automatically be converted into common stock at the completion of this offering. For purposes of calculating amounts beneficially owned by a shareholder before the offering, the number of shares deemed issued and outstanding was 9,903,047 shares of common stock as of December 31, 2008. The percentage of beneficial ownership after this offering is based on 17,778,545 shares of common stock. For purposes of calculating the percentage beneficially owned after the offering, the number of shares deemed outstanding includes all shares deemed to be outstanding before the offering, all shares into which our outstanding shares of preferred stock will be converted as a result of the offering and all shares being sold in the offering.

Unless otherwise indicated, the address for each person listed is c/o Cumberland Pharmaceuticals Inc., 2525 West End Ave., Suite 950, Nashville, Tennessee 37203.

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Principal shareholders

Executive officers and directors	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned After Offering
A.J. Kazimi[1]	7,278,542	49.61%	32.28%
Thomas R. Lawrence[2]	242,576	2.44%	1.36%
Robert G. Edwards[3]	432,764	4.31%	2.42%
Lawrence W. Greer[4]	814,640	8.12%	4.55%
Martin E. Cearnal[5]	126,602	1.28%	*
Leo Pavliv[6]	194,250	1.92%	1.08%
Jean W. Marstiller[7]	641,844	6.18%	3.52%
Gordon R. Bernard[8]	108,455	1.09%	*
David L. Lowrance[9]	101,000	1.01%	*
J. William Hix[10]	65,250	*	*
Directors and executive officers as a group (10 persons)	10,005,923	63.14%	42.18%
5% Shareholders			
Douglas J. Marchant[11]	700,000	7.07%	3.94%
Mr. and Mrs. J. Kenneth Hazen[12][13]	557,904	5.63%	3.14%
S.C.O.U.T. Healthcare Fund, L.P.[14][15]	696,368	6.97%	3.90%

* Less than 1.0% of the outstanding common stock.

(1) Includes 4,767,920 shares that Mr. Kazimi has the right to acquire upon the exercise of outstanding stock options.

(2) Includes 38,466 shares Mr. Lawrence has the right to acquire upon exercise of outstanding stock options.

(3) Includes 132,566 shares Dr. Edwards has the right to acquire upon exercise of outstanding stock options.

(4) Includes (i) 613,248 shares owned of record by S.C.O.U.T., a limited partnership with respect to which Dr. Greer is the President and majority shareholder of the general partner, (ii) 43,120 shares S.C.O.U.T. has the right to acquire upon exercise of outstanding stock options, (iii) 40,000 shares S.C.O.U.T. has the right to acquire immediately from us pursuant to a warrant, and (iv) 52,000 shares Dr. Greer has the right to acquire immediately upon exercise of outstanding stock options.

(5) Includes (i) 26,400 shares Mr. Cearnal has the right to acquire upon exercise of outstanding stock options and (ii) 15,400 shares Mr. Cearnal will receive upon conversion of his preferred stock.

(6) Includes 194,250 shares Mr. Pavliv has the right to acquire upon exercise of outstanding stock options.

(7) Includes 476,810 shares Ms. Marstiller has the right to acquire upon exercise of outstanding stock options.

(8) Includes 5,179 shares Dr. Bernard has the right to acquire upon exercise of outstanding stock options.

(9) Includes 101,000 shares Mr. Lowrance has the right to acquire upon exercise of outstanding stock options.

(10) Includes 65,250 shares Mr. Hix has the right to acquire upon exercise of outstanding stock options.

(11) The address for Mr. Marchant is 60 Germantown Court, Suite 220, Cordova, Tennessee, 38018.

(12) The address for Mr. and Mrs. J. Kenneth Hazen is 260 St. Andrews Fairway, Memphis, Tennessee, 38111.

(13) The number of shares reflected above as beneficially held by Mr. and Mrs. J. Kenneth Hazen are held jointly.

(14) Includes (i) 43,120 shares S.C.O.U.T. has the right to acquire upon exercise of outstanding stock options, and (ii) 40,000 shares S.C.O.U.T. has the right to acquire immediately from us pursuant to a warrant.

(15) The address for S.C.O.U.T. is 2200 Woodcrest Place, Suite 309, Birmingham, Alabama, 35209.

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Description of capital stock

GENERAL

Our authorized capital stock consists of one hundred million shares of common stock, no par value, three million shares of Series A preferred stock, no par value, and twenty million shares of undesignated preferred stock, no par value.

COMMON STOCK

As of December 31, 2008, 9,903,047 shares of common stock were issued and outstanding (which does not include 7,910,986 shares of common stock issuable upon exercise of outstanding options or warrants to purchase common stock, 2,550 shares of unvested restricted stock, and 1,625,498 shares of common stock issuable upon conversion of all outstanding shares of our preferred stock). We plan to issue additional stock options to our directors, employees and consultants, and we may issue shares of common stock to sellers of rights to certain pharmaceutical products. Giving effect to the sale of 6,250,000 shares offered hereby and the conversion of all outstanding shares of our preferred stock, there would be 17,778,545 shares of common stock outstanding following this offering.

The holders of shares of common stock are entitled to one vote per share on any matter that comes before the shareholders. Cumulative voting is not authorized. Holders of shares of common stock do not have preemptive rights to purchase securities that we may subsequently issue. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive such dividends as may be declared by our board of directors out of funds legally available for payment as dividends. However, we do not anticipate paying any dividends in the foreseeable future to holders of our common stock. In the event of a liquidation, dissolution, or winding up of our affairs, the holders of outstanding shares will be entitled to share pro rata according to their respective interests in our assets and funds remaining after payment of all of our debts and other liabilities and the liquidation preference of any outstanding preferred stock. All of the shares of common stock currently outstanding are fully paid and nonassessable.

On July 6, 2007, the Board of Directors declared a 2-for-1 stock split of our company s common stock effective on such date. All applicable common stock share and per share amounts have been retroactively adjusted in the accompanying consolidated financial statements and condensed consolidated financial statements for such stock split. In accordance with the anti-dilution provisions of the respective agreements, the share and per share amounts associated with our company s stock option grants, warrants and preferred stock conversion rights reflected in the accompanying consolidated financial statements and condensed consolidated financial statements have also been adjusted to reflect the effects of the stock split.

PREFERRED STOCK

Our board of directors is authorized, without approval of our shareholders, to provide for the issuance of shares of preferred stock in one or more series, to establish the number of shares in each series, and to fix the designations, powers, preferences, and rights of each such series and the qualifications, limitations, or restrictions. Among the specific matters that may be determined by our board are:

Ø the designation of each series;

Ø the number of shares of each series;

Ø the rights in respect of dividends, if any;

Ø whether dividends, if any, shall be cumulative or non-cumulative;

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Description of capital stock

- Ø the terms of redemption, repurchase obligation or sinking fund, if any;
- Ø the rights in the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs;
- Ø rights and terms of conversion, if any;
- Ø restrictions on the creation of indebtedness, if any;
- Ø restrictions on the issuance of additional preferred stock or other capital stock, if any;
- Ø restrictions on the payment of dividends on shares ranking junior to the preferred stock; and
- Ø voting rights, if any.

Upon completion of this offering, no shares of preferred stock will be outstanding and we have no current plans to issue preferred stock. The issuance of shares of preferred stock, or the issuance of rights to purchase preferred stock, could be used to discourage an unsolicited acquisition proposal. For example, a business combination could be impeded by the issuance of a series of preferred stock containing class voting rights that would enable the holder or holders of such series to block any such transaction. Alternatively, a business combination could be facilitated by the issuance of a series of preferred stock having sufficient voting rights to provide a required percentage vote of our shareholders. In addition, under some circumstances, the issuance of preferred stock could adversely affect the voting power and other rights of the holders of common stock. Although prior to issuing any series of preferred stock our board is required to make a determination as to whether the issuance is in the best interests of our shareholders, our board could act in a manner that would discourage an acquisition attempt or other transaction that some, or a majority, of our shareholders might believe to be in their best interests or in which our shareholders might receive a premium for their stock over prevailing market prices of such stock. Our board of directors does not at present intend to seek shareholder approval prior to any issuance of currently authorized preferred stock, unless otherwise required by law or applicable stock exchange requirements.

OUTSTANDING OPTIONS AND WARRANTS

As of December 31, 2008, in addition to outstanding options to acquire 7,711,554 shares of common stock issued pursuant to our 1999 Plan and our 2007 Plan, we have issued options to purchase 284,902 shares of our common stock in connection with two debt financing rounds in 2001 and 2003 of which 199,432 remain outstanding. These options have ten-year terms with exercise prices of $1.63 and $6.00 per share, respectively. Total options outstanding as of December 31, 2008 have an average exercise price of $1.65 per share. We have also issued warrants to purchase 65,000 shares of our common stock at a price of $6.00 per share to Bank of America and to S.C.O.U.T., a consulting and investment company in which Dr. Lawrence W. Greer, one of our directors, is a principal, and warrants to purchase 3,958 shares of our common stock at a price of $9.00 per share to Bank of America.

ANTI-TAKEOVER EFFECTS OF TENNESSEE LAW AND PROVISIONS OF OUR CHARTER AND BYLAWS

The Tennessee Business Combination Act, the Tennessee Investor Protection Act, the Tennessee Greenmail Act and the Tennessee Control Share Acquisition Act provide certain anti-takeover protections for Tennessee corporations.

The Tennessee Business Combination Act

The Tennessee Business Combination Act, or TBCA, governs all Tennessee corporations. It imposes a five-year standstill on transactions such as mergers, share exchanges, sales of assets, liquidations and other interested party transactions between Tennessee corporations and interested shareholders and

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their associates or affiliates, unless the business combination is approved by the board of directors before the interested shareholder goes above the 10% ownership threshold. Thereafter, the transaction either requires a two-thirds vote of the shareholders other than the interested shareholder or satisfaction of certain fair price standards.

The TBCA also provides for additional exculpatory protection for the board of directors in resisting mergers, exchanges and tender offers if a Tennessee corporation s charter specifically opts-in to such provisions. A Tennessee corporation s charter may specifically authorize the members of a board of directors, in the exercise of their judgment, to give due consideration to factors other than price and to consider whether a merger, exchange, tender offer or significant disposition of assets would adversely affect the corporation s employees, customers, suppliers, the communities in which the corporation operates, or any other relevant factor in the exercise of their fiduciary duty to the shareholders.

Our charter expressly opts-in and provides for exculpation of the board of directors to the full extent permitted under the TBCA. The opt-in will have the effect of protecting us from unwanted takeover bids, because the board of directors is permitted by the charter to take into account all relevant factors in performing its duly authorized duties and acting in good faith and in our best interests.

The Tennessee Investor Protection Act

The Tennessee Investor Protection Act, or TIPA, generally requires the registration, or an exemption from registration, before a person can make a tender offer for shares of a Tennessee corporation which, if successful, will result in the offeror beneficially owning more than 10% of any class of shares. Registration requires the filing with the Tennessee Commissioner of Commerce and Insurance of a registration statement, a copy of which must be sent to the target company, and the public disclosure of the material terms of the proposed offer. Additional requirements are imposed under that act if the offeror beneficially owns 5% or more of any class of equity securities of the target company, any of which was purchased within one year prior to the proposed takeover offer. TIPA also prohibits fraudulent and deceptive practices in connection with takeover offers, and provides remedies for violations.

TIPA does not apply to an offer involving a vote by holders of equity securities of the offeree company, pursuant to its charter, on a share exchange, consolidation or sale of corporate assets in consideration of the issuance of securities of another corporation, or on a sale of its securities in exchange for cash or securities of another corporation. Also exempt from TIPA are tender offers which are open on substantially equal terms to all shareholders, are recommended by the board of directors of the target company, and include full disclosure of all terms.

The Tennessee Greenmail Act

The Tennessee Greenmail Act, or TGA, prohibits us from purchasing or agreeing to purchase any of our securities, at a price higher than fair market value, from a holder of 3% or more of any class of its securities who has beneficially owned the securities for less than two years. We can, however, make this purchase if the majority of the outstanding shares of each class of voting stock issued by us approves the purchase or if we make an offer of at least equal value per share to all holders of shares of the same class of securities as those held by the prospective seller.

The Tennessee Control Share Acquisition Act

Sections 48-103-301 through 48-103-312 of the Tennessee Control Share Acquisition Act, or TCSA, limit the voting rights of shares owned by a person above certain percentage thresholds, unless the non-interested shareholders of the corporation approve the acquisition above the designated threshold.

