

CUMBERLAND PHARMACEUTICALS INC

Form S-1/A

June 20, 2008

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As filed with the Securities and Exchange Commission on June 20, 2008

Registration No. 333-142535

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

**Amendment No. 12
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

*(State or other jurisdiction of
incorporation or organization)*

2834

*(Primary Standard Industrial
Classification Code Number)*

62-1765329

*(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

2525 West End Avenue, Suite 950

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:

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.

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.

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.

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 June 20, 2008

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 , 2008.

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 _____, 2008 (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 nearing completion of Phase III clinical trials 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 completing development 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 2005, 2006 and 2007, our net revenue was \$10.7 million, \$17.8 million and \$28.1 million, respectively, and our net income was \$2.0 million, \$4.4 million and \$4.0 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 currently in Phase III clinical trials. We expect to complete our clinical program to support regulatory approval of the product in early 2008 and are preparing to submit our new drug application, or NDA, to the FDA for review. There currently are no injectable

products approved for sale in the United States for the treatment of both pain and fever. If we complete clinical development and 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.

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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 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 2006.

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 Sourcetm 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 86%-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;

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

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:

- Ø Successfully develop and commercialize Amelior, our lead product candidate in Phase III clinical trials;
- Ø Maximize sales of our marketed products, Acetadote and Kristalose;
- Ø Expand our dedicated hospital and gastroenterology sales forces;
- Ø Expand our product portfolio by acquiring rights to additional marketed products and late-stage product candidates; and
- Ø 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:

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

In addition, as of March 31, 2008, we had an accumulated deficit of (\$1.9) million.

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 18,056,150 shares

Fully diluted common stock to be outstanding after this offering 25,196,333 shares

Use of proceeds We estimate that the net proceeds from this offering will be approximately \$83.7 million, or approximately \$96.8 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 11,806,150 shares outstanding as of March 31, 2008 and excludes:

- Ø 7,847,752 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of \$1.43 per share;
- Ø 68,958 shares of common stock issuable upon exercise of outstanding warrants at a weighted- average exercise price of \$6.17 per share; and
- Ø 2,650,000 shares of common stock reserved for future issuance under our current stock option plans.

Fully diluted common stock to be outstanding after this offering represents the sum of the 18,056,150 shares to be outstanding after this offering and the 7,916,710 shares of common stock issuable upon exercise of options and warrants outstanding as of March 31, 2008, reduced by the 776,527 shares of common stock that could theoretically be repurchased with the approximately \$11.6 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 March 31, 2008 and has been adjusted to reflect or assume the following:

- Ø the conversion of all outstanding shares of our preferred stock into 1,710,990 shares of common stock;
- Ø a 2-for-1 stock split of our common stock, which became effective on July 6, 2007; and

Ø 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 855,495 shares of our preferred stock into 1,710,990 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,			Three Months	
	2005	2006	2007	Ended March 31, 2007	2008
	(in thousands, except per share data)				
	(unaudited)				
Net revenues:					
Acetadote	\$ 10,111	\$ 10,722	\$ 18,817	\$ 3,863	\$ 5,799
Kristalose	1,812	6,511	9,013	1,982	2,478
Other ⁽¹⁾	(1,233) ⁽²⁾	582	234	61	26
Total net revenues ⁽⁴⁾	\$ 10,690	\$ 17,815	\$ 28,064	\$ 5,907	\$ 8,304
Operating income	750	2,224	6,725	1,251	1,794
Net income before income taxes	770	1,708	6,469	1,149	1,762
Net income	1,954	4,404	4,044	739	1,395
Earnings per share basic	\$ 0.21	\$ 0.45	\$ 0.40	\$ 0.07	\$ 0.14
Earnings per share diluted	\$ 0.12	\$ 0.27	\$ 0.24	\$ 0.04	\$ 0.09
Pro forma earnings per share basic (unaudited)					\$ 0.12
Pro forma earnings per share diluted (unaudited)					\$ 0.09
Weighted-average shares outstanding basic	9,496	9,797	10,032	9,869	10,094
Weighted-average shares outstanding diluted	16,306	16,454	16,582	16,621	16,412
Pro forma weighted-average shares outstanding basic (unaudited)					11,805
Pro forma weighted-average shares outstanding diluted (unaudited)					16,412

As of March 31, 2008

Pro Forma

Balance sheet data:	Actual	Pro Forma	as Adjusted⁽³⁾
		(in thousands) (unaudited)	
Cash and cash equivalents	\$ 11,912	\$ 11,912	\$ 95,600
Working capital	7,829	7,829	91,516
Total assets	30,631	30,631	114,319
Total long-term debt and other long-term obligations (including current portion)	7,207	7,207	7,207
Convertible preferred stock	2,743		
Accumulated deficit	(1,920)	(1,920)	(1,920)
Total shareholders' equity	18,235	18,235	101,923

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

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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 Phase III clinical trials to test its efficacy and safety. Delays in the completion of these clinical trials, 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.

If the results of our clinical trials are favorable, we intend to submit an application to the FDA for marketing approval for Amelior. The FDA may decline to accept our application. If the FDA declines our application, 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.

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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.

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 April 30, 2008, we had 45 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. Even if we become able to pay dividends in the future, we expect that we would retain such earnings to enhance capital and/or reduce long-term debt.

RISKS RELATING TO GOVERNMENT REGULATION

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

Virtually all aspects of our business activities are regulated by government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution, promotion and sampling, and advertising of our products, and disposal of waste products arising from such activities, are subject to governmental

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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 our planned NDA submission 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 our planned NDA submission, and this loss may 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:

- Ø new product launches, which could increase revenues but also increase sales and marketing expenses;
- Ø acquisition activity and other one-time charges (such as for inventory expiration);
- Ø 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. The value of these intangible assets represents the excess of the acquisition purchase price over the fair value of the separate assets we acquired. As of March 31, 2008, intangible assets relating to product and data acquisitions represented approximately 29.4% 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 and 2007. As of March 31, 2008, however, we still had an accumulated deficit of (\$1.9) million, representing the amount by which our historical losses have exceeded our historical profits. 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 \$9.85 per share, based on an assumed initial public offering price of \$15.00 per share;
- Ø contribute 82.3% 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 34.6% 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 7,916,710 shares of common 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 and process evaluation and testing of our internal controls over financial reporting to allow

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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, 2009, 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 clinical trials for Amelior and 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 18,056,150 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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Risk factors

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 holders of 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, 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:

- Ø 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;
- Ø 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;
- Ø competition; and
- Ø 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 \$83.7 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 \$96.8 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 NDA filing 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 86%-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 March 31, 2008:

Ø on an actual basis;

Ø on a pro forma basis to give effect to the conversion of all of our outstanding preferred stock into 1,710,990 shares of common stock; and

Ø 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 March 31, 2008		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands)		
Cash and cash equivalents ⁽¹⁾	\$ 11,912	\$ 11,912	\$ 95,600
Long-term debt and long-term obligations (less current portion)	\$ 3,637	\$ 3,637	\$ 3,637
Shareholders' equity ⁽¹⁾			
Convertible preferred stock, no par value; 3,000,000 shares authorized, 855,495 shares issued and outstanding, actual; and 3,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted ⁽²⁾	2,743		
Common stock, no par value; 100,000,000 ⁽⁴⁾ shares authorized; 10,095,160 shares issued and outstanding, actual; 100,000,000 ⁽⁴⁾ shares authorized, 11,806,150 shares issued and outstanding, pro forma; and 100,000,000 ⁽⁴⁾ shares authorized, 18,056,150 shares issued and outstanding, pro forma as adjusted ⁽³⁾	17,412	20,155	103,843
Accumulated deficit	(1,920)	(1,920)	(1,920)
Total shareholders' equity ⁽¹⁾	18,235	18,235	101,923
Total capitalization ⁽¹⁾	\$ 21,872	\$ 21,872	\$ 105,560

(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 1,710,990 shares of common stock.
- (3) Excludes:
 - Ø 7,847,752 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of \$1.43 per share;
 - Ø 2,650,000 shares of common stock reserved for future issuance under our current stock option plans; and
 - Ø 68,958 shares of common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of \$6.17 per share.
- (4) In April 2007, the shareholders approved an amendment to the charter which increased the authorized shares to 100,000,000.

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Our net tangible book value as of March 31, 2008 was \$9.2 million, or \$0.92 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 March 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 1,710,990 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 March 31, 2008 would have been approximately \$93.0 million, or approximately \$5.15 per share. This amount represents an immediate increase in pro forma net tangible book value of \$4.37 per share to our existing shareholders and an immediate dilution in pro forma net tangible book value of approximately \$9.85 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 March 31, 2008	\$ 0.92	
Effect on net tangible book value per share on conversion of preferred stock into common stock	(0.14)	
Pro forma net tangible book value per share as of March 31, 2008	0.78	
Increase per share attributable to this offering	4.37	
Pro forma as adjusted net tangible book value per share after this offering		5.15
Dilution per share to new investors		\$ 9.85

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 March 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 assume no exercise of stock options and warrants after March 31, 2008. As of March 31, 2008, we had outstanding options to purchase a total of 7,847,752 shares of common stock at a weighted-average exercise price of \$1.43 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 as of March 31, 2008, pro forma as adjusted net tangible book value per share would have been \$4.03 per share, and dilution to new investors would have been \$10.97 per share.

