# Targeting Patient Needs... Delivering Results



# acquisition, developme Cumberland Pharmaceuticals

is a specialty pharmaceutical company that acquires, develops and commercializes branded prescription products. Our primary target markets include hospital acute care and gastroenterology. We focus on delivering products for the U.S. market, and we are partnering with companies to make our products available internationally.

We currently market two established brands: Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning and Kristalose® (lactulose) for Oral Solution, a prescription laxative. We also recently launched Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever approved in the United States.

The completion of our initial public offering in August 2009 provided us with the strongest balance sheet in the history of our company. We intend to use that capital to add select new products to our portfolio that will advance patient care and enhance shareholder value.



SEP 2009 Caldolor launched with expanded hospital and field sales forces



# To Our Shareholders, Partners and Employees:

This first annual report as a public company marks an important milestone for Cumberland Pharmaceuticals, and celebrates a turning point in our history. Since inception, we have had the opportunity to touch the lives of many individuals through our products, which we believe offer significant advancements in patient care. With the launch of Caldolor and our initial public offering in 2009, we are now positioned to impact a greater number of constituents. A landmark year for Cumberland, 2009 saw us opening our doors to new investors, doubling our number of employees and beginning to address a much larger patient population.

### REFLECTING ON 2009

In 2009, our total net revenues grew 24% over the prior year. This is attributable to the performance of our two established brands, Acetadote and Kristalose, as well as to our launch of Caldolor.

Acetadote, our injectable treatment for acetaminophen poisoning, has become one of the leading antidotes in the United States. We obtained FDA approval for Acetadote in 2004, and since the product's introduction it has become a standard of care for treating liver damage associated with acetaminophen overdose. We followed our original approval for this product with an expanded indication for pediatric use in 2006, and were pleased to add new safety data to the product's labeling in 2008. We continue to explore its potential use for other indications as well. In late 2009, important new pharmacoeconomic study data was published indicating that Acetadote can generate significant cost savings for the health system compared to the alternative oral treatment.

A new, patient-focused marketing campaign and refined targeting plan have helped make 2009 a turnaround year for Kristalose, our prescription laxative product. We acquired rights to this brand in 2006, inheriting a downtrend in sales and re-launching the product with the goal of rejuvenating it. Since then, we have worked hard to communicate the benefits of Kristalose to the medical community, and in 2009 delivered several of our best months since re-launch in prescription growth and shipment volume. We also completed our first new study to support this product in 2009, demonstrating that patients prefer the taste and convenience of Kristalose over alternative liquid and syrup options.

In June 2009, we were very pleased to receive FDA approval for Caldolor, our injectable ibuprofen product. Our work with Caldolor began when we developed a patented, proprietary formulation of intravenous ibuprofen. We then embarked on a development program to study the product in more than 1,400 individuals, including patients with fever and surgical patients requiring pain relief. Our results showed Caldolor to be both safe and effective in treating fever and pain, and following a four-month, priority review the FDA approved its use in the United States.

We launched Caldolor ahead of schedule in September 2009, following an expansion of our hospital sales force that tripled its size. In total, we have 113 experienced sales professionals promoting Caldolor to hospitals and surgical centers across the country. We are working diligently to communicate the benefits that the product has to offer over existing injectable treatments for pain and we are introducing Caldolor as the only FDA approved injectable treatment for fever.

We are also partnering with companies to register and introduce Caldolor internationally, and now have agreements in place for Australia, New Zealand, South Korea and Canada. We believe Caldolor represents our most significant product opportunity to date, as it has the potential to benefit the largest patient population of all our products.

"A landmark year for Cumberland, 2009 saw us opening our doors to new investors, doubling our number of employees and beginning to address a much larger patient population."

Meanwhile, in August 2009, we completed our initial public offering, raising gross proceeds of \$85 million and becoming a NASDAQ-listed, publicly-traded company. With difficult financial market conditions in 2007 as we were originally planning to price our IPO, Cumberland decided to remain in registration in order to price our deal at the appropriate time. In August 2009, following the first glimpse of a window for new issues in our industry, we were able to complete our offering and Cumberland became the first U.S. biopharmaceutical company to complete an IPO in nearly two years.

We have historically run a lean, efficient organization and have been profitable since 2004. Following our IPO, Cumberland's balance sheet is the strongest in the history of the company. Proceeds from the IPO supported our Caldolor launch, and will help fund the planned expansion of our product portfolio. We are working diligently to identify our next product offering, focusing primarily on opportunities to leverage our existing capabilities in the hospital acute care and gastroenterology markets.



