CUMBERLAND PHARMACEUTICALS INC Form 10-Q August 16, 2010

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

(Mark One)

b QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2010

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-33637 Cumberland Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Tennessee 62-1765329

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

2525 West End Avenue, Suite 950, Nashville, Tennessee 37203

(Zipcode)

(Address of principal executive offices)

(615) 255-0068

(Registrant s telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\beta$  No o Indicate by check mark whether the registrant has submitted electronically and posted on its Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer b Smaller reporting company o

(Do not check if a smaller

reporting company)

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No b

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class

Outstanding at August 12, 2010

Common stock, no par value

20,253,767

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#### PART I FINANCIAL INFORMATION

#### **Item 1: Financial Statements**

#### CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$71,495,305	\$ 78,701,682
Accounts receivable, net of allowances	3,960,129	6,176,585
Inventories	7,967,089	4,822,873
Other current assets	3,238,151	3,472,455
Total current assets	86,660,674	93,173,595
Property and equipment, net	958,766	918,412
Intangible assets, net	7,705,084	7,956,009
Other assets	1,377,506	1,676,304
Total assets	\$ 96,702,030	\$ 103,724,320
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 6,000,000	\$ 9,061,973
Current portion of other long-term obligations	24,592	144,828
Accounts payable	5,993,006	5,632,796
Other accrued liabilities	3,409,097	3,784,777
Total current liabilities	15,426,695	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	5,938,027	8,938,027
Other long-term obligations, excluding current portion	209,327	184,632
Total liabilities	23,400,000	29,572,984
Commitments and contingencies		
Redeemable common stock		1,930,000
Equity: Shareholders equity:		

Common stock no par value; 100,000,000 shares authorized; 20,358,586 and		
20,180,486 <sup>(1)</sup> shares issued and outstanding as of June 30, 2010 and		
December 31, 2009, respectively	68,199,165	67,711,746
Retained earnings	5,153,008	4,542,126
Total shareholders equity	73,352,173	72,253,872
Noncontrolling interests	(50,143)	(32,536)
Total equity	73,302,030	72,221,336
Total liabilities and equity	\$ 96,702,030	\$ 103,724,320

# (1) Number of shares issued and outstanding represent total shares of common stock regardless of classification on the consolidated balance sheet. The number of shares of redeemable common stock at December 31,

2009 was 142,016.

See accompanying notes to unaudited condensed consolidated financial statements.

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#### CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Income (Unaudited)

	Three months ended June 30,			Six months ended June				
	2010 2009		2010		lucu	2009		
Net revenues	\$ 1	0,739,935	\$	9,820,613	\$2	0,870,587	\$ 1	19,225,212
Costs and expenses:								
Cost of products sold		863,725		777,076		1,723,013		1,510,294
Selling and marketing		5,848,123		4,383,802		1,455,635		8,523,989
Research and development		1,034,800		2,630,725		1,808,668		3,400,842
General and administrative		1,782,834		1,236,435		3,664,037		2,681,298
Amortization of product license right		171,726		171,726		343,452		343,452
Other		28,867		26,733		55,414		54,196
Total costs and expenses		9,730,075		9,226,497	1	9,050,219	1	16,514,071
Operating income		1,009,860		594,116		1,820,368		2,711,141
Interest income		50,334		10,160		111,013		27,756
Interest expense		(405,956)		(84,224)		(751,908)		(181,935)
Net income before income taxes		654,238		520,052		1,179,473		2,556,962
Income tax expense		(374,461)		(232,637)		(586,198)		(1,063,696)
Net income		279,777		287,415		593,275		1,493,266
Net loss at subsidiary attributable to								
noncontrolling interests		7,527		8,456		17,607		20,695
N								
Net income attributable to common shareholders	\$	287,304	\$	295,871	\$	610,882	\$	1,513,961
E's and the state of the								
Earnings per share attributable to common shareholders								
- basic	\$	0.01	\$	0.03	\$	0.03	\$	0.15
- diluted	\$	0.01	\$	0.02	\$	0.03	\$	0.09
Weighted-average shares outstanding								
- basic		0,445,560		10,467,781		0,340,000		10,394,883
- diluted	2	1,207,645		16,046,844	2	1,302,119	1	16,087,448

See accompanying notes to unaudited condensed consolidated financial statements.

