CUMBERLAND PHARMACEUTICALS INC
Form S-1/A
July 17, 2009

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As filed with the Securities and Exchange Commission on July 17, 2009
Registration No. 333-142535

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

Amendment No. 19
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

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

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

A.J. Kazimi
Chairman and CEO
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: o

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

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

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

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

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

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION July 17, 2009

5,000,000 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 5,000,000 shares of our common stock offered by this prospectus. We expect the public offering price to be between $19.00 and $21.00 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 7 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 750,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $, and our total proceeds, before expenses, will be $.

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

UBS Investment Bank **Jefferies & Company** **Wells Fargo Securities**

Morgan Joseph

The date of this prospectus is , 2009.

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

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

Caldolor™, 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 that we believe can be penetrated effectively by relatively small, targeted sales forces. In June 2009, we received FDA approval for Caldolor, our lead product for use in the hospital market. In addition to Caldolor, we market and sell Acetadote and Kristalose through our dedicated hospital and gastroenterology sales forces, which together comprise 66 sales representatives and managers as of July 1, 2009. For the years 2006, 2007 and 2008, our net revenue was $17.8 million, $28.1 million and $35.1 million, respectively, and our net income was $4.4 million, $4.0 million and $4.8 million, respectively.

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 five years. 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.

OUR PRODUCTS

Our key products include:

Product	Indication	Delivery	Status
Caldolor™	Pain and Fever	Injectable	FDA Approved
Acetadote®	Acetaminophen Poisoning	Injectable	Marketed
Kristalose®	Chronic and Acute Constipation	Oral Solution	Marketed

Caldolor, our intravenous formulation of ibuprofen, is the first injectable product approved in the United States for the treatment of both pain and fever. To support Caldolor s regulatory approval, we completed a comprehensive clinical program, which culminated in an NDA filing in December 2008. We received FDA approval to market Caldolor in the United States in June 2009. We plan to promote Caldolor in the United States through a dedicated hospital sales force of 77 experienced representatives and managers and internationally through alliances with marketing partners. We are currently preparing for the commercial launch of Caldolor in the United States, which we expect to initiate in the fourth quarter of 2009. We believe Caldolor represents our most significant market

opportunity to date.

According to IMS Health, the U.S. market for injectable analgesics, or pain relievers, exceeded $332 million, or 681 million units, in 2008. 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 2004, or 5% of the market, to approximately 46 million units in 2008, or 7% of the market, according to IMS Health. Injectable opioids such as morphine and meperidine accounted for approximately 635 million units sold in 2008. While opioids

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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 Caldolor represents a potentially safer alternative to ketorolac, the only non-opioid injectable pain relief drug available in the U.S. Caldolor is the only approved injectable treatment for fever in the U.S.

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

NAC is accepted worldwide as the standard of care for treating acetaminophen overdose, which is well-documented and is supported by a 2005 article in volume 17 of *Current Opinion in Pediatrics*. Until our 2004 launch of Acetadote, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Medical literature suggests that, for a number of patients, IV treatment is the only reasonable route of administration due to nausea and vomiting associated with the administration of oral NAC for acetaminophen overdose. Sales of Acetadote have increased consistently since we launched the product in June 2004. According to Wolters Kluwer Health Source[tm] Pharmaceutical Audit Suite, Acetadote sales to hospitals grew 33% from 2007 to 2008. Total sales to hospitals in 2008 were $24.3 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 Caldolor.

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 $269 million in 2004 to $344 million in 2008, representing a compound annual growth rate of 6%. Wholesaler sales of Kristalose to pharmacies were $9.4 million in 2008. In April 2006, we acquired exclusive U.S. commercialization rights to Kristalose, subsequently assembling a dedicated field sales force and re-launching the product in September 2006 under the Cumberland brand. We believe that we can increase market share for Kristalose given its many positive, competitive attributes including better taste, consistency, ease of use and cost relative to competing products.

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

OUR COMPETITIVE STRENGTHS

We believe our key competitive strengths include the following:

Ø A significant product opportunity in Caldolor;

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;

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.

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OUR STRATEGY

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

- Successfully launch and commercialize Caldolor;
- Maximize sales of our marketed products, Acetadote and Kristalose;
- Expand our product portfolio by acquiring rights to additional marketed products and late-stage product candidates;
- Expand our dedicated hospital and gastroenterology sales forces; and
- Develop a pipeline of early-stage products through CET, our majority-owned subsidiary.