#### FUTURE OUTLOOK

While much has changed for Cumberland Pharmaceuticals over the past year, our mission and primary goals have not. We are working to become a leading specialty pharmaceutical company. We focus on acquisition, development and commercialization of branded, prescription products that address unmet or poorly met medical needs for select target markets. We are dedicated to providing outstanding value for our shareholders, our partners and our employees by delivering products that improve patient care.

I am extremely proud of our team for accomplishing so much last year. I also believe that our success in 2009 is representative of our future potential. Looking forward to 2010, we plan to continue to grow Acetadote and Kristalose and further expand acceptance of Caldolor in the hospital market. We plan to make additional strides in building our network of international partners for commercialization of our products outside the United States. We are working on opportunities to expand indications for our existing products and to support existing indications through further clinical development. Finally, we are evaluating potential new offerings in order to selectively expand our product portfolio.

I would like to thank our board, employees and advisors for their unwavering dedication. Cumberland's most important asset and key resource is our people, who are determined to excel at our mission and who consistently and efficiently deliver outstanding results. We are grateful to our partners for being an important and trusted component of our team. To our long-term private investors, we thank you for traveling the road with us this far as well as for your continued support. To our new shareholders, we welcome you and thank you for joining us in our vision. I look forward to keeping all of you apprised of our progress and plans.

Best wishes,

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**Innovative Solutions** 

Opportunity to Improve Patient Care

# Business Formula

Cumberland Pharmaceuticals' primary strengths in business development, product development and commercialization enable us to identify opportunities for improvement and turn them into meaningful solutions. We work hard to ensure that our success in delivering patient solutions translates into positive outcomes for our employees, partners and shareholders as well.

# What We Do

# **ACQUISITION**

Our business development efforts are led by a multi-disciplinary team with significant pharmaceutical and transactional expertise. We evaluate product leads and candidates from a variety of sources, including an international network of pharmaceutical and medical industry insiders. A rigorous review process and highly critical selection criteria guide our acquisition strategy, and we believe our current product portfolio is representative of our discriminating efforts.

### DEVELOPMENT

Our product development capabilities include the proven ability to take late-stage product candidates through clinical development and regulatory approval, as we were directly responsible for obtaining FDA approval of Acetadote and Caldolor. Our team develops proprietary product formulations, designs and manages our clinical trials, prepares regulatory submissions and manages our medical call center.

#### COMMERCIALIZATION

We focus on commercializing products for the U.S. market, specifically for medical segments that have relatively concentrated physician bases. Our sales and marketing executives manage our national marketing campaigns, market research, national sales accounts and hospital and field sales forces. We are expanding our sales team to coincide with planned growth, recently tripling the size of our hospital sales group for the launch of Caldolor.

# Introducing Caldolor

Caldolor® (ibuprofen) Injection is the first and only FDA-approved intravenous treatment for pain and fever available in the United States.

Following completion of our development program involving more than 1,400 patients, we received U.S. marketing approval for Caldolor in June 2009. We launched the product in September, culminating a multifaceted program addressing manufacturing, market research, promotional materials and expansion and training of our sales force. We secured national distribution and are introducing Caldolor to U.S.

Beyond the clinical data included in the product labeling, we completed three additional studies in 2009 to support marketing of Caldolor. A pharmacokinetic study demonstrated that the product can be safely administered over 5-7 minutes, with peak plasma concentration for Caldolor at 6.5 minutes (as compared to 1.5 hours for oral ibuprofen). Another study in patients undergoing orthopedic surgeries supports Caldolor's safety and efficacy in treating pain with the first dose initiated pre-operatively. A third study demonstrated that Caldolor significantly reduced fever in hospitalized burn patients while also validating the safety of the product over five days of treatment.

We furthered our international licensing initiative in 2009 through agreements with Phebra Ptv Limited to register and commercialize Caldolor in Australia and New Zealand, and with DB Pharm Korea to handle registration and commercialization in South Korea. We are working with our partners to pursue regulatory approval in these territories and continue to pursue partnerships for other international territories as well.



#### PAIN

Opioids such as morphine, while effective in addressing pain, are known to cause side effects such as nausea, sedation, constipation and respiratory depression. Both the World Health Organization and the American Society of Anesthesiologists Task Force recommend a multi-modal approach to pain management, with non-opioid analgesics such as ibuprofen recommended as first-line treatment and opioids added as needed. Our clinical data demonstrates that Caldolor significantly reduces opioid use while significantly improving pain relief in post-operative patients with open access to morphine.

