

CUMBERLAND PHARMACEUTICALS INC

Form S-1/A

July 23, 2007

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**As filed with the Securities and Exchange Commission on July 23, 2007**

**Registration No. 333-142535**

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

**Amendment No. 4  
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)*

*Copies to:*

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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                      JULY 23, 2007

**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 , 2007.

**UBS Investment Bank**

**Jefferies & Company**

**Wachovia Securities**

**Morgan Joseph**

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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 \_\_\_\_\_, 2007 (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 three years. Our portfolio consists of two products approved by the U.S. Food and Drug Administration, or FDA, one late-stage development 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 41 sales representatives and 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 2004, 2005 and 2006, our net revenue was \$12.0 million, \$10.7 million and \$17.8 million, respectively, and our net income was \$558,000, \$2.0 million and \$4.4 million, respectively.

**OUR PRODUCTS**

Our key products and product candidates include:

<b>Product</b>	<b>Indication</b>	<b>Delivery</b>	<b>Status</b>
<b>Amelior®</b>	Pain and Fever	Injectable	Phase III
<b>Acetadote®</b>	Acetaminophen Poisoning	Injectable	Marketed
<b>Kristalose®</b>	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 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 in the country. If approved, we plan to market Amelior in the U.S. through our hospital sales force and to market Amelior 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 491 million units, in 2006. This market consists primarily of the non-steroidal anti-inflammatory drug ketorolac and generic opioids. 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 43 million units in 2006, or 9% of the market, according to IMS Health. Injectable opioids such as morphine and meperidine accounted for approximately 447 million units sold in 2006. 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 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 Toxic Exposure Surveillance System, acetaminophen was the leading cause of poisonings presenting to emergency departments in the U.S. in 2005, with approximately 77,000 cases treated.

NAC is accepted worldwide as the standard of care for treating acetaminophen overdose, which is well-documented and is supported by a 2005 article in volume 17 of *Current Opinion in Pediatrics*. Until our 2004 launch of Acetadote, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Medical literature suggests that, for a number of patients, IV treatment is the only reasonable route of administration due to nausea and vomiting associated with the administration of oral NAC for acetaminophen overdose. Sales of Acetadote have increased consistently since we launched the product in June 2004. According to Wolters Kluwer Health Source<sup>tm</sup> Pharmaceutical Audit Suite, Acetadote sales to hospitals grew 43% from 2005 to 2006. Total sales to hospitals in 2006 were \$12.8 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 \$389 million in 2006, representing a compound annual growth rate of 24%. Wholesaler sales of Kristalose to pharmacies were \$10.5 million in 2006. 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 October 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, 2007, we had an accumulated deficit of (\$6.6) 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 17,838,680 shares

Fully diluted common stock to be outstanding after this offering 25,161,348 shares

Use of proceeds We estimate that the net proceeds from this offering will be approximately \$85.4 million, or approximately \$98.5 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 11,588,680 shares outstanding as of March 31, 2007 and excludes:

- Ø 8,067,302 shares of common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$1.46 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 2,682,698 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 17,838,680 shares to be outstanding after this offering and the 8,136,260 shares of common stock issuable upon exercise of options and warrants outstanding as of March 31, 2007, reduced by the 813,592 shares of common stock that could theoretically be repurchased with the approximately \$12.2 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, 2007 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 Ended	
	2004	2005	2006	2006	2007
	(in thousands, except per share data)				
	(unaudited)				
Net revenues:					
Acetadote	\$ 6,515	\$ 10,111	\$ 10,722	\$ 865	\$ 3,863
Kristalose	2,734	1,812	6,511	271	1,982
Other <sup>(1)</sup>	2,783	(1,233) <sup>(2)</sup>	582	252	62
Total net revenues	\$ 12,032	\$ 10,690	\$ 17,815	\$ 1,388	\$ 5,907
Operating income (loss)	1,569	750	2,224	(1,203)	1,251
Net income (loss) before income taxes	558	770	1,708	(1,217)	1,149
Net income (loss)	558	1,954	4,404	(1,217)	739
Net income (loss) per share basic	\$ 0.06	\$ 0.21	\$ 0.45	\$ (0.12)	\$ 0.07
Net income (loss) per share diluted	\$ 0.04	\$ 0.12	\$ 0.27	\$ (0.12)	\$ 0.04
Pro forma net income (loss) per share basic (unaudited)			\$ 0.38		\$ 0.06
Pro forma net income (loss) per share diluted (unaudited)			\$ 0.27		\$ 0.04
Weighted average shares outstanding basic	9,082	9,496	9,797	9,790	9,869
Weighted average shares outstanding diluted	15,482	16,306	16,454	9,790	16,621
Pro forma weighted average shares outstanding basic (unaudited)			11,508		11,580
Pro forma weighted average shares outstanding diluted (unaudited)			16,454		16,621



<b>Balance sheet data:</b>	<b>As of March 31, 2007</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma as Adjusted<sup>(3)</sup></b>
	<b>(in thousands) (unaudited)</b>		
Cash and cash equivalents	\$ 8,999	\$ 8,999	\$ 94,387
Working capital	4,431	4,431	89,818
Total assets	26,854	26,854	112,241
Total long-term debt and other long-term obligations (including current portion)	9,947	9,947	9,947
Preferred stock	2,743		
Accumulated deficit	(6,621)	(6,621)	(6,621)
Total shareholders' equity	12,223	12,223	97,611

- (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.