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#### CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Cash Flows (Unaudited)

	Six Months l 2010	Ended June 30, 2009
Cash flows from operating activities:		
Net income	\$ 593,275	\$ 1,493,266
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	463,676	398,341
Non-employee equity compensation	45,554	1,008,381
Stock-based compensation employee stock options	318,139	313,064
Excess tax benefit derived from exercise of stock options	(462,814)	(2,842,825)
Non-cash interest expense	132,866	29,376
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	2,216,456	(125,024)
Inventory	(3,144,216)	654,400
Other current assets and other assets	349,777	743,951
Accounts payable and other accrued liabilities	337,995	(986,592)
Other long-term obligations	(95,541)	582,254
Net cash provided by operating activities	755,167	1,268,592
Cash flows from investing activities:		
Additions to property and equipment	(126,315)	(85,863)
Additions to property and equipment  Additions to patents	(80,734)	(34,551)
raditions to patents	(00,754)	(54,551)
Net cash used in investment activities	(207,049)	(120,414)
Cash flows from financing activities:		
Costs of initial public offering		(154,179)
Principal payments on note payable	(6,061,973)	(416,667)
Costs of financing for long-term debt and credit facility	(55,000)	(15,475)
Proceeds from exercise of stock options	979,292	4,296
Excess tax benefit derived from exercise of stock options	462,814	2,842,825
Payments made in connection with repurchase of common shares	(3,079,628)	(2,707,419)
Net cash used in financing activities	(7,754,495)	(446,619)
Net (decrease) increase in cash and cash equivalents	(7,206,377)	701,559
Cash and cash equivalents at beginning of period	78,701,682	11,829,551
Cash and cash equivalents at end of period	\$71,495,305	\$12,531,110

Supplemental disclosure of cash flow information:

Cash paid during the year for:

Interest	\$ 503,250	\$ 116,848
Income taxes	50,650	93,969
Non-cash investing and financing activities:		
Increase in accounts payable and accrued expenses of initial public offering		119,646

Increase in accounts payable and accrued expenses of initial public offering Common shares repurchased during period but not paid as of the end of the

period 203,802

See accompanying notes to unaudited condensed consolidated financial statements.

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#### CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Equity and Comprehensive Income (Unaudited)

				Non-		
	Common stock		Retained	controlling	Total	
	Shares	Amount	earnings	interests	equity	
Balance, December 31, 2009	20,180,486	\$67,711,746	\$4,542,126	\$ (32,536)	\$72,221,336	
Stock-based compensation -						
nonemployees	5,636	80,604			80,604	
Exercise of options and related						
tax benefit, net of mature shares						
redeemed for the exercise price	531,910	1,442,106			1,442,106	
Stock-based compensation -						
employees		318,139			318,139	
Repurchase of shares	(359,446)	(3,283,430)			(3,283,430)	
Reclass of redeemable common						
stock		1,930,000			1,930,000	
Net and comprehensive income			610,882	(17,607)	593,275	
Balance, June 30, 2010	20,358,586	\$ 68,199,165	\$ 5,153,008	\$ (50,143)	\$ 73,302,030	
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See accompanying notes to unaudited condensed consolidated financial statements.

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# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to condensed consolidated financial statements (unaudited)

#### (1) BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed consolidated financial statements (condensed consolidated financial statements) of Cumberland Pharmaceuticals Inc. and its subsidiaries (collectively, the Company or Cumberland) have been prepared on a basis consistent with the December 31, 2009 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly present the information set forth herein. All significant intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in accordance with the regulations of the Securities and Exchange Commission, or SEC, and omit certain information and footnote disclosure necessary to present the statements in accordance with U.S. generally accepted accounting principles. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2009. The results of operations for the three and six months ended June 30, 2010 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

Total comprehensive income was comprised solely of net income for the three and six months ended June 30, 2010 and 2009.

#### **Accounting Policies:**

In preparing the condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles, management must make decisions that impact the reported amounts and the related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgments based on its understanding and analysis of the relevant circumstances, historical experience, and other available information. Actual amounts could differ from those estimated at the time the condensed consolidated financial statements are prepared.