Caldolor is the only U.S.-approved injectable treatment for fever. Hospitalized patients subject to intubation, sedation, reduced gastric motility or recent surgery are frequently unable to ingest or tolerate oral products to reduce fever. Treatment for these patients ranges from suppository delivery of medication to measures such as tepid baths, ice packs and cooling blankets. Our clinical studies have shown Caldolor to be safe and effective in providing IV fever reduction within 30 minutes.

# 70 million

There is a substantial market for Caldolor (shown to significantly reduce pain and morphine use in post-surgical patients), with 70 million surgeries performed annually in the U.S.

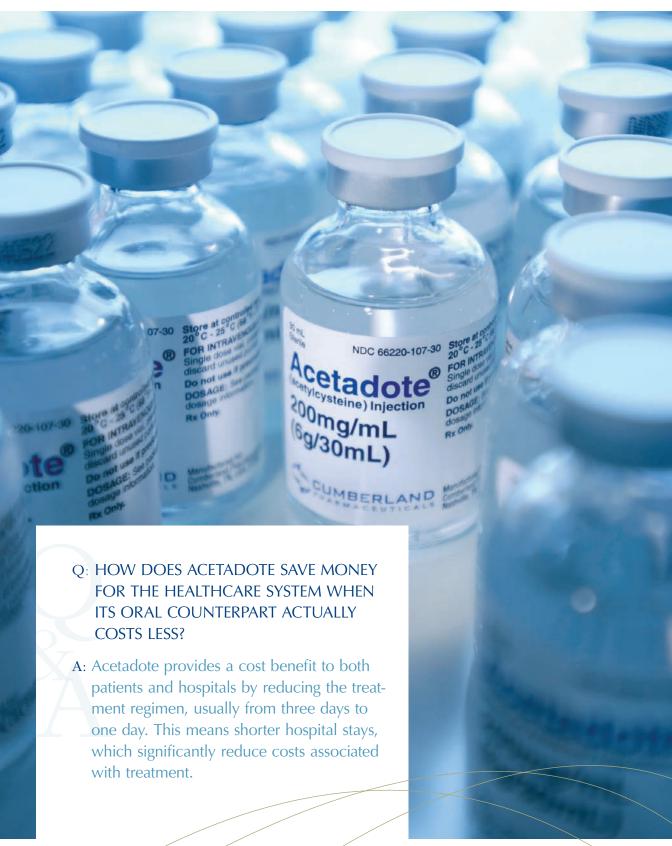
77%

The first U.S.-approved IV fever-reducing agent, Caldolor works within 30 minutes. 77% of patients achieved temperature reduction (<101.0° F) after one 400-mg dose.

# 6.5 minutes

Peak plasma levels in 6.5 minutes with Caldolor versus 1.5 hours for oral ibuprofen.







# About Acetadote

Acetadote® (acetylcysteine) Injection is the only FDA-approved IV treatment for acetaminophen overdose.

Acetadote is used in the emergency department and hospital inpatient setting to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter and prescription medications. Though safe at recommended doses, acetaminophen can cause liver damage with excessive use. According to the American Association of Poison Control Centers' National Poison Data System, acetaminophen is the leading cause of toxic drug ingestions reported to U.S. poison control centers. Acetaminophen overdose is also the most common cause of acute liver failure in adults in the U.S.

Until our introduction of Acetadote in 2004, the only treatment for acetaminophen poisoning available in the U.S. was an oral medication. Medical literature suggests that for many patients IV treatment is the only reasonable route of administration due to nausea and vomiting associated with the administration of the oral treatment for this overdose. Promoted by Cumberland's hospital sales force, Acetadote has become a standard of care for acetaminophen overdose in the U.S.

Our product development team managed the clinical program to obtain regulatory approval for Acetadote, and we have since expanded the product label with a pediatric indication and additional safety data. We are exploring other potential uses for the product through investigator-sponsored clinical studies at several research institutions.

In 2009, the *Journal of Medical Economics* published a study showing that treatment of acetaminophen overdose with Acetadote can provide substantial cost savings for healthcare systems compared to oral therapy, and that Acetadote is the less costly regimen in all evaluated scenarios. This cost differential is primarily due to time required to complete recommended treatment—72 hours for oral treatment versus 21 hours for Acetadote—resulting in shorter hospital stays for patients treated with Acetadote.



# Offering Kristalose

Kristalose® (lactulose) for Oral Solution is a prescription laxative that we believe has significant advantages over other laxative products. It offers the established safety and efficacy of lactulose, plus the convenience of a pre-measured powder dose.

