CORNERSTONE THERAPEUTICS INC
Form 10-Q
August 04, 2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
Form 10-Q

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

For the Quarterly Period Ended June 30, 2011

or

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

For the Transition Period From to

Commission File Number: 000-50767

CORNERSTONE THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
1255 Crescent Green Drive, Suite 250 Cary, North Carolina	**27518**
(Address of Principal Executive Offices)	*(Zip Code)*

(919) 678-6611

(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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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 þ No o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of August 1, 2011, the registrant had 25,955,606 shares of Common Stock, $0.001 par value per share, outstanding.

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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, tar 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 ceased manufacturing and distributing at the end of 2010, and from our propoxyphene products, which we voluntarily withdrew from the U.S. market in November 2010 at the request of the U.S. Food and Drug Administration, or FDA; 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, product acquisition, 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, 2010 filed with the Securities and Exchange Commission, or SEC, on March 3, 2011. 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 other date. We anticipate that subsequent events and developments will cause our expectations and beliefs 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, except as required by law. 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.

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ITEM 1. ***FINANCIAL STATEMENTS***

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

	June 30, 2011 (Unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 92,793	$ 50,945
Accounts receivable, net	25,833	76,476
Inventories, net	14,043	15,174
Prepaid and other current assets	3,343	5,111
Income tax receivable	1,409	197
Deferred income tax asset	5,490	6,599
Total current assets	142,911	154,502
Property and equipment, net	1,576	1,486
Product rights, net	102,642	112,328
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Long-term accounts receivable		7,866
Other assets	1,312	687
Total assets	$ 261,710	$ 290,138
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 9,029	$ 7,671
Accrued expenses	38,593	46,599
License agreement liability	1,449	1,368
Current portion of capital lease	86	83
Current portion of deferred revenue	30,871	37,616
Total current liabilities	80,028	93,337
Capital lease, less current portion	102	146
Deferred revenue, less current portion	1,558	19,578
Deferred income tax liability	4,038	4,679
Total liabilities	85,726	117,740
Commitments and contingencies, Note 6		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		

Common stock $0.001 par value, 90,000,000 shares authorized; 25,769,664 and 25,472,963 shares issued and outstanding as of June 30, 2011 and December 31, 2010, respectively	26	25
Additional paid-in capital	161,752	160,106
Retained earnings	14,206	12,267
Total stockholders equity	175,984	172,398
Total liabilities and stockholders equity.	$ 261,710	$ 290,138

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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net revenues	$ 28,039	$ 28,465	$ 58,036	$ 64,871
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	7,041	8,153	14,578	14,972
Selling, general and administrative	11,604	12,814	24,874	25,239
Royalties	2,148	2,648	4,645	7,246
Research and development	614	1,795	1,173	2,701
Amortization of product rights	6,092	3,595	9,686	7,190
Total costs and expenses	27,499	29,005	54,956	57,348
Income (loss) from operations	540	(540)	3,080	7,523
Other expenses:				
Interest expense, net	(42)	(9)	(83)	(10)
Total other expenses	(42)	(9)	(83)	(10)
Income (loss) before income taxes	498	(549)	2,997	7,513
(Provision for) benefit from income taxes	(301)	149	(1,058)	(2,900)
Net income (loss)	$ 197	$ (400)	$ 1,939	$ 4,613
Net income (loss) per share, basic	$ 0.01	$ (0.02)	$ 0.08	$ 0.18
Net income (loss) per share, diluted	$ 0.01	$ (0.02)	$ 0.07	$ 0.18
Weighted-average common shares, basic	25,673,667	25,405,165	25,577,314	25,377,575
Weighted-average common shares, diluted	26,246,073	25,405,165	26,167,997	25,997,176

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)

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities		
Net income	$ 1,939	$ 4,613
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	7,429	7,365
Provision for prompt payment discounts	1,998	2,049
Recovery of inventory allowances	(235)	(367)
Impairment of product rights	2,500	
Stock-based compensation	884	655
Benefit from (provision for) deferred income taxes	468	(2,431)
Changes in operating assets and liabilities:		
Accounts receivable	48,645	323
Inventories	1,366	(1,659)
Prepaid expenses, long-term accounts receivable and other assets	9,009	2,086
Accounts payable	1,358	(1,809)
Accrued expenses and license agreement liability	(7,925)	4,305
Income taxes receivable	(1,212)	954
Deferred revenue	(24,765)	10,822
Net cash provided by operating activities	41,459	26,906
Cash flows from investing activities		
Purchase of property and equipment	(333)	(278)
Net cash used in investing activities	(333)	(278)
Cash flows from financing activities		
Proceeds from exercise of common stock options and warrants	311	516
Excess tax benefit from stock-based compensation	452	455
Principal payments on capital lease obligation	(41)	(6)
Net cash provided by financing activities	722	965
Net increase in cash and cash equivalents	41,848	27,593
Cash and cash equivalents as of beginning of period	50,945	18,853
Cash and cash equivalents as of end of period	$ 92,793	$ 46,446

