

July 27, 2009

United States Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549  
Attention: Mr. Jeffrey Riedler

**Re: Cumberland Pharmaceuticals Inc.  
Registration Statement on Form S-1/A, Amendment No. 19  
Filed July 17, 2009  
File No. 333- 142535**

Ladies and Gentlemen:

We are responding to comments received in a letter dated July 23, 2009 from Mr. Jeffrey Riedler to A.J. Kazimi of Cumberland Pharmaceuticals Inc. with respect to Amendment No. 19 to the Registration Statement on Form S-1/A of Cumberland Pharmaceuticals filed July 17, 2009. For your convenience, we have repeated in bold type the comments and requests for additional information exactly as set forth in Mr. Riedler's letter.

The following paragraphs set forth the responses of Cumberland Pharmaceuticals to the comments contained in Mr. Riedler's letter of July 23, 2009. Page references in our responses are to page locations in the attached pages, which are marked to reflect the changes we are making to Amendment 19. In connection with recent developments, we are also attaching pages 3, 45, and II-1, which are marked to reflect changes we are making to Amendment 19.

**Form S-1**

**Summary consolidated financial data, page 5**

- 1. Please expand your disclosure in footnote (3) to show how the pro forma amounts, that give effect to the adjustments related to the expected Option Transaction, are computed. This comment also applies to your disclosure in footnote (1) to the capitalization table.**
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Response: To comply with this comment, the Company plans to amend the disclosure in footnote (3) on the attached pages 5 and 6 to show how the pro forma amounts, that give effect to the adjustments related to the expected Option Transaction, are computed. To further comply with this comment, the Company also plans to amend the disclosure in footnote (1) to the Capitalization Table on the attached pages 26 and 27 in order to show how the pro forma amounts, that give effect to the adjustments related to the expected Option Transaction, are computed.

**Use of Proceeds, page 24**

- 2. We note your disclosure that you will use \$4.2 million for the repayment of your term loan under your loan agreement with Bank of America. Please revise the discussion of the use of proceeds to clarify that you will enter into a new loan agreement with Bank of America for \$18 million of term debt and a \$4 million credit facility and that the proceeds of this loan will be used to pay a portion of the \$29.0 million minimum statutory tax withholding requirements relating to the option exercises by Mr. Kazimi and Ms. Marsteller.**

Response: To comply with this comment, the Company is revising the description of the repayment on page 24 (see attached) and inserting new descriptions on page 25 (see attached) in order to clarify that the Company has entered into a new loan agreement with Bank of America for \$18 million of term debt and a \$4 million credit facility and that the proceeds of this loan will be used to pay a portion of the \$29.0 million minimum statutory tax withholding requirements relating to the Option Transaction.

**Liquidity and Capital Resources, page 43**

- 3. Please revise to quantify the net proceeds from the option exercises.**

Response: To comply with this comment, the Company is revising the Liquidity and Capital Resources section by inserting additional language on pages 43 and 44 (see attached) in order to quantify the net proceeds from the option exercises.

**Products, page 55**

- 4. Please revise your disclosure relating to p values to explain what these values mean.**

Response: To comply with this comment, the Company is revising its disclosure relating to p values in the Products section in the attached page 58 in order to explain what these values mean.

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**Certain relationships and related party transactions, page 99**

5. Please revise the discussion of each of A.J. Kazimi's and Jean M. Marstiller's exercises to quantify the following information:

- The aggregate option exercise price paid by each individual;
- The number of shares that will be repurchased from each individual, assuming a fair market value at the midpoint of your offering range; and
- The net proceeds to the company from the exercises and repurchases.

Response: To comply with this comment, the Company is revising its discussion of each of A.J. Kazimi's and Jean M. Marstiller's exercises by amending existing language and inserting new language in the Certain Relationships and Related Party Transaction Section on the attached pages 99 and 100 in order to quantify (i) the aggregate option exercise price paid by each individual; (ii) the number of shares that will be repurchased from each individual, assuming a fair market value at the midpoint of the offering range; and (iii) the net proceeds to the Company from the exercises and repurchases.

We would welcome the opportunity to discuss any questions you may have with the Commission staff. I can be reached, at your convenience, at (615) 259-1450. In my absence, please ask to speak with Kolin Holladay.