The Company has evaluated events occurring subsequent to June 30, 2010 for accounting and disclosure implications. (2) EARNINGS PER SHARE

The following tables reconcile the numerator and denominator used to calculate diluted earnings per share for the three and six months ended June 30, 2010 and 2009:

		s Ended June 0,
	2010	2009
Numerator: Net income attributable to common shareholders	\$ 287,304	\$ 295,871
Denominator: Weighted-average shares outstanding basic Convertible preferred stock shares Dilutive effect of other securities	20,445,560 762,085	10,467,781 1,625,498 3,953,565
Weighted-average shares outstanding diluted	21,207,645	16,046,844
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# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to condensed consolidated financial statements continued (unaudited)

		Six Months 2010	s Ended June 30, 2009
Numerator: Net income attributable to common sha	reholders	\$ 610,882	\$ 1,513,961
Denominator: Weighted-average shares outstanding Convertible preferred stock shares Dilutive effect of other securities	basic	20,340,000 962,119	1,625,498
Weighted-average shares outstanding	diluted	21,302,119	16,087,448

As of June 30, 2010 and 2009, options to purchase 657,532 and 256,532 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

#### (3) SEGMENT REPORTING

We operate in one segment, specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. All of the Company s assets are located in the United States. The Company did not have any sales to non-U.S. customers during the three months ended June 30, 2010 and 2009, respectively. The Company had sales of less than \$0.1 million to non-U.S. customers during the six months ended June 30, 2010 and \$0.7 million during the six months ended June 30, 2009.

The Company s net revenues consisted of the following for the three and six months ended June 30, 2010 and 2009:

	Three Months	Six Months E	nded June 30,	
	2010	2010 2009		2009
Products:				
Acetadote	\$ 8,308,560	\$7,239,776	\$ 16,031,833	\$ 14,373,206
Kristalose	2,271,418	2,518,728	4,581,401	4,747,344
Caldolor	45,776		65,081	
Other	114,181	62,109	192,272	104,662
Total net revenues	\$ 10,739,935	\$ 9,820,613	\$ 20,870,587	\$ 19,225,212

#### (4) SHAREHOLDERS EQUITY

In May 2010, the Company announced a share repurchase program to repurchase up to \$10.0 million of its outstanding common shares. Pursuant to the plan, the Company repurchased 196,424 shares for approximately \$1.4 million during the three months ended June 30, 2010.

During 2010, the Company repurchased 163,022 shares of common stock totaling approximately \$1.9 million for the settlement of tax liabilities associated with the exercise of certain options in 2009. As of December 31, 2009, this amount was included in redeemable common stock in the condensed consolidated balance sheet. The repurchase amount was based on the fair-market value of common stock on the date of settlement.

During 2010, options to purchase 549,856 shares of common stock were exercised. In connection with an exercise, 17,946 shares of mature stock were tendered as consideration for the exercise price and minimum statutory tax withholding requirements. The exercise of these options created a tax deduction of approximately \$4.4 million, of which approximately \$0.9 million was used to offset the estimated tax liability arising from the results of operations for the six months ended June 30, 2010. As of June 30, 2010, the Company has unrecognized tax deductions of approximately \$69.1 million that will be recognized when the deduction reduces income taxes payable.

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# CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES Notes to condensed consolidated financial statements continued (unaudited)

#### (5) INCOME TAXES

During the second quarter of 2010, the Internal Revenue Service completed its review of the Company s 2007 and 2008 federal tax returns. As a result of the audits, the Company does not have any federal tax returns open for audit.

#### (6) COLLABORATIVE AGREEMENTS

The Company is a party to several collaborative arrangements with certain research institutions to identify and pursue promising pre-clinical pharmaceutical product candidates. The Company has determined these collaborative agreements do not meet the criteria for accounting under Accounting Standards Codification 808, Collaborative Agreements. The agreements do not specifically designate each party s rights and obligations to each other under the collaborative arrangements. Except for patent defense costs, expenses incurred by one party are not required to be reimbursed by the other party. The funding for these programs is generally provided through private sector investments or federal Small Business (SBIR/STTR) grant programs. Expenses incurred under these collaborative agreements are included in research and development expenses in the condensed consolidated statements of income. Funding received from private sector investments and grants are recorded as net revenues in the condensed consolidated statements of income.

#### (7) SUBSEQUENT EVENTS

Pursuant to our share repurchase plan announced in May 2010, the Company repurchased an additional 104,819 for approximately \$0.6 million subsequent to June 30, 2010. The weighted-average repurchase price was \$6.12 per share.