Table of Contents**Dilution**

The following table summarizes, as of March 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 1,710,990 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
	Number	%	Number	%	Price
					per Share
Existing shareholders	11,806,150	65.4%	\$ 20,155,359	17.7%	\$ 1.71
New investors	6,250,000	34.6	93,750,000	82.3	15.00
Total	18,056,150	100.0%	\$ 113,905,359	100.0%	

Assuming that all options and warrants outstanding as of March 31, 2008 had been exercised for 7,916,710 shares of common stock, and the aggregate exercise price of approximately \$11.6 million had been applied to repurchase 776,527 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 24.8% 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), the number of shares of common stock held by existing shareholders would be reduced to 62.2% 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 37.8% 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, 2005, 2006 and 2007 and consolidated balance sheet data as of December 31, 2006 and 2007 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, 2003 and 2004 and the consolidated balance sheet data as of December 31, 2003, 2004 and 2005 have been derived from our audited consolidated financial statements that do not appear in this prospectus. The consolidated statements of operations data for the three months ended March 31, 2007 and 2008 and the consolidated balance sheet data as of March 31, 2008 have been derived from our unaudited financial statements which are included elsewhere in this prospectus. Our unaudited consolidated financial statements include, in the opinion of management, all adjustments consisting of only normal recurring adjustments necessary for a fair presentation of these statements. The historical results are not necessarily indicative of the results to be expected for any future periods.

Statement of operations data ⁽¹⁾ :	2003	Years Ended December 31,				Three Months Ended	
		2004	2005	2006	2007	2007	2008
(in thousands, except per share data)							
Net revenues	\$ 2,943	\$ 12,032	\$ 10,690	\$ 17,815	\$ 28,064	\$ 5,907	\$ 8,304
Costs and expenses:							
Cost of products sold		816	533	2,399	2,670	571	755
Selling and marketing	2,726	6,802	5,647	7,349	10,053	2,417	3,364
Research and development	1,658	746	1,158	2,233	3,694	452	1,110
General and administrative	2,265	2,358	2,588	2,999	4,138	1,019	1,083
Amortization of product license rights				515	687	172	172
Other	5	6	13	96	97	25	26
Total costs and expenses	6,654	10,729	9,940	15,592	21,338	4,656	6,510
Gain on insurance recovery		266					
Operating income (loss)	(3,710)	1,569	750	2,224	6,725	1,251	1,794
Interest income	8	1	89	209	383	90	82
Interest (expense)	(765)	(1,012)	(63)	(722)	(640)	(192)	(114)
Other income (expense)	(2)		(6)	(3)			
Net income (loss) before minority interest and income taxes	(4,469)	558	770	1,708	6,469	1,149	1,762
Income tax benefit (expense)			1,184	2,697	(2,424)	(410)	(367)
Net income (loss)	\$ (4,469)	\$ 558	\$ 1,954	\$ 4,404	\$ 4,044	\$ 739	\$ 1,395

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Earnings (loss) per share basic	\$ (0.52)	\$ 0.06	\$ 0.21	\$ 0.45	\$ 0.40	\$ 0.07	\$ 0.14
Earnings (loss) per share diluted	\$ (0.52)	\$ 0.04	\$ 0.12	\$ 0.27	\$ 0.24	\$ 0.04	\$ 0.09
Weighted-average shares outstanding basic	8,522	9,082	9,496	9,797	10,032	9,869	10,094
Weighted-average shares outstanding diluted	8,522	15,482	16,306	16,454	16,582	16,621	16,412

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

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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 nearing completion of Phase III clinical trials intended to support 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 grown consistently because of our program to develop Amelior. We expect research and development expenses to continue to be significant as we continue our clinical work related to Amelior. We plan to complete the clinical program for Amelior intended to support regulatory approval in early 2008.

We have funded our operations with private equity capital of approximately \$14 million during the past seven years. 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.

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 \$299,000, \$147,000 and \$151,000 as of December 31, 2006 and 2007 and March 31, 2008, respectively, for chargebacks, discounts and allowances for product damaged in shipment. We had accrued liabilities of \$743,000, \$738,000 and \$778,000 as of December 31, 2006 and 2007 and March 31, 2008, respectively, for rebates, product returns, service fees, and administrative fees.

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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	343,740
Current Provision for Prior Period Sales	(55,000)
Actual Returns/Credits	(249,096)
Balance as of March 31, 2008	\$ 778,006

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 \$743,000, \$738,000 and \$778,000 as of December 31, 2006 and 2007 and March 31, 2008, respectively. Of these amounts, our estimated liability for rebates represented \$598,000, \$261,000 and \$167,000, respectively, while our accrual for product returns totaled \$51,000, \$324,000 and \$403,000, 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 \$26,000 for the year ended December 31, 2007 and three month period ended March 31, 2008, respectively. A change in our product return estimate of one percentage point would have impacted net sales by \$302,000 and \$89,000 for the year ended December 31, 2007 and three month period ended March 31, 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-

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

promotion fees were calculated based on a percent of gross sales or similar calculation. Contract sales revenue is included in net revenues.

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 one percent of net revenues in 2007.

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 \$2.2 million as of December 31, 2007, we will need to generate future taxable income of approximately \$14.1 million prior to the expiration of the net operating loss carry-forwards in 2026.

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;

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

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- Ø review of third-party valuation reports secured from time to time by management, such as those secured from Morgan Joseph & Co. Inc. most recently in 2006; and
- 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 2006, we determined that the equity value of our company was approximately \$219 million. In the event of liquidation, aggregate preferential payments to holders of our preferred stock would be less than \$2.8 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 2006, 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).

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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 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	\$ 2.00	\$ 4.18
June 30, 2006	48,600	\$ 9.37	\$ 1.63	\$ 4.95
September 30, 2006	18,150	\$ 9.00	\$ 2.00	\$ 5.58
December 31, 2006	5,200	\$ 9.00	\$ 2.00	\$ 5.50
March 31, 2007	90,920	\$ 11.00	\$ 0.00	\$ 7.21
June 30, 2007				
September 30, 2007				
December 31, 2007				
March 31, 2008				

(1) Calculated as of March 31, 2008

Under SFAS No. 123(R), the fair value of employee options granted during 2006 and 2007 were estimated using the Black-Scholes option-pricing model and the following assumptions:

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

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

	2006	2007
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Dividend yield	%	%
Expected term (years)	.17-10	10
Expected volatility	37% - 63%	74%
Risk-free interest rate	4.34% - 4.42%	4.83%

For employee stock option grants, the weighted-average expected option terms for 2006 and 2007 represent the application of the simplified method as defined in SEC Staff Accounting Bulletin (SAB) No. 107 issued in March 2005. 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 and 2007 represent the contractual term.

We estimated volatility for 2006 and 2007 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 of certain publicly-traded companies that we consider to be our peers. The comparable peer companies

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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 March 31, 2008, we had approximately \$501,000 of unrecognized share-based compensation expense related to unvested option awards. Additionally, as of March 31, 2008, we had outstanding vested options to purchase 7,644,842 shares of our common stock and unvested options to purchase 202,910 shares of our common stock. Furthermore, as of March 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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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,			Three Months Ended		% Change		%
	2005	2006	2007	March 31, 2007	2008	2005-2006	2006-2007	Change Three Months Ended March 31, 2007-2008
Net revenues	100.0%	100.0%	100.0%	100.0%	100.0%	66.7%	57.5%	40.6%
Costs and expenses:								
Cost of products sold	5.0	13.5	9.5	9.7	9.1	349.9	11.3	32.3
Selling and marketing	52.8	41.2	35.8	40.9	40.5	30.1	36.8	39.2
Research and development	10.8	12.5	13.2	7.7	13.4	92.9	65.4	145.5
General and administrative	24.2	16.8	14.7	17.3	13.0	15.9	38.0	6.3
Amortization of product license rights		2.9	2.4	2.9	2.1		33.3	0.0
Other	0.1	0.5	0.3	0.4	0.3	614.9	0.1	4.2
Total costs and expenses ⁽²⁾	93.0	87.5	76.0	78.8	78.4	56.9	36.9	39.8
Operating income	7.0	12.5	24.0	21.2	21.6	196.5	202.4	43.4
Interest income	0.8	1.2	1.4	1.5	1.0	133.8	83.5	(8.6)
Interest expense	(0.6)	(4.1)	(2.3)	3.3	1.4	(1)	(11.4)	(40.9)
Other expense	(0.1)	(0.0)				(50.3)		
Net income before income taxes ⁽²⁾	7.2	9.6	23.0	19.4	21.2	121.7	278.7	53.4
Income tax benefit (expense)	11.1	15.1	(8.6)	(6.9)	(4.4)	127.7	(189.9)	(10.4)

Net income ⁽²⁾	18.3	24.7	14.4	12.5	16.8	125.4	(8.2)	88.8
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(1) Not meaningful

(2) The sum of the individual amounts may not agree to the total 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 primarily of the cost of 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 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.

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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.

Income tax benefit in 2005 and 2006 consists primarily of the realization of our deferred tax assets less taxes incurred on income. *Income tax expense* in 2007 consists primarily of the utilization of our deferred tax assets.

Three months ended March 31, 2008 compared to the three months ended March 31, 2007

Net revenues. Net revenues for the three months ended March 31, 2008 totaled approximately \$8.3 million, representing an increase of approximately \$2.4 million, or 41%, over the same period in 2007. Of this increase, approximately \$1.9 million related to Acetadote and \$0.5 million related to Kristalose. The increase in revenue for Acetadote was primarily due to increased volume as our market share increased in our target market in the first quarter of 2008 as compared to the first quarter of 2007. The increase in revenue for Kristalose was primarily due to increased volume in the first quarter of 2008 as we continue to gain market share in our target territories.

For the three months ended March 31, 2008, gross sales were reduced by approximately \$0.6 million, of which approximately \$0.2 million related to cash discounts and approximately \$0.3 million related to damaged and expired product returns. For the three months ended March 31, 2007, gross sales were reduced by approximately \$0.5 million, of which approximately \$0.1 million related to cash discounts, approximately \$0.1 million related to damaged and expired product returns, approximately \$0.1 million related to fee-for-service costs, and approximately \$0.2 million related to estimated rebates and chargebacks.

