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

Table of Contents

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

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

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

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

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

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

A.J. Kazimi
Chairman and CEO
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.

Table of Contents

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

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION February 18, 2009

6,250,000 Shares

Common Stock

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

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

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

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

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

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

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

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

Morgan Joseph

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

TABLE OF CONTENTS

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

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

Table of Contents

Prospectus summary

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

OUR COMPANY

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

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

OUR PRODUCTS

Our key products and product candidates include:

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

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

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

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

Table of Contents

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

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

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

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

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

OUR COMPETITIVE STRENGTHS

We believe our key competitive strengths include the following:

Ø A significant late-stage product opportunity in Amelior;

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

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

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.

Table of Contents

OUR STRATEGY

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

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

RISKS AFFECTING US

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

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

CORPORATE INFORMATION

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

Table of Contents

The offering

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

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

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

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

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

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

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

Table of Contents

Summary consolidated financial data

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

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

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

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

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

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

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

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

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

Table of Contents

Risk factors

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

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

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

6

Table of Contents

Risk factors

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

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

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

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

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

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

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

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

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

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

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

If demand for either Acetadote or Kristalose weakens, our revenues and profitability will likely decline.

Known adverse effects of our marketed products are documented in product labeling, including the product package inserts, medical information disclosed to medical professionals, and all marketing related materials. No unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products. The most frequently reported adverse events attributed to Acetadote include rash, urticaria (hives) and pruritus (itching), and anaphylactoid reactions. The most frequently reported adverse events attributed to Kristalose, and reported to us, include flatulence and nausea.

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

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

We do not manufacture any of our products or product candidates, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of products could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to sell our products as planned. Furthermore, if we encounter delays or difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected. In either event, we may

Table of Contents

Risk factors

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

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

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

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

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

Ø fines and civil penalties;

Ø suspension of production or distribution;

Ø suspension or delay in product approval;

Ø product seizure or recall; and

Ø withdrawal of product approval.

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

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

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

Table of Contents

Risk factors

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

Ø Vanderbilt University and the Tennessee Technology Development Corporation, co-owners with us of Cumberland Emerging Technologies, Inc., or CET, and the universities that collaborate with us in connection with CET s research and development programs.

If these third parties do not continue to provide services to us, or collaborate with us, we might not be able to obtain others who can serve these functions. This could disrupt our business operations, delay completion of clinical trials, regulatory approval and market launch of Amelior or any future product candidate, increase our operating expenses and otherwise adversely affect our operating results.

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

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

As we grow, we may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully market and sell our products. This risk would be accentuated if we acquire products in areas outside of acute care/emergency medicine and gastroenterology, since our sales forces specialize in these areas. If we are unable to expand our sales and marketing capability or any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. If we are unable to establish and maintain adequate sales and marketing capabilities:

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

Ø we may generate increased expenses; and

Ø we may not continue to be profitable.

Competitive pressures could reduce our revenues and profits.

The pharmaceutical industry is intensely competitive. Our strategy is to target differentiated products in specialized markets. However, this strategy does not relieve us from competitive pressures, and can entail distinct competitive risks. For example, a new entrant into a smaller market could have a disproportionately large impact on others in the market. In addition, certain of our competitors do not aggressively promote their products in our markets. A relatively modest increase in promotional activity in our markets could result in large shifts in market share, adversely affecting us.

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

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

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

Table of Contents

Risk factors

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

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

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

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

We acquired rights to Amelior, Acetadote and Kristalose. Our business strategy is to continue to acquire rights to FDA-approved products as well as pharmaceutical product candidates in the late stages of development. We do not plan to conduct basic research or pre-clinical product development, except to the extent of our investment in CET. We have limited resources to acquire third-party products, businesses and technologies and integrate them into our current infrastructure. Many acquisition opportunities involve competition among several potential purchasers including large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. In addition, our bank credit agreement requires that we obtain the consent of the bank prior to making acquisitions unless the acquisitions meet certain criteria. See Management s discussion and analysis of financial condition and results of operations Liquidity and capital resources.

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

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

Ø incurring higher than expected acquisition and integration costs;

Ø assuming or otherwise being exposed to unknown liabilities;

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

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

Ø incurring substantial debt or 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.

