

CORNERSTONE THERAPEUTICS INC

Form 10-Q

November 04, 2010



**CORNERSTONE THERAPEUTICS INC.  
FORM 10-Q  
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**PART I FINANCIAL INFORMATION**

**Cautionary Statement Regarding Forward-Looking Statements**

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management's prospects, plans and objectives; and any other statements about management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; our ability to replace the revenues from our marketed unapproved products, which we plan to cease manufacturing and distributing at the end of 2010; the possibility that the Food and Drug Administration, or FDA, will take enforcement action against us or one or more of our marketed drugs that do not have FDA-approved marketing applications prior to the end of 2010; patient, physician and third-party payor acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products with FDA-approved marketing applications; our ability to obtain FDA approval to market and sell our products under development; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail in Part I Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission, or SEC, on March 4, 2010. Any material changes to the risk factors disclosed in the annual report are discussed below in Part II Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this quarterly report on Form 10-Q represent our views only as of the date of this quarterly report on Form 10-Q and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make.

**Table of Contents****ITEM 1. FINANCIAL STATEMENTS**

**CORNERSTONE THERAPEUTICS INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	<b>September 30, 2010 (Unaudited)</b>	<b>December 31, 2009 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 49,672	\$ 18,853
Accounts receivable, net	15,845	16,548
Inventories, net	19,762	18,106
Prepaid and other current assets	3,024	4,808
Income tax receivable	991	
Deferred income tax asset	3,858	3,507
 Total current assets	 93,152	 61,822
 Property and equipment, net	 1,587	 1,312
Product rights, net	116,271	126,806
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Other assets	374	113
 Total assets	 \$ 224,653	 \$ 203,322
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,344	\$ 7,172
Accrued expenses	28,582	23,703
Current portion of license agreement liability	1,227	1,019
Current portion of capital lease	81	10
Income taxes payable		1,606
Deferred revenue	9,195	
 Total current liabilities	 48,429	 33,510
 License agreement liability, less current portion	 1,341	 1,341
Capital lease, less current portion	167	39
Deferred income tax liability	3,496	4,564
 Total liabilities	 53,433	 39,454
 Commitments and contingencies, Note 6		
Stockholders equity		
Preferred stock \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		

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Common stock \$0.001 par value, 90,000,000 shares authorized; 25,442,596 and 25,022,644 shares issued and outstanding as of September 30, 2010 and December 31, 2009, respectively	25	25
Additional paid-in capital	159,720	157,745
Retained earnings	11,475	6,098
Total stockholders equity	171,220	163,868
Total liabilities and stockholders equity	\$ 224,653	\$ 203,322

The accompanying notes are an integral part of the consolidated financial statements.

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**CORNERSTONE THERAPEUTICS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**

(In thousands, except share and per share data)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Net revenues	\$ 27,932	\$ 23,078	\$ 92,803	\$ 78,776
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	7,742	4,143	22,714	10,245
Selling, general and administrative	12,850	13,186	38,089	34,023
Royalties	2,600	4,593	9,846	16,535
Research and development	1,047	691	3,748	3,041
Amortization of product rights	3,595	1,507	10,785	2,528
Total costs and expenses	27,834	24,120	85,182	66,372
Income (loss) from operations	98	(1,042)	7,621	12,404
Other expenses:				
Interest (expense) income, net	(37)	1	(47)	(113)
Other expense, net	(25)		(25)	
Total other (expenses) income	(62)	1	(72)	(113)
Income (loss) before income taxes	36	(1,041)	7,549	12,291
Benefit from (provision for) income taxes	728	503	(2,172)	(4,776)
Net income (loss)	\$ 764	\$ (538)	\$ 5,377	\$ 7,515
Net income (loss) per share, basic	\$ 0.03	\$ (0.03)	\$ 0.21	\$ 0.50
Net income (loss) per share, diluted	\$ 0.03	\$ (0.03)	\$ 0.21	\$ 0.46
Weighted-average common shares, basic	25,430,785	20,741,322	25,395,506	15,009,285
Weighted-average common shares, diluted	26,056,928	20,741,322	26,017,288	16,249,578

The accompanying notes are an integral part of the consolidated financial statements.