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#### Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains certain forward-looking statements which reflect management s current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We caution you that our actual results may differ significantly from the results we discuss in these forward looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital required to finance the business model; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; and management of our growth and integration of potential acquisitions. Other important factors that may cause actual results to differ materially from forward-looking statements are discussed in Risk Factors on pages 20 through 32 and Special note regarding forward-looking statements on page 32 of our Annual Report on Form 10-K for the year ended December 31, 2009. The Company does not undertake to publicly update or revise any of its forward-looking statements, even in the event that experience or future changes indicate that the anticipated results will not be realized. The following presentation of management s discussion and analysis of financial condition and results of operations should be read in conjunction with the Company s unaudited condensed consolidated financial statements and related notes thereto included in this Form 10-O.

#### **OVERVIEW**

#### **Our Business**

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 bases that we believe can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products which improve quality of care for patients.

Our product portfolio includes Acetadote<sup>®</sup> (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor<sup>®</sup> (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose<sup>®</sup> (*lactulose*) for Oral Solution, a prescription laxative. We market and sell our products through our dedicated hospital and field sales forces in the United States, and are working with partners to reach international markets.

We have both product development and commercialization capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, sales and marketing and finance and accounting. Our internal product development and regulatory executives develop proprietary product formulations, design and manage our clinical trials, prepare all regulatory submissions and manage our medical call center. Cumberland s operations and quality affairs professionals play an active role in the manufacture of our products through our manufacturing partners. All aspects of commercialization are handled by our sales and marketing professionals, and we work closely with our distribution partner to make our products available across the United States.

We have been profitable since 2004, and have generated sufficient cash flows to fund our development and marketing programs. In 2009, we completed an initial public offering of our common stock to help facilitate further growth. Our strategy includes maximizing the potential of our existing products and continuing to build a portfolio of new, differentiated products. Our current products are approved for sale in the United States, and we are working to bring them to select international markets. We also look for opportunities to expand into additional patient populations with new product indications, whether through our own resources or by supporting investigator-initiated studies at research institutions. We actively pursue opportunities to acquire additional late-stage development product candidates as well as marketed products in our target medical specialties. Further, we are supplementing the aforementioned growth strategies with the early-stage drug development activities of Cumberland Emerging Technologies, Inc. (CET), our majority-owned subsidiary. CET partners with university research centers to

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identify and cost-effectively develop promising, early-stage product candidates, which Cumberland has the opportunity to commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our website address is www.cumberlandpharma.com. We make available through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments, as well as other documents, as soon as reasonably practicable after their filing with the SEC. These filings are also available to the public through the Internet by the SEC at www.sec.gov.

#### **Recent Developments**

#### Acetadote®

Supplemental New Drug Application

In March 2010, we submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA includes data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. The study showed that these patients can also survive a significant number of days longer without transplant, which would provide patients requiring transplant increased time for a donor organ to become available.

Acute liver failure is associated with a high mortality rate and frequent need for liver transplantation. Approximately half of acute liver failure cases are caused by acetaminophen poisoning while the other half result from a variety of causes including hepatitis and alcohol. Currently, transplantation of the liver is the only treatment for patients with liver failure not caused by acetaminophen overdose.

In May 2010, the FDA officially accepted the sNDA and granted a priority review. In addition to expanded labeling for Acetadote, we have requested additional exclusivity for the product. If approved, we expect to begin marketing Acetadote with the new indication in 2011.

#### Australian Regulatory Approval

In April 2010, the Therapeutic Goods Administration (TGA) approved Acetadote for marketing in Australia. We previously granted an exclusive license to Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, to commercialize Acetadote in Australia. Phebra is now preparing for the Australian launch of the product, which it expects to commence this year.

Under our agreement, Phebra is responsible for ongoing regulatory requirements, marketing, distribution and sales of Acetadote in Australia while we maintain responsibility for product formulation, development and manufacturing. In exchange for the product license, Cumberland receives upfront and milestone payments, a transfer price and royalties on future sales.

#### Caldolor®

#### License Agreement for Canada

In April 2010, we entered into an exclusive agreement with Alveda Pharmaceuticals Inc., a Toronto-based specialty pharmaceutical company, for the commercialization of Caldolor in Canada. Under the agreement, Alveda will seek Canadian regulatory approval for Caldolor and, upon approval, will handle ongoing regulatory requirements as well as product marketing, distribution and sales throughout Canada. Cumberland will maintain responsibility for product formulation, development and manufacturing. In exchange for the license to the product, Cumberland will receive royalties on future sales of Caldolor in addition to upfront and milestone payments as well as a transfer price.

