

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

November 15, 2010

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

(Mark One)

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

**For the quarterly period ended September 30, 2010**

**or**

☐ **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**

(State or other jurisdiction  
of incorporation or organization)

**62-1765329**

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

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

(Address of principal executive offices)

**37203**

(Zipcode)

**(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 ☒ No ☐

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 ☐ No ☐

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 ☐

Accelerated filer ☐

Non-accelerated filer ☒  
(Do not check if a smaller  
reporting company)

Smaller reporting  
company ☐

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

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 November 8, 2010

Common stock, no par value

20,310,328

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**CUMBERLAND PHARMACEUTICALS INC.**  
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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1: Financial Statements****CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets  
(Unaudited)**

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 65,518,340	\$ 78,701,682
Accounts receivable, net of allowances	4,791,682	6,176,585
Inventories	7,646,228	4,822,873
Other current assets	1,940,778	3,472,455
Total current assets	79,897,028	93,173,595
Property and equipment, net	1,139,946	918,412
Intangible assets, net	7,580,168	7,956,009
Other assets	1,292,724	1,676,304
Total assets	\$ 89,909,866	\$ 103,724,320
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 2,666,668	\$ 9,061,973
Current portion of other long-term obligations	12,035	144,828
Accounts payable	3,416,370	5,632,796
Other accrued liabilities	3,817,822	3,784,777
Total current liabilities	9,912,895	18,624,374
Revolving line of credit	1,825,951	1,825,951
Long-term debt, excluding current portion	3,333,332	8,938,027
Other long-term obligations, excluding current portion	211,757	184,632
Total liabilities	15,283,935	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; 20,353,849 and 20,180,486<sup>(1)</sup> shares issued and outstanding as of September 30, 2010 and

December 31, 2009, respectively	68,521,470	67,711,746
Retained earnings	6,161,252	4,542,126

Total shareholders' equity	74,682,722	72,253,872
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Noncontrolling interests	(56,791)	(32,536)
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Total equity	74,625,931	72,221,336
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Total liabilities and equity	\$ 89,909,866	\$ 103,724,320
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(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)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Net revenues	\$ 12,190,870	\$ 13,597,760	\$ 33,061,457	\$ 32,822,972
Costs and expenses:				
Cost of products sold	909,434	1,761,069	2,632,447	3,271,363
Selling and marketing	5,692,048	6,087,807	17,147,683	14,611,796
Research and development	1,138,955	640,877	2,947,623	4,041,719
General and administrative	1,806,975	2,537,627	5,471,012	5,218,925
Amortization of product license right	171,732	171,726	515,184	515,178
Other	27,869	26,595	83,283	80,791
Total costs and expenses	9,747,013	11,225,701	28,797,232	27,739,772
Operating income	2,443,857	2,372,059	4,264,225	5,083,200
Interest income	48,675	14,285	159,688	42,041
Interest expense	(547,795)	(248,272)	(1,299,703)	(430,207)
Income before income taxes	1,944,737	2,138,072	3,124,210	4,695,034
Income tax expense	(943,141)	(855,660)	(1,529,339)	(1,919,356)
Net income	1,001,596	1,282,412	1,594,871	2,775,678
Net loss at subsidiary attributable to noncontrolling interests	6,648	5,725	24,255	26,420
Net income attributable to common shareholders	\$ 1,008,244	\$ 1,288,137	\$ 1,619,126	\$ 2,802,098
Earnings per share attributable to common shareholders				
- basic	\$ 0.05	\$ 0.08	\$ 0.08	\$ 0.23
- diluted	\$ 0.05	\$ 0.07	\$ 0.08	\$ 0.16
Weighted-average shares outstanding				
- basic	20,327,867	15,745,069	20,335,911	12,197,876
- diluted	20,803,182	19,183,606	21,135,762	17,143,348