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**CORNERSTONE THERAPEUTICS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**  
**(In thousands)**

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 5,377	\$ 7,515
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	11,070	2,695
Provision for prompt payment discounts	2,909	2,316
Provision for inventory allowances	199	506
Loss on sale of fixed assets	25	
Stock-based compensation	970	2,970
Benefit from deferred income taxes	(1,419)	(4,664)
Changes in operating assets and liabilities:		
Accounts receivable	(2,206)	(16,812)
Inventories	(1,855)	(5,271)
Prepaid expenses and other assets	1,523	(2,086)
Accounts payable	2,172	(2,186)
Accrued expenses	5,087	5,796
Income taxes payable/receivable	(2,597)	228
Deferred revenue	9,195	
Net cash provided by (used in) operating activities	30,450	(8,993)
<b>Cash flows from investing activities</b>		
Proceeds from sale of marketable securities		300
Proceeds from sale of fixed assets	2	
Purchase of property and equipment	(361)	(250)
Purchase of product rights	(250)	(5,169)
Net cash used in investing activities	(609)	(5,119)
<b>Cash flows from financing activities</b>		
Proceeds from exercise of common stock options	538	401
Proceeds from issuance of shares of common stock		15,465
Payments for cancellation of warrants		(41)
Excess tax benefit from stock-based compensation	467	
Principal payments on capital lease obligation	(27)	(7)
Net cash provided by financing activities	978	15,818
Net increase in cash and cash equivalents	30,819	1,706
<b>Cash and cash equivalents as of beginning of period</b>	18,853	9,286
<b>Cash and cash equivalents as of end of period</b>	\$ 49,672	\$ 10,992



**Supplemental disclosure of non-cash investing and financing activities**

Acquisition of product rights through equity issued and liabilities assumed	\$	\$ 110,050
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The accompanying notes are an integral part of the consolidated financial statements.

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**CORNERSTONE THERAPEUTICS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION**

**Nature of Operations**

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on acquiring, developing and commercializing products primarily for the respiratory and related markets. Key elements of the Company's strategy are to pursue acquisition or licensing transactions to acquire the rights to patent-protected, branded respiratory or related pharmaceutical products, or late-stage product candidates; to implement life cycle management strategies to maximize the potential value and competitive position of the Company's currently marketed products, newly acquired products and product candidates that are currently in development; to grow product revenue through the Company's specialty sales forces; and to maintain and strengthen the intellectual property position of the Company's currently marketed products, newly acquired products and product candidates.

**Principles of Consolidation**

The Company's consolidated financial statements include the accounts of Cornerstone Therapeutics Inc. and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

**Interim Financial Statements**

The accompanying unaudited consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of these financial statements. The consolidated balance sheet at December 31, 2009 has been derived from the Company's audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2009, and these financial statements should be read in connection with those financial statements.

Certain information and footnote disclosure normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2009.

Operating results for the three and nine-month periods ended September 30, 2010 are not necessarily indicative of the results for the full year.

**Reclassifications**

Sales and marketing expenses and other charges, which were both previously stated separately on the consolidated statements of operations, are included in selling, general and administrative expenses in the accompanying consolidated statements of operations. These reclassifications had no effect on net income as previously reported.

**NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company's consolidated

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financial statements include certain judgments regarding revenue recognition, product rights, inventory valuation, accrued expenses and stock-based compensation. Actual results could differ from those estimates or assumptions.

**Concentrations of Credit Risk and Limited Suppliers**

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents and accounts receivable. The Company's cash and cash equivalents are maintained with one financial institution and are monitored against the Company's investment policy, which limits concentrations of investments in individual securities and issuers.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient ( API ) from any of these sources could have a material adverse effect on the Company's business, financial position and results of operations. During the nine months ended September 30, 2010, one supplier individually accounted for 64% of the Company's total inventory purchases during this period. Amounts due to this supplier represented 36% of total accounts payable as of September 30, 2010.

The Company sells its products primarily to large national wholesalers, which in turn resell the products to smaller or regional wholesalers, hospitals, retail pharmacies, chain drug stores, government agencies and other third parties. The following tables list the Company's customers that individually comprise greater than 10% of total gross product sales for the three and nine months ended September 30, 2010 and 2009 or 10% of total accounts receivable as of September 30, 2010 and December 31, 2009:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010 Gross Product Sales</b>	<b>2009 Gross Product Sales</b>	<b>2010 Gross Product Sales</b>	<b>2009 Gross Product Sales</b>
Cardinal Health, Inc.	38%	34%	39%	35%
McKesson Corporation	29	30	32	34
AmerisourceBergen Drug Corporation	25	21	22	18
Total	92%	85%	93%	87%

	<b>September 30, 2010 Accounts Receivable</b>	<b>December 31, 2009 Accounts Receivable</b>
	Cardinal Health, Inc.	33%
McKesson Corporation	35	37
AmerisourceBergen Drug Corporation	24	24
Total	92%	87%

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains cash deposits with a federally insured bank that exceed federally insured

limits. The Company is exposed to credit risk in the event of a default by the financial institution holding its cash deposits to the extent such deposits exceed federally insured limits. The Company has not experienced any losses due to such concentration of credit risk.

**Accounts Receivable**

The Company typically requires its customers to remit payments within the first 30 to 90 days, depending on the customer and the products purchased. In addition, the Company offers wholesale distributors a prompt payment

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discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company's wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of September 30, 2010 or December 31, 2009. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write offs during the three and nine months ended September 30, 2010 or 2009.