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#### Compassionate Use in Australia

In December 2009, we entered into an exclusive agreement with Phebra Pty Ltd. for distribution of Caldolor in Australia and New Zealand. As of April 2010, Phebra made the product available in Australia on a limited, compassionate use basis. The TGA, which regulates drugs and medical devices in Australia, operates compassionate use programs that allow patients with critical clinical needs to access products not yet approved through their medical practitioner. Phebra is also planning to submit an application to the TGA for regulatory approval of Caldolor.

#### RECENT LEGISLATION

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010, or HCERA, was enacted into law, which modified the revenue provisions of the PPACA. The PPACA as amended by the HCERA constitutes the healthcare reform legislation. The following highlights certain provisions of the legislation that may affect us in the future.

#### **Pharmaceutical Industry Fee**

Beginning in calendar-year 2011, an annual fee will be imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs (e.g., Medicare Part D, Medicare Part B, Medicaid, Department of Veterans Affairs programs, Department of Defense programs and TRICARE). The annual fee will be allocated to companies based on their previous calendar-year market share using sales data that the government agencies that purchase the pharmaceuticals will provide to the Treasury Department. Although we participate in governmental programs that would subject us to this fee, our sales volume in such programs is less than \$10 million, with the first \$5.0 million of sales being exempt from the fee. We do not anticipate this fee will have a material impact on our results of operations.

#### **Medicaid Rebate Rate**

We currently provide rebates for Kristalose sold to Medicaid beneficiaries. Effective January 1, 2010, the rebate increased from 11 percent to 13 percent of the average manufacturer price. Our sales of Kristalose under the Medicaid program have been increasing. We expect the increased rebate percentage will impact our net revenue for Kristalose by less than \$0.1 million for the year ended December 31, 2010.

#### **Therapeutic Discovery Project Credit**

The legislation established a 50 percent nonrefundable investment tax credit or grant for qualified investments in qualifying therapeutic discovery projects. The provision allocates \$1 billion during the two-year period (2009-2010) for the program. The credit is available only to companies with 250 or fewer employees. The qualified investment for any tax year is the aggregate amount of the costs paid or incurred in that year for expenses necessary for and directly related to the conduct of the qualifying therapeutic discovery project. We submitted our applications for four of our research projects prior to the deadline of July 21, 2010, and expect to receive a response from the Internal Revenue Service in the fourth quarter of 2010.

#### CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Please see a discussion of our critical accounting policies and significant judgments and estimates on pages 39 through 42 in Management s discussion and analysis of our Annual Report on Form 10-K for the year ended December 31, 2009.

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#### **Accounting Estimates and Judgments**

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

#### RECENTLY ISSUED ACCOUNTING STANDARDS

In March 2010, the Financial Accounting Standards Board, or FASB, issued guidance providing for the recognition of revenue using the milestone method. Under this new guidance, an entity can recognize revenue associated with milestones if the milestones are substantive and there is substantive uncertainty about whether the milestone will be achieved. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. The new guidance is effective for our third quarter ended September 30, 2010. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on our consolidated financial position or results of operations.

In October 2009, the FASB issued guidance setting forth requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. The overall arrangement fee will be allocated to each element based on their relative selling prices. If an entity does not have a selling price for an element, then management must estimate the selling price. This guidance is effective for us for all revenue arrangements entered into or materially modified after January 1, 2011. Early adoption is permitted. The future impact of adopting this standard will depend on the nature and extent of transactions covered by this standard.

#### **RESULTS OF OPERATIONS**

#### Three months ended June 30, 2010 compared to the three months ended June 30, 2009

*Net revenues*. Net revenues for the three months ended June 30, 2010 totaled approximately \$10.7 million, representing an increase of approximately \$0.9 million, or 9%, over the same period in 2009. With overall sales volume remaining consistent between the two periods, increased gross sales were partially offset with gross-to-net revenue adjustments from increased rebate expense associated with state and managed care activity, as well as additional fee-for-service expense due to additional agreements in 2010.

During the second quarter of 2009, we expanded our hospital sales force in connection with the commercial launch of Caldolor. In addition to the expansion of our hospital sales force, we realigned our field sales force to enable them to also promote Caldolor in the surgery-center market. The sales forces have been working diligently in the continued launch of Caldolor while maintaining a consistent level of focus on Acetadote and Kristalose, which is evidenced by consistent sales volume of those two products.