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However, the TCSA only applies to corporations whose charter or bylaws contain an express declaration that control share acquisitions are to be governed by the TCSA. In addition, the charter or bylaws must specifically provide for the redemption of control shares or appraisal rights for dissenting shareholders in a control share transaction.

Our charter makes all of the express declarations necessary to avail us of the full protection under the TCSA. The provisions described above will have the general effect of discouraging, or rendering more difficult, unfriendly takeover or acquisition attempts. Consequently, such provisions would be beneficial to current management in an unfriendly takeover attempt but could have an adverse effect on shareholders who might wish to participate in such a transaction. However, management believes that such provisions are advantageous to shareholders in that they will permit management and the shareholders to carefully consider and understand a proposed acquisition and may require a higher level of shareholder participation in the decision.

Pursuant to Section 48-103-308 of the TCSA, we, at our option, may redeem from an acquiring person all, but not less than all, control shares acquired in a control share acquisition, at any time during the period ending 60 days after the last acquisition of control shares by that person, for the fair value of those shares, if (1) no control acquisition statement has been filed, or (2) a control acquisition statement has been filed and the shares are not accorded voting rights by the shareholders of this corporation pursuant to Section 48-103-307. For these purposes, fair value shall be determined as of the effective date of the vote of the shareholders denying voting rights to the acquiring person, if a control acquisition statement is filed, or if no control acquisition statement is filed, as of the date of the last acquisition of control shares by the acquiring person in a control share acquisition.

Pursuant to Section 48-103-309 of the TCSA, if control shares acquired in a control share acquisition are accorded voting rights and the acquiring person has acquired control shares that confer upon that person a majority or more of all voting power entitled to vote generally with respect to the election of directors, all this corporation s shareholders of record, other than the acquiring person, who have not voted in favor of granting those voting rights to the acquiring person shall be entitled to an appraisal of the fair market value of their shares in accordance with Chapter 23 of the Tennessee Business Corporation Act.

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

- Ø the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval;
- Ø advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders;
- Ø limitations on persons authorized to call a special meeting of shareholders;
- Ø a staggered board of directors;
- Ø a 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

Ø no cumulative voting.

These and other provisions contained in our second 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

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Description of capital stock

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.

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for our common stock is BNY Mellon Shareowner Services.

NASDAQ GLOBAL MARKET LISTING

We have applied for our common stock to be quoted on The Nasdaq Global Market under the trading symbol CPIX .

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Shares eligible for future sale

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital in the future through the sale of our securities. Although we have applied to have our common stock approved for quotation on The Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Upon completion of this offering, we will have outstanding an aggregate of 17,778,545 shares of common stock, assuming the issuance of 6,250,000 shares of common stock offered in our initial public offering, conversion of our outstanding shares of preferred stock and no exercise of options and warrants or vesting of restricted stock after December 31, 2008. Of these shares, the shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to certain limitations and restrictions described below. See Lock-Up Agreements. Persons who may be deemed affiliates generally include individuals or entities that control, are controlled by or are under common control with us and may include our officers, directors and significant shareholders.

The remaining 11,528,545 shares of common stock, including the preferred, as converted, held by existing shareholders were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. Of these shares, 11,321,545 shares will be subject to lock-up agreements described below on the effective date of this offering. Upon expiration of the lock-up agreements 180 days after the effective date of this offering, shares will become eligible for sale, subject in most cases to the limitations of Rule 144. In addition, holders of stock options could exercise such options and sell certain of the shares issued upon exercise as described below. See Lock-Up Agreements.

Days after date of this prospectus	Shares eligible for sale	Comment
Upon effectiveness	6,250,000	Shares sold in the offering
Upon effectiveness	207,000	Freely tradable shares saleable under Rule 144 that are not subject to the lock-up
90 Days	207,000	Shares saleable under Rules 144 and 701 that are not subject to a lock-up
180 Days	11,321,545	Lock-up released; shares saleable under Rules 144 and 701

EMPLOYEE BENEFIT PLANS

As of December 31, 2008, there were a total of 7,711,554 shares of common stock subject to outstanding options under our 1999 Plan and 2007 Plan, of which 7,473,599 were vested and exercisable.

Immediately after the completion of this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock issued or reserved for future issuance under the 1999 Option Plan and the 2007 Long-Term Incentive Compensation Plan. On the date which is 180 days after the effective date of this offering, a total of approximately 7,473,599 shares of common stock subject to outstanding options will be vested and exercisable. After the effective dates of the registration statements on Form S-8, shares purchased under

the 1999 Option Plan and the 2007 Long-Term Incentive Compensation Plan generally would be available for resale in the public market.

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Shares eligible for future sale

LOCK-UP AGREEMENTS

We, all of our directors and executive officers and their affiliates, and holders of 11,321,545 shares of our outstanding stock have agreed that, without the prior written consent of UBS Securities LLC, we and they will not directly or indirectly, sell, offer, contract or grant any option to sell (including without limitation any short sale), pledge, transfer, establish an open put equivalent position or liquidate or decrease a call equivalent position or otherwise dispose of or transfer (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of), including the filing (or participation in the filing) of a registration statement with the SEC in respect of, any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially by such persons (except for the S-8 filings referred to in the previous paragraph), or publicly announce an intention to do any of the foregoing, for a period commencing on the date hereof and continuing through the close of trading on the date 180 days after the date of this prospectus, other than permitted transfers described below. In addition, we and they agree that, without the prior written consent of UBS Securities LLC, we and they will not, during such period, make any demand for or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The 180-day restricted period described in the preceding two paragraphs will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or announce material news or a material event relating to us occurs; or

- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding two paragraphs will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release, the announcement of material news or the occurrence of a material event.

UBS Securities LLC, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. When determining whether or not to release common stock and other securities from lock-up agreements, UBS Securities LLC will consider, among other factors, the holder s reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

RULE 144

The SEC recently amended Rule 144, effective February 15, 2008. In general under Rule 144, beginning 90 days after the date of this prospectus a person who has beneficially owned shares of our common stock for at least six months, including an affiliate, would be entitled to sell in broker s transactions or to market makers, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 181,000 shares immediately after this offering; or

Ø the average weekly trading volume in our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 are generally subject to the availability of current public information about us.

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Shares eligible for future sale

A person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale under Rule 144, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell such shares without having to comply with the manner of sale, public information, volume limitation or notice filing provisions of Rule 144. Therefore, unless otherwise restricted, these non-affiliate shares that have been held for at least one year may be sold immediately upon the completion of this offering.

RULE 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering is entitled to sell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period and notice filing requirements of Rule 144 and, in the case of non-affiliates, without having to comply with the public information, volume limitation or notice filing provisions of Rule 144.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus.

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Material U.S. federal income and estate tax consequences to non-U.S. holders

GENERAL

The following is a general summary of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock that may be relevant to a non-U.S. holder (as defined below). The summary is based on provisions of the Internal Revenue Code of 1986, as amended, U.S. Treasury regulations promulgated thereunder, rulings and pronouncements of the Internal Revenue Service, or IRS, and judicial decisions, all as in effect on the date of this prospectus and all of which are subject to change (possibly on a retroactive basis) or to differing interpretations. We have not sought, and will not seek, any ruling from the IRS with respect to the tax consequences discussed in this prospectus, and there can be no assurance that the IRS will not take a position contrary to the tax discussion below or that any such position would not be sustained.

This summary is limited to non-U.S. holders that purchase our common stock issued pursuant to this offering and that hold our common stock as a capital asset, which generally is property held for investment. This summary also does not address the tax considerations arising under the laws of any foreign, state or local jurisdiction, or under U.S. federal estate or gift tax laws except as specifically described below. In addition, this summary does not address tax considerations that may be applicable to a non-U.S. holder in light of its particular circumstances or to non-U.S. holders that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- partnerships or other pass through entities;
- U.S. expatriates;
- tax-exempt organizations;
- tax-qualified retirement plans;
- dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings; or
- persons that will hold common stock as a position in a hedging transaction, straddle or conversion transaction for tax purposes.

For purposes of this summary, the term non-U.S. holder means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual citizen or resident of the U.S.;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, that is created or organized under the laws of the United States or any political subdivision of the United States;
- an estate whose income, regardless of its source, is includible in gross income for U.S. federal income tax purposes;

- a trust (1) if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions regarding the trust, or (2) that has in effect a valid election to be treated as a U.S. person; or

- a partnership, or other entity treated as a partnership for U.S. federal income tax purposes.

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Material U.S. federal income and estate tax consequences to non-U.S. holders

If a partnership or other entity classified as such for U.S. federal income tax purposes holds shares of our common stock, the tax treatment of a partner or owner will generally depend on the status of the partner or owner and the activities of the partnership or other entity. It is advised that partnerships (and other entities classified as such for U.S. federal income tax purposes) owning shares of our common stock, and holders of interests in such entities, consult their tax advisors.

Any non-U.S. holder of our common stock should consult their tax advisor regarding the tax consequences of purchasing, holding, and disposing of these shares of stock.

DIVIDENDS

As previously discussed, we do not anticipate paying dividends on our common stock in the foreseeable future. If we pay dividends on our common stock, however, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those payments exceed our current and accumulated earnings and profits, the payments will constitute a return of capital and first reduce the non-U.S. holder s adjusted tax basis, but not below zero, and then will be treated as gain from the sale of stock, as described below under the heading Gain on Disposition of Common Stock. Any amount treated as a dividend paid to a non-U.S. holder will ordinarily be subject to a 30% U.S. federal withholding tax, or a lower rate if an applicable income tax treaty so provides. A non-U.S. holder will be required to satisfy certain certification and disclosure requirements in order to claim a reduced rate of withholding pursuant to an applicable income tax treaty.

Dividends that are effectively connected with a non-U.S. holder s conduct of trade or business within the United States (and, where an applicable tax treaty so requires, are attributable to a permanent establishment or fixed base in the U.S.) will not be subject to U.S. federal withholding tax, provided certain certification and disclosure requirements are met, but instead generally will be taxed in the same manner as if the non-U.S. holder were a U.S. person. Additionally, non-U.S. holders that are corporations receiving such dividends may be subject to an additional branch profits tax at a rate of 30%, or at a lower rate if provided by an applicable income tax treaty.

Non-U.S. holders are encouraged to consult their tax advisors regarding any claim to benefits under an applicable income tax treaty and the method of claiming the benefits of the treaty. A refund or credit for any non-U.S. holder that is subject to a reduced U.S. federal withholding income tax rate may be obtained by timely filing a claim for a refund with the IRS.

GAIN ON DISPOSITION OF COMMON STOCK

A non-U.S. holder of our common stock generally will not be taxed on gain recognized upon disposition unless:

Ø the non-U.S. holder is present in the U.S. for 183 days or more during the taxable year of the disposition and has met certain other requirements.

Ø the income or gain is effectively connected with the non-U.S. holder s conduct of trade or business within the U.S. and, if an applicable income tax treaty so requires, is attributable to a permanent establishment or fixed base of the non-U.S. holder in the U.S.; or

Ø we are or have been a United States real property holding corporation for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding such disposition or your holding period for our common stock, and certain other requirements are met. We believe that we are not, and that we will not become, a United States real property holding corporation.

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Material U.S. federal income and estate tax consequences to non-U.S. holders

If you are an individual described in the first bullet point immediately above you will be subject to a flat 30% tax on the amount by which gain resulting from the disposition of our common stock and any other U.S.-source capital gains realized in the same taxable year exceed the U.S.-source capital losses recognized in that taxable year, unless an applicable income tax treaty provides for an exemption or lower rate. If you are an individual described in the second bullet point immediately above you will be subject to tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates. If you are a corporation described in the second bullet point immediately above, you will be subject to tax on the net gain generally in the same manner as if you were a U.S. corporation for U.S. federal income tax purposes, and may also be subject to the branch profits tax equal to 30%, or such lower rate as may be specified by an applicable income tax treaty, on your effectively connected earnings and profits.

U.S. FEDERAL ESTATE TAX

Common stock owned or treated as owned by a non-U.S. holder who is an individual will be included in that non-U.S. holder s gross estate for U.S. federal estate tax purposes unless an applicable estate tax or other treaty provides otherwise and such non-U.S. holder therefore may be subject to U.S. federal estate tax.

U.S. INFORMATION REPORTING AND BACKUP WITHHOLDING

We must report to you and to the Internal Revenue Service on an annual basis the amount of dividends paid to you and any related taxes withheld from those dividends. Copies of the information returns reporting dividends and the related tax withheld may also be made available to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty.