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 developing, acquiring and commercializing products for the respiratory, hospital and related specialty markets. Key elements of the Company s strategy are to focus on identifying therapeutic niches within respiratory, hospital and related specialty markets to leverage existing business and create new opportunities; promote the Company s current products to high prescribing physicians through the Company s respiratory sales force and to hospital-based healthcare professionals through the Company s hospital sales force; license or acquire rights to existing patent- or trade secret-protected, branded products, which can be promoted through the same channels to generate on-going high-value earnings streams; advance the Company s development projects and further build a robust pipeline; and generate revenues by marketing approved generic products through the Company s wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

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, 2010 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, 2010, 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, 2010.

Operating results for the three and six-month periods ended June 30, 2011 are not necessarily indicative of the results for the full year.

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 financial statements include certain judgments regarding revenue recognition, goodwill and product rights, inventory valuation, accrued expenses, income taxes 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 two financial institutions.

The Company relies on certain materials used in its development and manufacturing processes, most of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number

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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 six months ended June 30, 2011, two suppliers accounted for 89% of the Company s total inventory purchases. Amounts due to these suppliers represented approximately 41% of total accounts payable as of June 30, 2011.

The Company sells its products primarily to large national wholesalers, which in turn may 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 comprised greater than 10% of total gross product sales for the three and six months ended June 30, 2011 and 2010 or 10% of total accounts receivable as of June 30, 2011 and December 31, 2010:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011 Gross Product Sales	2010 Gross Product Sales	2011 Gross Product Sales	2010 Gross Product Sales
Cardinal Health, Inc.	42%	32%	40%	39%
McKesson Corporation	34	37	35	33
AmerisourceBergen Drug Corporation	18	25	20	21
Total	94%	94%	95%	93%

	June 30, 2011 Accounts Receivable	December 31, 2010 Accounts Receivable
Cardinal Health, Inc.	57%	50%
McKesson Corporation	18	30
AmerisourceBergen Drug Corporation	23	15
Total	98%	95%

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 its cash deposits with federally insured banks. As of June 30, 2011, all cash deposits were federally insured.

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 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 June 30, 2011 or December 31, 2010. 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 six months ended June 30, 2011 or 2010.

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The following table represents accounts receivable, net, as of June 30, 2011 and December 31, 2010 (in thousands):

	June 30, 2011	December 31, 2010
Accounts receivable	$ 26,497	$ 78,491
Less allowance for prompt payment discounts	(664)	(2,015)
Accounts receivable, net	$ 25,833	$ 76,476

The Company has ceased manufacturing and distribution of ALLERX® and HYOMAX®. In connection with certain sales of its remaining inventory of these products, the Company offered various extended payment terms to certain customers, primarily national wholesalers, some of which extend through June 2012. The Company had classified accounts receivable of $7.9 million relating to such sales as long-term accounts receivable in the accompanying consolidated balance sheet as of December 31, 2010.

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 revenues.

The following table represents inventories, net, as of June 30, 2011 and December 31, 2010 (in thousands):

	June 30, 2011	December 31, 2010
Raw materials	$ 3,880	$ 5,542
Work in process	1,625	1,575
Finished goods:		
Pharmaceutical products trade	8,907	8,635
Pharmaceutical products samples	1,032	1,267
Total	15,444	17,019
Inventory allowances	(1,401)	(1,845)
Inventories, net	$ 14,043	$ 15,174

Revenue Recognition

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010

Gross product sales	$ 44,277	$ 44,140	$ 95,472	$ 99,108
Sales allowances	(16,313)	(15,680)	(37,533)	(34,256)
Net product sales	27,964	28,460	57,939	64,852
License and royalty agreement revenues	75	5	97	19
Net revenues	$ 28,039	$ 28,465	$ 58,036	$ 64,871

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.