RISKS AFFECTING US

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

- The commercial launch of Caldolor is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely affected;
- The FDA has approved Caldolor as a treatment for the reduction of pain and fever in adults in the U.S. and any attempt by us to expand the potential market for Caldolor is subject to limitations;
- Sales of Acetadote and Kristalose currently generate almost all of our revenues. An adverse development regarding either of these products could have a material and adverse impact on our future revenues and profitability;
- If any manufacturer we rely upon fails to produce our products and product candidates in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of Caldolor, or may be unable to meet demand for the product supplied by the manufacturer and may lose potential revenues;
- We are dependent on a variety of other third parties. If these third parties fail to perform as we expect, our operations could be disrupted and our financial results could suffer; and
- If we are unable to maintain and build an effective sales and marketing infrastructure, we will not be able to successfully commercialize and grow our products and product candidates.

CORPORATE INFORMATION

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

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The offering

Common stock we are offering	5,000,000 shares
Common stock to be outstanding after this offering	17,091,191 shares
Fully diluted common stock to be outstanding after this offering	23,617,523 shares
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $89.1 million, or approximately $103.1 million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of $20.00 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 the commercial introduction of Caldolor, as well as additional development of that product. We may also use the proceeds from this offering to expand operations, including expansion of our sales forces, for reduction of bank debt and for general corporate purposes.
Proposed Nasdaq Global Market Symbol	CPIX

Common stock to be outstanding after this offering is based on 12,091,191 shares outstanding as of March 31, 2009 and excludes:

- 6,550 shares of unvested restricted common stock;
- 7,207,247 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of $2.04 per share;
- 68,958 shares of common stock issuable upon exercise of outstanding warrants at a weighted- average exercise price of $6.17 per share;
- 2,361,322 shares of common stock reserved for future issuance under our current incentive plans; and
- 2,924,769 net shares issued in connection with the expected Option Transaction as described in the section entitled Certain relationships and related party transactions.

Fully diluted common stock to be outstanding after this offering represents the sum of the 17,091,191 shares to be outstanding after this offering, 6,550 shares of unvested restricted stock and the 7,276,205 shares of common stock issuable upon exercise of options and warrants outstanding as of March 31, 2009 of which we have received notice that 4,377,090 options will be exercised immediately prior to this offering pursuant to the Option Transaction. The number of outstanding options and warrants is reduced by the 756,423 shares of common stock that could theoretically be repurchased with the approximately $15.1 million in aggregate exercise price of such options and warrants at a repurchase price equal to the assumed initial public offering price of $20.00 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, 2009 and has been adjusted to reflect or assume the following:

Ø the conversion of all outstanding shares of our preferred stock into 1,625,498 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 income and balance sheet data below gives effect to the conversion of 812,749 shares of our preferred stock into 1,625,498 shares of common stock. The pro forma as adjusted balance sheet data below gives further effect to the sale of 5,000,000 shares of common stock that we are offering at an assumed initial public offering price of $20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	Years Ended December 31,			Three Months Ended March 31,	
Statement of income data:	**2006**	**2007**	**2008**	**2008**	**2009**
	(in thousands, except per share data)			**(unaudited)**	
Net revenues:					
Acetadote	$ 10,722	$ 18,817	$ 25,439	$ 5,799	$ 7,133
Kristalose	6,511	9,013	9,469	2,478	2,229
Other[1]	582	234	167	26	43
Total net revenues[2]	$ 17,815	$ 28,064	$ 35,075	$ 8,304	$ 9,405
Operating income	$ 2,224	$ 6,725	$ 7,282	$ 1,794	$ 2,117
Net income before income taxes	1,708	6,469	7,310	1,762	2,037
Net income attributable to common shareholders	4,404	4,044	4,766	1,395	1,218
Earnings per share attributable to common shareholders basic	$ 0.45	$ 0.40	$ 0.47	$ 0.14	$ 0.12
Earnings per share attributable to common shareholders diluted	$ 0.27	$ 0.24	$ 0.29	$ 0.09	$ 0.08
Pro forma earnings per share attributable to common shareholders basic			$ 0.41		$ 0.10
Pro forma earnings per share attributable to common shareholders diluted			$ 0.29		$ 0.08
Weighted-average shares outstanding basic	9,797	10,032	10,143	10,094	10,321
Weighted-average shares outstanding diluted	16,454	16,582	16,540	16,412	16,127
Pro forma weighted-average shares outstanding basic			11,768		11,947
Pro forma weighted-average shares outstanding diluted			16,540		16,127