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)**

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
Cash flows from operating activities:		
Net income	\$ 1,594,871	\$ 2,775,678
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization expense	723,687	605,514
Non-employee equity compensation	62,547	1,046,192
Stock-based compensation employee stock options	503,446	455,502
Excess tax benefit derived from exercise of stock options	(1,256,913)	(2,842,825)
Non-cash interest expense	328,475	83,420
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	1,384,903	(4,054,710)
Inventory	(2,823,355)	75,185
Other current assets and other assets	1,461,538	936,286
Accounts payable and other accrued liabilities	(840,429)	3,299,235
Other long-term obligations	(105,668)	(455,723)
Net cash provided by operating activities	1,033,102	1,923,754
Cash flows from investing activities:		
Additions to property and equipment	(311,301)	(199,312)
Additions to patents	(132,047)	(71,358)
Net cash used in investment activities	(443,348)	(270,670)
Cash flows from financing activities:		
Proceeds from initial public offering		85,000,000
Costs of initial public offering		(7,385,124)
Proceeds from borrowings on long-term debt		18,000,000
Principal payments on note payable	(12,000,000)	(5,000,000)
Costs of financing for long-term debt and credit facility	(82,500)	(189,660)
Proceeds from exercise of stock options	1,182,139	64,275
Excess tax benefit derived from exercise of stock options	1,256,913	2,842,825
Repurchase of common shares	(4,129,648)	(27,273,677)
Net cash (used in) provided by financing activities	(13,773,096)	66,058,639
Net (decrease) increase in cash and cash equivalents	(13,183,342)	67,711,723
Cash and cash equivalents at beginning of period	78,701,682	11,829,551

Cash and cash equivalents at end of period	\$ 65,518,340	\$ 79,541,274
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Supplemental disclosure of cash flow information:

Non-cash investing and financing activities:

Deferred financing costs		335,075
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Common shares repurchased during period but not paid as of the end of the period	22,207	
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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)**

	<b>Common stock</b>		<b>Retained</b>	<b>Non-</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>earnings</b>	<b>controlling</b>	<b>equity</b>
				<b>interests</b>	
Balance, December 31, 2009	20,180,486	\$ 67,711,746	\$ 4,542,126	\$ (32,536)	\$ 72,221,336
Stock-based compensation nonemployees	5,636	89,081			89,081
Exercise of options and related tax benefit, net of mature shares redeemed for the exercise price	672,794	2,439,052			2,439,052
Stock-based compensation employees		503,446			503,446
Repurchase of shares	(505,067)	(4,151,855)			(4,151,855)
Reclass of redeemable common stock		1,930,000			1,930,000
Net and comprehensive income			1,619,126	(24,255)	1,594,871
Balance, September 30, 2010	20,353,849	\$ 68,521,470	\$ 6,161,252	\$ (56,791)	\$ 74,625,931

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 nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

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.

Total comprehensive income was comprised solely of net income for the three and nine months ended September 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 September 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 nine months ended September 30, 2010 and 2009:

		<b>Three Months Ended September</b>	
		<b>2010</b>	<b>2009</b>
		<b>30,</b>	
Numerator:			
Net income attributable to common shareholders		\$ 1,008,244	\$ 1,288,137
Denominator:			
Weighted-average shares outstanding	basic	20,327,867	15,745,069
Convertible preferred stock shares			714,505
Dilutive effect of other securities		475,315	2,724,032
Weighted-average shares outstanding	diluted	20,803,182	19,183,606



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

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
Numerator:		
Net income attributable to common shareholders	\$ 1,619,126	\$ 2,802,098
Denominator:		
Weighted-average shares outstanding basic	20,335,911	12,197,876
Convertible preferred stock shares		1,320,717
Dilutive effect of other securities	799,851	3,624,755
Weighted-average shares outstanding diluted	21,135,762	17,143,348

As of September 30, 2010 and 2009, options to purchase 1,200,017 and 231,185 shares of common stock, respectively, were outstanding but were not included in the computation of diluted EPS because the effect would be antidilutive.

**(3) REVENUES**

The Company had sales to non-U.S. customers of \$0.1 million and \$0 during the three months ended September 30, 2010 and 2009, respectively. The Company had sales of approximately \$0.1 million to non-U.S. customers during the nine months ended September 30, 2010 and \$0.7 million during the nine months ended September 30, 2009.

