CUMBERLAND PHARMACEUTICALS INC
Form S-1/A
April 10, 2009

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As filed with the Securities and Exchange Commission on April 9, 2009
Registration No. 333-142535

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

Amendment No. 17
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

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

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

A.J. Kazimi
Chairman and CEO
2525 West End Avenue, Suite 950
Nashville, Tennessee 37203
(615) 255-0068
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed offering to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: o

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

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

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

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

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

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION April 9, 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.

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

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

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Prospectus summary

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

OUR COMPANY

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

Since our inception in 1999, we have successfully funded the acquisition and development of our product portfolio with limited external investment, while maintaining profitable operations over the past four years. Our portfolio consists of two products approved by the U.S. Food and Drug Administration, or FDA, one late-stage product candidate 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

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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.

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OUR STRATEGY

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

- Successfully 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.

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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.

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Summary consolidated financial data

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

The pro forma statement of operations and balance sheet data below gives effect to the conversion of 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.

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Risk factors

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

RISKS RELATED TO OUR BUSINESS

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

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

Amelior is undergoing 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.

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Risk factors

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

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

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

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

Ø Any unfavorable publicity concerning us, Acetadote or Kristalose, or th