Cost of products sold. Cost of products sold for the three months ended March 31, 2008 totaled approximately \$0.8 million, representing an increase of approximately \$0.2 million, or 32%, over the same period in 2007. As a percentage of net revenues, cost of products sold decreased from 9.7% of net revenues for the three months ended March 31, 2007 to 9.1% of net revenues for the three months ended March 31, 2008. The increase in cost of products sold, in dollars, is directly related to the increase in net revenues. The decrease in cost of products sold as a percentage of net revenues was primarily due to a change in the sales mix and the result of a price increase in the second half of 2007.

Selling and marketing. Selling and marketing expense for the three months ended March 31, 2008 totaled approximately \$3.4 million, representing an increase of approximately \$0.9 million, or 39%, over the same period in 2007. Of the increase, approximately \$0.5 million related to the expansion of our sales force, approximately \$0.2 million related to a new marketing campaign for Kristalose, and approximately \$0.2 million related to increased royalties. We anticipate selling and marketing expenses to increase as we expand both sales forces as well as our product lines.

Research and development. Research and development expense for the three months ended March 31, 2008 totaled approximately \$1.1 million, representing an increase of approximately \$0.7 million, or 145%, over the same period in 2007. The increase was primarily due to increased clinical studies costs for Amelior of approximately \$0.3 million, and approximately \$0.3 million associated with supplies and development costs, of which \$0.2 million related to a

validation batch of Amelior.

Interest expense. Interest expense totaled approximately \$0.1 million for the three months ended March 31, 2008, representing a decrease of approximately \$0.1 million, or 41%, over the same period

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in 2007. The decrease was primarily due to lower outstanding debt during the first quarter of 2008 as compared to the first quarter of 2007.

Income tax expense. Income tax expense for the three months ended March 31, 2008 totaled approximately \$0.4 million, representing a decrease of approximately \$43,000, or 10%, over the same period in 2007. As a percentage of net income before income taxes, income tax expense decreased from 35.7% for the three months ended March 31, 2007 to 20.8% for the three months ended March 31, 2008. The decrease was primarily due to the recognition in the first quarter of 2008 of approximately \$0.4 million 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, \$610,000 for cash discounts, \$368,000 related to fee-for-service costs and \$235,000 for estimated rebates, chargebacks, and discounts related to Kristalose. For 2006, this reduction included \$680,000 related to damaged and expired product returns, \$253,000 related to cash discounts, \$179,000 related to fee-for-service costs and \$990,000 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 (see Note 13 to the consolidated financial statements). 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

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increased clinical studies in 2007 as we worked towards completing the studies of Amelior. We expect 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 the utilization of the deferred tax assets from federal and state net operating loss carryforwards. In 2006, the income tax benefit was primarily due to the full recording of our deferred tax asset after determining that it was more likely than not that we would realize the benefits of the deferred tax asset.

Year ended December 31, 2006 compared to year ended December 31, 2005

Net revenues. Net revenues in 2006 totaled \$17.8 million, representing an increase of \$7.1 million, or 66.7%, over net revenues in 2005 of \$10.7 million. Of this increase, \$4.7 million was due to additional product revenue from sales of Kristalose, and \$0.6 million was due to an increase in sales of Acetadote. 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. In 2005, revenue was reduced by approximately \$2.0 million for promotional costs owed to a wholesaler. Additionally, unlike prior years, in 2006, we did not offer any special purchasing opportunities to our customers prior to product price increases.

Gross product sales were reduced by \$2.1 million and \$2.6 million in 2006 and 2005, respectively. For 2006, this reduction included \$680,000 related to damaged and expired product returns, \$253,000 related to cash discounts, \$179,000 related to fee-for-service costs and \$990,000 related to estimated rebates, chargebacks and discounts related to Kristalose. In 2005, this reduction included approximately \$2.0 million for promotional costs, \$232,000 related to

cash discounts, and \$378,000 related to damaged and expired product returns.

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Cost of products sold. Cost of products sold in 2006 totaled \$2.4 million, representing an increase of \$1.9 million, or 349.9%, over cost of products sold in 2005 of \$533,000. Cost of products sold as a percentage of net revenues was 13.5% and 5.0% in 2006 and 2005, respectively. Of this increase, \$1.6 million was due to recording the cost of products sold associated with Kristalose beginning in April 2006. Prior to that date, we recorded no Kristalose cost of products sold because of the co-promotion arrangement referred to above. Additionally, \$226,000 of this increase was due to the write-off of inventory for slow-moving product. Acetadote cost of products sold, as a percentage of Acetadote net revenue, was not materially different between 2006 and 2005.

Selling and marketing. Selling and marketing expense in 2006 totaled \$7.3 million, representing an increase of \$1.7 million, or 30.1%, over selling and marketing expense in 2005 of \$5.6 million. Selling and marketing expense as a percentage of net revenues was 41.2% and 52.8% in 2006 and 2005, respectively. Of this increase, \$1.9 million was due to the launch of our new dedicated gastroenterology field sales force as well as other sales and marketing costs associated with the re-launch of Kristalose, offset by approximately \$200,000 in reductions in other sales and marketing costs.

Research and development. Research and development expense in 2006 totaled \$2.2 million, representing an increase of \$1.1 million, or 92.9%, over research and development expense in 2005 of \$1.2 million. Research and development expense as a percentage of net revenues was 12.5% and 10.8% in 2006 and 2005, respectively. Of this increase, \$873,000 was due to increased clinical studies activities associated with the development of Amelior, and \$134,000 was due to other clinical study activity. The remainder of the increase was mainly due to increased personnel costs.

General and administrative. General and administrative expense in 2006 totaled \$3.0 million, representing an increase of \$411,000, or 15.9%, over general and administrative expense in 2005 of \$2.6 million. General and administrative expense as a percentage of net revenues was 16.8% and 24.2% in 2006 and 2005, respectively. The dollar increase in general and administrative expense was due to an increase of \$218,000 in salaries and related expenses from 2005 as a result of the addition of personnel to support our growth. The remaining increase of \$193,000 was the result of small increases in audit fees, travel, rent and other general and administrative items.

Amortization of product license rights. Amortization of product license rights totaled \$515,000 in 2006. This expense is a result of amortization associated with our acquisition of the exclusive U.S. commercialization rights to Kristalose.

Interest income. Interest income in 2006 totaled \$209,000 compared to interest income in 2005 of \$89,000. The increase in interest income was due to larger cash balances in 2006.

Interest expense. Interest expense in 2006 totaled \$722,000 compared to interest expense in 2005 of \$63,000. The increase in interest expense was due to \$557,000 related to debt incurred to finance the acquisition of Kristalose as well as \$102,000 of interest expenses associated with our line of credit and other long term obligations. In 2005, we had minimal debt and thus, minimal interest expense.

Income tax benefit. Net income tax benefit in 2006 totaled \$2.7 million compared to net income tax benefit in 2005 of \$1.2 million. The increase was due to full recording of our deferred tax asset after determining that it was more likely than not that we would realize the benefits of the deferred tax asset.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2008, cash and cash equivalents was \$11.9 million, working capital was \$7.8 million and our current ratio (current assets to current liabilities) was 1.89 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 March 31,

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2008, we also had the ability to make additional draws of up to approximately \$1.6 million on our line of credit, and will have substantial proceeds from this offering.

The following table summarizes our net increase in cash and cash equivalents for the years ended December 31, 2005, 2006 and 2007 and three months ended March 31, 2007 and 2008:

	Years Ended December 31,			Three Months Ended March 31,	
	2005	2006	2007	2007	2008
	(in thousands)				
Net cash provided by (used in):					
Operating activities	\$ 2,416	\$ 2,163	\$ 8,627	\$ 3,315	\$ 1,870
Investing activities	(318)	(6,553)	(163)	(32)	(46)
Financing activities	2,922	5,109	(3,904)	(539)	(726)
Net increase in cash and cash equivalents	\$ 5,020	\$ 719	\$ 4,559 ⁽¹⁾	\$ 2,744	\$ 1,098

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

Net cash provided by operating activities was \$1.9 million for the three months ended March 31, 2008, which was impacted by net income of \$1.4 million and adjustments for non-cash charges of \$0.5 million.

Net cash used in investing activities was \$46,000 for the three months ended March 31, 2008 and was primarily used for property and equipment.

Net cash used by financing activities was \$0.7 million for the three months ended March 31, 2008, including approximately \$0.5 million for payments on our long-term debt and costs related to the potential public offering of approximately \$0.2 million.

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 new 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 are collateralized by a first lien against all of our assets. We are paying off the term loan in quarterly installments, with the final payment due in 2009. This agreement contains various covenants, all of which we were in compliance with as of December 31, 2007. One covenant under this agreement requires that we obtain the bank's consent to acquire or purchase a business or its assets unless: (a) we acquire a business or assets related to a product that has already received FDA approval and the product is currently available for purchase, or (b) we acquire a business or assets related to a product that the bank determines is in the final stages of development and we have at least \$10 million in cash available following the acquisition. In addition, in order to make an acquisition without obtaining the bank's consent, we cannot rely on the proceeds of any bank debt to

fund the acquisition, and we must 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 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 this 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 expire in April 2016. The estimated fair value of such warrants of \$25,680, as determined using the Black-Scholes model, has been recorded in the accompanying financial statements as permanent equity in

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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*.