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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 June 30, 2011 and December 31, 2010, the Company had $32.4 million and $57.2 million, respectively, of deferred revenue related to sales made in 2010 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. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Changes in estimated allowances are recorded when information that gives rise to the changes becomes known. Estimated allowances were recorded as of December 31, 2010 and remain classified as accrued expenses in the accompanying consolidated balance sheet as of June 30, 2011. The cost of product sales as of June 30, 2011 of approximately $653,000 related to the deferred revenue has been deferred and classified in the accompanying consolidated balance sheet as prepaid and other current assets. The cost of product sales as of December 31, 2010 of approximately $1.3 million related to the deferred revenue has been deferred and classified in the accompanying consolidated balance sheet as prepaid and other current assets and other assets in the amounts of $1.1 million and $250,000, respectively.

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 that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company s products have an 18 to 48 month expiration period from the date of manufacture. 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 actual and historical return rates for expired lots, historical and forecasted product sales and consumer consumption data reported by external information management companies, estimated expiration dates or remaining shelf life of inventory in the distribution channel, estimates of inventory levels of its products in the distribution channel and any significant changes to these levels, and 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 through charges to income in the period in which the information that gives rise to the adjustment becomes known.

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 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).

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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 for the three and six months ended June 30, 2011 were $75,000. There were no license agreement revenues for the three and six months ended June 30, 2010.

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 product sales that occurred in the relevant period. Royalty agreement revenues for the three months ended June 30, 2011 and 2010 were $0 and $5,000, respectively. Royalty agreement revenues for the six months ended June 30, 2011 and 2010 were $22,000 and $19,000, respectively.

NOTE 3: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance as of June 30, 2011 and December 31, 2010 was $13.2 million and relates to the October 31, 2008 merger whereby the Company, which was then known as Critical Therapeutics, Inc. (Critical Therapeutics), merged (through a transitory subsidiary) with Cornerstone BioPharma Holdings, Inc., which was deemed to be the acquiring company for accounting purposes (the Merger). No amount of the goodwill balance at June 30, 2011 will be deductible for income tax purposes.

Product Rights

The following tables represent product rights, net, as of June 30, 2011 and December 31, 2010 (in thousands):

	June 30, 2011			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted - Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 19,728	$ 87,878	10.0
FACTIVE®	7,613	2,848	4,765	4.8
SPECTRACEF®	4,505	2,227	2,278	10.0
ZYFLO®	11,500	4,279	7,221	7.1
CRTX 067	500		500	n/a
Other	75	75		4.3
Total	$ 131,799	$ 29,157	$ 102,642	9.5

	December 31, 2010			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted - Average Amortization Period (yrs.)

CUROSURF	$ 107,606	$ 14,347	$ 93,259	10.0
FACTIVE	7,613	2,061	5,552	4.8
SPECTRACEF	4,505	2,017	2,488	10.0
ZYFLO	11,500	3,477	8,023	7.1
Products under development	3,000		3,000	n/a
Other	75	69	6	4.3
Total	$ 134,299	$ 21,971	$ 112,328	9.5

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During the three months ended June 30, 2011, the Company made the decision to not pursue several product development projects that no longer align with the Company s strategic focus and wrote off $2.5 million of related capitalized product rights. This write-off is included in amortization expense in the accompanying consolidated statements of income for the three and six months ended June 30, 2011. No portion of the impairment charge will result in future cash expenditures.

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which range from four to ten years. As of June 30, 2011, the Company had $500,000 of product rights related to its product candidate, CRTX 067, which it expects to launch in the future. The Company expects to begin amortization upon the commercial launch of this product, which is expected to be shortly after regulatory approval. The rights will be amortized over CRTX 067 s estimated useful life.

NOTE 4: ACCRUED EXPENSES

The components of accrued expenses are as follows (in thousands):

	June 30, 2011	December 31, 2010
Accrued product returns	$ 13,990	$ 15,025
Accrued rebates	3,043	3,034
Accrued price adjustments and chargebacks	15,309	21,520
Accrued compensation and benefits	2,275	2,760
Accrued royalties	3,030	3,303
Accrued expenses, other	946	957
Total accrued expenses	$ 38,593	$ 46,599

The Company has ceased manufacturing and distribution of ALLERX and HYOMAX. As of June 30, 2011 and December 31, 2010, the Company had $32.4 million and $57.2 million, respectively, of deferred revenue related to sales of its remaining inventory of these products for which future returns could not be reasonably estimated at the time of sale. Deferred revenue was recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances were recorded as accrued expenses as of December 31, 2010.