Cost of products sold. Cost of products sold as a percentage of net revenues increased slightly from 7.9% for the three months ended June 30, 2009 to 8.0% for the same period in 2010. The increase in cost of products sold as a percentage of net revenues was primarily due to (1) the weakening of the U.S. dollar during the second quarter ended June 30, 2010 as compared to the same period in 2009 and (2) an increase in our gross-to-net revenue adjustments previously discussed.

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*Selling and marketing*. Selling and marketing expense for the three months ended June 30, 2010 totaled approximately \$5.8 million, representing an increase of approximately \$1.5 million, or 33%, over the same period in 2009. The increase was primarily due to the expansion of our hospital sales force which occurred in the third quarter of 2009, and the resulting increases in payroll and related taxes, travel, meals and promotional activities.

Research and development. Research and development expense for the three months ended June 30, 2010 totaled approximately \$1.0 million, representing a decrease of approximately \$1.6 million, or 61%, over the same period in 2009. The decrease was primarily due to the inclusion in the second quarter of 2009 of approximately \$2.0 million of milestone expenses incurred upon the FDA approval of Caldolor in June 2009. This decrease was offset by additional costs incurred in 2010 related to annual FDA product and establishment fees and increased costs related to development efforts for our products and product candidates.

General and administrative. General and administrative expense for the three months ended June 30, 2010 totaled approximately \$1.8 million, representing an increase of approximately \$0.5 million, or 44%, over the same period in 2009. The increase is primarily due to additional expenses associated with being an SEC registrant, including legal and accounting-related costs and insurance. In addition, we incurred additional foreign currency expense associated with our products bought from overseas suppliers.

*Interest expense*. Interest expense for the three months ended June 30, 2010 totaled approximately \$0.4 million, representing an increase of approximately \$0.3 million as compared to the same period in 2009. The increase is primarily attributable to the increase in our average term debt balance in 2010 as compared to 2009.

*Income tax expense*. Income tax expense for the three months ended June 30, 2010 totaled approximately \$0.4 million, representing an increase of \$0.1 million over the same period in 2009. As a percentage of net income before income taxes, income tax expense increased from 44.7% for the three months ended June 30, 2009 to 57.2% for the three months ended June 30, 2010. The increase, in percentage of net income before income taxes, was due to an increase in our projected tax rate for 2010 as a result of an increase in our permanent differences relative to our net income before income taxes.

During 2009 and 2010, significant stock options were exercised that resulted in an excess tax benefit to us. As of June 30, 2010, we have approximately \$69.1 million of these tax deductions available to us that will be used to offset future income tax liabilities. In accordance with current accounting pronouncements, these deductions have not been recognized in the condensed consolidated balance sheet as of June 30, 2010. We will recognize the tax benefits in future periods when they are used to offset taxes payable. We expect our cash outflow related to income tax payments to be minimal during 2010 and 2011.

#### Six months ended June 30, 2010 compared to the six months ended June 30, 2009

*Net revenues*. Net revenues for the six months ended June 30, 2010 totaled approximately \$20.9 million, representing an increase of approximately \$1.6 million, or 9%, over the same period in 2009. With overall sales volume remaining consistent between the two periods, increased gross sales were partially offset with gross-to-net revenue adjustments from increased rebate expense associated with state and managed care activity, as well as additional fee-for-service expense due to additional agreements in 2010.

During the third quarter of 2009, we expanded our hospital sales force in connection with the commercial launch of Caldolor. In addition to the expansion of our hospital sales force, we realigned our field sales force to enable them to also promote Caldolor in the surgery-center market. The sales forces have been working diligently in the continued launch of Caldolor while maintaining a consistent level of focus on our other products, which is evidenced by consistent sales volume of Acetadote and Kristalose.

Cost of products sold. Cost of products sold as a percentage of net revenues increased slightly from 7.9% for the six months ended June 30, 2009 to 8.3% for the same period in 2010. The increase in cost of products sold as a percentage of net revenues was primarily due to an increase in our gross-to-net revenue adjustments previously discussed.