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 \$2.2 million of Kristalose and \$100,000 of Acetadote during 2008, \$2.5 million of Kristalose and \$100,000 of Acetadote during 2009, \$2.8 million of Kristalose and \$100,000 of Acetadote during 2010, and \$2.3 million of Kristalose and \$100,000 of Acetadote 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, 2007, we had met our purchase obligations for 2007 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 \$205,000, 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 point where we have determined it is probable the first milestone will be met. As such, we have recorded the obligation related to the first milestone of approximately \$205,000 as a current liability as of December 31, 2007. As of December 31, 2007, the total liability recorded related to Cato was approximately \$616,000. 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 NDA, Cato will vest in options to acquire up to 60,000 shares of our common stock depending on the timing of the approval.

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The following table sets forth a summary of our contractual cash obligations as of December 31, 2007:

Contractual obligations	Total	2008	Payments Due by Year			
			2009	2010	2011	2012+
(in thousands)						
<i>Amounts reflected in the balance sheet:</i>						
Line of credit	\$ 1,326	\$ 1,326	\$	\$	\$	\$
Term loan	2,750	1,833	917			
Estimated interest on debt/obligations ⁽¹⁾	228	203	25			
Other contractual obligations ⁽²⁾	3,615	410	3,205			
<i>Other cash obligations not reflected in the balance sheet</i>						
Operating leases	1,523	500	505	471	47	
Purchase obligations ⁽³⁾	10,123	1,687	2,512	2,812	3,112	
Total	\$ 19,565	\$ 5,959	\$ 7,164	\$ 3,283	\$ 3,159	\$

(1) Represents estimated interest payments on our company's line of credit and term loan based on the December 31, 2007 interest rate of LIBOR + 2.5% (7.4%). Interest payments are due and payable quarterly in arrears. The line of credit becomes due and payable in April 2008. Estimated interest for the line of credit is based on the assumption of a consistent outstanding balance. The term loan matures in April 2009 with principal payments due and payable quarterly.

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

(3) Represents minimum purchase obligations under Kristalose and Acetadote manufacturing agreements.

OFF-BALANCE SHEET ARRANGEMENTS

During 2005, 2006 and 2007 and the three months ended March 31, 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. Our company is currently evaluating the impact of SFAS 141(R) on our financial position and results of operations.

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 controlling interest, the investment in the subsidiary will be adjusted to fair value, and a gain or loss on

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

investment will be recognized in the statement of operations. Our company is currently evaluating the impact the adoption of SFAS 160 will have on our financial position and results of operations.

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. Our company is in the process of studying the potential financial statement impact of adopting EITF 07-1.

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 06-11, *Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards* (EITF 06-11), which applies to share-based payment arrangements in which the employee received dividends on the award during the vesting period. Tax benefits received on dividends associated with share-based awards that are charged to retained earnings should be recorded in additional paid-in capital and included in the pool of excess tax benefits available to absorb potential future tax deficiencies on share-based payment awards. This statement was effective for us on January 1, 2008. Our company does not anticipate paying any dividends in the foreseeable future. The adoption of EITF 06-11 did not have a material impact on our results of operations and financial position.

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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.

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 \$100,000 based on the cash and equivalents balance at March 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 2.5%. As of March 31, 2008, we had outstanding borrowings of \$3.6 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 \$36,000.

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 \$846,000 and \$1,080,000 in 2006 and 2007, respectively, and \$407,000 for the three months ended March 31, 2008.

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 nearing completion of a Phase III clinical development program 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 completing development 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 currently in Phase III clinical trials. We expect to complete our clinical program to support regulatory approval of the product in early 2008 and are preparing to submit our new drug application, or NDA, to the FDA for review. There currently are no injectable products approved for sale in the United States for the treatment of both pain and fever. If we complete clinical development of and 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 meperidine, 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 2006. 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 Sourcetm 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 86%-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 and expect to complete Phase III clinical studies in early 2008. 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 Director of Business 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 three 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 Phase III product candidate

Amelior is in late-stage Phase III clinical development for the treatment of pain and fever. We have gathered positive data regarding the safety and efficacy of this product, and we expect to complete clinical trials to support regulatory approval in early 2008. 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 1,680, 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 who are responsible for approximately 80% of 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 2006 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.

Table of Contents**Business****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 currently in Phase III clinical trials. We expect to complete clinical development by early 2008 and are preparing to submit our new drug application, or NDA, to the FDA for review. There currently are no injectable products approved for sale in the U.S. for the treatment of both pain and fever. If we complete clinical development and 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

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Vanderbilt University an exclusive, worldwide license to clinical trial data on the use of intravenous 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.

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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 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 intend to complete clinical development of Amelior in early 2008. 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 are preparing to submit the appropriate documentation to the FDA for review in the first half of 2008. We are also supporting a number of studies to explore other potential indications for the product.

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:

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

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

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

approximately \$1,825,000 in aggregate

Kristalose.

- Ø 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

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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 Misericordiae Hospital in Australia. We have no expected outstanding payment obligations pursuant to this contract.

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.
- 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

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.

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** .

in the public market.

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

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.

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

- Ø stabilizing transactions;
- Ø short sales;
- Ø purchases to cover positions created by short sales;
- Ø imposition of penalty bids; and
- Ø 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 than 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:

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

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

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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 (Wertpapierprospektgesetz - 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 finansiella 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, 2007 and 2006, and for each of the years in the three-year period ended December 31, 2007, 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, 2006 and 2007, and the related consolidated statements of income, shareholders equity (deficit) and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2007. 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, 2007. 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, 2006 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007, 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, present fairly, in all material respects, the information set forth herein.

/s/ KPMG LLP

Nashville, Tennessee
February 15, 2008

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Commitments and contingencies (see notes)

Shareholders' equity:

Convertible preferred stock, no par value. Authorized 3,000,000 shares; issued and outstanding 855,495 shares at December 31, 2006 and 2007	2,742,994	2,742,994
Common stock, no par value. Authorized 10,000,000 and 100,000,000 shares as of December 31, 2006 and 2007, respectively; issued and outstanding 9,844,150 and 10,091,260 shares at December 31, 2006 and 2007, respectively	15,742,590	17,318,713
Accumulated deficit	(7,359,924)	(3,315,538)
Total shareholders' equity	11,125,660	16,746,169
Total liabilities and shareholders' equity	\$ 26,481,124	28,918,667

See accompanying notes to consolidated financial statements.

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Notes to consolidated financial statements

(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 shipment, based on historical experience. The Company reviews its customer balances on an individual account basis for collectibility. As of December 31, 2006 and 2007, the allowance for uncollectible amounts, cash discounts, chargebacks, and credits for damaged product was \$298,913 and \$146,972, respectively.

Cash discounts are reductions to invoiced amounts offered to customers for payment within a specified period of time from the date of the invoice. The majority of the Company's products are distributed through independent pharmaceutical wholesalers. 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, 2006 and 2007. 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 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.

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Notes to consolidated financial statements

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 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 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

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal 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, 2007.

(i) Costs of Initial Public Offering

Specific, incremental costs directly attributable to the initial public offering of the Company's common stock of approximately \$2.7 million at December 31, 2007 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, approximately \$646,000 of unpaid costs related to the initial public offering are included in accounts payable and other accrued liabilities.

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Notes to consolidated financial statements

(j) Revenue Recognition

The Company recognizes revenue in accordance with the Securities and Exchange Commission's (SEC) Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104, and SFAS No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48). 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 \$298,913 and \$146,972 as of December 31, 2006 and 2007, respectively, for chargebacks, discounts, and allowances for product damaged in shipment reduce accounts receivable, and accrued liabilities of \$742,678 and \$738,362 as of December 31, 2006 and 2007, respectively, for rebates, product returns, and administrative fees increase 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 our 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:

2005

	Net Product Revenue	Revenue from Co-Promotional Agreements	Total
Acetadote	\$ 10,111,483		10,111,483
Kristalose ⁽¹⁾		1,812,242	1,812,242
Other products ⁽²⁾	(1,886,813) ⁽³⁾		(1,886,813)
	\$ 8,224,670	1,812,242	10,036,912

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 ⁽¹⁾	9,012,789		9,012,789
Other products	(8,436)		(8,436)

\$ 27,821,646

27,821,646

- (1) During 2005 and for the period from January 1, 2006 through April 9, 2006, the Company sold Kristalose under a co-promotion arrangement.
- (2) Includes revenues from products for which the Company no longer has the exclusive licensing rights.
- (3) Includes the revenue reduction for promotional costs owed to a wholesaler.

For the first quarter of 2006 and the year ended December 31, 2005, 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 \$253,000, \$375,000, and \$83,000 for the years ended December 31, 2005, 2006, and 2007, respectively.

Table of Contents**Notes to consolidated financial statements****(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 does not recognize a tax position in its consolidated financial statements unless it is more likely than not that the position will be sustained by the taxing authority.

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). 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. The adoption of FIN 48 requires an adjustment to retained earnings for the tax benefit of any uncertain tax positions existing prior to January 1, 2007. 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

Prior to fiscal year 2006, the Company applied the intrinsic-value method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and provided the required proforma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123*. Under this method, compensation expense was recorded only if the current market price of the underlying stock exceeded the exercise price on the date of grant. All options granted by the Company had an exercise price equal to or greater than the market price of the underlying stock on the date of grant.

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. Because the Company used the minimum value method for purposes of estimating fair value under SFAS 123, no proforma disclosures (as required by

SFAS 123 related to 2005) are permitted under SFAS 123(R).

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Table of Contents**Notes to consolidated financial statements****(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 \$479,361, \$738,647, and \$617,354 in 2005, 2006, and 2007, respectively.

(o) Distribution Costs

The Company expenses distribution costs as incurred. Distribution costs included in sales and marketing expenses amounted to \$365,331, \$436,115, and \$756,268 in 2005, 2006, and 2007, respectively.