NOTE 5: STOCK-BASED COMPENSATION

Stock Options

The Company currently uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company s expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

There were 642,547 and 252,841 stock options granted and exercised, respectively, during the six months ended June 30, 2011.

The following table shows the assumptions used to value stock options on the date of grant, as follows:

	Six Months Ended June 30, 2011
Estimated dividend yield	0.0%
Expected stock price volatility	80%
Risk-free interest rate	1.40-2.24%

Expected life of option (in years)		5.00
Weighted-average grant date fair value per share of options granted	$	3.74

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The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. The expected stock price volatility was based on Critical Therapeutics (now the Company s) historical volatility for the five year period preceding the grant date. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

As of June 30, 2011, the aggregate intrinsic value of options outstanding and exercisable was $10.6 million and $6.8 million, respectively.

As of June 30, 2011, there was $4.2 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.67 years.

Restricted Stock

During the six months ended June 30, 2011, 55,000 shares of restricted stock were issued and 43,860 shares vested. As of June 30, 2011, there were 183,640 restricted common shares outstanding and $1.0 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.57 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately $505,000 and $375,000 for the three months ended June 30, 2011 and 2010, respectively and $884,000 and $655,000 for the six months ended June 30, 2011 and 2010, respectively.

NOTE 6: COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes lease expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Lease expense was approximately $275,000 and $370,000 for the three months ended June 30, 2011 and 2010, respectively, and approximately $589,000 and $707,000 for the six months ended June 30, 2011 and 2010, respectively.

Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $16.0 million as of June 30, 2011, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management s estimates. As of June 30, 2011, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $10.7 million.

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or current licensors of certain product rights that have been acquired by or licensed to the Company. These royalties are typically based on a percentage of net sales of the particular licensed product. For the three months ended June 30, 2011 and 2010, total royalty expenses were $2.1 million and $2.6 million, respectively and for the six months ended June 30, 2011 and 2010, total royalty expenses were $4.6 million and $7.2 million, respectively. Certain of these royalty agreements also require minimum annual payments, which have been included in royalty expense on the consolidated statements of operations. Pursuant to these agreements, the Company is obligated to pay future minimum royalties of $465,000.

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Collaboration Agreements

The Company is committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. The Company may be required to make $38.6 million in additional payments to various parties if all milestones under the agreements are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on the accompanying consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

As of June 30, 2011, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately $2.4 million.

Co-Promotion and Marketing Services Agreements

The Company has entered into a co-promotion and marketing service agreement and a co-promotion agreement that grant third parties the exclusive rights to promote and sell certain products in conjunction with the Company. Under these agreements, the third parties are responsible for the costs associated with their sales representatives and the product samples distributed by their sales representatives, as well as certain other promotional expenses related to the products. Under one agreement, the Company pays the third party co-promotion fees equal to the ratio of total prescriptions written by pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of the products covered by the agreement, after third-party royalties. Under the other agreement, the Company pays the third parties fees based on a percentage of the net profits from sales of the product above a specified baseline within assigned sales territories. The co-promotion agreement is also subject to sunset fees that require the Company to pay additional fees for up to three months in the event of certain defined terminations of this agreement.

As of June 30, 2011, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $7.4 million.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. As of June 30, 2011, the Company had no amounts recorded as accrued severance.

NOTE 7: INCOME TAXES

The Company computes an estimated annual effective tax rate for interim financial reporting purposes. The estimated annual effective tax rate is used to compute the tax expense or benefit related to ordinary income or loss. Tax expense or benefit related to all other items is individually computed and recognized when the items occur. The Company s effective tax rate for the three and six months ended June 30, 2011 was 60.4% and 35.3%, respectively. The Company s effective tax rate for the three and six months ended June 30, 2010 was 27.1% and 38.6%, respectively. The increase in the effective tax rate for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 was due primarily to an increase in the estimated taxable income for the year ending December 31, 2011 resulting in a higher estimated effective annual tax rate.

The estimated annual effective tax rate for the year ending December 31, 2011 includes a benefit of approximately 9% related to a reduction in the valuation allowance offsetting deferred tax assets. As of the date of the Merger, Critical Therapeutics had approximately $64.0 million in deferred tax assets, primarily relating to net operating loss carryforwards (NOLs) and tax credits. The Company determined that utilization of these deferred tax assets was limited due to the requirements of Section 382 of the Internal Revenue Code. Therefore, the deferred tax assets resulting from these NOLs and tax credits were offset by a full valuation allowance. The reversal of the valuation allowance that relates to the Company s use of these deferred tax assets in 2011 is projected to be $663,000 and is being recorded as a reduction to tax expense. The Company has not established any other valuation allowances.