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2010 and 2009:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Products:				
Acetadote	\$ 9,600,427	\$ 7,686,250	\$ 25,632,260	\$ 22,059,455
Kristalose	2,506,894	2,476,400	7,088,294	7,223,744
Caldolor	14,103	3,246,370	79,184	3,246,370
Other	69,446	188,740	261,719	293,403
Total net revenues	\$ 12,190,870	\$ 13,597,760	\$ 33,061,457	\$ 32,822,972

**(4) DEBT**

On September 29, 2010, the Company entered into an amendment of its loan agreement with Bank of America, N.A. (the Agreement). The amendment provided for an increase in the availability under the existing line of credit from \$4.0 million to \$6.0 million, with interest payable monthly at LIBOR plus an Applicable Margin, as defined in the Agreement (5.76% at September 30, 2010). In addition, the term debt was reduced to \$6.0 million, with quarterly payments under the term debt reduced from \$1.5 million to \$666,667, plus interest at the same rate as the line of credit, beginning December 31, 2010. The Company reduced its commitment fee from three-quarters of one percent (0.75%) to one-half of one percent (0.50%) per annum on the unused line of credit. The borrowings are collateralized by a first priority lien on all of the Company's assets.

The Agreement's covenants include a Leverage Ratio, as defined in the Agreement, of 2.00 to 1.00 for the quarter ended December 31, 2010, 1.75 to 1.00 for each of the three quarters ended March 31, 2011, June 30, 2011 and September 30, 2011 and 1.25 to 1.00 for quarter ending December 31, 2011 and thereafter, as well as a Fixed Charge Coverage Ratio, as defined in the Agreement, of at least 1.25 to 1.00 at each quarter-annual reporting period. In addition, the Company must maintain deposits with Bank of America, N.A. at amounts equal to at least the sum of (a) the maximum amount of the line of credit plus (b) the aggregate principal amount then outstanding under the term debt.

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**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**

**Notes to condensed consolidated financial statements continued**

**(unaudited)**

The Company is subject to additional loan fees if certain performance metrics measured at March 31, 2011 and September 30, 2011 are not met. If required, the additional loan fee amounts of \$102,000 each are due within 45 days of the end of the respective period. As of September 30, 2010, the Company has not recognized any additional loan fees.

Concurrent with the amendment of the Agreement, the Company elected to prepay approximately \$5.9 million of its term debt, incurring a prepayment penalty of approximately \$0.2 million. The prepayment penalty is included as a component of interest expense for the three and nine months ended September 30, 2010.

**(5) SHAREHOLDERS' EQUITY**

In February and April 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.

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 342,045 shares for approximately \$2.2 million through September 30, 2010.

During 2010, options to purchase 690,740 shares of common stock were exercised. In connection with these exercises, 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 \$5.0 million, of which approximately \$2.6 million was used to offset the estimated tax liability arising from the results of operations for the nine months ended September 30, 2010. As of September 30, 2010, the Company has unrecognized tax deductions of approximately \$67.9 million that will be recognized when the deduction reduces income taxes payable.

**(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 50,921 shares for approximately \$0.3 million for the period from October 1, 2010 to November 8, 2010. The weighted-average repurchase price was \$6.43 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-Q.

## **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 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® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. We market and sell our products through our 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 projected 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 became profitable in 2004, and since then 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.

### **Growth Strategy**

Our growth strategy involves maximizing the potential of our existing products and continuing to build a portfolio of new, differentiated products. Specifically, we expect to grow by executing the following plans:

We market our products in the United States through a comprehensive marketing and promotional effort, and we are working to bring our products to select international markets with our first international launch occurring in the third quarter of 2010.

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We look for opportunities to expand into additional patient populations with new product indications, whether through our own development work or by supporting promising 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.

We are supplementing the aforementioned growth tactics with the early-stage drug development activities of Cumberland Emerging Technologies, Inc. (CET), our majority-owned subsidiary. CET partners with university research centers to identify and cost-effectively develop promising early-stage product candidates, which Cumberland Pharmaceuticals 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](http://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](http://www.sec.gov).

## **Recent Developments**

### *Submission of Application for New Formulation of Acetadote*

In October 2010, we submitted an application to the U.S. Food and Drug Administration (FDA) for approval of a new formulation of Acetadote. The new formulation is designed to replace the currently marketed product and is the result of our commitment to further developing our products, whether to expand into new patient populations or to improve upon our products. We believe the testing and manufacturing work we undertook with this new formulation of Acetadote demonstrates that it offers improvements over the currently marketed product and, upon potential approval by the FDA, plan to introduce it to the hospital community.