(p) 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, and the exercise of stock options, 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		
	2005	2006	2007
Numerator:			
Net income	\$ 1,954,319	4,404,451	4,044,386
Denominator:			
Weighted-average shares outstanding basic	9,495,732	9,797,190	10,032,083
Preferred stock shares convertible to common	1,710,990	1,710,990	1,710,990
Dilutive effect of stock options and warrants	5,099,068	4,945,932	4,838,829
Weighted-average shares outstanding diluted	16,305,790	16,454,112	16,581,902

As of December 31, 2005, 2006, and 2007, options to purchase 24,276, 32,978, and 35,230 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.

(q) Comprehensive Income

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

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Notes to consolidated financial statements

(r) 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 financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to estimates and assumptions include those related to chargebacks, rebates, discounts, credits for damaged product and returns, the valuation and determination of useful lives of intangible assets and the rate such assets are amortized, the realization of deferred tax assets, and stock-based compensation. Actual results could differ from those estimates.

(s) 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 include variable interest rates, which approximate current market rates. The interest rates associated with the long-term debt approximate current market rates. The imputed interest rate on the other long-term obligations approximate current market rates.

(t) Reclassifications

Certain prior year amounts were reclassified to conform to current year presentation. These reclassifications included segregating the line of credit balance from the long-term debt balance.

(u) Recently Issued 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 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company does not expect the adoption of SFAS 157 will have a material impact on its consolidated 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. The Company is required to adopt SFAS 159 beginning on January 1, 2008. The Company does not expect the adoption of SFAS 159 will have a material impact on its consolidated results of operations and financial position.

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

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Notes to consolidated financial statements

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 Company is currently evaluating the impact of SFAS 141(R) on its consolidated financial position and results of operations.

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 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. The statement is effective for the Company beginning on January 1, 2009. The Company is currently evaluating the impact the adoption of SFAS 160 will have on its consolidated financial position and results of operations.

In June 2007, the FASB issued EITF 06-11, *Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards* (EITF 06-11), which applies to share-based payment arrangements in which the employee receives dividends on the award during the vesting period. Tax benefits received on dividends associated with share-based awards that are charged to retained earnings should be recorded in additional paid-in capital and included in the pool of excess tax benefits available to absorb potential future tax deficiencies on share-based payment awards. This statement is effective for fiscal years beginning after December 15, 2007. The Company does not anticipate paying any dividends in the foreseeable future. As a result, the Company does not expect the adoption of EITF 06-11 will have a material impact on its consolidated results of operations and financial position.

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. The Company is required to adopt EITF 07-3 effective January 1, 2008. The Company does not expect the adoption of EITF 07-3 will have a material impact on its consolidated results of operations or financial position.

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 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 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 Company is in the process of studying the potential financial statement impact of adopting EITF 07-1.

Table of Contents**Notes to consolidated financial statements****(3) PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31:

	Range of useful lives	2006	2007
Computer hardware and software	3-5 years	\$ 119,143	140,621
Office equipment	3-15 years	24,167	30,722
Furniture and fixtures	5-10 years	140,866	246,202
Leasehold improvements	3-15 years, or remaining lease term	289,265	318,796
		573,441	736,341
Less accumulated depreciation and amortization		(207,667)	(276,498)
		\$ 365,774	459,843

Depreciation expense, including amortization expense related to leasehold improvements, during 2005, 2006, and 2007 was \$48,862, \$67,884, and \$70,635, 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:

	2006	2007
Trademarks	\$ 46,986	46,986
Less accumulated amortization	(31,000)	(35,682)
Total trademarks	15,986	11,304
License	10,303,595	10,303,595
Less accumulated amortization	(515,181)	(1,202,086)
Total license	9,788,414	9,101,509
Patents	29,870	40,938
	\$ 9,834,270	9,153,751

Amortization expense related to trademarks and license rights is expected to be approximately \$690,000 in each of the years 2008 through 2012.

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 includes cash paid on the effective date of the agreement of \$6,500,000, an installment payment of \$1,500,000 (inclusive of \$102,440 of imputed interest) paid in April 2007, \$2,426,377 (discounted using an interest rate of 7.33%) due in 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 service agreement. The fair value of these services was expensed over the transition period in 2006 and was included in selling and marketing expenses.

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Table of Contents**Notes to consolidated financial statements****(5) OTHER ACCRUED LIABILITIES**

Other accrued liabilities consisted of the following at December 31:

	2006	2007
Rebates, fee for services, and product returns	\$ 742,678	738,362
Employee wages and benefits	558,321	664,518
Costs related to potential initial public offering		359,664
Outside sales force and related expenses		332,774
Other	36,473	462,377
	\$ 1,337,472	2,557,695

(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 new 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 term loan is due in 2009, and is being paid off in quarterly principal installments of \$458,334. Interest is paid quarterly. Through the expiration date of the agreement (April 2008), the Company can borrow under the revolving line of credit the lesser of \$4.0 million, or 80% of eligible accounts receivable plus 50% of eligible inventory. 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, except for the Company's equity interest in Cumberland Emerging Technologies, Inc. The credit agreement contains an adverse subjective acceleration clause and also requires the Company maintain a lockbox. 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, 2007. As of December 31, 2007, the Company has additional credit available of \$989,853 under its line of credit.

In conjunction with these 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, 2007. 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 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.

In the second quarter of 2005, the Company received approximately \$2,000,000 from various individuals and companies in exchange for uncollateralized 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 note, the principal value of the note of \$2,000,000, plus accrued interest of \$32,488, converted into 225,832 shares of the Company's common stock. Accrued interest of \$2,205 was paid in cash at the request of a note holder.

Principal payments on the term note of \$1,833,332 and \$916,664 are due in 2008 and 2009, respectively.

Table of Contents**Notes to consolidated financial statements****(7) OTHER LONG-TERM OBLIGATIONS**

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

	2006	2007
Deferred purchase price, net of discount of \$465,843 and \$250,904, respectively	\$ 4,034,157	2,749,096
Third-party development costs	410,846	615,846
Product promotional costs	578,111	
Other	110,746	182,055
	5,133,860	3,546,997
Less current portion	(2,052,501)	(410,423)
	\$ 3,081,359	3,136,574

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 \$3,000,000, inclusive of unamortized debt discount of \$250,904 as of December 31, 2007, is due in April 2009. The discount was imputed at 7.33% on the acquisition date, and is being accreted using the effective-interest method.

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 \$1,010,000 during the fiscal years 2001 through 2003. As of December 31, 2007, the Company has paid approximately \$600,000 of this balance and accrued the remaining balance of approximately \$410,000. The balance of approximately \$410,000 is due in the following timeframe: (a) approximately \$205,000 due no later than submission of an application to the FDA and (b) approximately \$205,000 due no later than FDA approval. The Company has recognized the amount specified in (a) as a current portion of other long-term obligations in the consolidated balance sheet as of December 31, 2007. The remaining balance of approximately \$205,000 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 \$410,000 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, submission of a new drug application (NDA) and FDA acceptance of the submission for review, a contingent payment of approximately \$205,000 will become due and payable. The Company has substantially completed all actions necessary to submit an application to the FDA. Consequently, the Company has recognized the first milestone payment of approximately \$205,000 as a current portion of other long-term obligations in the consolidated balance sheet. Upon meeting the second milestone, FDA approval, a contingent payment of approximately \$1,005,000 will become due and payable as follows: approximately \$800,000 immediately and approximately \$205,000 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, 2007, the contingent liability for this milestone has not been recognized in the consolidated financial statements.

In connection with the aforementioned agreement, the Company granted 100,000 stock options with contingent vesting clauses to purchase the Company's common stock at an exercise price of \$1.63. Vesting for up to 40,000 of these options was contingent upon an NDA submission for the product

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candidate and FDA acceptance of the submission for review on or before January 31, 2004. None of the 40,000 options vested since the milestone was not met by January 31, 2004. 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 within 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. As of December 31, 2007, the NDA submission for the product candidate has not been submitted to the FDA for review. 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.

In 2005, the Company entered into an agreement with a key wholesaler for settlement of amounts owed under a contract in the amount of \$2,100,000 to be paid in installments over 28 months. The Company initially recorded this liability based on its net present value of the payments of approximately \$1,976,000 using an interest rate of 10%. At December 31, 2006, the Company recognized a current liability of approximately \$578,000 related to this liability. The liability was paid in 2007. Interest expense in 2006 and 2007 included accretion of the discount of \$101,709 and \$21,889, respectively, related to this liability.

(8) INCOME TAXES

Income tax benefit (expense) includes the following components:

	2005	2006	2007
Current:			
Federal	\$	(121,359)	(543,115)
State		(15,429)	(100,078)
		(136,788)	(643,193)
Deferred:			
Federal	1,146,580	2,861,859	(1,646,209)
State	37,420	(28,555)	(134,859)
	1,184,000	2,833,304	(1,781,068)
	\$ 1,184,000	2,696,516	(2,424,261)

The Company's deferred tax benefits for 2005 and 2006 were 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 is primarily the result of the utilization of the deferred tax assets from federal and state net operating loss carryforwards. The deferred tax expense for 2007 does not agree to the change in the net deferred tax assets from December 31, 2006 to December 31, 2007 due to the reclassification of a reserve for unrecognized tax benefits from taxes payable to deferred tax assets upon the adoption of FIN 48 on January 1, 2007.