	As of March 31, 2009

Balance sheet data:	Actual	Pro Forma	Pro Forma as Adjusted[3]
		(in thousands) (unaudited)	
Cash and cash equivalents	$ 10,072	$ 10,072	$ 95,006
Working capital	11,262	11,262	97,029
Total assets	30,986	30,986	115,919
Total long-term debt and other long-term obligations (including current portion)[4]	7,261	7,261	3,094
Convertible preferred stock	2,604		
Retained earnings	2,669	2,669	2,669
Total equity	18,452	18,452	107,552

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

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $20.00 per share would increase or decrease, as applicable, our cash and cash equivalents, working capital, total assets and total shareholders equity by approximately

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$4.7 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. These amounts exclude adjustments related to the expected Option Transaction as described in the section entitled Certain relationships and related party transactions. If these adjustments were included and if the shares to be repurchased in the first quarter of 2010 were repurchased on March 31, 2009 at the offering price of $20.00 per share, then as of March 31, 2009, cash and cash equivalents would have been $81,275, working capital would have been $81,798, total assets would have been $132,311, total long-term debt and other long-term obligations (including current portion) would have been $21,094, and total equity would have been $105,944. These amounts exclude the effect of payment of the exercise price of approximately $2.4 million which may be settled in cash or tender of 119,670 shares (assuming an offering price of $20.00 per share).

(4) In connection with this offering, we will use part of the proceeds to repay approximately $4.2 million of the term loan. As of March 31, 2009, the term loan balance was $5.0 million. Subsequent to March 31, 2009, we have paid approximately $0.8 million of the term loan during the normal course of business.

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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 other 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

The commercial launch of Caldolor is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.

We are dependent on Caldolor for a substantial portion of our future growth. While Caldolor was approved by the U.S. Food and Drug Administration, or FDA, in June 2009, we have not commercialized Caldolor in any jurisdiction. The successful commercial launch of Caldolor is dependent on our ability to coordinate large-scale supply, distribution, marketing, sales and education efforts. We cannot assure you that we will be able to successfully commercialize Caldolor on our current timeline or at all.

Internally, the successful launch of Caldolor will depend on our ability to recruit, train and retain a qualified sales force, to equip our sales force with effective supportive materials, to target appropriate markets and to accurately price Caldolor. As of July 1, 2009, our hospital sales force was comprised of 30 representatives and managers, but none of these has ever sold Caldolor before. We are planning, and have begun, to add additional representatives to be able to effectively launch Caldolor. In addition, as Caldolor is a newly marketed drug, our sales force will need to be sufficiently trained, credible and persuasive in order to convince physicians and pharmacists in target markets to use Caldolor. Finally, we will need to train our sales force to ensure that a consistent and appropriate message about Caldolor is being delivered to physicians and pharmacists. If we are unable to add enough new sales force representatives, if we are unable to add sufficiently qualified representatives, or if we are not able to effectively train our sales force, our ability to successfully launch Caldolor could be jeopardized. We must also equip our sales force with effective materials, including clinical papers, sales literature and formulary kits, to help them inform and educate physicians and pharmacists about the benefits and risks of Caldolor as well as the proper administration of the drug. If we are unable to provide our sales force with convincing supportive materials, they may not be able to sell Caldolor in sufficient quantities or at all. We must also ensure that we maximize our sales efforts for Caldolor by targeting the right hospitals across the U.S. Any failure in sales force coverage could limit our ability to generate market acceptance for Caldolor and ultimately, the successful commercialization of the drug. Finally, we must set a price for Caldolor that hospitals and other purchasers will be willing to pay, but that will also generate sufficient profits. If we set a price for Caldolor that hospitals consider too high, we may need to subsequently reduce the price for Caldolor. If we set the initial price for Caldolor too low, we may not generate adequate profits and may not be able to raise the price of the drug in the future.