We expect to receive a response from the FDA in January 2011 and, if the new formulation is approved, would commence with the new product launch immediately. We have also filed a patent application with the U.S. Patent and Trademark Office to protect the proprietary new formulation.

### *Supplemental New Drug Applications for Acetadote*

In March 2010, we submitted a supplemental new drug application (sNDA) to the 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 with a response expected in September 2010. In August 2010, we announced that the FDA extended its review of the sNDA by three months, resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010.

In addition to expanded labeling for Acetadote, we have requested additional exclusivity for the product. As discussed in our Annual Report on Form 10-K for the year ended December 31, 2009, our original market exclusivity continues until January 2011.

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### *Launch of Acetadote in Australia*

In April 2010, the Therapeutic Goods Administration granted approval to our partner Phebra Pty Ltd., an Australian-based specialty pharmaceutical company, for the commercialization of Acetadote in Australia. In October 2010, Phebra commenced with the Australian launch of Acetadote and began reaching out to hospitals to promote wide distribution of the product. This introduction of Acetadote in Australia marked Cumberland's entry into international markets.

In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country. Phebra is also our marketing partner for Acetadote in certain Asia Pacific markets, and continues to work toward obtaining approval for the product in those areas.

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

### *Transfer of License Rights*

As previously reported, CET entered into an agreement with Vanderbilt University to license a new product candidate. In the third quarter of 2010, Cumberland Pharmaceuticals entered into an agreement with CET to assume the rights and responsibilities associated with the product candidate.

## **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 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 eleven percent to thirteen 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 fifty-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 applications for four of our research projects prior to the deadline of July 21, 2010. In November 2010, we received a response from the Internal Revenue Service indicating that all four projects were approved. We have the ability to receive grants of up to approximately \$860,000 based on actual 2009 and 2010 expenditures. We anticipate receiving these funds in late 2010 or early 2011.

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**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.

**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. The adoption of this guidance did not 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 September 30, 2010 compared to the three months ended September 30, 2009**

*Net revenues.* Net revenues for the three months ended September 30, 2010 totaled approximately \$12.2 million, representing a decrease of approximately \$1.4 million, or 10%, over the same period in 2009. With the initial launch of Caldolor in the third quarter of 2009, which represented approximately \$3.2 million of net revenue, we achieved our goal of national distribution of Caldolor with our wholesalers in preparation of the launch. Acetadote revenue for the three months ended September 30, 2010 increased \$1.9 million as compared to the same period in 2009 and Kristalose revenue remained consistent between the periods. Also impacting net revenue was an increase in our gross-to-net revenue adjustments associated with expired products, rebates for state and managed-care activity and fee for service arrangements.

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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 promotion of Caldolor while maintaining a consistent level of focus on Acetadote and Kristalose, which is evidenced by the sales performance of these two products.

*Cost of products sold.* Cost of products sold as a percentage of net revenues decreased from 13.0% for the three months ended September 30, 2009 to 7.5% for the same period in 2010. The decrease in cost of products sold as a percentage of net revenues was primarily due to the sales mix in the periods.

*Research and development.* Research and development expense for the three months ended September 30, 2010 totaled approximately \$1.1 million, representing an increase of approximately \$0.5 million, or 78%, over the same period in 2009. The increase was primarily due to 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 September 30, 2010 totaled approximately \$1.8 million, representing a decrease of approximately \$0.7 million, or 29%, over the same period in 2009. The decrease is primarily due to the inclusion in 2009 of approximately \$1.0 million of payroll tax associated with the exercise of nonqualified stock options by an employee, offset by increased expenses of being an SEC registrant, including legal, accounting and insurance costs. In addition, we incurred additional foreign currency expense associated with our products bought from overseas suppliers in 2009.