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

	2005	2006	2007
Deferred tax (benefit) expense exclusive of components listed below	\$ (309,894)	(287,624)	229,754
Benefits of operating loss carryforwards	602,073	764,495	(2,002,955)
Change in valuation allowance due to changes in net deferred tax asset balances	(292,179)	(476,871)	(7,867)
Adjustments to the valuation allowance because of a change in circumstances that caused a judgment about the realizability of the related deferred tax assets in future years	1,184,000	2,833,303	
Deferred income tax benefit (expense)	\$ 1,184,000	2,833,303	(1,781,068)

In 2005, the Company reduced the valuation allowance by \$1,184,000 due to positive evidence that deferred tax assets, primarily net operating losses, would be utilized in future years. In 2006, the Company further reduced the valuation allowance by \$2,833,303 since additional positive evidence suggested that the majority of the deferred tax assets would be utilized in future years. The remaining valuation allowance at December 31, 2007 is primarily related to state tax benefits that will likely not be realized.

The Company's effective income tax rate for 2005, 2006, and 2007 reconciles with the federal statutory tax rate as follows:

	2005	2006	2007
Federal tax expense at statutory rate	(34)%	(34)%	(34)%
State income tax benefit (net of federal income tax benefit)	(3)	(2)	(3)
Permanent differences	1		(1)
Other	(2)		1
Change in deferred tax asset valuation allowance	192	194	
Net income tax benefit (expense)	154%	158%	(37)%

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

	2006	2007
Net operating loss and tax credits	\$ 2,834,870	999,665
Depreciation and amortization	71,412	148,502
Allowance for accounts receivable	30,841	54,294
Reserve for expired product		119,309
Rebate liability		38,328
Inventory write-off	175,961	416
Deferred charges	399,010	294,764
Investment income	(10,448)	
Employee stock-based compensation	37,747	
Expense for options and stock grants to nonemployees	517,523	583,358
Total deferred tax assets	4,056,916	2,238,636
Less deferred tax asset valuation allowance	(39,612)	(47,479)
Net deferred tax assets	\$ 4,017,304	2,191,157

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. In order to fully realize the deferred tax assets, the Company will need to generate future taxable income of approximately \$14,100,000 prior to the expiration of the net operating loss carryforwards in 2026. Taxable income for the years ended December 31, 2005, 2006, and 2007 was \$1,938,296, \$2,139,954, and \$5,478,309, 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, 2007. The valuation allowance at December 31, 2007 represents the deferred tax assets associated with CPSC and CET that the Company believes are not more likely than not will be utilized. 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.

As of December 31, 2007, the Company has federal credit carryforwards of \$491,227 that expire starting in 2021. The federal and state net operating loss carryforwards will expire as follows:

Year of expiration	Federal	State
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2015	2017		\$	2,841,279
2018	2020			3,106,121
2021	2023	443,009		289,172
2024	2026	265,489		
			\$ 708,498	6,236,572

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

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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 reclassified as the beginning of period unrecognized tax benefits.

Changes in the beginning balance of unrecognized tax benefits during 2007 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

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, the Company evaluated its tax positions for all years that remain subject to examination by the taxing authorities. Federal tax years that remain open to examination are 2004 to 2007. State tax years that remain open to examination are 2003 to 2007. The Company is currently undergoing an examination of its federal taxes, which could result in a change in the realizability of the unrecognized tax benefits in the next twelve months. The Company is currently unable to estimate a range of possible changes in the realizability of these unrecognized tax benefits.

(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 \$3.25 per share liquidation preference 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 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

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Notes to consolidated financial statements

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

In March 2005, the Company initiated a private placement offering of its common stock. The purpose of this offering was for working capital and for other general corporate purposes, including, but not limited to, the acquisition and development of pharmaceutical products. The offering was a private, limited offering by the Company in reliance upon exemptions from the federal registration provisions of the Securities Act of 1933, as amended, promulgated by the SEC under Regulation D. This offering was completed in 2005, and the Company issued 200,000 shares of common stock at \$9.00 per share, for total net proceeds of \$1,789,364 (gross proceeds of \$1,800,000, net of cash offering costs of \$10,636). The Company issued 7,000 stock options with a fair value of \$51,806 to a non-employee as compensation for consulting services associated with the private placement. The fair value of these options has been recorded as additional offering costs and as stock options granted for services received.

In 2005, the Company issued 225,832 shares of common stock upon conversion of certain promissory notes into shares of the Company's common stock. See Note 6 for a more in-depth discussion of these transactions.

During 2005, 2006, and 2007, the Company issued 50,002, 27,518, and 25,236 shares of common stock, respectively, valued at \$300,012, \$273,298, and \$222,596, 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 46,240, 24,818, and 11,036 in 2005, 2006, and 2007, respectively, for consulting services rendered. The expense associated with these grants to board members was \$277,400, \$248,998, and \$121,396 in 2005, 2006, and 2007, respectively. In addition, the Company issued 17,650, 36,334, and 10,304 net shares of common stock to key executives and an advisor, who exercised options in 2005, 2006, and 2007, respectively.

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

(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, 2007.

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, 2007.

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

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Notes to consolidated financial statements

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, 2007. 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.

(10) STOCK OPTIONS

The Cumberland Pharmaceuticals Inc. 1999 Stock Option Plan (the 1999 Plan) that includes 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 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 10% shareholders. Vesting is determined on a grant-by-grant basis in accordance with the terms of the plans and the related grant agreements.

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Stock option activity for the three-year period ended December 31, 2007, was as follows:

	Number of shares	Weighted- average exercise price per share
Options outstanding, December 31, 2004	8,065,216	\$ 1.17
Options granted	262,700	6.49
Options exercised	(19,110)	0.95
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	(346,832)	2.63
Options outstanding, December 31, 2006	8,009,956	1.37
Options granted	90,920	11.00
Options exercised	(223,878)	2.38
Options forfeited	(23,246)	8.35
Options outstanding, December 31, 2007	7,853,752	1.44

Of the options outstanding at December 31, 2005, 2006, and 2007, 4,776,036, 4,783,728 and 4,771,420, respectively, were options issued to a key executive.

The following table summarizes information concerning outstanding options as of December 31, 2007:

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	845,680	1.06	\$ 0.11	\$ 9,212,062
1999	0.50-0.55	4,644,758	1.70	0.54	48,565,105
2000	0.93	128,400	2.54	0.93	1,292,988
2001	1.63	781,366	3.21	1.63	7,321,399
2002	1.63	311,908	4.03	1.63	2,922,577

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2002	3.13-3.50	14,644	4.52	3.15	115,022
2003	3.13-6.00	454,752	5.26	4.11	3,134,790
2004	6.00-6.60	256,570	6.29	6.01	1,280,810
2005	6.00-9.00	256,304	6.13	6.49	1,154,920
2006	9.00-9.90	69,450	7.07	9.26	120,900
2007	11.00	89,920	9.08	11.00	
		7,853,752			\$ 75,120,573

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The following table summarizes information concerning exercisable options as of December 31, 2007:

Year	Range of exercise prices	Options exercisable	Remaining contractual life (in years)	Weighted average exercise price	Aggregate intrinsic value
1999	\$0.10-0.11	845,680	1.06	\$ 0.11	\$ 9,212,062
1999	0.50-0.55	4,644,758	1.70	0.54	48,565,105
2000	0.93	128,400	2.54	0.93	1,292,988
2001	1.63	781,366	3.21	1.63	7,321,399
2002	1.63	311,908	4.03	1.63	2,922,577
2002	3.13-3.50	14,644	4.52	3.15	115,022
2003	3.13-6.00	454,752	5.26	4.11	3,134,790
2004	6.00-6.60	256,570	6.29	6.01	1,280,810
2005	6.00-9.00	141,384	5.76	6.85	586,680
2006	9.00-9.90	36,950	7.17	9.24	64,900
2007	11.00	34,430	9.08	11.00	
		7,650,842			\$ 74,496,333

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

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

The fair value of non-employee options was estimated using the Black-Scholes option-pricing model and the following assumptions:

	2005	2006	2007
Dividend yield	%	%	%

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Expected term (years)	10	.17-10	10
Expected volatility	77%	37%-63%	74%
Risk-free interest rate	4.13%-4.39%	4.34%-4.42%	4.83%

The Company determined the expected life of employee share options based on the simplified method allowed by SEC Staff Accounting Bulletin No. 107. 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 non-employees 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 entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, size, and financial leverage. The risk-free rate is based on a zero-coupon U.S. Treasury bond 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, 2005, 2006, and 2007 was approximately \$2.87, \$4.95, and \$7.21, respectively. Upon exercise, the Company issues new shares of stock. During the years ended December 31, 2005, 2006,

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and 2007, the aggregate intrinsic value of options exercised under the 1999 Plan was \$153,899, \$357,730, and \$1,929,259, 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, 2007, there was approximately \$556,570 of unrecognized compensation cost related to share-based payments granted, which is expected to be recognized over a period of four years. This amount consists of non-employee unrecognized compensation cost of \$51,530 and employee unrecognized compensation cost of \$505,040.

The Company issued a total of 47,600, 24,000, and 14,000 stock options to non-employees for services rendered by these individuals in 2005, 2006, and 2007 as compensation for assisting the Company's management and supporting operations. The amount of compensation expense recorded for such services was \$226,709, \$37,751, and \$93,836 in 2005, 2006, and 2007, respectively. Such expense is presented as a component of general and administrative expenses. Included in these amounts are options to purchase 22,000 shares of common stock at an exercise price of \$9.00 in 2005 that were granted to two board members.