In addition to the extensive internal efforts required, the successful launch of Caldolor will require the assistance of many third-parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P&T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to be administered primarily to hospitalized patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can attempt to sell Caldolor in hospitals, Caldolor must be approved for addition to a hospital s formulary list by the hospital s P&T committee. A hospital s P&T committee generally governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations

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Risk factors

of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly for its commercialization to be successful. Because Caldolor is a new drug with little track record, any mistakes made in the timely supply of Caldolor, education about how to properly administer Caldolor or any unexpected side effects that develop from use of the drug, particularly early in product launch, may lead physicians to not accept Caldolor as a viable treatment alternative. Similar to physicians, our ability to sell Caldolor to pharmacists will depend on price and education efforts, and the lack of a track record for Caldolor could magnify any delays in delivery or side effects of the drug and prevent widespread pharmacist acceptance of Caldolor.

The FDA has approved Caldolor as a treatment for the reduction of pain and fever in adults in the U.S. and any attempt by us to expand the potential market for Caldolor is subject to limitations.

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

In addition, we have only obtained regulatory approval to market Caldolor in the U.S. In foreign jurisdictions such as Canada and Australia we have licensed the right to market Caldolor to third parties. These third parties are responsible for seeking regulatory approval for Caldolor in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for Caldolor will ever be obtained outside the U.S.

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;

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Risk factors

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 Caldolor, 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. As Caldolor is a new product, the effect of any delays or failure to deliver could be magnified due to the lack of a track record for Caldolor with physicians and pharmacists. In either event, we may 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.

Caldolor is manufactured at Hospira Australia Pty. Ltd. s facility in Australia and Bayer s facility in Kansas. Acetadote is manufactured primarily at a facility in Ireland and Bayer s manufacturing plant in Kansas is an alternative manufacturing source for Acetadote. The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy. If any one of these facilities is damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our products. Kristalose is manufactured through a complex process 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.

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Risk factors

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:

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

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.

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. For example, in connection with the commercial launch of Caldolor, we expect we will need to add approximately 47 new hospital sales representatives, and we may not be able to hire these representatives in accordance with our timeline. 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:

- we may not be able to increase our product revenue;
- we may generate increased expenses; and
- we may not continue to be profitable.

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

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

- Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which warehouses and ships our marketed products;

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

- 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 market launch of Caldolor or any future product candidate, increase our operating expenses or otherwise adversely affect our operating results.

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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. We have an exclusive patent license that gives us limited protection against direct competition for Kristalose. Acetadote competes domestically with several orally administered prescription products for treating acetaminophen overdose. We are aware of products under development which could compete with Caldolor, including an intravenous acetaminophen product for which Cadence Pharmaceuticals Inc. recently submitted a new drug application to the FDA and for which the FDA granted a priority review.

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 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 Caldolor, 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 Caldolor, 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;

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- Ø incurring higher than expected acquisition and integration costs;
- Ø assuming or otherwise being exposed to unknown liabilities;
- Ø developing or integrating new products that could disrupt our business and divert our management s time and attention;
- Ø not being able to preserve key suppliers or distributors of any acquired products;
- Ø incurring substantial debt or issuing dilutive securities to pay for acquisitions; and
- Ø acquiring products that could substantially increase our amortization expenses.

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

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

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.

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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.

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

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

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 1, 2009, we had 59 full-time employees, which includes 30 hospital sales force representatives and managers. In connection with the commercial launch of Caldolor, we expect to add an additional 47 hospital sales force 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, including Caldolor. 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.

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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.

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.

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

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

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

RISKS RELATING TO GOVERNMENT REGULATION

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

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

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

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

Under the FDC Act, the federal government has extensive enforcement powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to, the authority to initiate court action to seize unapproved or non-complying products, to enjoin non-complying activities, to halt manufacturing operations that are not in compliance with cGMP, and to seek civil monetary and criminal penalties.

The initiation of any of these enforcement

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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.

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 for Caldolor, 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 Caldolor. Additionally, the active ingredient in Caldolor 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 Caldolor. Upon receipt of FDA approval in June 2009, we received three-years

of marketing exclusivity for Caldolor.

Kristalose is manufactured under a contract with Inalco, which owns U.S. Patent No. 5,480,491, related to the manufacture of Kristalose. This patent is not directed to the composition or use of Kristalose and does not prevent a competitor from developing a formulation and developing and seeking FDA approval for a product that competes with Kristalose.