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There were no changes in unrecognized tax positions for the six months ended June 30, 2011. As of June 30, 2011, the Company had no unrecognized tax benefits, including those that would affect the effective tax rate. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next 12 months.

The Company recognizes any annual interest and penalties related to uncertain tax positions as operating expenses in its statements of operations. For the three and six months ended June 30, 2011, the Company recognized no interest or penalties related to uncertain tax positions in the statements of operations.

The 2007 through 2010 tax years of the Company are open to examination by federal tax and state tax authorities. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years is under examination.

NOTE 8: RELATED PARTY TRANSACTIONS

Chiesi Farmaceutici S.p.A. (Chiesi), the Company s majority stockholder, manufactures all of the Company s requirements for CUROSURF pursuant to a license and distribution agreement that became effective on July 28, 2009. The Company began promoting and selling CUROSURF in September 2009. Inventory purchases from Chiesi aggregated $6.0 million and $9.8 million for the three and six months ended June 30, 2011, respectively and $4.6 million and $11.8 million for the three and six months ended June 30, 2010, respectively. As of June 30, 2011 and December 31, 2010, the Company had accounts payable due to Chiesi of $2.8 million and $2.1 million, respectively.

NOTE 9: NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during each period. Diluted net income (loss) per share is computed by dividing net income (loss) by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants and the impact of non-vested restricted stock grants.

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	**2010**	**2011**	**2010**
Numerator:				
Net income (loss)	$ 197	$ (400)	$ 1,939	$ 4,613
Denominator:				
Weighted-average common shares, basic	25,673,667	25,405,165	25,577,314	25,377,575
Dilutive effect of stock options, warrants and restricted stock	572,406		590,683	619,601
Weighted-average common shares, diluted	26,246,073	25,405,165	26,167,997	25,997,176
Net income (loss) per share, basic	$ 0.01	$ (0.02)	$ 0.08	$ 0.18
Net income (loss) per share, diluted	$ 0.01	$ (0.02)	$ 0.07	$ 0.18
Anti-dilutive weighted-average shares	1,581,781	3,108,184	1,569,180	1,549,444

NOTE 10: SUBSEQUENT EVENTS

The Company has evaluated all events or transactions that occurred after June 30, 2011. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements.

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NOTE 11: RECENT ACCOUNTING PRONOUNCEMENTS

There were no recent accounting pronouncements that have not yet been adopted by the Company that are expected to have a material impact on the Company s consolidated financial statements.

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ITEM 2. ***MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The following discussion is designed to provide a better understanding of our unaudited consolidated financial statements, including a brief discussion of our business and products, key factors that impact our performance and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our unaudited consolidated financial statements and the related notes included in Part I Item 1. Financial Statements of this Quarterly Report on Form 10-Q and the consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2010. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth under Part I Item1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2010 and any material changes to those risk factors discussed below in Part II Item 1A. Risk Factors.

Executive Overview

Strategy

We are a specialty pharmaceutical company focused on identifying therapeutic niches within the respiratory, hospital and related specialty markets. We seek to develop, acquire and commercialize products that leverage our existing business competencies.

Our strategy is to:

Grow the value of our existing portfolio of strategic products by increasing penetration in our markets;

Build a focused development pipeline;

License or acquire patent- or trade secret-protected, branded products in the respiratory, hospital or related specialty markets, to which we can add value by leveraging our existing commercial capabilities; and

Market approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

We believe that if we implement this strategy successfully, we can deliver consistent long-term revenue and earnings growth.

Second Quarter 2011 Highlights

The following summarizes certain key financial measures as of, and for the three months, ended June 30, 2011:

Cash and cash equivalents equaled $92.8 million as of June 30, 2011.

Net product sales were $28.0 million and $28.5 million for the three months ended June 30, 2011 and 2010, respectively. The percentage of net product sales generated from strategic products increased from 64% for the three months ended June 30, 2010 to 67% for the three months ended June 30, 2011, reflecting the continued transition of our business to sales of strategic products.

When calculated in accordance with accounting principles generally accepted in the United States, or GAAP, income from operations was $540,000 for the three months ended June 30, 2011 compared to a loss from operations of $540,000 for the three months ended June 30, 2010. On a GAAP basis, net income for the three months ended June 30, 2011 was $197,000 compared to a net loss of $400,000 for the three months ended June 30, 2010.