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*Selling and marketing*. Selling and marketing expense for the six months ended June 30, 2010 totaled approximately \$11.5 million, representing an increase of approximately \$2.9 million, or 34%, over the same period in 2009. The increase was primarily due to the expansion of our hospital sales force in the third quarter of 2009, and the resulting increases in payroll and related taxes, travel, meals and promotional activities.

Research and development. Research and development expense for the six months ended June 30, 2010 totaled approximately \$1.8 million, representing a decrease of approximately \$1.6 million, or 47%, over the same period in 2009. The decrease was primarily due to the inclusion in the second quarter of 2009 of approximately \$2.0 million of milestone expenses incurred upon the FDA approval of Caldolor in June 2009. This decrease was offset by additional costs incurred in 2010 related to annual FDA product and establishment fees and increased costs related to development efforts for our products and product candidates.

General and administrative. General and administrative expense for the six months ended June 30, 2010 totaled approximately \$3.7 million, representing an increase of approximately \$1.0 million, or 37%, over the same period in 2009. The increase is primarily due to additional expenses associated with being an SEC registrant, including legal and accounting-related costs and insurance. In addition, we incurred additional foreign currency expense associated with our products bought from overseas suppliers.

*Interest expense*. Interest expense for the six months ended June 30, 2010 totaled approximately \$0.8 million, representing an increase of approximately \$0.6 million as compared to the same period in 2009. The increase is primarily attributable to the increase in our average term debt balance in 2010 as compared to 2009.

*Income tax expense*. Income tax expense for the six months ended June 30, 2010 totaled approximately \$0.6 million, representing a decrease of approximately \$0.5 million, over the same period in 2009. As a percentage of net income before income taxes, income tax expense increased from 41.6% for the six months ended June 30, 2009 to 49.7% for the six months ended June 30, 2010. The decrease, in dollars, was due to lower earnings for the six months ended June 30, 2010 as compared to the same period in 2009 offset by an increase in our projected tax rate for 2010 as a result of an increase in our permanent differences relative to our net income before income taxes.

#### LIQUIDITY AND CAPITAL RESOURCES

#### **Working Capital**

Our primary sources of liquidity are cash flows provided by our operations, our borrowings and the cash proceeds from our initial public offering of common stock that was completed in August 2009. We believe that our internally generated cash flows, amounts available under our credit facilities and cash on hand will be adequate to service existing debt, finance internal growth and fund capital expenditures. As of June 30, 2010 and December 31, 2009, cash and cash equivalents was \$71.5 million and \$78.7 million, respectively, working capital (current assets minus current liabilities) was \$71.2 million and \$74.5 million, respectively, and our current ratio (current assets to current liabilities) was 5.6x and 5.0x, respectively. As of June 30, 2010, we had an additional \$2.2 million available to us on our line of credit.

Our term debt agreement with Bank of America requires an additional loan fee of \$440,000 based on certain metrics as of September 30, 2010, which would be due on or before November 15, 2010. We are in negotiations with the bank to amend certain terms and conditions of the debt agreement, and are evaluating other options available to us, including the prepayment of the term debt. Currently, any prepayment prior to December 31, 2010 shall be accompanied by a prepayment fee of 4% of the amount prepaid. In addition, if we prepay the term debt, we would write off the remaining deferred loan costs, which was approximately \$0.3 million as of June 30, 2010. If we elect to prepay the term debt prior to September 30, 2010, we would not be subject to any additional loan fee. Any additional loan fee would be a component of interest expense.

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The following table summarizes our net changes in cash and cash equivalents for the six months ended June 30, 2010 and 2009:

	Six Montl June		
	2010	2009	
	(in thou	ands)	
Net cash provided by (used in):			
Operating activities	\$ 755	\$ 1,269	
Investing activities	(207)	(120)	
Financing activities	(7,754)	(447)	
Net (decrease) increase in cash and cash equivalents (1)	\$ (7,206)	\$ 702	

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

The net decrease in cash and cash equivalents of \$7.2 million for the six months ended June 30, 2010 was primarily due to cash used in financing activities, which included (1) principal payments on our term debt of approximately \$6.1 million, (2) the repurchase of common stock of approximately \$3.1 million, (3) proceeds from the exercise of stock options of approximately \$1.0 million and (4) the excess tax benefit derived from the exercise of nonqualified options of approximately \$0.5 million.

The share repurchase program discussed in Part II, Item 2, is incorporated by reference into this Item.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

During the six months ended June 30, 2010, the Company did not engage in any off-balance sheet arrangements.