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Risk factors

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.

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

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

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

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

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

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

Under an agreement between us and Vanderbilt University, we have received certain clinical data to support regulatory approval for Caldolor. Either we or Vanderbilt may terminate this agreement upon substantial breach of the agreement if the breach is not cured within 45 days following written notice. If

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our agreement with Vanderbilt were terminated, we would lose our right to use the data, and this loss might hinder our ability to commercialize Caldolor 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:

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

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

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

Our total assets include intangible assets related to our acquisitions. As of March 31, 2009, intangible assets relating to product and data acquisitions represented approximately 27% 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.

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

We were incorporated in 1999 and incurred operating losses until 2004. We recorded our first year of profitability in 2004 and have remained profitable in each of 2005, 2006, 2007 and 2008. As of March 31, 2009, we had retained earnings of $2.7 million, representing the amount by which our historical profits have exceeded our historical losses. We may not be able to maintain or improve our current levels of revenue or net income. In such event, investors are likely to lose confidence in our ability to grow, and our stock price would suffer.

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 $14.16 per share, based on an assumed initial public offering price of $20.00 per share;

Ø contribute 85.9% of the total amount invested to date to fund our company based on an assumed initial offering price to the public of $20.00 per share;

Ø but will own only 29.3% 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 7,276,205 shares of common stock or the vesting of 6,550 shares of restricted stock, of which we have received notice that 4,377,090 options will be exercised immediately prior to this offering. 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.

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

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

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

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

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

We will have broad discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering to acquire new products and product candidates, to fund continued development of Caldolor as well as other research, marketing and development activities, and to fund working capital, capital expenditures, reduction of bank debt and other general corporate purposes. 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.

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Risk factors

In addition, the sale of these shares in the public market could impair our ability to raise capital through the sale of additional common or preferred stock. After this offering, we will have 17,091,191 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.

Some provisions of our third 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 restriction prohibiting shareholders from removing directors without cause;
- 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 third amended and restated charter and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our shareholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of shareholders to remove our current management or approve transactions that our shareholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

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 in control of us and therefore could discourage attempts to acquire our company. For more information, see Description of capital stock Anti-takeover effects of Tennessee law and provisions of our charter and bylaws.

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

Holders of our preferred stock have rights to be included in registration statements we file with the U.S. SEC. These rights could interfere with our ability to raise capital. To the extent that these rights might have applied to this offering, we have obtained waivers from preferred holders for all but approximately 1% of our shares to be outstanding after this offering. We do not believe that these rights apply to this offering, although the non-waiving parties might claim otherwise.

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Special note regarding forward-looking statements

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

- legislative, regulatory or other changes in the healthcare industry at the local, state or federal level which increase the costs of, or otherwise affect our operations;
- changes in reimbursement available to us by government or private payers, including changes in Medicare and Medicaid payment levels and availability of third-party insurance coverage;
- competition; and
- changes in national or regional economic conditions, including changes in interest rates and availability and cost of capital to us.

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Use of proceeds

We estimate that the net proceeds to us from the sale of the 5,000,000 shares of common stock offered hereby will be approximately $89.1 million, assuming an initial public offering price of $20.00, 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 $103.1 million. Each $1.00 increase (decrease) in the assumed initial public offering price of $20.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $4.7 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 $3.1 million for ongoing clinical work, product development and other costs related to Caldolor;

Ø approximately $8.4 million for expected commercial introduction of Caldolor to the U.S. market;

Ø approximately $6.6 million for expansion of our hospital sales force to a total of approximately 77 representatives and managers;

Ø approximately $4.2 million for repayment of the term loan under our Third Amended and Restated Loan Agreement with Bank of America;

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

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

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

The amounts we actually expend for the above-specified purposes may vary depending on a number of factors, including the extent of our success in identifying and completing acquisitions, changes in our business strategy, the amount of our future revenues and expenses and our future cash flow. If our

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Use of proceeds

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.