On a non-GAAP basis, income from operations increased from $3.4 million for the three months ended June 30, 2010 to $7.1 million for the three months ended June 30, 2011, a 108% increase. On a non-GAAP basis, net income for the same periods increased from $2.5 million to $2.8 million, a 13% increase.

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Opportunities and Trends

We generate revenue by promoting our products to targeted physicians whose practices focus on the treatment of respiratory disorders. Primarily, these physicians are specialists. However, we also identify and target the highest decile physicians who are treating patients with respiratory ailments. Our goal is to continue to increase our sales force productivity and profitability by refining our focus on specialists and only the highest prescribing general practitioners. To help achieve this goal we are investing in upgrading the infrastructure that supports our commercial operation. We have developed a master data management system and an internal sales and marketing data warehouse, and we expect to deploy a business intelligence reporting infrastructure in the near future. We believe these tools combined with our enhanced specialty focus and the experience and expertise of our management team will drive the future growth of our strategic products revenue.

Our strategic products generated $39.7 million in net product sales for the six months ended June 30, 2011, an 11% increase over the comparable 2010 time period. The growth of our strategic products and our overall product sales mix continue to reflect the transformation of our business, with strategic products accounting for 68% of total year-to-date net product sales. This achievement is in line with our 2011 strategic goal of having approximately 70% of 2011 net product sales generated from our strategic products.

There continue to be unmet patient needs in the respiratory area. We believe that we can systematically focus our efforts on developing and acquiring products or acquiring companies whose products or other assets can meet these needs. We believe the combination of product development or acquisition and company acquisition will enhance our growth opportunities.

Additionally, we continue to leverage our alliance and partner relationships. In particular, our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, as a commercial partner continues to strengthen as we jointly explore ways to commercialize products within the United States.

Also, we are operating in challenging economic and industry environments. The challenges we face are compounded by the continued uncertainty around the impact of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, which we refer to collectively herein as Health Care Reform. Given this business climate, we will need to sharpen our strategic focus, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships in order to be well-positioned to identify and capitalize upon potential growth opportunities.

Finally, in 2011, as we execute our strategy, we will monitor and evaluate success through the following measures:

Net product sales generated from our strategic products;

Progress of our development pipeline, which includes CRTX 067 (which is awaiting marketing approval by the FDA) and CRTX 073 and CRTX 078, two life-cycle management projects to expand our zileuton franchise; and

Acquisition of product rights that align with our strategy and that offer potential for sustainable growth.

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Results of Operations

Comparison of the Three Months Ended June 30, 2011 and 2010

The following table sets forth certain consolidated statement of operations data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Three Months Ended June 30,		Change	
	2011	2010	$	%
Net product sales				
CUROSURF®	$ 8,547	$ 8,619	$ (72)	(1)%
ZYFLO® product family	6,585	8,007	(1,422)	(18)
FACTIVE®	1,664	1,206	458	38
SPECTRACEF® product family	1,892	307	1,585	516
ALLERX® Dose Pack products	9,173	5,924	3,249	55
HYOMAX® product family	623	1,900	(1,277)	(67)
Other products	(520)	2,497	(3,017)	(121)
Total net product sales	27,964	28,460	(496)	(2)
License and royalty agreement revenues	75	5	70	1400
Net revenues	28,039	28,465	(426)	(1)
Cost of product sales (exclusive of amortization of product rights)	7,041	8,153	(1,112)	(14)
Selling, general and administrative	11,604	12,814	(1,210)	(9)
Royalties	2,148	2,648	(500)	(19)
Research and development	614	1,795	(1,181)	(66)
Amortization of product rights	6,092	3,595	2,497	69
Income (loss) from operations	540	(540)	1,080	200
Total other expenses, net	(42)	(9)	33	367
Income (loss) before income taxes	498	(549)	1,047	191
(Provision for) benefit from income taxes	(301)	149	(450)	(302)
Net income (loss)	$ 197	$ (400)	$ 597	149%
Net income (loss) per share, diluted	$ 0.01	$ (0.02)	$ 0.03	150%
Non-GAAP income from operations (1)	$ 7,137	$ 3,430	$ 3,707	108%
Non-GAAP net income (1)	$ 2,807	$ 2,493	$ 314	13%
Non-GAAP net income per share, diluted (1)	$ 0.11	$ 0.10	$ 0.01	10%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.

Net Revenues

Net Product Sales.

CUROSURF net product sales decreased $72,000, or 1%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010, primarily due to the timing of sales orders placed by our customers.