Sincerely,

**ADAMS AND REESE LLP**

Martin S. Brown, Jr.

MSB/smm

Attachments

cc: Rose Zukin, Esq., United States Securities and Exchange Commission  
Mr. A.J. Kazimi, Cumberland Pharmaceuticals Inc.  
Donald J. Murray, Esq., Dewey & LeBoeuf LLP, Counsel to the underwriters

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## OUR STRATEGY

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

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

## RISKS AFFECTING US

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

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

## RECENT DEVELOPMENTS

Management is in the process of preparing our consolidated financial statements for the quarter ended June 30, 2009. Though our financial statements for that quarter are not yet complete, our preliminary internal financial information indicates that net revenues for the quarter were between \$9.0 million and \$10.0 million, compared to \$8.4 million for the same period in the prior year, that operating income for the quarter was between \$0.2 million and \$0.65 million, compared to \$1.8 million for the same period in 2008, and that net income per share was between \$0.01 and \$0.03 (diluted), as compared to \$0.07 (diluted) for the same period during 2008. The increase in net revenue is primarily attributable to growth of Acetadote with modest growth from Kristalose. The decrease in operating income and net income per share is primarily attributable to approximately \$2 million in milestone payments due as a result of the FDA's approval of Caldolor.

Because the second quarter is only recently ended, this information is, by necessity, preliminary in nature and based only upon preliminary information available to us as of the date of this prospectus. Further, developments subsequent to the end of the quarter can impact a reported quarter positively or

negatively. In addition, the financial information for the second quarter has not been subject to a quarterly review by our independent auditors, and therefore, is subject to change. Investors should exercise caution in relying on the information contained herein and should not draw any inferences from this information regarding financial or operating data that is not discussed herein.

## **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](http://www.cumberlandpharma.com). The information on, or accessible through, our website is not part of this prospectus.

### **3.1**

## Summary consolidated financial data

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

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

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

Balance sheet data:	As of March 31, 2009		
	Actual	Pro Forma	Pro Forma as Adjusted(3)
	(in thousands) (unaudited)		
Cash and cash equivalents	\$ 10,072	\$ 10,072	\$ 95,006
Working capital	11,262	11,262	97,029
<b>Total assets</b>	<b>30,986</b>	<b>30,986</b>	<b>115,919</b>
Total long-term debt and other long-term obligations (including current portion)(4)	7,261	7,261	3,094
Convertible preferred stock	2,604	—	—
Retained earnings	2,669	2,669	2,669
<b>Total equity</b>	<b>18,452</b>	<b>18,452</b>	<b>107,552</b>

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

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

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

\$4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. These amounts exclude adjustments related to the expected Option Transaction as described in the section entitled "Certain relationships and related party transactions." If these adjustments were included and if the shares to be repurchased in the first quarter of 2010 were repurchased on March 31, 2009 at an assumed offering price of \$20.00 per share, then as of March 31, 2009:

- Ø Cash and cash equivalents would have been \$81,275. The adjustments include proceeds from the new term debt of \$18.0 million less the payment of approximately \$1.2 million of the employer's portion of payroll-related taxes less the payment of approximately \$29.0 million to repurchase shares of common stock to cover the optionee's minimum statutory tax liability at the time of exercise less the payment of approximately \$1.5 million to repurchase shares of common stock in the first quarter of 2010;
  - Ø Working capital would have been \$81,798. The adjustments include proceeds from the new term debt of \$18.0 million less the amount classified as a current liability of \$1.5 million less the payment of approximately \$1.2 million of the employer's portion of payroll-related taxes less the payment of approximately \$29.0 million to repurchase shares to cover the optionee's minimum statutory tax liability at the time of exercise less the payment of approximately \$1.5 million to repurchase shares of common stock in the first quarter of 2010;
  - Ø Total assets would have been \$132,311. The adjustments include proceeds from the new term debt of \$18.0 million plus the expected creation of approximately \$30.1 in deferred tax assets resulting from the exercise of the stock options less the payment of approximately \$1.2 million of the employer's portion of payroll-related taxes less the payment of approximately \$29.0 million to repurchase shares to cover the optionee's minimum statutory tax liability at the time of exercise less the payment of approximately \$1.5 million to repurchase shares of common stock in the first quarter of 2010;
  - Ø Total long-term debt and other long-term obligations (including current portion) would have been \$21,094. The adjustments include \$18.0 million of new term debt; and
  - Ø Total equity would have been \$105,944. The adjustments include the expected creation of approximately \$30.1 million in deferred tax assets (increase in equity) resulting from the exercise of the stock options less the employer's payroll-related expense of approximately \$1.2 million less the payment of approximately \$29.0 million to repurchase shares to cover the optionee's minimum statutory tax liability at the time of exercise less the payment of approximately \$1.5 million to repurchase shares of common stock in the first quarter of 2010. These amounts exclude the effect of payment of the exercise price of approximately \$2.4 million which may be settled in cash or tender of 119,670 shares (assuming an offering price of \$20.00 per share).
- (4) In connection with this offering, we will use part of the proceeds to repay approximately \$4.2 million of the term loan with Bank of America. As of March 31, 2009, the term loan balance was \$5.0 million. Subsequent to March 31, 2009, we have paid approximately \$0.8 million of the term loan during the normal course of business.

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## Use of proceeds

We estimate that the net proceeds to us from the sale of the 5,000,000 shares of common stock offered hereby will be approximately \$89.1 million, assuming an initial public offering price of \$20.00, which is the midpoint of the range listed on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately \$103.1 million. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$20.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus.

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

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

- ∅ the majority for potential acquisition of rights to additional products or product candidates, as discussed above;
- ∅ approximately \$3.1 million for ongoing clinical work, product development and other costs related to Caldolor;
- ∅ approximately \$8.4 million for expected commercial introduction of Caldolor to the U.S. market;
- ∅ approximately \$6.6 million for expansion of our hospital sales force to a total of approximately 77 representatives and managers;
- ∅ approximately \$4.2 million to pay down our term loan from Bank of America;
- ∅ approximately \$1.0 million for product development by CET, our 85%-owned subsidiary; and
- ∅ 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

## Use of proceeds

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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.

We expect to use approximately \$4.2 million of the net proceeds of this offering to repay our outstanding borrowings under a recently amended term loan agreement with Bank of America. Effective July 2009, we amended our debt agreement with Bank of America to provide for \$18.0 million in term debt and a \$4.0 million revolving credit facility.

We expect to draw down on our amended debt agreement with Bank of America in the third quarter of 2009 in connection with the Option Transaction as described in the section titled "Certain relationships and related party transactions". We expect to use the proceeds from the term debt to pay in part the minimum statutory tax withholding requirements of approximately \$29.0 million due upon completion of the Option Transaction. The consideration for that payment will be the transfer to us of 1,452,321 shares of our common stock. In connection with the Option Transaction, we expect to generate a deferred tax asset of approximately \$30.1 million to offset future tax liabilities.

## 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.

## Capitalization

The following table sets forth our capitalization as of March 31, 2009:

- ∅ 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 5,000,000 shares of common stock that we are offering at an assumed initial public offering price of \$20.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

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

	As of March 31, 2009		
	Actual	Pro Forma	Pro Forma as Adjusted <sup>(1)</sup>
	(in thousands)		
Cash and cash equivalents	\$10,072	\$ 10,072	\$ 95,006
Long-term debt and long-term obligations (less current portion)	\$ 5,545	\$ 5,545	\$ 2,212
Shareholders’ equity:			
Convertible preferred stock, no par value; 3,000,000 shares authorized, 812,749 shares issued and outstanding, actual; and 3,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted <sup>(2)</sup>	2,604	—	—
Common stock, no par value; 100,000,000 shares authorized, 10,465,693 shares issued and outstanding, actual; 100,000,000 shares authorized, 12,091,191 shares issued and outstanding, pro forma; and 100,000,000 shares authorized, 17,091,191 shares issued and outstanding, pro forma as adjusted <sup>(3)</sup>	13,191	15,795	104,895
Retained earnings	2,669	2,669	2,669
Total shareholders’ equity	18,464	18,464	107,564
Noncontrolling interests	(12)	(12)	(12)
Total equity <sup>(4)</sup>	18,452	18,452	107,552
Total capitalization <sup>(4)</sup>	\$23,997	\$ 23,997	\$ 109,764