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, 2009:

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 1,625,498 shares of common stock; and

Ø on a pro forma as adjusted basis to give further effect to the sale of 5,000,000 shares of common stock that we are offering at an assumed initial public offering price of $20.00 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, 2009		
	Actual	Pro Forma	Pro Forma as Adjusted[1]
	(in thousands)		
Cash and cash equivalents	$ 10,072	$ 10,072	$ 95,006
Long-term debt and long-term obligations (less current portion)	$ 5,545	$ 5,545	$ 2,212
Shareholders equity:			
Convertible preferred stock, no par value; 3,000,000 shares authorized, 812,749 shares issued and outstanding, actual; and 3,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted[2]	2,604		
Common stock, no par value; 100,000,000 shares authorized, 10,465,693 shares issued and outstanding, actual; 100,000,000 shares authorized, 12,091,191 shares issued and outstanding, pro forma; and 100,000,000 shares authorized, 17,091,191 shares issued and outstanding, pro forma as adjusted[3]	13,191	15,795	104,895
Retained earnings	2,669	2,669	2,669
Total shareholders equity	18,464	18,464	107,564
Noncontrolling interests	(12)	(12)	(12)
Total equity[4]	18,452	18,452	107,552
Total capitalization[4]	$ 23,997	$ 23,997	$ 109,764

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $20.00 per share would increase or decrease, as applicable, the amount of cash and cash equivalents, total shareholders equity, total equity and total capitalization by approximately $4.7 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. These amounts exclude adjustments related to the expected Option Transaction as described in the section entitled Certain relationships and related party transactions. If these adjustments were included and if the shares to be repurchased in the first quarter of 2010 were repurchased on March 31, 2009 at the offering price of $20.00 per share, then as of March 31, 2009, cash and cash equivalents would have been $81,275, long-term debt and long-term obligations (less current portion) would have been $18,712, common stock outstanding would have been 19,939,520 shares, common stock (in dollars) would have been $104,442, retained earnings would have been $1,513, total shareholders equity would have been $105,956, total equity would have been $105,944, and total capitalization would have been $124,655. These amounts exclude the effect of payment of the exercise price of approximately $2.4 million which may be settled in cash or tender of 119,670 shares (assuming an offering price of $20.00 per share).

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

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Capitalization

(3) Excludes:

- Ø 6,550 shares of unvested restricted common stock;
- Ø 7,207,247 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of $2.04 per share for which we have received notice that, upon the pricing of this offering, certain holders will exercise options to purchase an aggregate of 4,377,090 shares and that they are electing to use a net-share settlement that permits option holders to use 1,452,321 shares acquired upon exercise to satisfy their minimum statutory withholding requirements of approximately $29.0 million;
- Ø 2,361,322 shares of common stock reserved for future issuance under our current incentive plans;
- 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; and
- Ø 10,000 shares of common stock issuable to a research institution as a result of FDA approval of Caldolor.

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

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Dilution

Our net tangible book value as of March 31, 2009 was $10.7 million, or $1.02 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, 2009 was $0.89. Pro forma net tangible book value per share gives effect to the conversion of all of our preferred stock into 1,625,498 shares of our common stock, which will occur upon completion of this offering.

After giving further effect to the sale by us of 5,000,000 shares of common stock in this offering at an assumed initial public offering price of $20.00 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, 2009 would have been approximately $99.8 million, or approximately $5.84 per share. This amount represents an immediate increase in pro forma net tangible book value of $4.95 per share to our existing shareholders and an immediate dilution in pro forma net tangible book value of approximately $14.16 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		$ 20.00
Net tangible book value per share as of March 31, 2009	$ 1.02	
Effect on net tangible book value per share on conversion of preferred stock into common stock	(0.13)	
Pro forma net tangible book value per share as of March 31, 2009	0.89	
Increase per share attributable to this offering	4.95	
Pro forma as adjusted net tangible book value per share after this offering		5.84
Dilution per share to new investors		$ 14.16

A $1.00 increase (decrease) in the assumed initial public offering price of $20.00 per share would increase (decrease) our pro forma as adjusted net tangible book value as of March 31, 2009 by approximately $4.7 million, the pro forma as adjusted net tangible book value per share after this offering by $0.27 and the dilution in pro forma as adjusted net tangible book value to new investors in this offering by $0.73 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