Backup withholding generally will not apply to payments of dividends made by us or our paying agents, in their capacities as such, to a non-U.S. holder of our common stock if the holder has provided the required certification that it is not a U.S. person or certain other requirements are met.

In general, backup withholding and information reporting will not apply to proceeds from the disposition of our common stock paid to a non-U.S. holder if the holder has provided the required certification that it is a non-U.S. holder.

Backup withholding is not an additional tax. Any amounts withheld may be refunded or credited against the holder s U.S. federal income tax liability, if any, provided that the required information is furnished to the IRS in a timely manner.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the particular tax consequences to them of owning and disposing of our common stock, including the consequences under the laws of any state, local or foreign jurisdiction or under any applicable tax treaty.

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Underwriting

We are offering the shares of our common stock described in this prospectus through the underwriters named below. UBS Securities LLC, Jefferies & Company, Inc., Wachovia Capital Markets, LLC and Morgan Joseph & Co. Inc. are the representatives of the underwriters. UBS Securities LLC, Jefferies & Company, Inc. and Wachovia Capital Markets, LLC are the joint book-running managers of this offering. We have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase the number of shares of common stock listed next to its name in the following table.

Underwriters	**Number of Shares**
UBS Securities LLC	
Jefferies & Company, Inc	
Wachovia Capital Markets, LLC	
Morgan Joseph & Co. Inc.	
Total	6,250,000

The underwriting agreement provides that the underwriters must buy all of the shares if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters over-allotment option described below.

Our common stock is offered subject to a number of conditions, including:

Ø receipt and acceptance of our common stock by the underwriters, and

Ø the underwriters right to reject orders in whole or in part.

We have been advised by the representatives that the underwriters intend to make a market in our common stock, but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

OVER-ALLOTMENT OPTION

We have granted the underwriters an option to buy up to an aggregate of 937,500 additional shares of our common stock. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with this offering. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares approximately in proportion to the amounts specified in the table above.

COMMISSIONS AND DISCOUNTS

Shares sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. Any of these securities dealers may resell any shares purchased from the underwriters to other brokers or dealers at a discount of up to $ per share from the initial public offering price. If all the shares are not sold at the initial public offering price, the representatives may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at

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Underwriting

the prices and upon the terms stated therein and, as a result, will thereafter bear any risk associated with changing the offering price to the public or other selling terms. The representatives of the underwriters have informed us that they do not expect to sell more than an aggregate of 312,500 shares of common stock to accounts over which such representatives exercise discretionary authority.

The following table shows the per share and total underwriting discounts and commissions we will pay to the underwriters assuming both no exercise and full exercise of the underwriters option to purchase up to an additional shares.

	No exercise	Full exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately $3.9 million.

NO SALES OF SIMILAR SECURITIES

We, our executive officers and directors and shareholders owning substantially all of our stock have entered into lock-up agreements with the underwriters. Under these agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, offer, sell, contract to sell or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. At any time and without public notice, UBS Securities LLC may, in its sole discretion, release some or all of the securities from these lock-up agreements.

INDEMNIFICATION

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

NASDAQ GLOBAL MARKET QUOTATION

We have applied to have our common stock approved for quotation on The Nasdaq Global Market under the trading symbol CPIX .

PRICE STABILIZATION, SHORT POSITIONS

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. These transactions

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Underwriting

may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be covered short sales, which are short positions in an amount not greater than the underwriters over-allotment option referred to above, or may be naked short sales, which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

As a result of these activities, the price of our common stock may be higher that the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. The underwriters may carry out these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

DETERMINATION OF OFFERING PRICE

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation by us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to representatives;
- our history and prospects, and the history of and prospects for the industry in which we compete;
- our past and present financial performance and an assessment of our management;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

AFFILIATIONS

Certain of the underwriters and their affiliates may from time to time provide certain commercial banking, financial advisory, investment banking and other services for us for which they were and will be entitled to receive separate fees. The underwriters and their affiliates may from time to time in the future engage in transactions with us and perform services for us in the ordinary course of their business.

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Notice to investors

EUROPEAN ECONOMIC AREA

In relation to each Member State of the European Economic Area, or EEA, which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, our common stock will not be offered to the public in that Relevant Member State prior to the publication of a prospectus in relation to our common stock that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, our common stock may be offered to the public in that Relevant Member State at any time:

- Ø to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

- Ø to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts; or

- Ø in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

As used above, the expression offered to the public in relation to any of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common stock to be offered so as to enable an investor to decide to purchase or subscribe for our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/ EC and includes any relevant implementing measure in each Relevant Member State.

The EEA selling restriction is in addition to any other selling restrictions set out below.

UNITED KINGDOM

Our common stock may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000, or the FSMA, with respect to anything done in relation to our common stock in, from or otherwise involving the United Kingdom. In addition, each underwriter has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. Without limitation to the other restrictions referred to herein, this prospectus is directed only at (1) persons outside the United Kingdom, (2) persons having professional experience in matters relating to investments who fall within the definition of investment professionals in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005; or (3) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Without limitation to the other restrictions referred to herein, investment or

investment activity to which this prospectus relates is available only to, and will be

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Notice to investors

engaged in only with, such persons, and persons within the United Kingdom who receive this communication (other than persons who fall within (2) or (3) above) should not rely or act upon this communication.

FRANCE

No prospectus (including any amendment, supplement or replacement thereto) has been prepared in connection with the offering of our common stock that has been approved by the Autorité des marchés financiers or by the competent authority of another State that is a contracting party to the Agreement on the European Economic Area and notified to the Autorité des marchés financiers; no common stock has been offered or sold and will be offered or sold, directly or indirectly, to the public in France except to permitted investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (investisseurs qualifiés) acting for their own account and/or corporate investors meeting one of the four criteria provided in Article 1 of Decree N7 2004-1019 of September 28, 2004 and belonging to a limited circle of investors (cercle restreint d investisseurs) acting for their own account, with qualified investors and limited circle of investors having the meaning ascribed to them in Article L. 411-2 of the French Code Monétaire et Financier and applicable regulations thereunder; none of this prospectus or any other materials related to the offer or information contained therein relating to our common stock has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any common stock acquired by any Permitted Investors may be made only as provided by articles L. 412-1 and L. 621-8 of the French Code Monétaire et Financier and applicable regulations thereunder.

ITALY

The offering of shares of our common stock has not been cleared by the Italian Securities Exchange Commission (Commissione Nazionale per le Società e la Borsa, or the CONSOB) pursuant to Italian securities legislation and, accordingly, shares of our common stock may not and will not be offered, sold or delivered, nor may or will copies of this prospectus or any other documents relating to shares of our common stock or the offering be distributed in Italy other than to professional investors (operatori qualificati), as defined in Article 31, paragraph 2 of CONSOB Regulation No. 11522 of July 1, 1998, as amended, or Regulation No. 11522.

Any offer, sale or delivery of shares of our common stock or distribution of copies of this prospectus or any other document relating to shares of our common stock or the offering in Italy may and will be effected in accordance with all Italian securities, tax, exchange control and other applicable laws and regulations, and, in particular, will be: (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Legislative Decree No. 385 of September 1, 1993, as amended, or the Italian Banking Law, Legislative Decree No. 58 of February 24, 1998, as amended, Regulation No. 11522, and any other applicable laws and regulations; (ii) in compliance with Article 129 of the Italian Banking Law and the implementing guidelines of the Bank of Italy; and (iii) in compliance with any other applicable notification requirement or limitation which may be imposed by CONSOB or the Bank of Italy.

Any investor purchasing shares of our common stock in the offering is solely responsible for ensuring that any offer or resale of shares of common stock it purchased in the offering occurs in compliance with applicable laws and regulations.

This prospectus and the information contained herein are intended only for the use of its recipient and are not to be distributed to any third party resident or located in Italy for any reason. No person

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Notice to investors

resident or located in Italy other than the original recipients of this document may rely on it or its content.

In addition to the above (which shall continue to apply to the extent not inconsistent with the implementing measures of the Prospective Directive in Italy), after the implementation of the Prospectus Directive in Italy, the restrictions, warranties and representations set out under the heading European Economic Area above shall apply to Italy.

GERMANY

Shares of our common stock may not be offered or sold or publicly promoted or advertised by any underwriter in the Federal Republic of Germany other than in compliance with the provisions of the German Securities Prospectus Act (Wertpapierprospektgestz WpPG) of June 22, 2005, as amended, or of any other laws applicable in the Federal Republic of Germany governing the issue, offering and sale of securities.

SPAIN

Neither the common stock nor this prospectus have been approved or registered in the administrative registries of the Spanish National Securities Exchange Commission (Comisión Nacional del Mercado de Valores). Accordingly, our common stock may not be offered in Spain except in circumstances which do not constitute a public offer of securities in Spain within the meaning of articles 30bis of the Spanish Securities Markets Law of 28 July 1988 (Ley 24/1988, de 28 de Julio, del Mercado de Valores), as amended and restated, and supplemental rules enacted thereunder.

SWEDEN

This is not a prospectus under, and has not been prepared in accordance with the prospectus requirements provided for in, the Swedish Financial Instruments Trading Act [lagen (1991:980) om handel med finasiella instrument] nor any other Swedish enactment. Neither the Swedish Financial Supervisory Authority nor any other Swedish public body has examined, approved, or registered this document.

SWITZERLAND

The common stock may not and will not be publicly offered, distributed or re-distributed on a professional basis in or from Switzerland and neither this prospectus nor any other solicitation for investments in our common stock may be communicated or distributed in Switzerland in any way that could constitute a public offering within the meaning of Articles 1156 or 652a of the Swiss Code of Obligations or of Article 2 of the Federal Act on Investment Funds of March 18, 1994. This prospectus may not be copied, reproduced, distributed or passed on to others without the underwriters prior written consent. This prospectus is not a prospectus within the meaning of Articles 1156 and 652a of the Swiss Code of Obligations or a listing prospectus according to article 32 of the Listing Rules of the Swiss Exchange and may not comply with the information standards required thereunder. We will not apply for a listing of our common stock on any Swiss stock exchange or other Swiss regulated market and this prospectus may not comply with the information required under the relevant listing rules. The common stock offered hereby has not and will not be registered with the Swiss Federal Banking Commission and has not and will not be authorized under the Federal Act on Investment Funds of March 18, 1994. The investor protection afforded to acquirers of investment fund certificates by the Federal Act on Investment Funds of March 18, 1994 does not extend to acquirers of our common stock.

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Legal matters

The validity of the shares of common stock issued in this offering will be passed upon for us by the law firm of Adams and Reese LLP, Nashville, Tennessee. Dewey & LeBoeuf LLP, New York, New York is counsel to the underwriters in connection with this offering.

Experts

The consolidated financial statements and schedule of our company as of December 31, 2008 and 2007, and for each of the years in the three-year period ended December 31, 2008, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Where you can find additional information

We filed a registration statement on Form S-1 with the Commission with respect to the registration of the common stock offered for sale with this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information about us, the common stock we are offering by this prospectus and related matters, you should review the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits that were filed with the registration statement may be inspected without charge at the public reference facilities maintained by the Securities and Exchange Commission Headquarters Office, 100 F Street, N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information on the operation of the public reference facilities may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a world wide web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is *http://www.sec.gov*.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and, in accordance with such requirements, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the regional offices, public reference facilities and web site of the SEC referred to above.

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

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Report of Independent Registered Public Accounting Firm

The Board of Directors
Cumberland Pharmaceuticals Inc.