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$20.00 per share would increase or decrease, as applicable, the amount of cash and cash equivalents, total shareholders’ equity, total equity and total capitalization by approximately \$4.7 million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions payable by us. These amounts exclude adjustments related to the expected Option Transaction as described in the section entitled “Certain relationships and related party transactions.” If these adjustments were included and if the shares to be repurchased in the first quarter of 2010 were repurchased on March 31, 2009 at an assumed offering price of \$20.00 per share, then as of March 31, 2009:

- ∅ Cash and cash equivalents would have been \$81,275. The adjustments include proceeds from the new term debt of \$18.0 million less the payment of approximately \$1.2 million of the employer’s portion of payroll-related taxes less the payment of approximately \$29.0 million to repurchase shares of common stock to cover the optionee’s minimum statutory tax liability at the time of exercise less the payment of approximately \$1.5 million to repurchase shares of common stock in the first quarter of 2010;
- ∅ Total long-term debt and other long-term obligations (less current portion) would have been \$18,712. The adjustments include \$18.0 million of new term debt less \$1.5 million to be classified as a current liability;

## Capitalization

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- Ø Total common stock outstanding would have been 19,939,520. The adjustments include the issuance of 4,377,090 shares from the Option Transaction less 1,452,321 shares tendered in satisfaction of the minimum statutory tax liability due at the time of exercise less 76,440 shares tendered in the first quarter of 2010 in satisfaction of the expected future tax liability associated with the Option Transaction. These adjustments exclude the effect of the potential payment of the exercise price of \$2.4 million, or 119,670 shares using an assumed offering price of \$20.00 per share;
  - Ø Total common stock (in dollars) would have been \$104,442. The adjustments include the expected creation of approximately \$30.1 million in deferred tax assets (increase in equity) resulting from the exercise of the stock options less the repurchase of approximately \$29.0 million of common stock to settle the optionee's minimum statutory tax liability at the time of exercise less the repurchase of approximately \$1.5 million of common stock in the first quarter of 2010;
  - Ø Retained earnings would have been \$1,513. The adjustments include the recognition of approximately \$1.2 million of payroll-related tax expense associated with the exercise of stock options;
  - Ø Total shareholders' equity would have been \$105,956. The adjustments include the expected creation of approximately \$30.1 million in deferred tax assets (increase in equity) resulting from the exercise of the stock options less the employer's payroll-related expense of approximately \$1.2 million less the repurchase of approximately \$29.0 million of common stock to settle the optionee's minimum statutory tax liability at the time of exercise less the repurchase of approximately \$1.5 million of common stock in the first quarter of 2010;
  - Ø Total equity would have been \$105,944. The adjustments include the expected creation of approximately \$30.1 million in deferred tax assets (increase in equity) resulting from the exercise of the stock options less the employer's payroll-related expense of approximately \$1.2 million less the repurchase of approximately \$29.0 million of common stock to settle the optionee's minimum statutory tax liability at the time of exercise less the repurchase of approximately \$1.5 million of common stock in the first quarter of 2010; and
  - Ø Total capitalization would have been \$124,655. The adjustments include the expected creation of approximately \$30.1 million in deferred tax assets (increase in equity) resulting from the exercise of the stock options plus the increase in long-term debt (excluding current portion) of \$16.5 million less the employer's payroll-related expense of approximately \$1.2 million less the repurchase of approximately \$29.0 million of common stock to settle the optionee's minimum statutory tax liability at the time of exercise less the repurchase of approximately \$1.5 million of common stock in the first quarter of 2010.
- (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) Excludes:
- Ø 6,550 shares of unvested restricted common stock;
  - Ø 7,207,247 shares of common stock issuable upon exercise of outstanding options at a weighted-average exercise price of \$2.04 per share for which we have received notice that, upon the pricing of this offering, certain holders will exercise options to purchase an aggregate of 4,377,090 shares and that they are electing to use a net-share settlement that permits option holders to use 1,452,321 shares acquired upon exercise to satisfy their minimum statutory withholding requirements of approximately \$29.0 million;
  - Ø 2,361,322 shares of common stock reserved for future issuance under our current incentive plans;
  - Ø 68,958 shares of common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of \$6.17 per share; and
  - Ø 10,000 shares of common stock issuable to a research institution as a result of FDA approval of Caldolor.
- (4) The sum of the individual amounts may not agree due to rounding.