ZYFLO CR and ZYFLO net product sales decreased $1.4 million, or 18%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This decrease was primarily due to the timing of customer purchases and product availability, partially offset by an increase in price and the impact of an additional reserve of $717,000 recorded during the three months ended June 30, 2010 for an increase in estimated product returns related to short-dated products sold.

FACTIVE net product sales increased $458,000, or 38%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This increase was primarily due to an increase in sales volume as a result of additional promotional efforts for our anti-infective products combined with a price increase, partially offset by increases in our estimated rates for product returns and voucher redemption.

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SPECTRACEF product family net product sales increased $1.6 million, or 516%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This increase was primarily due to an additional reserve of $1.5 million for potential returns of discontinued product on net product sales for the three months ended June 30, 2010. Excluding this impact, net product sales increased approximately $100,000 during the three months ended June 30, 2011 compared to the three months ended June 30, 2010.

ALLERX Dose Pack net product sales increased $3.2 million, or 55%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This increase was primarily due to increased prescription volume. During the three months ended June 30, 2011, revenue continued to be recognized as prescriptions were filled instead of at the time of sale. At June 30, 2011, we had deferred revenue of approximately $31.4 million related to previous sales of ALLERX products.

HYOMAX net product sales decreased $1.3 million, or 67%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This decrease was primarily due to lower net prices and lower volume as a result of increased competition from other manufacturers. During 2011, revenue has been recognized as prescriptions were filled instead of our historic practice of recognizing revenue at the time of sale. This change was due to our inability to estimate product returns as a result of changes in market dynamics, large amounts of channel inventory and extended payment terms offered on certain sales. As a result, at June 30, 2011, we had deferred revenue of approximately $1.0 million related to previous sales of HYOMAX products.

Net product sales from other products decreased $3.0 million, or 121%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010, primarily due to the November 2010 withdrawal from the market of our propoxyphene/ acetaminophen products, which included BALACET® 325; APAP 325, our generic formulation of BALACET 325; and APAP 500. We voluntarily withdrew these products in response to the FDA s actions requiring the withdrawal of the branded versions of propoxyphene, specifically Darvon®, Darvon-N® and Darvocet-N®. Net product sales for these products during the three months ended June 30, 2010 were $2.5 million, whereas we had no product sales from these products during the three months ended June 30, 2011. During the three months ended June 30, 2011, we also recorded returns in excess of our original estimates related to these products resulting in an additional $515,000 decrease in net product sales.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $6.1 million and $3.6 million for the three months ended June 30, 2011 and 2010, respectively) decreased $1.1 million, or 14%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Three Months Ended June 30,		Change	
	2011	2010	$	%
Net product sales	$ 27,964	$ 28,460	$ (496)	(2)%
Cost of product sales (exclusive of amortization of product rights)	7,041	8,153	(1,112)	(14)
Gross profit	$ 20,923	$ 20,307	$ 616	3%
Gross margin	75%	71%		

Gross margin of net product sales for the three months ended June 30, 2011 increased four percentage points compared to the three months ended June 30, 2010. The lower gross margin of net product sales for the three months ended June 30, 2010 was due to a reduction in product sales due to additional reserves of approximately $3.0 million for potential product returns of ZYFLO CR, SPECTRACEF, and certain ALLERX Dose Pack products.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.2 million, or 9%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This decrease was primarily due to

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decreases in our marketing and promotional spending relating to FACTIVE and decreases in co-promotion expenses related to our propoxyphene/acetaminophen products, which were withdrawn from the market in November 2010.

Royalty Expenses. Royalty expenses decreased $500,000, or 19%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This decrease was primarily due to lower net product sales of the HYOMAX and propoxyphene/acetaminophen products, partially offset by an increase in net product sales of ALLERX Dose Pack products.

Research and Development Expenses. Research and development expenses decreased $1.2 million, or 66%, during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. This decrease is due primarily to a reduction in expenses related to CRTX 067 and the timing of our other product development expenses, which remains consistent with our development plan. Our product development expenses for particular product candidates vary significantly from period to period depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given reporting period.

Amortization of Product Rights. Amortization of product rights increased $2.5 million, or 69%, during the three months ended June 30, 2011 compared to three months ended June 30, 2010. During the three months ended June 30, 2011, we made the decision to not pursue several product development projects that no longer align with our strategic focus and wrote off $2.5 million of related capitalized product rights.