We have audited the accompanying consolidated balance sheets of Cumberland Pharmaceuticals Inc. and subsidiaries (the Company) as of December 31, 2007 and 2008, and the related consolidated statements of income, shareholders equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2008. In connection with our audits of the consolidated financial statements, we have also audited the financial statement Schedule II Valuation and Qualifying Accounts for each of the years in the three-year period ended December 31, 2008. These consolidated financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cumberland Pharmaceuticals Inc. and subsidiaries as of December 31, 2007 and 2008, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

/s/ KPMG LLP

Nashville, Tennessee
February 17, 2009

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated balance sheets
December 31, 2007 and 2008

	2007	2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,814,518	11,829,551
Accounts receivable, net of allowances	2,373,537	3,129,347
Inventories	949,109	1,762,776
Prepaid and other current assets	288,241	481,312
Deferred tax assets	363,175	507,212
Total current assets	14,788,580	17,710,198
Property and equipment, net	459,843	432,413
Intangible assets, net	9,153,751	8,528,732
Deferred tax assets	1,827,982	1,000,031
Other assets	2,688,511	3,447,813
Total assets	$ 28,918,667	31,119,187
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 1,833,332	1,250,000
Revolving line of credit	1,325,951	
Current portion of other long-term obligations	410,423	457,915
Accounts payable	1,921,101	3,257,164
Other accrued liabilities	2,628,453	2,640,855
Total current liabilities	8,119,260	7,605,934
Revolving line of credit		1,825,951
Long-term debt, excluding current portion	916,664	3,750,000
Other long-term obligations, excluding current portion	3,136,574	382,487
Total liabilities	12,172,498	13,564,372
Commitments and contingencies (see notes)		
Shareholders equity:		
Convertible preferred stock no par value. Authorized 3,000,000 shares; issued and outstanding 855,495 and 812,749 shares at December 31, 2007 and 2008, respectively	2,742,994	2,604,070
Common stock no par value. Authorized 100,000,000 shares as of December 31, 2007 and 2008; issued and outstanding 10,091,260 and 9,903,047 shares at December 31, 2007 and 2008, respectively	17,318,713	13,500,034
Retained earnings (accumulated deficit)	(3,315,538)	1,450,711

Total shareholders equity	16,746,169	17,554,815
Total liabilities and shareholders equity	$ 28,918,667	31,119,187

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated Statements of Income
Years ended December 31, 2006, 2007, and 2008

	2006	2007	2008
Revenues:			
Net product revenue	$ 16,980,898	27,821,646	34,889,967
Revenue from co-promotion agreements	286,624		
Other revenue	547,958	241,943	185,193
Net revenues	17,815,480	28,063,589	35,075,160
Operating costs and expenses:			
Cost of products sold	2,399,133	2,669,628	3,045,672
Selling and marketing	7,348,540	10,053,355	14,387,153
Research and development	2,232,984	3,693,917	4,429,064
General and administrative	2,999,347	4,137,942	5,139,937
Amortization of product license right	515,181	686,905	686,904
Other	96,433	96,524	104,209
Total operating costs and expenses	15,591,618	21,338,271	27,792,939
Operating income	2,223,862	6,725,318	7,282,221
Interest income	208,677	382,919	241,282
Interest expense	(721,804)	(639,590)	(213,303)
Other expense	(2,800)		
Net income before income taxes	1,707,935	6,468,647	7,310,200
Income tax benefit (expense)	2,696,516	(2,424,261)	(2,543,951)
Net income	$ 4,404,451	4,044,386	4,766,249
Earnings per share basic	$ 0.45	0.40	0.47
Earnings per share diluted	$ 0.27	0.24	0.29
Weighted-average shares outstanding basic	9,797,190	10,032,083	10,142,807
Weighted-average shares outstanding diluted	16,454,112	16,581,902	16,539,662

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated statements of shareholders equity and comprehensive income
Years ended December 31, 2006, 2007, and 2008

	Preferred stock		Common stock		Retained earnings (accumulated deficit)	Total shareholders equity
	Shares	Amount	Shares	Amount		
Balance, December 31, 2005	855,495	$ 2,742,994	9,780,298	$ 15,255,029	$ (11,764,375)	$ 6,233,648
Issuance of common stock warrants				25,680		25,680
Stock-based compensation employee stock option grants				104,085		104,085
Issuance of common stock for services received			27,518	273,298		273,298
Stock-based compensation nonemployee stock option grants				37,751		37,751
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price			36,334	46,747		46,747
Net and comprehensive income					4,404,451	4,404,451
Balance, December 31, 2006	855,495	2,742,994	9,844,150	15,742,590	(7,359,924)	11,125,660
Stock-based compensation employee stock option grants				299,212		299,212
Issuance of common stock for services received			25,236	222,596		222,596
Stock-based compensation nonemployee stock option grants				93,836		93,836
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price			221,874	960,479		960,479
Net and comprehensive income					4,044,386	4,044,386

Balance, December 31, 2007	855,495	2,742,994	10,091,260	17,318,713	(3,315,538)	16,746,169
Stock-based compensation employee stock option grants				397,500		397,500
Issuance of common stock for services received			7,961	106,558		106,558
Stock-based compensation nonemployee stock option grants				58,646		58,646
Conversion of preferred stock into common stock	(42,746)	(138,924)	85,492	138,924		
Repurchase of common shares			(384,615)	(4,999,995)		(4,999,995)
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price			102,949	479,688		479,688
Net and comprehensive income					4,766,249	4,766,249
Balance, December 31, 2008	812,749	$ 2,604,070	9,903,047	$ 13,500,034	$ 1,450,711	$ 17,554,815

See accompanying notes to consolidated financial statements.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Consolidated statements of cash flows
Years ended December 31, 2006, 2007, and 2008

	2006	2007	2008
Cash flows from operating activities:			
Net income	$ 4,404,451	4,044,386	4,766,249
Adjustments to reconcile net income to net cash provided by operating activities:			
Gain on early extinguishment of other long-term obligations			(38,577)
Depreciation and amortization expense	587,742	762,222	786,597
Deferred tax (benefit) expense	(2,833,304)	2,230,596	683,914
Nonemployee stock granted for services received	273,298	222,596	106,558
Nonemployee stock option grant expense	37,751	93,836	58,646
Stock-based compensation employee stock options	104,085	299,212	397,500
Excess tax benefit derived from exercise of stock options	(37,747)	(449,528)	(398,529)
Noncash interest expense	339,593	273,714	71,933
Net changes in assets and liabilities affecting operating activities:			
Accounts receivable	(2,705,649)	2,746,925	(755,810)
Inventory	(124,716)	(278,011)	(813,667)
Prepaid, other current assets and other assets	(71,844)	(184,268)	(163,274)
Accounts payable, accrued interest and other accrued liabilities	3,308,017	(811,107)	1,652,911
Other long-term obligations	(1,118,422)	(323,691)	42,501
Net cash provided by operating activities	2,163,255	8,626,882	6,396,952
Cash flows from investing activities:			
Purchase of intangible assets license	(6,479,658)		
Additions to property and equipment	(59,714)	(152,420)	(67,572)
Additions to trademarks and patents	(13,558)	(11,069)	(66,576)
Net cash used in investing activities	(6,552,930)	(163,489)	(134,148)
Cash flows from financing activities:			
Costs of initial public offering		(2,031,416)	(687,977)
Proceeds from issuance of note payable	5,500,000		4,083,340
Costs of financing for long-term debt and credit facility	(65,733)		(29,491)
Principal payments on note payable	(916,668)	(1,833,336)	(1,833,336)
Payment of other long-term obligations		(1,500,000)	(2,760,000)
Net borrowings on line of credit	544,742	500,000	500,000
Payments made in connection with repurchase of common shares			(4,999,995)
Proceeds from exercise of stock options	9,000	510,951	81,159
Excess tax benefit derived from exercise of stock options	37,747	449,528	398,529

Net cash provided by (used in) financing activities		5,109,088	(3,904,273)	(5,247,771)
Net increase in cash and cash equivalents		719,413	4,559,120	1,015,033
Cash and cash equivalents, beginning of year		5,535,985	6,255,398	10,814,518
Cash and cash equivalents, end of year	$	6,255,398	10,814,518	11,829,551
Supplemental disclosure of cash flow information:				
Cash paid during the year for:				
Interest	$	377,202	419,100	221,000
Income taxes		55,659	89,075	1,486,991
Noncash investing and financing activities:				
Liability for license acquired		4,500,000		
Deferred financing costs		25,680		125,000
Exercise of options paid with mature shares of stock			22,031	23,100
Increase in accounts payable and accrued expenses of initial public offering			645,934	

See accompanying notes to consolidated financial statements.

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to consolidated financial statements

(1) ORGANIZATION

Cumberland Pharmaceuticals Inc. and its subsidiaries (the Company or Cumberland) is a specialty pharmaceutical company incorporated in Tennessee on January 6, 1999. Its mission is to provide high quality products to address underserved medical needs. Cumberland is focused on acquiring rights to, developing, and commercializing branded prescription products for the acute care and gastroenterology markets.

The Company s corporate operations and product acquisitions have been funded by a combination of equity and debt financings. The Company focuses its resources on maximizing the commercial potential of its products, as well as developing new product candidates, and has outsourced manufacturing and distribution to carefully selected entities with the appropriate expertise and infrastructure to support these activities.

In order to create access to a pipeline of early stage product candidates, the Company formed a subsidiary, Cumberland Emerging Technologies, Inc. (CET), which assists universities and other research organizations to help bring biomedical projects from the laboratory to the marketplace. The Company s ownership in CET is 85%. The remaining interest is owned by Vanderbilt University and the Tennessee Technology Development Corporation. During 2002, CET s losses reduced its equity to a deficit position. Accordingly, the Company reduced minority interest to zero and has recorded 100% of the losses associated with the joint venture since that time in accordance with Accounting Research Bulletin No. 51, *Consolidated Financial Statements*. These losses amounted to approximately $172,000, $171,000 and $272,000 for the years ended December 31, 2006, 2007 and 2008, respectively. As a result of adopting Statement of Financial Accounting Standards (SFAS) No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160), on January 1, 2009, the Company expects to allocate future operating results, including operating losses, to minority interest shareholders.

Beginning January 1, 2007, the Company s new wholly-owned subsidiary, Cumberland Pharma Sales Corp. (CPSC), began full operations for the purpose of employing the newly converted Hospital Sales Force that promotes the Company s products, Acetadote® and Kristalose®, in the acute care market. Previously, this sales force was contracted through a third-party contract sales organization.

The Company operates in a single operating segment of specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. All of the Company s assets are located in the United States. Total revenues are primarily attributable to U.S. customers. Net revenues from non-U.S. customers were less than $0.1 million for the year ended December 31, 2006, and totaled approximately $0.9 million and $0.6 million for the years ended December 31, 2007 and 2008, respectively.

(2) SIGNIFICANT ACCOUNTING POLICIES

(a) Principles of Consolidation

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

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Notes to consolidated financial statements

(b) Cash and Cash Equivalents

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

(c) Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company records allowances for uncollectible amounts, cash discounts, chargebacks and credits to be taken by customers for product damaged in shipments, based on historical experience. The Company reviews its customer balances on an individual account basis for collectibility. The allowance for uncollectible amounts, cash discounts, chargebacks and credits for damaged product was approximately $0.1 million as of December 31, 2007 and 2008.

Cash discounts are reductions to invoiced amounts offered to customers for payment within a specified period of time from the date of the invoice. The majority of the Company s products are distributed through independent pharmaceutical wholesalers. In conjunction with recognizing a sale to a wholesaler, net product revenue and accounts receivable take into account the sale of the product at the wholesale acquisition cost, and an accrual is recorded to reflect the difference between the wholesale acquisition cost and the estimated average end-user contract price. This accrual is calculated on a product-specific basis and is based on the estimated number of outstanding units sold to wholesalers that will ultimately be sold under end-user contracts. When the wholesaler sells the product to the end-user at the agreed upon end-user contract price, the wholesaler charges the Company for the difference between the wholesale acquisition price and the end-user contract price and that chargeback is offset against the initial accrual balance.

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

(d) Inventories

The Company utilizes third parties to manufacture and package finished goods for sale, takes title to the finished goods at the time of shipment from the manufacturer and warehouses such goods until distribution and sale. The Company s inventory was comprised completely of finished goods at December 31, 2007 and 2008. Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method.

(e) Prepaid Assets

Prepaid assets consist of the prepaid premium for directors and officers insurance, product liability insurance, prepaid consulting services, etc. The Company expenses all prepaid amounts as used or over the period of benefit on a straight-line basis, as applicable.

(f) Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the

shorter of the initial lease term plus its renewal options, if renewal is reasonably assured, or the remaining useful life of the asset. Upon retirement or disposal of assets, the asset and accumulated depreciation accounts are adjusted accordingly and any gain or loss is reflected in

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operations. Repairs and maintenance costs are expensed as incurred. Improvements that extend an asset s useful life are capitalized.

(g) Intangible Assets

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

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

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

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

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

(h) Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and purchased intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by an asset to the carrying value of the asset. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment charge is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including quoted market prices, third-party independent appraisals and discounted cash flow models, as considered necessary. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and no longer depreciated. The assets and liabilities of a disposed group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet. The Company recorded no impairment charges during the three-year period ended December 31, 2008.

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(i) Costs of Initial Public Offering

Incremental costs directly attributable to the initial public offering of the Company s common stock of approximately $3.3 million at December 31, 2008 have been deferred and included in other assets. These costs will be accounted for as a reduction to the proceeds received from a successful offering, or will be expensed in the event the offering is postponed indefinitely or abandoned. As of December 31, 2007 and 2008, approximately $0.6 million of unpaid costs related to the initial public offering are included in accounts payable and other accrued liabilities.