An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient compliance and acceptance. It is the only prescription-strength laxative available in pre-measured powder packets, making it easily portable. Kristalose dissolves quickly in 4 oz. of water, offering patients a virtually

In 2009, we completed a patient preference study evaluating Kristalose compared to similar products in liquid forms. Overall, more patients preferred Kristalose, with portability a key differentiating feature

We licensed exclusive U.S. commercial rights to Kristalose in April 2006, and re-launched the product under the Cumberland brand. Kristalose is promoted by a dedicated sales force to high prescribers of laxatives, including gastroenterologists and pediatricians. Since re-launch we have reversed a downtrend

# Practical

Once-daily powder dosing
Dissolves quickly in 4 oz. of water
Virtually tasteless
No sticky sweet taste

# Portable

Pre-measured packet No bulky or heavy bottles



# Our Partners

# Manufacturing and Distribution

We rely on trusted partners for manufacturing and distribution of our products. Our management team is highly experienced in these areas, and oversees these relationships with a focus on quality assurance. Partnering these capital-intensive functions to manufacturing and logistics experts allows Cumberland to focus resources on our core capabilities—acquiring, developing and commercializing innovative pharmaceutical products.



# Financial Results

At Cumberland we focus sharply on creating value for investors and strive to deliver consistent growth in revenues while maintaining profitability. In 2009, we accomplished these goals while significantly strengthening our balance sheet through our initial public offering.

In August, we completed an initial public offering of 5,000,000 shares of our common stock and began trading on the NASDAQ Global Select Market under the symbol "CPIX". Gross proceeds from the IPO were \$85 million. Our product revenues grew 24% in 2009 over the prior year, and we have remained profitable and cash flow positive since 2004.



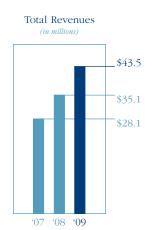
# Key Investment Highlights

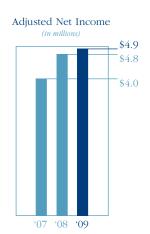
- > Integrated specialty pharmaceutical company
- > Proven development and commercialization capabilities
- > Strong growth potential for Acetadote and Kristalose
- > Significant new market opportunity for Caldolor
- > Profitable business with steady revenue growth

# FINANCIAL HIGHLIGHTS

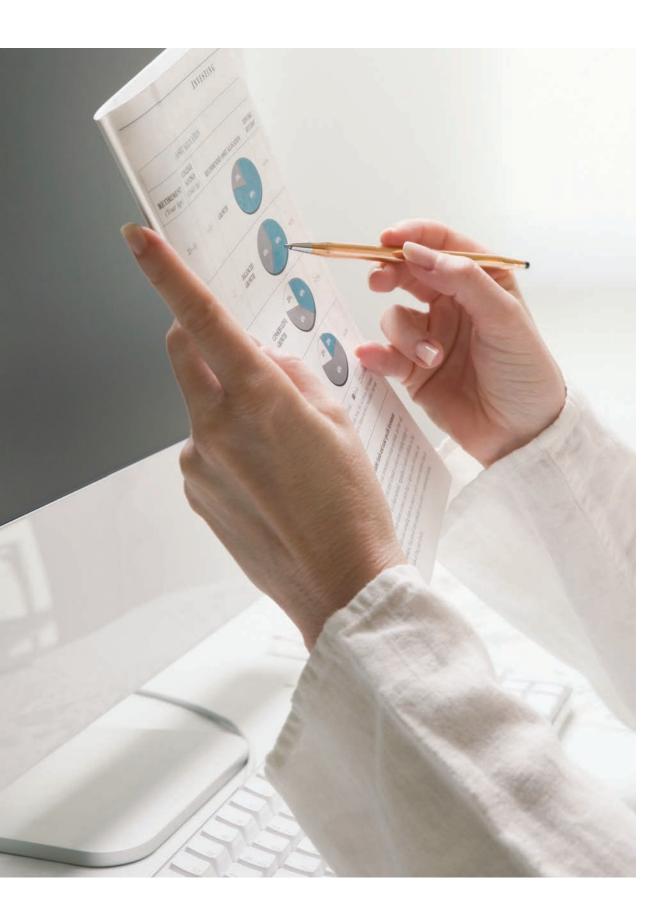
(dollars in thousands except per share data)	As Reported (GAAP)			As Adjusted*
	2007	2008	2009	2009
Net Revenues	\$28,064	\$35,075	\$ 43,537	\$ 43,537
Gross Margin	90.5%	91.3%	90.5%	90.5%
Operating Income	6,725	7,282	5,777	8,820
Operating Margin	24%	20.8%	13.3%	20.3%
Net Income	4,044	4,766	3,091	4,924
Diluted Earnings Per Share	0.24	0.29	0.17	0.27
Total Assets	28,919	31,119	103,724	103,724
Long-Term Obligations	7,623	7,666	20,155	20,155
Shareholders' Equity	16,746	17,555	72,221	72,221