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

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

*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.

*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 March 31, 2009, cash and cash equivalents was \$10.1 million, working capital was \$11.3 million and our current ratio (current assets to current liabilities) was 2.77 to 1. Management expects funds for our operating and capital requirements will be provided by continuing operations, existing cash balances, and availability under our credit facilities. As of March 31, 2009, we had an additional \$5.7 million available to us on our line of credit. Upon completion of this offering, we expect to have substantial proceeds.

In connection with the Option Transaction as described in the section titled "Certain relationships and related party transactions", effective July 2009, we amended our debt agreement with Bank of America to provide for \$18.0 million in term debt and a \$4.0 million revolving credit facility. We expect to use the proceeds from the term debt to pay in part the minimum statutory tax withholding requirements of approximately \$29.0 million due from option holders who have submitted notice that prior to or at the pricing of this offering, they are exercising options to purchase shares of our common stock. The consideration for that payment will be the transfer to us of 1,452,321 shares of our common stock of the option holders. In connection with the Option Transaction, we expect to generate a deferred tax asset of approximately \$30.1 million to offset future tax liabilities. The aggregate exercise price of the options is approximately \$2.4 million for which payment may be satisfied using cash or 119,670 shares

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

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(using the assumed offering price of \$20.00 per share, which is the midpoint of the range listed on the cover page of this prospectus). We expect the aggregate exercise price to be satisfied by the tendering of shares, resulting in no cash proceeds to us.

The following table summarizes our net changes in cash and cash equivalents for the years ended December 31, 2006, 2007 and 2008 and three months ended March 31, 2008 and 2009:

	Years Ended December 31,			Three Months Ended March 31,	
	2006	2007	2008	2008	2009
	(in thousands)			(unaudited)	
Net cash provided by (used in):					
Operating activities	\$ 2,163	\$ 8,627	\$ 6,397	\$1,870	\$(1,735)
Investing activities	(6,553)	(163)	(134)	(46)	(32)
Financing activities	5,109	(3,904)	(5,248)	(726)	10
Net increase (decrease) in cash and cash equivalents <sup>(1)</sup>	<u>\$ 719</u>	<u>\$ 4,559</u>	<u>\$ 1,015</u>	<u>\$1,098</u>	<u>\$(1,757)</u>

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

The net decrease in cash and cash equivalents of \$1.8 million for the three months ended March 31, 2009 was primarily due to cash used in operating activities. The cash used in operating activities was primarily due to the recognition of the excess tax benefit of approximately \$2.8 million on the exercise of nonqualified options in the first quarter of 2009 as a cash outflow from operations offset by net income of approximately \$1.2 million for the three months ended March 31, 2009. The excess tax benefit is included as a cash inflow from financing activities that was substantially offset by the cash paid to repurchase shares to settle the minimum statutory tax withholding requirements from the exercise of those options.

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%. 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. 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, we 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 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 with Bank of America 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 carried an interest rate of LIBOR plus an applicable margin, as defined in the agreement (4.42% as of December 31, 2008). The borrowings were collateralized by a first lien against all our assets. We have been paying off the term loan in quarterly installments, with the final payment due in 2011. The line of credit was also due in

2011. This agreement contained various covenants, all of which we were in compliance with as of December 31, 2008.

In connection with the Option Transaction as described in the section titled "Certain relationships and related party transactions", effective July 2009, we amended the revolving credit facility via the Fourth Amended and Restated Loan Agreement to provide for a \$4.0 million line of credit and a term loan of \$18.0 million. Both the line of credit and the term loan carry an interest rate of LIBOR plus an applicable margin, as defined in the agreement. The borrowings are collateralized by a first lien against all our assets. The loan agreement requires us to pay off the term loan in quarterly installments beginning March 31, 2010, with the final payment due in December 2012. We may be required to make additional principal payments on the term loan if our leverage ratio, as defined, exceeds 1.75 to 1.0 on an annual basis. We issued Bank of America a ten-year warrant to purchase 7,500 shares of our common stock and also agreed to issue to Bank of America 7,500 shares of our common stock within thirty days of the execution of the loan agreement. The line of credit is due in December 2012.