*Interest expense.* Interest expense for the three months ended September 30, 2010 totaled approximately \$0.5 million, representing an increase of approximately \$0.3 million as compared to the same period in 2009. The increase is primarily attributable to the inclusion in 2010 of approximately \$0.1 million of deferred financing costs and approximately \$0.2 million of prepayment fees associated with the early extinguishment and modification of our term debt facility in September 2010. As noted in footnote 4 to the condensed consolidated financial statements included herein, we amended our debt facility with Bank of America, N.A. in September 2010.

*Income tax expense.* Income tax expense for the three months ended September 30, 2010 totaled approximately \$0.9 million, representing an increase of \$0.1 million over the same period in 2009. As a percentage of income before income taxes, income tax expense increased from 40.0% for the three months ended September 30, 2009 to 48.5% for the three months ended September 30, 2010. The increase in the percentage was due to an increase in our projected tax rate for 2010 as a result of an increase in our permanent differences, primarily option expense for incentive stock options, relative to our income before income taxes.

During 2009 and 2010, significant stock options were exercised that resulted in an excess tax benefit to the Company. As of September 30, 2010, we have approximately \$67.9 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 September 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.

### **Nine months ended September 30, 2010 compared to the nine months ended September 30, 2009**

*Net revenues.* Net revenues for the nine months ended September 30, 2010 totaled approximately \$33.1 million, representing an increase of approximately \$0.2 million, or 1%, over the same period in 2009. Net revenue increased \$3.6 million for Acetadote and decreased \$0.1 million and \$3.2 million for Kristalose and Caldolor, respectively. During the third quarter of 2009, we achieved our goal of national distribution of Caldolor with our wholesalers in preparation of the launch. The increase in Acetadote revenue was positively impacted by a 5% increase in volume and an increase in the average selling price, offset by an increase in fee-for-service deductions due to additional arrangements with our wholesalers. While Kristalose gross revenue increased, net revenue was impacted by an increase in the gross-to-net revenue deductions primarily associated with rebates and expired product returns. Additionally, in the third quarter of 2009, we completed the commercial launch of Caldolor, and recognized \$3.2 million of net revenue in 2009. Our sales forces continue to maintain a consistent level of focus on Acetadote and Kristalose while they progress the promotion of Caldolor.



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*Cost of products sold.* Cost of products sold as a percentage of net revenues decreased from 10.0% for the nine months ended September 30, 2009 to 8.0% for the same period in 2010. This decrease was primarily due to the sales mix in the periods.

*Selling and marketing.* Selling and marketing expense for the nine months ended September 30, 2010 totaled approximately \$17.1 million, representing an increase of approximately \$2.5 million, or 17%, over the same period in 2009. The increase was primarily due to the expansion of our hospital sales force during the third quarter of 2009, and the resulting increases in payroll and related taxes, travel, meals and promotional activities. These increases were offset by a decrease in market research, advertising, hiring and meeting expenses related to Caldolor in 2010 as compared to the significant investment made in 2009 related to the Caldolor launch.

*Research and development.* Research and development expense for the nine months ended September 30, 2010 totaled approximately \$2.9 million, representing a decrease of approximately \$1.1 million, or 27%, over the same period in 2009. The decrease was primarily due to the inclusion in 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, increased salary and related expenses resulting from an increase in personnel and increased costs related to furthering our development efforts for our products and product candidates.

*General and administrative.* General and administrative expense for the nine months ended September 30, 2010 totaled approximately \$5.5 million, representing an increase of approximately \$0.3 million, or 5%, over the same period in 2009. The increase is primarily due to additional expenses associated with being an SEC registrant, including legal, accounting and insurance costs.

*Interest income.* Interest income for the nine months ended September 30, 2010 totaled approximately \$0.2 million, representing an increase of approximately \$0.1 million, or 280%, over the same period in 2009. The increase was primarily due to the higher cash balances maintained in 2010 as a result of the proceeds received from the initial public offering in the third quarter of 2009.

*Interest expense.* Interest expense for the nine months ended September 30, 2010 totaled approximately \$1.3 million, representing an increase of approximately \$0.9 million as compared to the same period in 2009. The increase is primarily attributable to (1) an average higher outstanding debt balance in 2010 as compared to 2009 and (2) the inclusion of approximately \$0.1 million of deferred financing costs and approximately \$0.2 million of prepayment fees associated with the early extinguishment and amendment of our term debt facility in September 2010. As noted in footnote 4 to the condensed consolidated financial statements included herein, we amended our debt facility with Bank of America, N.A. in September 2010.