<sup>\*</sup>Adjusted to exclude \$2.0 million one-time milestone payment associated with the FDA approval of Caldolor, \$1.1 million in payroll-related tax expense from exercise of non-qualified options, and \$1.2 million in additional tax expense related to those two items.









# Meet Our Team

A.J. Kazimi Chairman and Chief Executive Officer



## Q: WHAT'S YOUR VISION FOR CUMBERLAND IN THE FUTURE?

A: We are building a leading specialty pharmaceutical company with a portfolio of differentiated, safe and effective products that improve patient care. We work to deliver consistent growth in revenues and to maintain profitability, and we are dedicated to providing outstanding value for our shareholders.

Martin E. Cearnal Director, Senior Vice President, and Chief Commercial Officer



## Q: WHAT IS THE MARKET OPPORTUNITY FOR CALDOLOR?

A: The market for this class of products is significant, with 671 million units of injectable analgesics sold in 2009 according to IMS. While these figures demonstrate a substantial opportunity, we focus on probable patient candidates as well as realistic penetration and usage rates. We estimate that approximately 57 million surgical, ER and ICU patients will be candidates for Caldolor annually. We expect modest, single-digit penetration of this market.

David L. Lowrance Vice President, Finance & Accounting and Chief Financial Officer



# Q: WHAT IS YOUR PHILOSOPHY FOR FUNDING THE COMPANY GOING FORWARD?

A: Over the past several years we have employed a strategy that has enabled us to fund day-to-day activities with cash flow from operations. We plan to continue to operate in this manner for the foreseeable future, and to utilize financing proceeds to grow the company through expansion of our product portfolio.







- 1 | Jean W. Marstiller Senior Vice President, Administrative Services and Corporate Secretary
- 2 | Leo Pavliv, R.Ph. Senior Vice President, Operations
- 3 | James L. Herman Senior Director, National Accounts and Corporate Compliance Officer
- 4 | Amy D. Rock, Ph.D. Senior Director, Regulatory and Scientific Affairs
- 5 | Barry L. Lee Product Director





# Corporate Information

#### BOARD OF DIRECTORS

A.J. Kazimi

Chairman

Martin E. Cearnal

Dr. Robert G. Edwards

Dr. Lawrence W. Greer

Thomas R. Lawrence

#### SENIOR MANAGEMENT

A.J. Kazimi

Chief Executive Officer

Jean W. Marstiller

Senior Vice President, Administrative Services and Corporate Secretary

Dr. Gordon R. Bernard

Senior Vice President and Medical Director

Martin E. Cearnal

Senior Vice President and Chief Commercial Officer

Leo Pavliv, R.Ph.

Senior Vice President, Operations

David L. Lowrance

Vice President, Finance & Accounting and Chief Financial Officer

James L. Herman

Senior Director, National Accounts and Corporate Compliance Officer

Amy D. Rock, Ph.D.

Senior Director, Regulatory and Scientific Affairs

Dr. Arthur P. Wheeler Director, Medical Affairs

Barry L. Lee Product Director

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COMPANY HEADQUARTERS

Fax: (615) 255-0094

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#### STOCK LISTING

NASDAQ Select Global Market Ticker Symbol: CPIX

#### ANNUAL MEETING

10:00 a.m. Central Time Tuesday, April 20, 2010 University Club 2402 Garland Avenue Nashville, Tennessee 37212

# INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

KPMG LLP 401 Commerce Street Suite 1000 Nashville, Tennessee 37219 (615) 244-1602

### TRANSFER AGENT AND REGISTRAR

Continental Stock Transfer & Trust Company 17 Battery Place New York, New York 10004 (800) 509-5586 (212) 509-4000 cstmail@continentalstock.com

### FORWARD-LOOKING STATEMENTS

This annual report includes forward-looking statements regarding expected future results of the company. A variety of factors could cause actual results to differ materially from expected results. Please see the risk factors more fully described in our Annual Report on Form 10-K for the year ended December 31, 2009, which is filed with the U.S. Securities and Exchange Commission.