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 required 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. In April 2009, we amended our agreement with Inalco so that our minimum purchase requirements for Kristalose will be not less than 25% of the purchases in the immediately preceding calendar year. 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.

During 2001, we signed an agreement with Cato Research Ltd., or Cato, to cover a variety of development efforts related to Caldolor, 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. Upon FDA approval of Caldolor in June 2009, we were required to pay approximately \$1.6 million to Cato under the agreement in connection with the fulfillment of this remaining milestone. Additionally, because the FDA approved the product within eighteen months of acceptance of the NDA, Cato vested in options to acquire up to 60,000 shares of our common stock.

### Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated IV ibuprofen safety database combining data from our clinical trials as well as previously published study data. We used this data to support our NDA filing and will continue to use and update the data as a part of our ongoing safety evaluation. In addition, this data will be used by our sales force and in our marketing materials to promote Caldolor.

In clinical trials supporting our proposed indications, no serious adverse events have been directly attributed to Caldolor. The number and percentage of all patients in pivotal studies who reported treatment emergent adverse events was comparable between IV ibuprofen and placebo treatment groups. Additionally, there have been no safety related differences between Caldolor and placebo involving side effects sometimes observed with oral NSAIDs, such as changes in renal function, bleeding events or gastrointestinal disorders.

### Clinical Studies for Pain

After receiving FDA guidance through a Special Protocol Assessment, we conducted a Phase III, multi-center, randomized, double-blind, placebo-controlled study to evaluate Caldolor for treatment of pain.

#### Phase III Adult Dose Ranging Pain Study

Hospitalized patients, all with access to patient controlled analgesia (PCA) with morphine, were randomized to also receive one of two doses (400mg or 800mg) of Caldolor (multi-modal therapy) or placebo treatment (standard therapy) four times daily for up to five days. The first dose was administered intra-operatively at the initiation of surgical closure. The primary endpoint of this study was reduction in morphine use after 24 hours of treatment.

We enrolled 406 adult surgical patients undergoing a variety of abdominal and orthopedic surgeries. Statistical testing of the data for the primary efficacy endpoint demonstrated the data was not normally distributed. As a result, appropriate transformations of the data were conducted to provide appropriate models for statistical testing of significance, and analog non-parametric procedures were applied. This analysis shows that the p-value for the 800mg dose of Caldolor versus placebo was significant (p=0.030), but that the placebo versus 400mg dose comparison was not significant for the primary endpoint (p=0.458) (p-value measures strength of evidence; p<0.05 represents statistical significance).

The FDA acknowledged that data were not normally distributed, that transformation of the data was appropriate and that median values could reflect the data more accurately. However, FDA concluded that the statistical analysis plan did not sufficiently pre-specify for the non-parametric analyses of the data. Therefore, the data was not included in the package insert for Caldolor.

In this study, we also investigated the efficacy of Caldolor in reducing pain as measured by a Visual Analog Scale (VAS). In addition to using less morphine, patients receiving 800mg of Caldolor reported a 20% greater reduction in pain intensity over the 24 hours following surgery (p=0.001; at rest Area Under the Curve (AUC) of VAS). Patients receiving 400mg of Caldolor reported a 7% reduction in pain intensity over the 24 hours following surgery (p=0.057; at rest AUC of VAS). At 24 hours after the first dose of ibuprofen was administered, patients receiving 800mg of Caldolor reported a 33% greater reduction in pain measured at rest (p=0.009) and 18% greater reduction with movement (p<0.005).