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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 neither been approved nor marketed 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 to the FDA an application 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 are currently studying 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. Our agreement with Bioniche Teoranta, or Bioniche, for the exclusive manufacture and supply of Acetadote requires that we obtain Acetadote only from Bioniche, even if we could obtain Acetadote from another supplier on terms more favorable than the terms of our agreement with Bioniche.

We have minimum purchase obligations under our Acetadote supply agreement with Bioniche and our Kristalose supply agreement with Inalco S.p.A. and Inalco Biochemicals, Inc., or collectively Inalco. If our purchase obligations exceed demand for these 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 exclusive manufacturer of Amelior, was acquired by Hospira, Inc. 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 could be interrupted.

Amelior is manufactured at a single facility in Australia. Acetadote is manufactured at a single facility in Ireland, and 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;
- Ø Inventiv Commercial Services, LLC, which provides a field sales force that is the primary selling team for Kristalose; and

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**Risk factors**

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. Recently, 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 branded prescription laxative products, including Amitiza<sup>®</sup> and Zelnorm<sup>®</sup>. Amitiza<sup>®</sup> is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. Zelnorm<sup>®</sup> is a product of Novartis Pharma AG, which withdrew Zelnorm<sup>®</sup> from the U.S. market in March 2007 based on a recent finding of an increased risk of serious cardiovascular adverse events associated with the use of the drug. 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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### **Risk factors**

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 issue dilutive securities to pay for acquisitions; and
- Ø acquiring products that could substantially increase our amortization expenses.

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

We may not be able to engage in future product acquisitions, and those we do complete may not be beneficial to us in the long term.

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

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

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

Our financial success depends, in part, on the availability of adequate reimbursement from third-party healthcare payors. Such third-party payors include governmental health programs such as Medicare and Medicaid, managed care providers and private health insurers. Third-party payors are increasingly challenging the pricing of medical products and services, while governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of such legislation could further limit reimbursement for pharmaceuticals. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare beneficiaries in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Under this program, drug prices for certain prescription drugs are negotiated by drug plans, with the goal to lower costs for Medicare beneficiaries. Future cost control initiatives could decrease the price that we would receive for any products, which would limit our revenue and profitability. In addition, legislation and regulations affecting the pricing of pharmaceuticals might change.

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

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

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

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

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



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### **Risk factors**

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 July 16, 2007, we had 35 full-time employees, which includes the sales staff we recently acquired from Cardinal, now comprised of 15 representatives. 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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**Risk factors**

**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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### **Risk factors**

#### **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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### **Risk factors**

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**

### **We have identified material weaknesses and a significant deficiency in our internal controls that, if not properly corrected, could result in material misstatements in our financial statements.**

In connection with our fiscal year 2006 financial statement audit, we identified three material weaknesses, and an additional significant deficiency (not rising to the level of a material weakness), in our internal controls. A significant deficiency is a control deficiency, or a combination of control deficiencies, that adversely affects our ability to initiate, authorize, record, process, or report external financial data reliably in accordance with U.S. generally accepted



accounting principles such that there is more than a remote likelihood that a misstatement of our annual or interim financial statements that is more than inconsequential will not be prevented or detected by our internal controls. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote

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### **Risk factors**

likelihood that a material misstatement of our annual or interim financial statement will not be prevented or detected by our internal controls. We have undertaken a remediation plan designed to correct these issues.

We summarize below the nature of the material weaknesses referenced above as well as the related remediation steps that we are implementing or plan to implement:

- Ø *Non-Routine Transactions.* We did not maintain adequate policies and procedures related to our financial reporting in order to account for significant, non-routine transactions in accordance with U.S. generally accepted accounting principles. To remedy this material weakness, we are implementing a new policy requiring management to review quarterly the accounting treatment for all transactions and contracts entered into.
- Ø *Financial Statement Review Process.* We lack adequate personnel resources possessing sufficient expertise in U.S. generally accepted accounting principles to effectively perform a review of the annual financial statements. To remedy this material weakness, we intend to establish a new internal position that will be primarily responsible for SEC and other external reporting requirements. This position will report to the Vice President of Finance and Accounting.
- Ø *Taxes.* We do not have an adequate number of personnel with appropriate qualifications and training in accounting for income taxes to perform a sufficient review of the income tax provision. To remedy this material weakness, we are implementing new procedures that, among other things, require us to further review the work of our external tax provider and to increase communication and information-sharing between our external tax provider and us.

The significant deficiency relates to our policies and procedures for the review of our master listing of stock options granted. To remedy this significant deficiency, we are reviewing each transaction on our master listing against the relevant source documents and implementing new policies requiring quarterly review of the master listing by departments including our finance and accounting departments.

If we are not able to timely remedy the material weaknesses and significant deficiency described above, we may be unable to provide to our shareholders the required financial information in a timely and reliable manner, and we may misreport financial information, either of which could subject us to stockholder litigation and regulatory enforcement actions. This could materially and adversely impact our financial condition and the market value of our securities.

### **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;

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.

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### **Risk factors**

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, 2007, intangible assets relating to product and data acquisitions represented approximately 36.0% 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 increased profitability in each of 2005 and 2006. As of March 31, 2007, however, we still had an accumulated deficit of (\$6.6) 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.

### **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



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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 \$10.07 per share, based on an assumed initial public offering price of \$15.00 per share;
- Ø contribute 88.5% of the total amount invested to date to fund our company based on an assumed initial offering price to the public of \$15.00 per share;
- Ø but will own only 35.0% 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 8,136,260 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.