(j) Revenue Recognition

Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction.

The Company s net product revenue reflects reduction of gross product revenue for estimated allowances for chargebacks, discounts, and damaged goods and accruals for rebates, product returns, certain administrative fees, and fee for services. Allowances of $0.1 million as of December 31, 2007 and 2008 for chargebacks, discounts and allowances for product damaged in shipment reduce accounts receivable, and accrued liabilities of $0.7 million and $1.0 million as of December 31, 2007 and 2008, respectively, for rebates, product returns and administrative fees are included in other accrued liabilities.

As discussed in 2(c) above, the allowances for chargebacks, discounts and damaged goods are determined on a product-by-product basis, and are established by management as the Company s best estimate at the time of sale based on each product s historical experience adjusted to reflect known changes in the factors that impact such allowances. These are established based on the contractual terms with direct and indirect customers and analyses of historical levels of chargebacks, discounts and credits claimed for damaged product.

Other organizations, such as managed care providers, pharmacy benefit management companies and government agencies, may receive rebates from the Company based on negotiated contracts to carry the Company s product or reimbursements for filled prescriptions. These entities represent indirect customers of the Company. In addition, the Company may provide rebates to the end-user. In conjunction with recognizing a sale to a wholesaler, sales revenues are reduced and accrued expenses are increased by the Company s estimates of the rebates that will be owed.

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. The Company s estimate of the provision for returns is based upon historical experience with actual returns. Any changes in the assumptions used to estimate the provision for returns is recognized in the period those assumptions were changed.

The Company has agreements with certain key wholesalers, including fee for service costs. In accordance with Emerging Issues Task Force (EITF) No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*, these administrative costs have been netted against product revenues.

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The Company s net product revenue and revenue from co-promotional agreements consist of the following as of December 31:

2006

	Net Product Revenue	Revenue from Co-Promotional Agreements	Total
Acetadote	$ 10,722,330		10,722,330
Kristalose[1]	6,223,931	286,624	6,510,555
Other products[2]	34,637		34,637
	$ 16,980,898	286,624	17,267,522

2007

	Net Product Revenue	Revenue from Co-Promotional Agreements	Total
Acetadote	$ 18,817,293		18,817,293
Kristalose	9,012,789		9,012,789
Other products	(8,436)		(8,436)
	$ 27,821,646		27,821,646

2008

	Net Product Revenue	Revenue from Co-Promotional Agreements	Total
Acetadote	$ 25,438,774		25,438,774
Kristalose	9,468,562		9,468,562
Other products	(17,369)		(17,369)

	$ 34,889,967	34,889,967

(1) For the period from January 1, 2006 through April 9, 2006, the Company promoted Kristalose under a co-promotion arrangement.

(2) Includes revenues from products for which the Company no longer has the exclusive licensing rights.

For the first quarter of 2006, the Company had two products for which it received a co-promotion fee under the related co-promotion agreements. The Company recognized the promotional fees as revenue from co-promotion agreements during the period in which the sales of the respective product occurred.

Other revenue is primarily comprised of revenue generated by CET through consulting services, development funding from private sector investment or federal Small Business (SBIR/STTR) grant programs and lease income generated by CET s Life Sciences Center. The Life Sciences Center is a research center that provides scientists with access to flexible lab space and other resources to develop their products. Revenue related to grants is recognized when all conditions related to such grants have been met. Grant revenue totaled approximately $375,000, $83,000 and $7,000 for the years ended December 31, 2006, 2007 and 2008, respectively.

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(k) Income Taxes

The Company provides for deferred taxes using the asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for future tax consequences attributable to operating loss and tax credit carryforwards, as well as differences between the carrying amounts of existing assets and liabilities and their respective tax bases. The Company s principal differences are related to timing of deductibility of certain items, such as depreciation, amortization and expense for options issued to nonemployees. Deferred tax assets and liabilities are measured using enacted tax rates that are expected to apply to taxable income in the years such temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment.

The Company adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48) in January 2007. FIN 48 provides a recognition threshold and guidance for measurement of income tax positions taken or expected to be taken on a tax return. These standards require that the Company eliminate the income tax benefits associated with any income tax position where it is not more likely than not that the position would be sustained upon examination by the taxing authorities. As of January 1, 2007, the Company s uncertain tax positions were previously reserved under SFAS No. 5, *Accounting for Contingencies* (SFAS 5). As a result, the adoption of FIN 48 did not result in any adjustment to shareholders equity.

The Company s accounting policy with respect to interest and penalties arising from income tax settlements is to recognize them as part of the provision for income taxes.

(l) Share-Based Payments

Effective January 1, 2006, the Company adopted the requirements of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), utilizing the prospective method of adoption. Under this approach, SFAS 123(R) applies to new grants and the modification, repurchase or cancellation of outstanding awards beginning on January 1, 2006. Under the prospective method of adoption, compensation cost recognized subsequent to the adoption of SFAS 123(R) includes only share-based compensation cost for all share-based payments granted or modified subsequent to January 1, 2006. The cost is measured based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R) and is recognized as expense over the employee s requisite service period. The Company calculates the fair value of options using the Black-Scholes option-pricing model.

(m) Research and Development

Research and development costs are expensed in the period incurred. Research and development costs are comprised mainly of clinical trial expenses, salary and wages and other related costs such as materials and supplies. Development expense includes activities performed by third-party providers participating in the Company s clinical studies. The Company accounts for these costs based on estimates of work performed, patient enrollment or fixed fee for services.

(n) Advertising Costs

Advertising costs are expensed as incurred and amounted to $0.7 million, $0.6 million and $0.7 million in 2006, 2007 and 2008, respectively.

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(o) Distribution Costs

The Company expenses distribution costs as incurred. Distribution costs included in sales and marketing expenses amounted to $0.4 million, $0.8 million and $1.0 million in 2006, 2007 and 2008, respectively.

(p) Selling and Marketing Expense

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

(q) Cost of Products Sold

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

(r) Earnings per Share

The Company accounts for earnings per share in accordance with SFAS No. 128, *Earnings per Share*. Basic earnings per share is calculated by dividing net income by the weighted-average number of shares outstanding. Except where the result would be antidilutive to income from continuing operations, diluted earnings per share is calculated by assuming the conversion of convertible instruments and the elimination of related interest expense, if any, the vesting of unvested restricted stock and the exercise of stock options and warrants, as well as their related income tax benefits.

The following table reconciles the numerator and the denominator used to calculate diluted earnings per share:

	Year Ended December 31,		
	2006	2007	2008
Numerator:			
Net income	$ 4,404,451	4,044,386	4,766,249
Denominator:			
Weighted-average shares outstanding basic	9,797,190	10,032,083	10,142,807
Convertible preferred stock shares	1,710,990	1,710,990	1,710,990
Dilutive effect of other securities	4,945,932	4,838,829	4,685,865
Weighted-average shares outstanding diluted	16,454,112	16,581,902	16,539,662

As of December 31, 2006, 2007 and 2008, options to purchase 32,978, 35,230 and 57,397 shares of common stock, respectively, were outstanding but were not included in the computation of diluted earnings per share because the effect would be antidilutive.

(s) Comprehensive Income

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

(t) Accounting Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the

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

(u) Fair Value of Financial Instruments

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

(v) Reclassifications

Certain prior year amounts were reclassified to conform to current year presentation. Accrued interest is now included in other accrued liabilities in the consolidated balance sheet.

(w) Recently Issued Accounting Standards

In December 2007, the FASB issued SFAS No. 141 (revised), *Business Combinations* (SFAS 141(R)). SFAS 141(R) relates to business combinations and requires the acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date measured at fair values on the acquisition date. This statement must be adopted prospectively by the Company for all business combinations occurring on or after January 1, 2009. Early adoption is not allowed. The impact of adoption of SFAS 141(R) will depend on future acquisitions.

In December 2007, the FASB issued SFAS 160. This statement establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. It also requires consolidated results of operations to include amounts attributable to both the parent and noncontrolling interest, with disclosure on the consolidated statement of operations of the amounts attributable to the parent and noncontrolling interest. The statement also requires that equity transactions by and between each party be accounted for as equity transactions unless the parent company loses its controlling interest in the subsidiary. In the event the parent company loses its controlling interest, the investment in the subsidiary will be adjusted to fair value, and a gain or loss on investment will be recognized in the consolidated statement of operations. As discussed in Note 1, the Company s ownership in CET is 85%. The adoption of SFAS 160 will result in the allocation of future operating results, including losses, to the noncontrolling interest of CET. In addition, the Company s consolidated balance sheet and statement of shareholders equity will reflect amounts attributable to the noncontrolling interest.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1), that prohibits companies from applying the equity method of accounting to activities performed outside a separate legal entity by a virtual joint venture. Instead, revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented

gross or net by the collaborators based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other applicable accounting literature. EITF 07-1 should be applied to collaborative arrangements in existence at the date of adoption using a modified retrospective method that requires reclassification in all periods presented for those arrangements still in effect at the transition date, unless

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that application is impracticable. EITF 07-1 is effective for the Company beginning on January 1, 2009. The Company currently collaborates with certain research institutions to identify and pursue promising pre-clinical programs. The Company has negotiated rights to develop and commercialize these product candidates. The adoption of EITF 07-1 is not expected to have a material impact on the Company s consolidated financial position or results of operations.

(3) PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31:

	Range of useful lives	2007	2008
Computer hardware and software	3-5 years	$ 140,621	162,515
Office equipment	3-15 years	30,722	30,276
Furniture and fixtures	5-10 years	246,202	242,591
Leasehold improvements	3-15 years, or remaining lease term	318,796	331,557
		736,341	766,939
Less accumulated depreciation and amortization		(276,498)	(334,526)
		$ 459,843	432,413

Depreciation expense, including amortization expense related to leasehold improvements, during 2006, 2007 and 2008 was approximately $68,000, $71,000 and $95,000, respectively, and is included in general and administrative expense in the consolidated statements of income.

(4) INTANGIBLE ASSETS

Intangible assets consisted of the following at December 31:

	2007	2008
Trademarks	$ 46,986	46,986
Less accumulated amortization	(35,682)	(40,371)
Total trademarks	11,304	6,615
License	10,303,595	10,303,595
Less accumulated amortization	(1,202,086)	(1,888,990)

Total license	9,101,509	8,414,605
Patents	40,938	107,512
	$ 9,153,751	8,528,732

Amortization expense related to trademarks and license rights totaled approximately $692,000 in 2007 and 2008, and is expected to be approximately $690,000 in each of the years 2009 through 2013.

In April 2006, the Company acquired the exclusive U.S. commercialization rights (product license) for Kristalose® from Inalco Biochemicals, Inc. and Inalco S.p.A. (collectively Inalco) for $10,303,595. This amount included cash paid on the effective date of the agreement of $6,500,000, discounted future obligations totaling $3,823,937 due in April 2007 and April 2009, and acquisition costs of $13,775, and is net of the fair value of services received by the Company in 2006 of $34,117 under a transition

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service agreement. The fair value of these services was expensed over the transition period in 2006 and was included in selling and marketing expenses. In April 2007, the Company made an installment payment of $1,500,000 (inclusive of $102,440 of imputed interest). In April 2008, the Company amended its agreement and paid the remaining obligation related to the purchase of the Kristalose rights. The terms of the amendment provided for an 8% discount on the $3,000,000 face value of the obligation for a net payment of $2,760,000.

(5) OTHER ACCRUED LIABILITIES

Other accrued liabilities consisted of the following at December 31:

	2007	2008
Rebates, fee for services, and product returns	$ 738,362	1,040,204
Employee wages and benefits	664,518	707,638
Costs related to initial public offering	359,664	196,746
Outside sales force and related expenses	332,774	181,140
Other	533,135	515,127
	$ 2,628,453	2,640,855

(6) LONG-TERM DEBT

In April 2006, the Company completed its transaction with Inalco to acquire exclusive U.S. commercialization rights for Kristalose®. In order to complete this transaction, funding was obtained from Bank of America in the form of a three-year term loan for $5,500,000 and a two-year revolving line of credit agreement, both with an interest rate of LIBOR plus 2.5%. The term loan was due in 2009, and was being paid off in quarterly principal installments of $458,334, plus interest. In April 2008, the Company amended its revolving line of credit agreement to extend the maturity date to April 2009.