(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, on a straight-line basis. Rent expense for 2005, 2006, and 2007 was \$151,479, \$286,037, and \$387,862, respectively, and sublease income was \$49,131, \$71,173, and \$77,071, respectively. Future minimum lease payments under noncancelable operating leases (with initial or remaining lease terms in excess of one year) are:

Year ending December 31:	
2008	\$ 499,612
2009	504,875
2010	470,988
2011	46,711
2012	
Thereafter	
Total minimum lease payments	\$ 1,522,186

(12) MANUFACTURING AND SUPPLY AGREEMENTS

The Company utilizes one supplier to manufacture each of its products and product candidates. 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 \$2.3 million during 2008, \$2.6 million during 2009, \$2.9 million during 2010, and \$2.4 million during 2011. Beginning in October 2011 and continuing through the life of the agreement, which expires in

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Notes to consolidated financial statements

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 2007 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 \$258,000 for these activities. The original two-year agreement expires in August 2008 and has a one-year renewal option. 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.

During the second quarter of 2006, the Company's Chief Executive Officer, a Company Vice President, and the Company were named as co-defendants in *Parniani v. Cardinal Health, Inc. et al.*, Case No. 0:06-cv-02514-PJS-JJG in the U.S. District Court in the District of Minnesota for unspecified damages based on workers' compensation and related claims. On July 27, 2007, the federal district court dismissed the case against the Company and the Company's Chief Executive Officer and Vice President. The plaintiff has appealed the ruling to the Eighth Circuit Court of Appeals. The plaintiff is a former employee of a third-party service provider to the Company. The service provider, which was also named as a co-defendant, agreed to assume control of the Company's defense at its cost pursuant to a contract between it and the Company. Based upon the information available to the Company to date, the Company believes that all asserted claims against the Company and the individual defendants are without merit. However, if the plaintiff appeals the ruling and any of the claims are deemed meritorious on appeal, the Company expects to be indemnified by the service provider so that resolution of this matter is not expected to have a material adverse effect on the Company's future financial results or financial condition.

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

(15) MARKET CONCENTRATIONS

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

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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:

	2005	2006	2007
Customer 1	34%	22%	35%
Customer 2	33	20	26
Customer 3	13	25	31

Additionally, 67% and 92% of the Company's accounts receivable balances were due from these three customers at December 31, 2006 and 2007, 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 or 2007.

Table of Contents**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	Charged to other accounts describe	Column D Deductions describe(1)	Column E Balance at end of period
Allowance for uncollectible amounts, cash discounts, chargebacks, and credits issued for damaged products: For the period ended:					
December 31, 2005	\$ 189,959	553,460		(559,085)	184,334
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
Valuation allowance for deferred tax assets: For the period ended:					
December 31, 2005	\$ 4,825,965	(1,476,179) ⁽²⁾			3,349,786
December 31, 2006	3,349,786	(3,310,174) ⁽³⁾			39,612
December 31, 2007	39,612	7,867			47,479

- (1) Write-off of uncollectible accounts, net of recoveries, discounts, chargebacks, and credits taken by customers.
- (2) Includes a \$1,184,000 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.
- (3) Includes a \$2,833,303 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.

Table of Contents**Cumberland Pharmaceuticals Inc. and Subsidiaries**

Condensed consolidated balance sheets
(Unaudited)

	As of	
	December 31, 2007	March 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,814,518	\$ 11,912,357
Accounts receivable, net of allowance	2,373,537	2,917,657
Inventories	949,109	1,173,805
Prepaid assets	288,241	220,576
Deferred tax assets	363,175	363,175
Total current assets	14,788,580	16,587,570
Property and equipment, net	459,843	470,802
Intangible assets, net	9,153,751	8,993,798
Deferred tax assets	1,827,982	1,659,504
Other assets	2,688,511	2,919,610
Total assets	\$ 28,918,667	\$ 30,631,284
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 1,833,332	\$ 1,833,336
Revolving line of credit	1,325,951	1,325,951
Current portion of other long-term obligations	410,423	410,423
Accounts payable	1,921,101	3,287,122
Other accrued liabilities	2,628,453	1,901,955
Total current liabilities	8,119,260	8,758,787
Long-term debt, excluding current portion	916,664	458,326
Other long-term obligations, excluding current portion	3,136,574	3,179,100
Total liabilities	12,172,498	12,396,213
Commitments and contingencies (see note 6)		
Shareholders equity:		
Convertible Preferred stock no par value; 3,000,000 shares authorized; 855,495 shares issued and outstanding	2,742,994	2,742,994
Common stock no par value; 100,000,000 shares authorized; 10,091,260 and 10,095,160 shares issued and outstanding as of December 31, 2007 and	17,318,713	17,412,365

March 31, 2008, respectively		
Accumulated deficit	(3,315,538)	(1,920,288)
Total shareholders' equity	16,746,169	18,235,071
Total liabilities and shareholders' equity	\$ 28,918,667	\$ 30,631,284

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Cumberland Pharmaceuticals Inc. and Subsidiaries**

Condensed consolidated statements of operations
(Unaudited)

	Three Months Ended March 31,	
	2007	2008
Net revenues	\$ 5,906,785	\$ 8,303,827
Costs and expenses:		
Cost of products sold	571,092	755,491
Selling and marketing	2,417,053	3,364,006
Research and development	452,199	1,109,942
General and administrative	1,019,129	1,083,094
Amortization of product license right	171,727	171,726
Other	24,978	26,029
Total costs and expenses	4,656,178	6,510,288
Operating income	1,250,607	1,793,539
Interest income	90,157	82,372
Interest expense	(192,071)	(113,604)
Net income before income taxes	1,148,693	1,762,307
Income tax expense	(409,589)	(367,057)
Net income	\$ 739,104	\$ 1,395,250
Net income per share basic	\$ 0.07	\$ 0.14
Net income per share diluted	\$ 0.04	\$ 0.09
Weighted-average shares outstanding basic	9,869,314	10,093,831
Weighted-average shares outstanding diluted	16,620,808	16,411,672

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Cumberland Pharmaceuticals Inc. and Subsidiaries**Condensed consolidated statements of cash flows
(Unaudited)

	Three Months Ended	
	March 31,	
	2007	2008
Cash flows from operating activities:		
Net cash provided by operating activities	\$ 3,314,509	\$ 1,869,841
Cash flows from investing activities:		
Additions to property and equipment	(28,611)	(33,192)
Additions to patents	(3,157)	(12,946)
Net cash used in investment activities	(31,768)	(46,138)
Cash flows from financing activities:		
Costs of potential initial public offering	(80,328)	(267,530)
Principal payments on note payable	(458,347)	(458,334)
Net cash used in financing activities	(538,675)	(725,864)
Net increase in cash and cash equivalents	2,744,066	1,097,839
Cash and cash equivalents at beginning of period	6,255,398	10,814,518
Cash and cash equivalents at end of period	\$ 8,999,464	\$ 11,912,357
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$ 121,616	\$ 77,588
Income taxes	4,325	138,485
Non-cash investing and financing activities:		
Increase in accrued but unpaid costs of potential initial public offering	613,918	

See accompanying notes to unaudited condensed consolidated financial statements.

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CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Notes to condensed consolidated financial statements
(Unaudited)

(1) BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed consolidated financial statements (condensed consolidated financial statements) of Cumberland Pharmaceuticals Inc. and its subsidiaries (collectively, the Company or Cumberland) have been prepared on a basis consistent with the December 31, 2007 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly present the information set forth herein. The condensed consolidated financial statements have been prepared in accordance with the regulations of the Securities and Exchange Commission (SEC), and omit certain information and footnote disclosure necessary to present the statements in accordance with U.S. generally accepted accounting principles. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2007. The results of operations for the first three months of 2008 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income was comprised solely of net income for the three months ended March 31, 2007 and 2008.

Accounting Policies:

In preparing the condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles, management must make decisions that impact the reported amounts and the related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgments based on its understanding and analysis of the relevant circumstances, historical experience, and other available information. Actual amounts could differ from those estimated at the time the consolidated financial statements are prepared.

Note 2 in the Company s consolidated financial statements for the year ended December 31, 2007 provides a summary of significant accounting policies followed in the preparation of the condensed consolidated financial statements. Other footnotes in the Company s 2007 consolidated financial statements describe various elements of the condensed consolidated financial statements and the assumptions made in determining specific amounts.

Initial public offering costs of \$2.9 million are included in non-current assets and will be accounted for as equity or expense based on the outcome of the initial public offering. As of March 31, 2008, approximately \$0.6 million of unpaid costs related to our initial public offering are included in accounts payable and other accrued liabilities.

The condensed consolidated financial statements include the accounts of Cumberland Pharmaceuticals Inc. and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

(2) ADOPTION OF NEW ACCOUNTING PRONOUNCEMENTS

Effective January 1, 2008, the Company adopted the provisions of Statement of Financial Accounting (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). This pronouncement did not require any new fair value measurements. The adoption of this pronouncement did not impact the condensed consolidated financial statements

for the three months ended March 31, 2008.

SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), was effective on January 1, 2008. SFAS 159 permits entities to measure many financial instruments and

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Table of Contents**Notes to condensed consolidated financial statements**

certain other items at fair value. As of the date of adoption, the Company elected to recognize its financial assets and liabilities at historical cost. The Company may elect, on a case-by-case basis, to recognize new assets acquired or liabilities assumed at fair value.

Effective January 1, 2008, the Company adopted the provisions of EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. During the first quarter of 2008, the Company did not make any nonrefundable advance payments for research and development activities. Consequently, the adoption of this pronouncement did not impact the condensed consolidated financial statements for the three months ended March 31, 2008.

(3) INCOME TAXES

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainties in Income Taxes* an interpretation of FASB Statement No. 109 (FIN 48), which clarified the accounting and disclosure for uncertainty in income tax positions. Changes in the beginning balance of unrecognized tax benefits during the three months ended March 31, 2008 were as follows:

	Gross	Federal Unrecognized Benefits	State Unrecognized Benefit	Total
Unrecognized tax benefits, December 31, 2007	\$ 378,736	\$ 378,736	\$	\$ 378,736
Decrease due to settlement with taxing authority	(378,736)	(378,736)		(378,736)
Unrecognized tax benefits, March 31, 2008	\$	\$	\$	\$

Based on the results of the examination of its federal taxes, the Company reevaluated its previously unrecognized tax positions and determined it was more likely than not that the benefits would be realized. As a result, the Company recognized these tax benefits during the first quarter of 2008.