*Income tax expense.* Income tax expense for the nine months ended September 30, 2010 totaled approximately \$1.5 million, representing a decrease of approximately \$0.4 million, over the same period in 2009. As a percentage of income before income taxes, income tax expense increased from 40.9% for the nine months ended September 30, 2009 to 49.0% for the nine months ended September 30, 2010. The increase in the percentage was due to an increase in our projected tax rate for 2010 as a result of an increase in our permanent differences, primarily option expense for incentive stock options, relative to our income before income taxes.

**Table of Contents****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 September 30, 2010 and December 31, 2009, cash and cash equivalents was \$65.5 million and \$78.7 million, respectively, working capital (current assets minus current liabilities) was \$70.0 million and \$74.5 million, respectively, and our current ratio (current assets to current liabilities) was 8.1x and 5.0x, respectively. As of September 30, 2010, we had an additional \$4.2 million available to us under our line of credit.

The information included in footnote 4 to the condensed consolidated financial statements included herein is hereby incorporated by reference into this Item.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 1,033	\$ 1,924
Investing activities	(443)	(271)
Financing activities	(13,773)	66,059
Net (decrease) increase in cash and cash equivalents <sup>(1)</sup>	\$ (13,183)	\$ 67,712

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

The net decrease in cash and cash equivalents of \$13.2 million for the nine months ended September 30, 2010 was primarily due to cash used in financing activities, which included (1) principal payments on our term debt of \$12.0 million, (2) the repurchase of common stock of approximately \$4.1 million. These expenditures were offset by proceeds from the exercise of stock options of approximately \$1.2 million and the excess tax benefit derived from the exercise of nonqualified options of approximately \$1.3 million. Cash provided by operating activities for the nine months ended September 30, 2010 was primarily due to net income for the period and the collection of the receivables associated with these sales.

The net increase in cash and cash equivalents of \$67.7 million for the nine months ended September 30, 2009 was primarily due to the net cash proceeds from our initial public offering in August 2009 offset by the repurchase of common shares associated with the tendering of shares to settle the minimum statutory tax withholding requirement resulting from the exercise of nonqualified options by an employee.

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

**OFF-BALANCE SHEET ARRANGEMENTS**

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





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### **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 (5.76% at September 30, 2010). As of September 30, 2010, we had outstanding borrowings of approximately \$7.8 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 September 30, 2010, our outstanding payables denominated in a foreign currency totaled \$0.1 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 nine months ended September 30, 2010. Neither a 10% increase nor decrease from current exchange rates would have a significant effect on our operating results or financial condition.

### **Item 4: 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 September 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 third 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 September 30, 2010, we have used approximately \$4.2 million of the net proceeds to pay off existing term debt with Bank of America and approximately \$13.3 million for the launch of Caldolor, including \$7.0 million for marketing and commercialization and approximately \$6.3 million for the expansion of our sales force, and approximately \$1.6 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.

**Table of Contents****Purchases of Equity Securities**

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

<b>Period</b>	<b>Total Number of Shares (or Units) Purchased</b>	<b>Average Price Paid per Share (or Unit)</b>	<b>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plan or Programs</b>
July 1 – July 31	104,819	\$ 6.16	301,243	\$ 8,007,858 <sup>(1)</sup>
August 1 – August 31				
September 1 – September 30	40,802	\$ 5.47	342,045	\$ 7,784,699
<b>Total</b>	<b>145,621</b>			

(1) 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.

**Item 6: Exhibits**

<b>No.</b>	<b>Description</b>
10.18#	2007 Long-Term Incentive Compensation Plan of Cumberland Pharmaceuticals Inc., as amended on November 4, 2010
31.1	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.

# Indicates a management contract or compensatory plan.

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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: November 15, 2010

By: */s/ A. J. Kazimi*  
A. J. Kazimi  
Chief Executive Officer

Dated: November 15, 2010

By: */s/ David L. Lowrance*  
David L. Lowrance  
Vice President and Chief Financial  
Officer