On December 30, 2008, the Company amended its debt agreements (Third Amended and Restated Loan Agreement) to provide for $5.0 million of term debt and up to $7.5 million under its revolving line of credit, both with an interest rate of LIBOR plus an applicable margin (4.42% at December 31, 2008) based on the Company s leverage ratio, as defined in the agreement. For the first five business days after the date of the amended agreement, the availability under the revolving line of credit was limited to $2.0 million. These agreements expire in December 2011. The term loan is being paid off in quarterly installments of $416,667, plus interest, beginning April 2009. The Company must pay an annual commitment fee of 1/2 of 1% on the unused portion of the commitment. The credit agreement provides that borrowings are collateralized by a first priority lien on all of the Company s assets. The credit agreement contains an adverse subjective acceleration clause and also requires the Company to maintain bank accounts and a lockbox at the lender. However, cash received in the lockbox is not required to be applied against amounts borrowed under the line of credit. This credit agreement contains various covenants and the Company was in compliance with all covenants at December 31, 2008.

In conjunction with the original agreements, the Company issued warrants to purchase up to 3,958 shares of common stock at an exercise price of $9.00 per share, which expire in April 2016 and are outstanding and exercisable as of December 31, 2008. The estimated grant-date fair value of these warrants of $25,680, as determined using the Black-Scholes model utilizing an expected term of 10 years, risk-free interest rate of 4.89%, volatility of 60%, and 0% dividend yield, was recorded in the

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accompanying consolidated financial statements as equity and deferred financing costs. Deferred financing costs are a component of other assets, and are being expensed to interest expense using the effective-interest method over the respective terms of the line of credit and term note.

Payments due on all long-term debt obligations over the next five years are as follows:

Year ending December 31:	
2009	$ 1,250,000
2010	1,666,668
2011	3,909,283
2012	
2013	
	$ 6,825,951

(7) OTHER LONG-TERM OBLIGATIONS

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

	2007	2008
Deferred purchase price, net of discount of $250,904	$ 2,749,096	
Third-party development costs	615,846	615,846
Other	182,055	224,556
	3,546,997	840,402
Less current portion	(410,423)	(457,915)
	$ 3,136,574	382,487

In connection with the acquisition of the exclusive commercialization rights for Kristalose®, the Company deferred a portion of the purchase price. The final payment of $3.0 million was due in April 2009. The discount was imputed at 7.33% on the acquisition date, and was being accreted using the effective-interest method. In April 2008, the Company amended its agreement and paid the remaining obligation related to the purchase of Kristalose. The terms of the amendment provided for an 8% discount on the $3.0 million face value of the obligation for a net payment of $2.76 million.

During 2000, the Company signed an agreement with a third party to cover a variety of development efforts related to a specific pharmaceutical drug, including preparation of submissions to the FDA. In accordance with the agreement, the Company was billed, and the Company expensed, approximately $1.0 million during the fiscal years 2001 through

2003. As of December 31, 2008, the Company has paid approximately $0.6 million of this balance and accrued the remaining balance of approximately $0.4 million. The remaining balance is due in the following timeframe: (a) approximately $0.2 million due no later than the submission and acceptance for review of a new drug application (NDA) to the FDA and (b) approximately $0.2 million due no later than FDA approval. The Company is in the process of completing the requisite steps believed necessary to obtain acceptance of its NDA. As such, the amount specified in (a) is recognized as a current portion of other long-term obligations in the accompanying consolidated balance sheet. The balance specified in (b) is reflected as an other long-term obligation in the accompanying consolidated balance sheet. If neither the submission of the FDA application nor FDA approval occurs due to the Company terminating the project, the $0.4 million will become due and payable and will accrue interest at 12.5% until paid.

The agreement also calls for contingent payments upon certain milestones. Upon meeting the first milestone, acceptance for review of a new drug application and FDA acceptance of the submission for

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review, a contingent payment of approximately $0.2 million will become due and payable. Upon meeting the second milestone, FDA approval, a contingent payment of approximately $1.0 million will become due and payable as follows: approximately $0.8 million immediately and approximately $0.2 million in twelve monthly installments starting on the date the milestone is met. Since the payment of the second milestone is contingent on specific events that may or may not occur in the future, and which have not occurred or are deemed probable of occurring as of December 31, 2008, the contingent liability for this milestone has not been recognized in the consolidated financial statements.

In connection with the aforementioned agreement, the third party will have the ability to vest in 60,000 options if FDA approval occurs within 13 months after the NDA is accepted for review. If approval occurs between 14 and 15 months after acceptance for review, the third party will vest in 30,000 options. If approval occurs between 15 and 18 months after acceptance, the third party will vest in 15,000 options. No options will vest after 18 months. The exercise price of these options is $1.63. Because vesting for these options is contingent on FDA approval, which may or may not occur, the expense for these options has not been accounted for in the accompanying consolidated financial statements.

(8) INCOME TAXES

Income tax benefit (expense) includes the following components:

	2006	2007	2008
Current:			
Federal	$ (121,359)	(543,115)	(1,593,865)
State	(15,429)	(100,078)	(266,172)
	(136,788)	(643,193)	(1,860,037)
Deferred:			
Federal	2,861,859	(1,646,209)	(571,114)
State	(28,555)	(134,859)	(112,800)
	2,833,304	(1,781,068)	(683,914)
	$ 2,696,516	(2,424,261)	(2,543,951)

The Company s deferred tax benefit for 2006 was the result of a combination of the utilization of deferred tax assets and a change in judgment about the realizability of deferred tax assets. The deferred tax expense in 2007 was primarily the result of the utilization of the deferred tax assets from federal and state net operating loss carryforwards. The deferred tax expense for 2008 was primarily due to the utilization of deferred tax assets from federal tax credit carryforwards.

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

	2006	2007	2008
Deferred tax benefit (expense) exclusive of components listed below	$ (232,390)	420,945	202,984
Benefits of operating loss carryforwards	764,495	(2,002,955)	(248,651)
Benefits of tax credit carryforwards	(55,234)	(191,191)	(626,956)
Change in valuation allowance due to changes in net deferred tax asset balances	(476,871)	(7,867)	(11,291)
Adjustments to the valuation allowance due to circumstances that caused a change in judgment about the realizability of the related deferred tax assets in future years	2,833,304		
Deferred income tax benefit (expense)	$ 2,833,304	(1,781,068)	(683,914)

In 2006, the Company reduced the valuation allowance by $2,833,304 since additional positive evidence suggested that the majority of the deferred tax assets would be utilized in future years. The valuation allowance at December 31, 2007 and 2008 is primarily related to state tax benefits at CET that will likely not be realized.

The Company s effective income tax rate for 2006, 2007 and 2008 reconciles with the federal statutory tax rate as follows:

	2006	2007	2008
Federal tax expense at statutory rate	(34)%	(34)%	(34)%
State income tax benefit (net of federal income tax benefit)	(2)	(3)	(4)
Permanent differences		(1)	(2)
Recognition of previously unrecognized tax benefits			4
Other		1	1
Change in deferred tax asset valuation allowance	194		
Net income tax benefit (expense)	158%	(37)%	(35)%

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

	2007	2008

Net operating loss and tax credits	$ 999,665	125,626
Property and equipment	148,502	123,227
Allowance for accounts receivable	54,294	55,425
Reserve for expired product	119,309	239,790
Rebate liability	38,328	
Inventory	416	
Deferred charges	294,764	394,467
Cumulative compensation costs incurred on nonqualified options	583,358	627,478
Total deferred tax assets	2,238,636	1,566,013
Less deferred tax asset valuation allowance	(47,479)	(58,770)
Net deferred tax assets	$ 2,191,157	1,507,243

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of

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deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. In order to fully realize the deferred tax assets, the Company will need to generate future taxable income of approximately $7.2 million prior to the expiration of the net operating loss carryforwards in 2023. Taxable income for the years ended December 31, 2006, 2007 and 2008 was approximately $2.1 million, $5.5 million and $7.0 million, respectively. Based upon the level of taxable income over the last three years and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will realize the benefits of these deductible differences, net of the existing valuation allowances, at December 31, 2008. The amount of the deferred tax asset considered realizable, however, could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

The federal and state net operating loss carryforwards will expire as follows:

Year of expiration:	Federal	State
2015 2017	$	499,034
2018 2020		1,863,553
2021 2023		529,195
	$	2,891,782

The Company s cumulative unrecognized benefits at January 1, 2007, net of federal benefits, were $357,178. The nature of these unrecognized benefits did not result in any accrual of interest and penalties. The tax benefits related to these amounts had been previously reserved under the provisions of SFAS 5. Therefore, the cumulative unrecognized benefits existing at January 1, 2007 did not result in an adjustment to beginning retained earnings. SFAS 5 reserves were evaluated under FIN 48 standards, and were reclassed as the beginning of period unrecognized tax benefits.

Changes in the balance of unrecognized tax benefits during 2007 and 2008 were as follows:

	Gross	Federal Unrecognized Benefits	State Unrecognized Benefit	Total
Unrecognized tax benefits, January 1, 2007	$ 357,178	357,178		357,178
Increase from current period tax positions	21,558	21,558		21,558
Unrecognized tax benefits, December 31, 2007	378,736	378,736		378,736
Decrease for tax positions related to prior years	(21,558)	(21,558)		(21,558)

Decrease due to settlement with taxing authority	(357,178)	(357,178)	(357,178)
Unrecognized tax benefits, December 31, 2008	$		

If the total amount of unrecognized tax benefits were recognized in the computation of income tax expense for 2007, the effective tax rate would decrease by 6%.

In determining the unrecognized tax benefits as of December 31, 2007 and 2008, the Company evaluated its tax positions for all years that remain subject to examination by the taxing authorities. In the first quarter of 2008, the Internal Revenue Service (IRS) completed its examinations of the U.S. income tax returns for 2005 and 2006, and as a result the Company effectively settled $357,178 of the previously unrecognized tax benefits.

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Federal tax years that remain open to examination are 2007 and 2008. State tax years that remain open to examination are 2004 to 2008.

(9) SHAREHOLDERS EQUITY

(a) Stock Split

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

(b) Preferred Stock

The Company s outstanding shares of preferred stock consist of Series A Convertible Preferred Stock. These shareholders are entitled to vote with the holders of common stock, as each preferred share is entitled to the number of votes the holder would be entitled to if converted to shares of common stock immediately prior to the vote. They are also entitled to receive dividends on an equal basis with holders of common stock on an if-converted equivalent.

The Series A Convertible Preferred Stock shareholders are entitled to receive a liquidation preference $3.25 per share in the event of the dissolution, liquidation or winding up of the Company. If assets are insufficient to permit full payment, preferred shareholders are entitled to a ratable distribution of the available assets. Preferred shares are convertible, at the option of the holder, at any time after issuance at the rate of two shares of common stock for each share of preferred stock. The preferred stock will automatically be converted into common stock in the event of an underwritten public offering of the Company s common stock or in the event of a consolidation, merger or sale of substantially all of the assets of the Company. In addition, preferred shareholders are entitled to adjustment of the ratio of conversion of Series A Convertible Preferred Stock into common stock to reduce dilution in the event that the Company issued additional equity securities at a purchase price of less than $3.25 per share.

The Company is also authorized to issue an additional 20,000,000 shares of preferred stock. The Board of Directors is authorized to divide these shares into classes or series, and to fix and determine the relative rights, preferences, qualifications and limitations of the shares of any class or series so established.

(c) Common Stock

During 2006, 2007 and 2008, the Company issued 27,518, 25,236 and 7,961 shares of common stock, respectively, valued at $273,000, $223,000 and $107,000, respectively, to executives, related parties, and advisors as compensation for services, and is included in general and administrative expenses in the consolidated statements of income. Included in these amounts are shares of common stock granted to board members of 24,818, 11,036 and 3,461 in 2006, 2007 and 2008, respectively, for services rendered. The expense associated with these grants to board members was approximately $249,000, $121,000 and $45,000 in 2006, 2007 and 2008, respectively. In addition, the Company issued 36,334, 10,304 and 87,142 net shares of common stock to key executives and an advisor, who exercised options in 2006, 2007 and 2008, respectively.

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In April 2007, the shareholders approved an amendment to the Company s charter, which increased the number of authorized shares to 100,000,000. Additionally, the Third Amended and Restated Loan Agreement prohibits the Company from declaring and paying a cash dividend.

(d) Warrants

In 2003, the Company issued a stock purchase warrant to purchase 25,000 shares of common stock at an exercise price of $6.00 per share as partial consideration for a modification to its line of credit. The warrants expire 10 years from the date of issuance. All of these warrants were outstanding and exercisable as of December 31, 2008.

