

CUMBERLAND PHARMACEUTICALS INC

Form 10-Q

August 16, 2010

Table of Contents

**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 June 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

Smaller reporting
company

(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 No

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

Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

Class	Outstanding at August 12, 2010
Common stock, no par value	20,253,767

**CUMBERLAND PHARMACEUTICALS INC.
INDEX**

<u>Part I Financial Information</u>	1
<u>Item 1: Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Income</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Condensed Consolidated Statements of Equity and Comprehensive Income</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
<u>Item 3: Quantitative and Qualitative Disclosure about Market Risk</u>	14
<u>Item 4T: Controls and Procedures</u>	15
<u>Part II Other Financial Information</u>	15
<u>Item 1a: Risk Factors</u>	15
<u>Item 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	15
<u>Item 6: Exhibits</u>	16
<u>Signatures</u>	17
<u>EX-10.7</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

Table of Contents**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:		

Edgar Filing: CUMBERLAND PHARMACEUTICALS INC - Form 10-Q

Common stock no par value; 100,000,000 shares authorized; 20,358,586 and 20,180,486 ⁽¹⁾ 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.

Table of Contents**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Income
(Unaudited)**

	Three months ended June		Six months ended June 30,	
	2010	2009	2010	2009
Net revenues	\$ 10,739,935	\$ 9,820,613	\$ 20,870,587	\$ 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	11,455,635	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	19,050,219	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
Net income attributable to common shareholders	\$ 287,304	\$ 295,871	\$ 610,882	\$ 1,513,961
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	20,445,560	10,467,781	20,340,000	10,394,883
- diluted	21,207,645	16,046,844	21,302,119	16,087,448

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Cash Flows
(Unaudited)**

	Six Months Ended June 30,	
	2010	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 patents	(80,734)	(34,551)
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
--	--	---------

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.

Table of Contents**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Equity and Comprehensive Income
(Unaudited)**

	Common stock		Retained	Non-	Total
	Shares	Amount	earnings	controlling	equity
				interests	
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

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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:

	Three Months Ended June	
	30,	
	2010	2009
Numerator:		
Net income attributable to common shareholders	\$ 287,304	\$ 295,871
Denominator:		
Weighted-average shares outstanding basic	20,445,560	10,467,781
Convertible preferred stock shares		1,625,498
Dilutive effect of other securities	762,085	3,953,565
Weighted-average shares outstanding diluted	21,207,645	16,046,844

Table of Contents

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

	Six Months Ended June 30,	2010	2009
Numerator:			
Net income attributable to common shareholders	\$	610,882	\$ 1,513,961
Denominator:			
Weighted-average shares outstanding basic		20,340,000	10,394,883
Convertible preferred stock shares			1,625,498
Dilutive effect of other securities		962,119	4,067,067
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 Ended June		Six Months Ended June 30,	
	2010	30,	2010	2009
	2010	2009	2010	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.

Table of Contents

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.

Table of Contents

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 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® (*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 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

Table of Contents

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.

Table of Contents

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.

Table of Contents