### Item 3: Quantitative and Qualitative Disclosure about Market Risk Interest Rate Risk

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

The interest rate related to borrowings under our revolving credit facility and term debt is a variable rate of LIBOR plus an applicable margin, as defined in the debt agreement (5.85% at June 30, 2010). As of June 30, 2010, we had outstanding borrowings of approximately \$13.8 million under our revolving credit facility and term debt combined. If interest rates increased by 1.0%, our annual interest expense on our borrowings would increase by approximately \$0.1 million.

#### **Exchange Rate Risk**

While we operate primarily in the U.S., we are exposed to foreign currency risk. Acetadote is manufactured by a supplier that denominates supply prices in Canadian dollars. One of our supply agreements for Caldolor is denominated in Australian dollars. Additionally, some of our research and development is performed abroad. As of June 30, 2010, our outstanding payables denominated in a foreign currency totaled \$0.3 million.

Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms, with much of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange gains and losses were not significant for the six months ended June 30, 2010. Neither a 10% increase nor decrease from current exchange rates would have a significant effect on our operating

#### **Item 4T: Controls and Procedures**

The Company s Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of the Company s disclosure controls and procedures as of June 30, 2010. Based on that evaluation, they have concluded that the Company s disclosure controls and procedures are effective to ensure that material information relating to the Company and the Company s consolidated subsidiaries is made known to officers within these entities in order to allow for timely decisions regarding required disclosure.

During the Company s second quarter of 2010, there have been no changes in the Company s internal controls over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f)).

#### PART II OTHER FINANCIAL INFORMATION

#### **Item 1a: Risk Factors**

Information regarding risk factors appears on pages 20 through 32 in our Annual Report on Form 10-K for the year ended December 31, 2009 under the sections titled Risk Factors. There have been no material changes from the risk factors previously discussed therein.

#### Item 2: Unregistered Sales of Equity Securities and Use of Proceeds **Use of Proceeds**

On August 10, 2009, our Registration Statement on Form S-1 (File No. 333-142535) for 5,000,000 shares of common stock was declared effective for the Company s initial public offering. As of June 30, 2010, we have used approximately \$4.2 million of the net proceeds to pay off the existing term debt with Bank of America, approximately \$6.7 million for the commercialization of Caldolor, approximately \$4.9 million for the expansion of our sales force and approximately \$1.5 million for ongoing clinical work, product development and other costs related to Caldolor. The remaining proceeds have been invested in money market accounts. There have been no material changes in the planned expected use of the net proceeds from the offering.

#### **Purchases of Equity Securities**

The following table summarizes the purchase of equity securities by the Company during the three months ended June 30, 2010:

	Period	Total Number of Shares (or Units) Purchased	of Shares (or Units) Purchased a  Part of Public Average Price Paid per Share		Total Part of P Number of Average Annou Shares (or Price Paid Plans Units) per Share		(or Units) Purchased as Part of Publicly Announced	D Sh	ximum Number (or Approximate ollar Value) of ares (or Units) that May t Be Purchased Under the
April 1 May 1	April 30 May 31	9,479(1)	\$	10.55					
June 1	June 30	196,424	\$	6.86	196,424	\$	8,653,124(2)		
Total		205,903							

(1) The purchase of 9,479 shares of common stock was made pursuant to a put

right held by an executive to provide for the settlement of the remaining tax liability associated with the exercise of stock options in 2009. The purchase price of this transaction was the then-current fair market value of common stock on the date of the transaction.

(2) On May 13, 2010, we announced a share repurchase program to purchase up to \$10 million of our common stock pursuant to Rule 10b-18 of the Securities

Act.

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#### **Item 6: Exhibits**

#### No. Description

- Exclusive Distribution Agreement, effective as of July 1, 2010, by and between Cardinal Health 105, Inc. and Cumberland Pharmaceuticals Inc.
- Certification of Chief Executive Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Confidential

treatment has

been requested

for portions of

this exhibit.

These portions

have been

omitted from

Exhibit 10.7 and

submitted

separately to the

Securities and

Exchange

Commission.

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#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cumberland Pharmaceuticals Inc.

Dated: August 16, 2010 By: /s/ A.J. Kazimi

A. J. Kazimi

Chief Executive Officer

Dated: August 16, 2010 By: /s/ David L. Lowrance

David L. Lowrance Vice President and Chief Financial Officer

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