The following table represents accounts receivable, net, as of September 30, 2010 and December 31, 2009 (in thousands):

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Trade accounts receivable	\$ 16,210	\$ 16,932
Less allowance for prompt payment discounts	(365)	(384)
Accounts receivable, net	\$ 15,845	\$ 16,548

**Inventories**

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method and consist of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being coated and/or packaged for sale and finished goods include pharmaceutical products ready for commercial sale or distribution as samples.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product sales.

The following table represents inventories, net, as of September 30, 2010 and December 31, 2009 (in thousands):

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 6,881	\$ 5,597
Work in process	1,761	2,007
Finished goods:		
Pharmaceutical products trade	9,010	9,962
Pharmaceutical products samples	3,124	2,342
Total	20,776	19,908
Inventory allowances	(1,014)	(1,802)
Inventories, net	\$ 19,762	\$ 18,106

**Revenue Recognition**

The Company's consolidated net revenues represent the Company's net product sales, license and royalty agreement revenues. The following table sets forth the categories of the Company's net revenues (in thousands):

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	<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>
Gross product sales	\$ 41,616	\$ 34,681	\$ 140,724	\$ 108,384
Sales allowances	(15,206)	(11,603)	(49,462)	(29,845)
Net product sales	26,410	23,078	91,262	78,539
License and royalty agreement revenues	1,522		1,541	237
Net revenues	\$ 27,932	\$ 23,078	\$ 92,803	\$ 78,776

The Company records all of its revenue from product sales, license agreements and royalty agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

**Net Product Sales**

*Product Sales.* The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated. As of September 30, 2010, the Company had \$9.2 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

*Product Returns.* Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the majority of its products within an 18-month period, from six months prior to and up to twelve months subsequent to the expiration date of its product. The Company's products, except for CUROSURF®, have a 24 to 36 month expiration period from the date of manufacture. CUROSURF has an 18-month expiration period. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

*Rebates.* The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program's administrator.

*Price Adjustments and Chargebacks.* The Company's estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. These estimates are also based on the contract fees the Company pays to certain group purchasing organizations (GPOs) in connection with the Company's sales of CUROSURF. In the event that the sales mix to third-party payors or the contract fees paid to GPOs are different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. The Company has initiated voucher programs for its promoted products whereby the



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Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company's completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

*Prompt Payment Discounts.* The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 90 days after the invoice date depending on the customer and the products purchased (see *Accounts Receivable* above).

***License and Royalty Agreement Revenues***

Payments from the Company's licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. If the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company's licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

License agreement revenues were \$1.5 million for the three and nine months ended September 30, 2010. In August 2010, in accordance with a license agreement with Targacept, Inc. ( *Targacept* ) under which the Company out-licensed certain rights with respect to its alpha-7 receptor technology, the Company received an upfront nonrefundable payment of \$1.5 million. The Company is also eligible for success-based milestone payments of up to \$74.9 million, depending on which compound is progressed by Targacept.

Royalty agreement revenues are earned under license agreements which provide for the payment of royalties based on sales of certain licensed products. These revenues are recognized based on products sales that occurred in the relevant period. Royalty agreement revenues were \$22,000 and \$0 during the three months ended September 30, 2010 and 2009, respectively. For the nine months ended September 30, 2010 and 2009, royalty agreement revenues were \$41,000 and \$237,000, respectively.

**NOTE 3: GOODWILL AND INTANGIBLE ASSETS**

**Goodwill**

The Company's goodwill balance as of September 30, 2010 and December 31, 2009 was \$13.2 million and relates to the merger whereby the Company, which was then known as Critical Therapeutics, Inc. ( *Critical Therapeutics* ), merged (through a transitory subsidiary) with Cornerstone BioPharma Holdings, Inc. ( *Cornerstone BioPharma* ) on October 31, 2008 (the *Merger* ). Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with GAAP. Accordingly, the total purchase price of \$25.2 million was allocated to acquired tangible and intangible assets and assumed liabilities of Critical Therapeutics based on their estimated fair values as of the closing date of the Merger. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill. No amount of the goodwill balance at September 30, 2010 will be deductible for income tax purposes.

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The following table represents product rights, net, as of September 30, 2010 and December 31, 2009 (in thousands):

	<b>September 30, 2010</b>			<b>Weighted - Average Amortization Period (yrs.)</b>
	<b>Gross Carrying</b>	<b>Accumulated</b>	<b>Net</b>	
	<b>Amount</b>	<b>Amortization</b>	<b>Amount</b>	
CUROSURF	\$ 107,606	\$ 11,658	\$ 95,948	10.0
FACTIVE®	7,613	1,667	5,946	4.8
SPECTRACEF®	4,505	1,912	2,593	10.0
ZYFLO®	11,500	3,076	8,424	7.1
Propoxyphene/acetaminophen products	7,550	7,550		n/a
Products under development	3,350		3,350	n/a