Table of Contents

Risk factors

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

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

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

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

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

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

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

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

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

Table of Contents

Risk factors

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

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

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

As of December 31, 2008, we had 49 full-time employees, which includes 22 hospital sales force representatives and district managers. We may need to continue to expand our managerial, operational, financial and other resources in order to increase our marketing efforts with regard to our currently marketed products, continue our business development and product development activities and commercialize our product candidates. We have experienced, and may continue to experience, rapid growth in the scope of our operations in connection with the commercial launch of new products. Our financial performance will depend, in part, on our ability to manage any such growth effectively. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth.

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

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

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

Table of Contents

Risk factors

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products. An individual may bring a liability claim against us if one of our product candidates or products causes, or appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Liability claims may result in:

Ø decreased demand for our products;

Ø injury to our reputation;

Ø withdrawal of clinical trial participants;

Ø significant litigation costs;

Ø substantial monetary awards to or costly settlement with patients;

Ø product recalls;

Ø loss of revenue; and

Ø the inability to commercialize our product candidates.

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

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

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

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

Table of Contents

Risk factors

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

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

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

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

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

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

Ø changes to manufacturing methods;

Ø expanded or different labeling;

Ø recall, replacement or discontinuance of certain products;

Ø additional record keeping; and

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

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

Table of Contents

Risk factors

RISKS RELATING TO INTELLECTUAL PROPERTY

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

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

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

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

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

15

Table of Contents

Risk factors

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

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

Table of Contents

Risk factors

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

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

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

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

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

Table of Contents

Risk factors

RISKS RELATED TO THIS OFFERING AND AN INVESTMENT IN OUR STOCK

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

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

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

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

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

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

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

The market price of our common stock may fluctuate substantially.

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

The realization of any of the risks described in these Risk factors could have a dramatic and material adverse impact on the market price of our common stock. In addition, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such securities litigation brought against us could result in substantial costs and a diversion of management s attention and resources, which could negatively impact our business, operating results and financial condition.

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

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

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

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

Table of Contents

Risk factors

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

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

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

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

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

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

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

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

Table of Contents

Risk factors

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

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

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

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

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

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

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

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

offering, we have obtained waivers from 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.

Table of Contents

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.

Table of Contents

Use of proceeds

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

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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.

Table of Contents

Capitalization

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

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

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

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

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

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

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

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

(4) Excludes:

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

Table of Contents

Dilution

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

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

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

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

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

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

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

Table of Contents

Dilution

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

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

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

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

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

Table of Contents

Selected consolidated financial data

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

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

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

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

Table of Contents

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

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

OVERVIEW

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

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

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

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

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

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

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

Table of Contents

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

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

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

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Accounting Estimates and Judgments

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

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

Revenue Recognition

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

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

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

30

Table of Contents

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

The following table reflects our sales-related accrual activity:

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

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

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

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

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

Table of Contents

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

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

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

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

Income Taxes

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

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

Stock-Based Compensation

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

(1) Calculated as of December 31, 2008

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

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

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

	2006	2007	2008

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

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

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

Table of Contents

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

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

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

Research and Development

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

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

Intangible Assets

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

Table of Contents

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

RESULTS OF OPERATIONS

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

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

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

Description of operating accounts

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

towards completing the studies of Amelior. We expect

Table of Contents

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

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

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

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

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

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

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

LIQUIDITY AND CAPITAL RESOURCES

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

OFF-BALANCE SHEET ARRANGEMENTS

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

RECENT ACCOUNTING PRONOUNCEMENTS

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

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

Table of Contents

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

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

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

RECENTLY ADOPTED ACCOUNTING STANDARDS

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

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

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

Table of Contents

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

QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISKS

Interest Rate Risk

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

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

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

Exchange Rate Risk

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

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

Table of Contents

Business

OVERVIEW

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

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

Our key products and product candidates include:

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

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

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

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

Table of Contents

Business

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

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

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

OUR COMPETITIVE STRENGTHS

Significant late-stage product opportunity in Amelior

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

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

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

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

Table of Contents

Business

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

Focus on underserved niche markets

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

Profitable business with a history of fiscal discipline

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

Integrated specialty pharmaceutical company with extensive management expertise

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

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

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

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

Table of Contents

Business

OUR STRATEGY

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

Successfully develop and commercialize Amelior, our lead product candidate

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

Maximize sales of our marketed products

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

Expand sales force operations

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

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

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

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

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

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

Table of Contents

Business

Develop a pipeline of early-stage products through CET

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

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

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

INDUSTRY

The hospital market

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

Market for injectable analgesics

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

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

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

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

Table of Contents

Business

Fever

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

Acetaminophen poisoning

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

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

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

Market for the treatment of Acetaminophen overdose

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

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

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

Table of Contents

Business

The gastrointestinal market

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

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

Prescription laxative market

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

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

PRODUCTS

Our key products and product candidates include:

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

Amelior

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

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

Table of Contents

Business

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

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

Development history

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

Business

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

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

Commercialization strategy

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

Acetadote

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

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

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

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

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

Table of Contents

Business

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

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

Kristalose

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

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

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

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

Early-stage product candidates

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

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

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

Table of Contents

Business

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

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

BUSINESS DEVELOPMENT

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

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

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

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

Ø exclusive U.S. commercial rights to Kristalose.

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

Ø Vanderbilt University;

Ø University of Mississippi, School of Pharmacy; and

Ø University of Tennessee Research Foundation.

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

CLINICAL AND REGULATORY AFFAIRS

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

Table of Contents

Business

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

Clinical development

Our in-house clinical development personnel are responsible for:

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

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

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

Professional and medical affairs

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

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

SALES AND MARKETING

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

Table of Contents

Business

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

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

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

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

International Sales and Marketing

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

Table of Contents

Business

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

MANUFACTURING AND DISTRIBUTION

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

Manufacturing

Our key manufacturing relationships include:

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

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

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

58

Table of Contents

Business

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

Distribution

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

INTELLECTUAL PROPERTY

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

Amelior

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

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

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

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

Acetadote

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

Table of Contents

Business

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

Kristalose

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

COMPETITION

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

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

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

Amelior

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

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

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

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

Table of Contents

Business

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

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

In addition to the injectable analgesic products above, many companies are developing analgesics for specific indications such as migraine and neuropathic pain, oral extended-release forms of existing narcotic and non-narcotic products, and products with new methods of delivery such as transdermal.

We are not aware of any approved injectable products indicated for the treatment of fever in the U.S. There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including acetaminophen, ibuprofen and aspirin. These drugs are manufactured by numerous pharmaceutical companies.

Acetadote

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

Kristalose

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

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

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

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

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

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

EMPLOYEES

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

Table of Contents

Business

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

FACILITIES

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

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

GOVERNMENT REGULATION

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

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

FDA Approval Process

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

Ø completion of pre-clinical laboratory and animal testing;

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

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

- Ø submission and approval of a NDA.

Table of Contents

Business

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

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

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

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

Section 505(b)(2) New Drug Applications

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

Table of Contents

Business

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

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

Special Protocol Assessment Process

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

On June 14, 2004, we submitted a request for SPA of our Amelior Phase III clinical study. During a meeting with the FDA on September 29, 2004, the FDA confirmed that the efficacy data from our study of post-operative pain with a positive outcome will be considered sufficient to support a 505(b)(2) application for the pain indication. Final determinations by the FDA with respect to a product candidate, including as to the scope of its labeling , are made after a complete review of the applicable NDA and are based on the entire data in the application. Moreover, notwithstanding any SPA, FDA approval of an NDA is subject to future public health concerns unrecognized at the time of protocol assessment.

Orphan Drug Designation

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

The Hatch-Waxman Act

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

Table of Contents

Business

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

Other regulatory requirements

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

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

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

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

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

LEGAL PROCEEDINGS

We are not currently engaged in any legal proceedings.

Table of Contents

Management

OFFICERS AND DIRECTORS

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

Name	Age	Position
Directors and executive officers:		
A.J. Kazimi	50	Chairman and Chief Executive Officer
Martin E. Cearnal[1]	64	Director and Senior Vice President, Commercial Development
Dr. Robert G. Edwards[2]	81	Director
Dr. Lawrence W. Greer[1],[2]	64	Director
Thomas R. Lawrence[1],[2]	69	Director
Jean W. Marstiller	58	Senior Vice President and Corporate Secretary
Dr. Gordon R. Bernard	57	Senior Vice President and Medical Director
Leo Pavliv		