#### Morphine-Sparing Effect of Caldolor, 24 Hours Post-Surgery

	400 mg	800 mg
% Decrease*	3%	22%
p-value†‡	p=0.458	p=0.030

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## Certain relationships and related party transactions

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

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

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

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

In January 2009, A.J. Kazimi exercised options to purchase 585,000 shares of common stock with an exercise price of \$0.11, or \$64,350 in the aggregate, per share and Jean M. Marsteller exercised options to purchase 145,680 shares of common stock with an exercise price of \$0.10 per share, or \$14,568 in the aggregate. The aggregate exercise price of \$78,910 was satisfied by the option holders with 6,070 shares, resulting in no cash proceeds to us. Options were exercised using a net-share settlement feature that provided for Mr. Kazimi to use 204,245 shares acquired upon exercise to settle the minimum statutory tax withholding requirements of approximately \$2.7 million. In connection with these exercises, we agreed to repurchase during the first quarter of 2010 at the then fair market value up to \$0.1 million in common stock from Mr. Kazimi, acquired upon exercise, and approximately \$0.5 million in common stock from Ms. Marsteller, acquired upon exercise, to provide for the settlement of the remaining tax liabilities associated with the respective exercises.

In July 2009, we entered into an amended debt agreement that replaced the existing \$5.0 million term debt and \$7.5 million revolving credit facility with an \$18.0 million term debt and a \$4.0 million revolving credit facility from Bank of America. In the third quarter of 2009, we expect Mr. Kazimi will exercise options to purchase 4,097,090 shares of common stock with an exercise price of \$0.55 per share, or \$2.3 million, and that Ms. Marsteller will exercise options to purchase 280,000 shares of common stock with an exercise price of \$0.50 per share, or \$140,000 (the Option Transaction). We expect Mr. Kazimi and Ms. Marsteller will tender 112,670 and 7,000 shares to satisfy their respective aggregate option exercise prices, assuming a price of \$20.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus, resulting in no cash proceeds to us. We expect Mr. Kazimi will exercise these options using a net-share settlement feature that will enable Mr. Kazimi to use shares acquired upon exercise to settle the minimum statutory tax withholding requirements of approximately

## Certain relationships and related party transactions

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\$29.0 million. Mr. Kazimi would use 1,452,321 shares acquired upon exercise to settle the minimum statutory tax withholding requirements, assuming a price of \$20.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus. In connection with the expected option exercises by Ms. Marstiller, we will repurchase up to approximately \$1.5 million in common stock from Ms. Marstiller, acquired upon exercise, during the first quarter of 2010 to provide for the settlement of the tax liabilities associated with those exercises. This would result in the repurchase of 76,440 shares assuming a price of \$20.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus. We intend to use the proceeds from the Bank of America term loan to fund in part the minimum statutory tax withholding requirements. In connection with the exercise of these options and the related minimum statutory tax withholding, we expect to generate a deferred tax asset of approximately \$30.1 million to offset future tax liabilities.

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

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

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

## Information not required in prospectus

### ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The expenses relating to the registration of the shares of common stock being offered hereby, other than underwriting discounts and commissions, will be borne by us. Such expenses are estimated to be as follows:

Item	Amount
SEC registration fee	\$ 4,000
FINRA filing fee	\$ 12,000
NASDAQ Global Market listing fee	\$ 100,000
Printing expenses	\$ 500,000
Legal fees and expenses	\$ 1,150,000
Accounting fees and expenses	\$ 1,500,000
Blue sky, qualification fees and expenses	\$ 20,000
Transfer agent and registrar expenses	\$ 15,000
Miscellaneous	\$ 599,000
<b>Total</b>	<b>\$ 3,900,000</b>

### ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

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

### ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

In April 2006, we issued a ten-year warrant to purchase 3,958 common shares at \$9.00 per share to Bank of America. In July 2009, we issued a ten-year warrant to purchase 7,500 common shares at \$17.00 per share to Bank of America. The issuances of these securities were exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act.

Since January 1, 2006, we have granted options to purchase 186,870 shares of our common stock under the 1999 Option Plan to our employees, directors and consultants at exercise prices ranging from \$9.00 to \$11.00 per share. An aggregate of 1,000 shares of our common stock have been issued upon exercise of these options.

Since January 1, 2006, we also issued an aggregate of 69,015 shares of common stock as compensation for services pursuant to contracts. Restricted-stock legends were affixed to the securities issued in these