In connection with the issuance of shares of stock to a related party in 2004, the Company issued a stock purchase warrant to purchase 40,000 shares of stock at $6.00 per share at any time within ten years of issuance. All of these warrants were outstanding and exercisable as of December 31, 2008.

In 2006, the Company signed a new line of credit agreement along with a term loan agreement with a financial institution. In conjunction with these agreements, the Company issued warrants to purchase up to 3,958 shares of common stock at $9.00 per share, which expire in April 2016, and are outstanding and exercisable as of December 31, 2008. The estimated fair value of these warrants of $25,680, as determined using the Black-Scholes model utilizing an expected term of 10 years, risk-free interest rate of 4.89%, volatility of 60%, and 0% dividend yield, has been recorded in the accompanying consolidated financial statements as equity and deferred financing costs, a component of other assets.

(e) Share Repurchase

On December 12, 2008, the Board of Directors authorized the Company to repurchase up to 384,615 shares of common stock at $13.00 per share. On December 30, 2008, the Company completed its $5.0 million repurchase of common stock. In connection with the repurchase, 42,746 shares of preferred stock were converted into 85,492 shares of common stock. The repurchase was financed, in part, by additional borrowings under its term debt with Bank of America. See Note 6 for additional discussion of the term debt.

(10) STOCK OPTIONS

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

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

The purposes of the Directors Plan are to strengthen the Company s ability to attract, motivate, and retain Directors of experience and ability, and to encourage the highest level of performance by providing Directors with a proprietary interest in the Company s financial success and growth. The Directors Plan supersedes and replaces the provisions pertaining to grants of stock options to Directors

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in the 1999 Plan, but does not impair the vesting or exercise of any options granted under the 1999 Plan. The Company has reserved 250,000 shares of common stock under the Directors Plan.

Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. The options granted to shareholders owning more than 10% of the common stock on the grant date must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date.

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

Stock option activity for the three-year period ended December 31, 2008 was as follows:

	Number of shares	Weighted-average exercise price per share
Options outstanding, December 31, 2005	8,308,806	$ 1.34
Options granted	95,950	9.19
Options exercised	(38,968)	0.96
Options expired	(9,000)	9.00
Options forfeited	(313,832)	2.54
Options outstanding, December 31, 2006	8,042,956	1.35
Options granted	90,920	11.00
Options exercised	(223,878)	2.38
Options forfeited	(23,246)	8.35
Options outstanding, December 31, 2007	7,886,752	1.42
Options granted	134,100	13.29
Options exercised	(105,049)	0.99
Options forfeited	(4,817)	7.87
Options outstanding, December 31, 2008	7,910,986	1.65

Of the options outstanding at December 31, 2006, 2007 and 2008, 4,783,728, 4,771,420 and 4,795,420, respectively, were options issued to a key executive.

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The following table summarizes information concerning outstanding options as of December 31, 2008:

Year	Range of exercise prices	Number outstanding and expected to vest	Remaining contractual life (in years)	Weighted-average exercise price	Aggregate intrinsic value
1999	$0.10-0.11	835,056	0.05	$ 0.11	$ 10,766,372
1999	0.50-0.55	4,602,758	0.70	0.54	57,329,621
2000	0.93	85,158	1.51	0.93	1,027,857
2001	1.63	781,366	2.20	1.63	8,884,131
2002	1.63	311,908	3.03	1.63	3,546,393
2002	3.13-3.50	14,644	3.52	3.15	144,310
2003	3.13-6.00	481,752	4.31	4.07	4,302,894
2004	6.00-6.60	256,570	5.29	6.01	1,793,950
2005	6.00-9.00	251,304	5.11	6.50	1,632,528
2006	9.00-9.90	66,450	6.00	9.27	247,800
2007	11.00	89,920	8.08	11.00	179,840
2008	13.00-14.30	134,100	8.46	13.29	(39,000)
		7,910,986			$ 89,816,696

The following table summarizes information concerning exercisable options as of December 31, 2008:

Year	Range of exercise prices	Options exercisable	Remaining contractual life (in years)	Weighted-average exercise price	Aggregate intrinsic value
1999	$0.10-0.11	835,056	0.05	$ 0.11	$ 10,766,372
1999	0.50-0.55	4,602,758	0.70	0.54	57,329,621
2000	0.93	85,158	1.51	0.93	1,027,857
2001	1.63	781,366	2.20	1.63	8,884,131
2002	1.63	311,908	3.03	1.63	3,546,393
2002	3.13-3.50	14,644	3.52	3.15	144,310
2003	3.13-6.00	481,752	4.31	4.07	4,302,894
2004	6.00-6.60	256,570	5.29	6.01	1,793,950
2005	6.00-9.00	158,144	4.56	6.80	980,408

2006	9.00-9.90	54,550	6.12	9.25	204,700
2007	11.00	55,260	8.08	11.00	110,520
2008	13.00-14.30	35,865	8.53	13.27	(9,750)
		7,673,031			$ 89,081,406

The fair value of employee options granted during 2006, 2007 and 2008 were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2006	**2007**	**2008**
Dividend yield			
Expected term (years)	3-7	5.5-6.4	3.5-6.0
Expected volatility	47%-54%	58%-64%	49%-51%
Risk-free interest rate	4.68%-5.08%	4.6%-4.8%	3.1%

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Notes to consolidated financial statements

The fair value of nonemployee options granted during 2006, 2007 and 2008 were estimated using the Black-Scholes option-pricing model and the following assumptions:

	2006	2007	2008
Dividend yield			
Expected term (years)	0.17-10	10	10
Expected volatility	37%-63%	74%	68%
Risk-free interest rate	4.34%-4.42%	4.83%	3.7%

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

The weighted-average grant date fair value of share options granted during the years ended December 31, 2006, 2007 and 2008 was approximately $4.95, $7.21 and $6.27, respectively. Upon exercise, the Company issues new shares of stock. During the years ended December 31, 2006, 2007 and 2008, the aggregate intrinsic value of options exercised was $0.4 million, $1.9 million and $1.2 million, respectively, determined as of the date of option exercise.

Stock compensation expense is presented as a component of general and administrative expenses in the accompanying consolidated statements of income. At December 31, 2008, there was approximately $0.9 million of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a period of four years. This amount relates primarily to unrecognized compensation cost for employees.

The Company issued a total of 24,000, 14,000 and 2,850 stock options to nonemployees for services rendered by these individuals in 2006, 2007 and 2008, respectively, as compensation for assisting the Company s management and supporting operations. The amount of compensation expense recorded for such services was approximately $38,000, $94,000 and $59,000 in 2006, 2007 and 2008, respectively. Such expense is presented as a component of general and administrative expenses.

(11) LEASES

The Company is obligated under long-term real estate leases for office space expiring at various times through December 2011. The Company also subleases a portion of the space under these leases. Rent expense is recognized over the expected term of the lease, including renewal option periods, if applicable, on a straight-line basis. Rent expense for 2006, 2007 and 2008 was approximately $286,000, $388,000 and $526,000, respectively, and sublease income was approximately $71,000, $77,000 and $170,000, respectively. Future minimum lease payments, including

renewal option periods

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for which the Company is expected to exercise, under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are:

Year ending December 31:	
2009	$ 590,430
2010	559,113
2011	137,781
2012	93,481
2013 and thereafter	297,603
Total minimum lease payments	$ 1,678,408

(12) MANUFACTURING AND SUPPLY AGREEMENTS

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

The Company s manufacturing and supply agreements with the manufacturers of its products contain minimum purchase obligations. These obligations require the Company to purchase approximately $2.8 million during 2009, $3.1 million during 2010 and $2.4 million during 2011. Beginning in October 2011 and continuing through the life of the agreement, which expires in 2021, one of the manufacturing and supply agreements requires minimum purchases of not less than 65% of the average purchases in each of the three immediately preceding annual periods. The Company met its purchase obligations for 2008 under these agreements.

(13) COMMITMENTS AND CONTINGENCIES

The Company outsources some of its sales force activities through an agreement with a third party. Under the terms of the agreement, the Company makes monthly payments to the third party of approximately $443,000 for these activities. The agreement expires in 2010. Should the Company not continue to receive these services from this third party, the Company would have to consider an alternative source such as another service organization or hiring an internal sales force.

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

(14) EMPLOYMENT AGREEMENTS

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

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

(15) MARKET CONCENTRATIONS

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

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

	2006	2007	2008
Customer 1	22%	35%	37%
Customer 2	20	26	25
Customer 3	25	31	31

Additionally, 92% and 93% of the Company s accounts receivable balances were due from these three customers at December 31, 2007 and 2008, respectively.

(16) EMPLOYEE BENEFIT PLAN

The Company sponsors an employee benefit plan that was established on January 1, 2006, the Cumberland Pharmaceuticals 401(k) Plan (the Plan), under Section 401(k) of the Internal Revenue Code of 1986, as amended, for the benefit of all employees over the age of 21, having been employed by the Company for at least six months. The Plan provides that participants may contribute up to the maximum amount of their compensation as set forth by the Internal Revenue Service each year. Employee contributions are invested in various investment funds based upon elections made by the employees. There were no contributions made by the Company to the Plan in 2006, 2007 or 2008. In 2008, the Company s board of directors adopted a plan to match 20% of the first 5% of participant s annual deferrals to the Plan. The match is expected to be paid in the first quarter of 2009.

(17) SUBSEQUENT EVENTS (Unaudited)

In January 2009, two executives exercised options to purchase 734,080 shares of common stock with a weighted-average exercise price of $0.14 per share. Options were exercised using a net-share settlement feature that provided for the option holder to use 204,245 shares acquired upon exercise to settle the minimum statutory tax withholding requirements of approximately $2.7 million. The Company obtained a waiver from the lender for violations of certain covenants in the Third Amended and Restated Loan Agreement resulting from this transaction.

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Cumberland Pharmaceuticals Inc. and Subsidiaries

Schedule II valuation and qualifying accounts

Column A Description	Column B Balance at beginning of period	Column C Charged to costs and expenses	Column C Charged to other accounts describe	Column D Deductions describe[1]	Column E Balance at end of period
			December 31, 2007 and 2008		
Allowance for uncollectible amounts, cash discounts, chargebacks, and credits issued for damaged products:					
For the period ended:					
December 31, 2006	$ 184,334	1,152,927		(1,038,348)	298,913
December 31, 2007	298,913	1,184,711		(1,336,652)	146,972
December 31, 2008	146,972	1,242,300		(1,242,226)	147,046
Valuation allowance for deferred tax assets:					
For the period ended:					
December 31, 2006	$ 3,349,786	(3,310,174)[2]			39,612
December 31, 2007	39,612	7,867			47,479
December 31, 2008	47,479	11,291			58,770

(1) Write-off of uncollectible accounts, net of recoveries, discounts, chargebacks, and credits taken by customers.

(2) Includes a $2,833,304 reduction in the valuation allowance reflecting the Company s belief that the future recognition of this amount of deferred tax assets is more likely than not. Remaining decrease is due to the utilization of deferred tax assets.

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Information not required in prospectus

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The expenses relating to the registration of the shares of common stock being offered hereby, other than underwriting discounts and commissions, will be borne by us. Such expenses are estimated to be as follows:

Item	Amount
SEC registration fee	$ 4,000
FINRA filing fee	$ 12,000
NASDAQ Global Market listing fee	$ 100,000
Printing expenses	$ 425,000
Legal fees and expenses	$ 1,100,000
Accounting fees and expenses	$ 1,350,000
Blue sky, qualification fees and expenses	$ 20,000
Transfer agent and registrar expenses	$ 15,000
Miscellaneous	$ 874,000
Total	$ 3,900,000

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Our charter and bylaws provide for indemnification of our directors to the fullest extent permitted by the Tennessee Business Corporation Act, as amended from time to time. Our directors shall not be liable to the corporation or its shareholders for monetary damages for breach of fiduciary duty as a director. The Tennessee Business Corporation Act provides that a Tennessee corporation may indemnify its directors and officers against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by them in connection with any proceeding, whether criminal or civil, administrative or investigative if, in connection with the matter in issue, the individual s conduct was in good faith, and the individual reasonably believed: in the case of conduct in the individual s official capacity with the corporation, that the individual s conduct was in its best interest; and in all other cases, that the individual s behavior was at least not opposed to its best interest; and in the case of a criminal proceeding, the individual had no reason to believe the individual s conduct was unlawful. In addition, we have entered into indemnification agreements with our directors. These provisions and agreements may have the practical effect in certain cases of eliminating the ability of our shareholders to collect monetary damages from directors. We believe that these contractual agreements and the provisions in our charter and bylaws are necessary to attract and retain qualified persons as directors.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

In April 2006, we issued a ten-year warrant to purchase 3,958 common shares at $9.00 per share to Bank of America. The issuance of this security was exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

Since January 1, 2006, we have granted options to purchase 186,870 shares of our common stock under the 1999 Option Plan to our employees, directors and consultants at exercise prices ranging from $9.00 to $11.00 per share. An aggregate of 1,000 shares of our common stock have been issued upon exercise of these options.