In addition, the above discussion and table do not account for the vesting of 6,550 shares of restricted stock or the exercise of stock options and warrants after March 31, 2009. As of March 31, 2009, we had outstanding options to purchase a total of 7,207,247 shares of common stock at a weighted-average exercise price of $2.04 per share and outstanding warrants to purchase a total of 68,958 shares of common stock at a weighted-average exercise price of $6.17 per share. If all such options and warrants had been exercised and the restricted stock had vested as of March 31, 2009, pro forma as adjusted net tangible book value per share, exclusive of the expected future tax benefit

(deferred tax asset) of approximately $40.0 million arising from the exercise of certain options, would have been $4.72 per share, and dilution to new investors would have been $15.28 per share. We have received notice that, upon the closing of this offering, in connection with the Option Transaction as described in the section Certain relationships and related party transactions , certain holders will exercise options to purchase 4,377,090 of these shares using a net-share settlement providing for the option holders to use

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Dilution

1,452,321 shares acquired upon exercise to satisfy the minimum statutory withholding requirements of approximately $29.0 million.

The following table summarizes, as of March 31, 2009, the differences between the number of shares purchased from us, the total consideration paid to us and the average price per share that existing shareholders and new investors paid. The table gives effect to the conversion of all of our outstanding preferred stock into 1,625,498 shares of common stock, which will occur upon completion of this offering. The calculation below is based on an assumed initial public offering price of $20.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, and before deducting underwriting discounts and commissions and estimated offering expenses that we must pay.

	Total Shares		Total Consideration		Average Price per Share
	Number	%	Number	%	
Existing shareholders	12,091,191	70.7%	$ 16,425,468	14.1%	$ 1.36
New investors	5,000,000	29.3%	100,000,000	85.9%	20.00
Total	17,091,191	100.0%	$ 116,425,468	100.0%	

Assuming that the 6,550 shares of restricted stock had vested, that all options and warrants outstanding as of March 31, 2009 had been exercised for 7,276,205 shares of common stock, and the aggregate exercise price of approximately $15.1 million had been applied to repurchase 756,423 shares of common stock (at a repurchase price equal to the assumed initial public offering price of $20.00 per share, which is the midpoint of the range listed on the cover page of this prospectus), new investors would have purchased 21.2% of our shares of common stock outstanding after this offering.

A $1.00 increase (decrease) in the assumed initial public offering price of $20.00 per share would increase (decrease) total consideration paid to us by investors participating in this offering by approximately $4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The discussion and tables above assume no exercise of the underwriters over-allotment option. If the underwriters over-allotment option is exercised in full (but assuming no exercise of outstanding options or warrants or vesting of restricted stock), the number of shares of common stock held by existing shareholders would be reduced to 67.8% 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 32.2% 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 income data for the years ended December 31, 2006, 2007 and 2008 and consolidated balance sheet data as of December 31, 2007 and 2008 are derived from consolidated financial statements audited by KPMG LLP and are included elsewhere in this prospectus. The consolidated statements of income data for the years ended December 31, 2004 and 2005 and the consolidated balance sheet data as of December 31, 2004, 2005 and 2006 have been derived from our audited consolidated financial statements that do not appear in this prospectus. The consolidated statements of income data for the three months ended March 31, 2008 and 2009 and the consolidated balance sheet data as of March 31, 2009 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.

	Years Ended December 31,					Three months Ended March 31,	
Statement of income data[1]:	**2004**	**2005**	**2006**	**2007**	**2008**	**2008**	**2009**
	(in thousands, except per share data)						
Net revenues	$ 12,032	$ 10,690	$ 17,815	$ 28,064	$ 35,075	$ 8,304	$ 9,405
Operating costs and expenses:							
Cost of products sold	816	533	2,399	2,670	3,046	755	733
Selling and marketing	6,802	5,647	7,349	10,053	14,387	3,364	4,140
Research and development	746	1,158	2,233	3,694	4,429	1,110	770
General and administrative	2,358	2,588	2,999	4,138	5,140	1,083	1,445
Amortization of product license rights			515	687	687	172	172
Other	6	13	96	97	104	26	27
Total operating costs and expenses	10,729	9,940	15,592	21,338	27,793	6,510	7,288
Gain on insurance recovery	266						
Operating income	1,569	750	2,224	6,725	7,282	1,794	2,117
Interest income	1	89	209	383	241	82	18
Interest expense	(1,012)	(63)	(722)	(640)	(213)	(114)	(98)
Other expense		(6)	(3)				