Income tax expense for the first quarter of 2008 has been provided for based on an estimated effective tax rate of 38.8% expected to be applicable for the 2008 fiscal year.

(4) NET INCOME PER SHARE

The following tables reconcile the numerator and the denominator used to calculate diluted net income per share for the three months ended March 31, 2007 and 2008:

Three Months Ended March 31,	
2007	2008

Numerator:		
Net income	\$ 739,104	\$ 1,395,250
Denominator:		
Weighted-average shares outstanding basic	9,869,314	10,093,831
Preferred stock shares	1,710,990	1,710,990
Dilutive effect of stock options and warrants	5,040,504	4,606,851
Weighted-average shares outstanding diluted	16,620,808	16,411,672

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As of March 31, 2007 and 2008, options to purchase 55,710 and 30,961 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

(5) SEGMENT REPORTING

We operate in one segment, 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. The Company did not have any sales to non-U.S. customers during the three months ended March 31, 2007 and 2008.

	Three Months Ended	
	March 31,	
	2007	2008
Products		
Acetadote	\$ 3,863,280	\$ 5,799,482
Kristalose	1,982,054	2,478,183
Other		
Other	61,451	26,162
Total	\$ 5,906,785	\$ 8,303,827

(6) CONTINGENCIES

During the second quarter of 2006, our Chief Executive Officer, a Vice President of ours, and we were named as co-defendants in *Parniani v. Cardinal Health, Inc. et al.*, Case No. 0:06-cv-02514-PJS-JJG in the U.S. District Court in the District of Minnesota for unspecified damages based on workers' compensation and related claims. On July 27, 2007, the federal district court dismissed the case against us and our Chief Executive Officer and Vice President. The plaintiff has appealed the ruling to the Eighth Circuit Court of Appeals. The plaintiff is a former employee of a third-party service provider to us. The service provider, which was also named as a co-defendant, agreed to assume control of our defense at its cost pursuant to a contract between it and us. Based upon the information available to us to date, we believe that all asserted claims against us and the individual defendants are without merit. However, if any of the claims are deemed meritorious on appeal, we expect to be indemnified by the service provider so that resolution of this matter is not expected to have a material adverse effect on our future financial results or financial condition.

(7) SUBSEQUENT EVENTS

In April 2008, the Company amended its line of credit to extend the maturity date to April 6, 2009. The terms of the amended line of credit are consistent with its original terms. In accordance with SFAS 6, *Classification of Short-Term Obligations Expected to Be Refinanced*, the line of credit is presented as a current liability in the condensed consolidated balance sheet as of March 31, 2008. The Company did not pay any bank fees associated with the line of credit.

In April 2008, the Company amended its agreement with Inalco and paid the remaining obligation related to the purchase of the Kristalose license right. 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 \$2,760,000.

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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	\$ 371,000
Legal fees and expenses	\$ 975,000
Accounting fees and expenses	\$ 1,200,000
Blue sky, qualification fees and expenses	\$ 20,000
Transfer agent and registrar expenses	\$ 15,000
Miscellaneous	\$ 803,000
Total	\$ 3,500,000

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 September 2003, we borrowed \$500,000 from nine existing and accredited shareholders pursuant to uncollateralized secured notes payable with original maturity dates of 130 days. These notes bore interest at 12% for the first 30 days and 15% thereafter. The holders of the notes had, at their option, until the maturity date of the notes payable, the right to convert all or a portion of the unpaid principal and interest into shares of our common stock at a rate of \$6.00 per share. We also issued to these lenders options to purchase shares of our common stock, at an exercise

price of \$6.00 per share, and at the rate of 3,080 shares of common stock per \$50,000 face value of the notes. If we had not prepaid all amounts due and owing under the notes, we agreed to grant additional options at the rate of 1,540 shares of common stock per \$50,000 face value on each of (i) the 30th day after the date of the notes and (ii) on a continuing basis, each successive 30-day period thereafter, or portion thereof, as the notes remained outstanding. At December 31, 2003, the notes payable had not been prepaid, so we

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granted options to acquire an additional 61,600 shares. We amended the notes agreements in January 2004 to extend the maturity date 130 days. The amendments granted an additional option to purchase 3,080 shares per \$50,000 face value upon extension of the notes and contained similar provisions for granting options in the event of nonpayment on the agreed-upon due dates. Based on the extension of the maturity date, rights to purchase a total of 123,200 shares were earned by the holders of the notes in 2004. We repaid these notes or settled these notes in shares in May 2004. The issuance of these securities was exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

In September 2003, we borrowed \$1,000,000 from S.C.O.U.T. Healthcare Fund, L.P., or S.C.O.U.T., in the form of a convertible promissory note with a maturity date of September 2004. The President and majority shareholder of the general partner of S.C.O.U.T., Dr. Lawrence W. Greer, serves on our board of directors. Pursuant to the terms of the note, on its maturity date, S.C.O.U.T. converted the principal value of the note plus all interest accrued at a fixed rate of ten percent per annum into 183,334 shares of our common stock at a price of \$6.00 per share.

On April 15, 2004, we issued 86,000 common shares at \$6.00 per share, for an aggregate consideration of \$516,000 and a five-year warrant to purchase 40,000 common shares at \$6.00 per share to S.C.O.U.T., which represented to us that it was an accredited investor. This issuance was exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

By an offering memorandum dated April 1, 2005, we offered 200,000 shares of our common stock at a purchase price of \$9.00 per share. Thirty investors subscribed for 200,000 shares in the aggregate, for an aggregate consideration of \$1,800,000. This issuance was exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

By an offering memorandum dated May 5, 2005, we received approximately \$2,000,000 from approximately 41 investors in exchange for uncollateralized convertible promissory notes with a maturity date six months from the date of issuance. Upon maturity, the principal and accrued interest payable on the notes converted into 225,832 shares of common stock at a rate of \$9.00 per share. This issuance was exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

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, 2004, we have granted options to purchase 575,220 shares of our common stock under the 1999 Option Plan to our employees, directors and consultants at exercise prices ranging from \$6.00 to \$11.00 per share. Of these, an aggregate of 1,650 shares of our common stock were issued upon the exercise of stock options.

Since January 1, 2004, we also issued an aggregate of 151,290 shares of common stock as compensation for services pursuant to contracts. Restricted-stock legends were affixed to the securities issued in these 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 \$6.00 to \$11.00 per share. The issuances of common stock in connection with awards of restricted stock were exempt either pursuant to Rule 701 or pursuant to Section 4(2) of the Securities Act as transactions by an issuer not involving a public offering.

The issuances of securities described in the first six paragraphs of Item 15 were exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder, as transactions by an issuer not

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involving any public offering. The purchasers of the securities in these transactions represented that they were accredited investors and they were acquiring the securities for investment only and not with a view toward the public sale or distribution thereof. Such purchasers received written disclosures that the securities had not been registered under the Securities Act of 1933, as amended, and that any resale must be made pursuant to a registration statement or an available exemption from registration. All purchasers either received adequate financial statement or non-financial statement information about the registrant or had adequate access, through their relationship with the registrant, to financial statement or non-financial statement information about the registrant. The sale of these securities was made without general solicitation or advertising.

The issuances of securities described in the seventh and eighth 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.
10.10 **	License Agreement, dated May 28, 1999, by and between Vanderbilt University and Cumberland Pharmaceuticals Inc.
10.11#**	Employment Agreement effective as of January 1, 2008 by and between A.J. Kazimi and Cumberland Pharmaceuticals Inc.
10.12#**	Employment Agreement effective as of January 1, 2008 by and between Jean W. Marstiller and Cumberland Pharmaceuticals Inc.
10.13#**	Employment Agreement effective as of January 1, 2008 by and between Leo Pavliv and Cumberland Pharmaceuticals Inc.
10.14#**	Employment Agreement effective as of January 1, 2008 by and between J. William Hix and Cumberland Pharmaceuticals Inc.
10.15#**	Employment Agreement effective as of January 1, 2008 by and between David L. Lowrance and Cumberland Pharmaceuticals Inc.
10.16.1 **	Second Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated April 6, 2006.
10.16.2**	First Amendment to Second Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated December 31, 2006.
10.16.3**	Second Amendment to Second Amended and Restated Loan Agreement by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated July 18, 2007.

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No.	Description
10.16.4**	Third Amendment to Second Amended and Restated Loan Agreement, by and between Cumberland Pharmaceuticals Inc. and Bank of America, N.A., dated April 6, 2008.
10.17#**	1999 Stock Option Plan of Cumberland Pharmaceuticals Inc.
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.
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.

Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

- (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. 12 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 20th day of June, 2008.

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. 12 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	Chairman and CEO (Principal Executive Officer)	June 20, 2008
A.J. Kazimi /s/ david l. lowrance	Vice President and CFO (Principal Financial and Accounting Officer)	June 20, 2008
David L. Lowrance *	Director	June 20, 2008
Robert G. Edwards *	Director	June 20, 2008
Thomas R. Lawrence *	Director	June 20, 2008
Lawrence W. Greer *	Director	June 20, 2008

Martin E. Cearnal
 *By: /s/ a.j. kazimi

 A.J. Kazimi
 Attorney-in-Fact

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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.

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No.	Description
10.25	Manufacturing Agreement, dated February 6, 2008, by and between Bayer HealthCare, LLC, 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 the 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.

Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.