Since January 1, 2006, we also issued an aggregate of 69,015 shares of common stock as compensation for services pursuant to contracts. Restricted-stock legends were affixed to the securities issued in these

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transactions. Our board of directors determined that the fair value of the services received equaled the value of the stock granted with values ranging from $9.00 - $13.00 per share.

Since January 1, 2007, we have granted options to purchase 264,960 shares of our common stock under the 2007 Long-Term Incentive Compensation Plan, or the 2007 Plan, to our employees, advisors and others associated with us at exercise prices ranging from $13.00 to $14.30 per share. To date, none of these options have been exercised.

The issuances of securities described in the second, third and fourth paragraphs of Item 15 were exempt from registration under the Securities Act of 1933, as amended, in reliance on either (1) Rule 701 of the Securities Act of 1933, as amended, as offers and sales of securities pursuant to compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (2) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering.

All certificates representing the securities issued in these transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)

No.	Description
1.1**	Form of Underwriting Agreement.
3.1**	Second Amended and Restated Charter of Cumberland Pharmaceuticals Inc.
3.2**	Amended and Restated Bylaws of Cumberland Pharmaceuticals Inc.
4.1**	Specimen Common Stock Certificate of Cumberland Pharmaceuticals Inc.
4.2**	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on October 21, 2003.
4.3**	Stock Purchase Warrant, issued to S.C.O.U.T. Healthcare Fund L.P. on April 15, 2004.
4.4**	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on April 6, 2006.
4.5#**	Form of Option Agreement under 1999 Stock Option Plan of Cumberland Pharmaceuticals Inc.
4.6.1#**	Form of Incentive Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc.
4.6.2#**	Form of Nonstatutory Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc.
4.7#**	Form of Nonstatutory Stock Option Agreement under 2007 Directors Compensation Plan of Cumberland Pharmaceuticals Inc.
5.1**	Opinion of Adams and Reese LLP.
10.1 **	Manufacturing and Supply Agreement for N-Acetylcysteine, dated January 15, 2002, by and between Bioniche Life Sciences, Inc. and Cumberland Pharmaceuticals Inc.

10.2**	Novation Agreement, dated January 27, 2006, by and among Bioniche Life Sciences, Inc., Bioniche Pharma Group Ltd., and Cumberland Pharmaceuticals Inc.

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No.	Description
10.3 **	First Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated November 16, 2006, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc.
10.3.1 **	Second Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated March 25, 2008, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc.
10.4 **	Cardinal Health Contract Sales and Services for Cumberland Pharmaceuticals Inc. Dedicated Sales Force Agreement, dated May 16, 2006, by and between Cardinal Health PTS, LLC and Cumberland Pharmaceuticals Inc.
10.5 **	First Amendment to Contract Sales and Service Agreement, dated July 19, 2006, by and between Cardinal Health PTS, LLC and Cumberland Pharmaceuticals Inc.
10.6**	Second Amendment to Contract Sales and Service Agreement, dated June 1, 2007, by and between Cumberland Pharmaceuticals Inc. and Inventiv Commercial Services, LLC, as successor in interest to Cardinal Health PTS, LLC.
10.6.1 **	Third Amendment to Contract Sales and Service Agreement, dated March 26, 2008, by and between Cumberland Pharmaceuticals Inc. and Ventiv Commercial Services, LLC.
10.7	Distribution Services Agreement, dated August 3, 2000, by and between CORD Logistics, Inc. and Cumberland Pharmaceuticals Inc.
10.8 **	Strategic Alliance Agreement, dated July 21, 2000, by and between F.H. Faulding & Co. Limited and Cumberland Pharmaceuticals Inc., including notification of assignment from F.H. Faulding & Co. Limited to Mayne Pharma Pty Ltd., dated April 16, 2002
10.9 **	Kristalose Agreement, dated April 7, 2006, by and among Inalco Biochemicals, Inc., Inalco S.p.A., and Cumberland Pharmaceuticals Inc.
10.9.1 **	Amendment to Kristalose Agreement, dated April 3, 2008, by and between Inalco S.p.A., Inalco Biochemicals, Inc., and Cumberland Pharmaceuticals Inc.
10.9.2	Second Amendment to Kristalose Agreement, dated July 1, 2008, by and among Inalco Biochemicals, Inc., Inalco S.p.A., and Cumberland Pharmaceuticals Inc.
10.10 **	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc.
10.11#	Employment Agreement effective as of January 1, 2009 by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10.12#	Employment Agreement effective as of January 1, 2009 by and between Jean W. Marstiller and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement effective as of January 1, 2009 by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.
10.14#	Employment Agreement effective as of January 1, 2009 by and between J. William Hix and Cumberland Pharmaceuticals Inc.
10.15#	Employment Agreement effective as of January 1, 2009 by and between David L. Lowrance and Cumberland Pharmaceuticals Inc.
10.16	Third Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated December 30, 2008.
10.17#**	1999 Stock Option Plan of Cumberland Pharmaceuticals Inc.

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Part II

No.	Description
10.18#**	2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc.
10.19#**	2007 Directors Compensation Plan of Cumberland Pharmaceuticals Inc.
10.20**	Form of Indemnification Agreement between Cumberland Pharmaceuticals Inc. and all members of its Board of Directors.
10.21 **	Lease Agreement, dated September 10, 2005, by and between Nashville Hines Development, LLC and Cumberland Pharmaceuticals Inc.
10.21.1 **	First Amendment to Office Lease Agreement, dated April 25, 2008, by and between 2525 West End, LLC (successor in interest to Nashville Hines Development LLC) and Cumberland Pharmaceuticals Inc.
10.22.1 **	Sublease Agreement, dated December 14, 2006, by and between Robert W. Baird & Co. Incorporated and Cumberland Pharmaceuticals Inc.
10.22.2**	Addendum to Sublease Agreement, dated May 5, 2007, by and between Robert W. Baird & Co. Incorporated and Cumberland Pharmaceuticals Inc. and consented to by Nashville Hines Development, LLC.
10.23 **	Amended and Restated Lease Agreement, dated November 11, 2004, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc.
10.24**	First Amendment to Amended and Restated Lease Agreement, dated August 23, 2005, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc.
10.24.1**	Second Agreement to Amended and Restated Lease Agreement, dated January 9, 2006, by and between The Gateway to Nashville LLC and Cumberland Emerging Technologies, Inc.
10.25 **	Manufacturing Agreement, dated February 6, 2008, by and between Bayer HealthCare, LLC, and Cumberland Pharmaceuticals Inc.
10.26#**	Employment Agreement effective as of July 1, 2008 by and between Martin E. Cearnal and Cumberland Pharmaceuticals Inc.
21**	Subsidiaries of Cumberland Pharmaceuticals Inc.
23.1	Consent of KPMG LLP.
23.2**	Consent of Adams and Reese, LLP (contained in Exhibit 5).
23.3	Consent of Morgan Joseph & Co. Inc.
24**	Powers of Attorney (contained on the signature page of Registration Statement on Form S-1 filed on May 1, 2007).

** Previously filed.

# Indicates a management contract or compensatory plan.

Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

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(b)

See Schedule II Valuation and qualifying accounts included in our audited financial statements included elsewhere in this registration statement.

All other schedules have been omitted because they are not applicable.

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Part II

ITEM 17. UNDERTAKINGS.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 15 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Nashville, State of Tennessee, on the 18th day of February, 2009.

CUMBERLAND PHARMACEUTICALS INC.

By: /s/ a.j. kazimi
A.J. Kazimi
Chairman and CEO
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 15 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ a.j. kazimi A.J. Kazimi	Chairman and CEO (Principal Executive Officer)	February 18, 2009
/s/ david l. lowrance David L. Lowrance	Vice President and CFO (Principal Financial and Accounting Officer)	February 18, 2009
* Robert G. Edwards	Director	February 18, 2009
* Thomas R. Lawrence	Director	February 18, 2009
* Lawrence W. Greer	Director	February 18, 2009
* Martin E. Cearnal	Director	February 18, 2009

*By: /s/ a.j. kazimi
A.J. Kazimi
Attorney-in-Fact

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Exhibit Index

No.	Description
1.1**	Form of Underwriting Agreement.
3.1**	Second Amended and Restated Charter of Cumberland Pharmaceuticals Inc.
3.2**	Amended and Restated Bylaws of Cumberland Pharmaceuticals Inc.
4.1**	Specimen Common Stock Certificate of Cumberland Pharmaceuticals Inc.
4.2**	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on October 21, 2003.
4.3**	Stock Purchase Warrant, issued to S.C.O.U.T. Healthcare Fund L.P. on April 15, 2004.
4.4**	Warrant to Purchase Common Stock of Cumberland Pharmaceuticals Inc., issued to Bank of America, N.A. on April 6, 2006.
4.5#**	Form of Option Agreement under 1999 Stock Option Plan of Cumberland Pharmaceuticals Inc.
4.6.1#**	Form of Incentive Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc.
4.6.2#**	Form of Nonstatutory Stock Option Agreement under 2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc.
4.7#**	Form of Nonstatutory Stock Option Agreement under 2007 Directors Compensation Plan of Cumberland Pharmaceuticals Inc.
5.1**	Opinion of Adams and Reese LLP.
10.1 **	Manufacturing and Supply Agreement for N-Acetylcysteine, dated January 15, 2002, by and between Bioniche Life Sciences, Inc. and Cumberland Pharmaceuticals Inc.
10.2**	Novation Agreement, dated January 27, 2006, by and among Bioniche Life Sciences, Inc., Bioniche Pharma Group Ltd., and Cumberland Pharmaceuticals Inc.
10.3 **	First Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated November 16, 2006, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc.
10.3.1 **	Second Amendment to Manufacturing and Supply Agreement for N-Acetylcysteine, dated March 25, 2008, by and between Bioniche Teoranta and Cumberland Pharmaceuticals Inc.
10.4 **	Cardinal Health Contract Sales and Services for Cumberland Pharmaceuticals Inc. Dedicated Sales Force Agreement, dated May 16, 2006, by and between Cardinal Health PTS, LLC and Cumberland Pharmaceuticals Inc.
10.5 **	First Amendment to Contract Sales and Service Agreement, dated July 19, 2006, by and between Cardinal Health PTS, LLC and Cumberland Pharmaceuticals Inc.
10.6**	Second Amendment to Contract Sales and Service Agreement, dated June 1, 2007, by and between Cumberland Pharmaceuticals Inc. and Inventiv Commercial Services, LLC, as successor in interest to Cardinal Health PTS, LLC.
10.6.1 **	Third Amendment to Contract Sales and Service Agreement, dated March 26, 2008, by and between Cumberland Pharmaceuticals Inc. and Ventiv Commercial Services, LLC.
10.7	Distribution Services Agreement, dated August 3, 2000, by and between CORD Logistics, Inc. and Cumberland Pharmaceuticals Inc.
10.8 **	Strategic Alliance Agreement, dated July 21, 2000, by and between F.H. Faulding & Co. Limited and Cumberland Pharmaceuticals Inc. including notification of assignment from F.H. Faulding & Co. Limited to Mayne Pharma Pty Ltd., dated April 16, 2002

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No.	Description
10.9 **	Kristalose Agreement, dated April 7, 2006, by and among Inalco Biochemicals, Inc., Inalco S.p.A., and Cumberland Pharmaceuticals Inc.
10.9.1 **	Amendment to Kristalose Agreement, dated April 3, 2008, by and between Inalco S.p.A., Inalco Biochemicals, Inc., and Cumberland Pharmaceuticals Inc.
10.9.2	Second Amendment to Kristalose Agreement, dated July 1, 2008, by and among Inalco Biochemicals, Inc., Inalco S.p.A., and Cumberland Pharmaceuticals Inc.
10.10 **	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc.
10.11#	Employment Agreement effective as of January 1, 2009 by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10.12#	Employment Agreement effective as of January 1, 2009 by and between Jean W. Marstiller and Cumberland Pharmaceuticals Inc.
10.13#	Employment Agreement effective as of January 1, 2009 by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.
10.14#	Employment Agreement effective as of January 1, 2009 by and between J. William Hix and Cumberland Pharmaceuticals Inc.
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