(Provision for) Benefit from Income Taxes

The provision for income taxes was $301,000 for the three months ended June 30, 2011 compared to a benefit of $149,000 for the three months ended June 30, 2010. Our effective tax rates for the three months ended June 30, 2011 and 2010 were 60.4% and 27.1%, respectively. The increase in the effective tax rate was due primarily to an increase in the estimated taxable income for the year ending December 31, 2011 resulting in a higher estimated effective annual tax rate.

Comparison of the Six Months Ended June 30, 2011 and 2010

The following table sets forth certain consolidated statement of operations data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Six Months Ended June 30,		Change	
	2011	**2010**	**$**	**%**
Net product sales				
CUROSURF	$ 16,055	$ 15,716	$ 339	2%
ZYFLO product family	13,997	14,281	(284)	(2)
FACTIVE	4,464	3,313	1,151	35
SPECTRACEF product family	5,169	2,284	2,885	126
ALLERX Dose Pack products	20,754	18,293	2,461	13
HYOMAX product family	1,411	5,799	(4,388)	(76)
Other products	(3,911)	5,166	(9,077)	(176)
Total net product sales	57,939	64,852	(6,913)	(11)
License and royalty agreement revenues	97	19	78	411
Net revenues	58,036	64,871	(6,835)	(11)
Cost of product sales (exclusive of amortization of product rights)	14,578	14,972	(394)	(3)
Selling, general and administrative	24,874	25,239	(365)	(1)
Royalties	4,645	7,246	(2,601)	(36)
Research and development	1,173	2,701	(1,528)	(57)
Amortization of product rights	9,686	7,190	2,496	35

Income from operations	3,080	7,523	(4,443)	(59)
Total other expenses, net	(83)	(10)	73	730
Income before income taxes	2,997	7,513	(4,516)	(60)
Provision for income taxes	(1,058)	(2,900)	(1,842)	(64)
Net income	$ 1,939	$ 4,613	$ (2,674)	(58)%
Net income per share, diluted	$ 0.07	$ 0.18	$ (0.11)	(61)%
Non-GAAP income from operations (1)	$ 13,650	$ 15,368	$ (1,718)	(11)%
Non-GAAP net income (1)	$ 8,778	$ 9,430	$ (652)	(7)%
Non-GAAP net income per share, diluted (1)	$ 0.34	$ 0.36	$ (0.02)	(6)%

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(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.

Net Revenues

Net Product Sales.

CUROSURF net product sales increased $339,000, or 2%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010, primarily due to an increase in price offset by an increase in the estimated fees to be paid to our distributors.

ZYFLO CR and ZYFLO net product sales decreased $284,000, or 2%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This decrease was primarily due to the timing of customer purchases and product availability, partially offset by an increase in price and the impact of an additional reserve of $861,000 recorded during the six months ended June 30, 2010 for an increase in estimated product returns related to short-dated products sold.

FACTIVE net product sales increased $1.2 million, or 35%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This increase was primarily due to an increase in sales volume as a result of additional promotional efforts for our anti-infective products combined with a price increase, partially offset by increases in our estimated rates for product returns and voucher redemption.

SPECTRACEF product family net product sales increased $2.9 million, or 126%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. Excluding the impact of an additional reserve of $1.5 million for potential returns of discontinued product on net product sales for the six months ended June 30, 2010, net product sales increased approximately $1.4 million during the six months ended June 30, 2011. The increase was driven by increased sales volume as a result of additional promotional efforts for our anti-infective products as well as an increase in price, partially offset by increases in our estimated rates for product returns and voucher redemption.

ALLERX Dose Pack net product sales increased $2.5 million, or 13%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This increase was due to increased prescription volume, partially offset by the impact of $2.4 million of additional product returns in excess of our estimates during the six months ended June 30, 2010. During the six months ended June 30, 2011, revenue was recognized as prescriptions were filled instead of at the time of sale. At June 30, 2011, we had deferred revenue of approximately $31.4 million related to previous sales of our ALLERX products.

HYOMAX net product sales decreased $4.4 million, or 76%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This decrease was due to lower net prices and lower volume as a result of increased competition from other manufacturers. During 2011, revenue was recognized as prescriptions were filled instead of our historic practice of recognizing revenue at the time of sale. This change was due to our inability to estimate product returns as a result of changes in market dynamics, large amounts of channel inventory and extended payment terms offered on certain sales. As a result, at June 30, 2011, we had deferred revenue of approximately $1.0 million related to previous sales of HYOMAX products.

Net product sales from our propoxyphene/acetaminophen products decreased $9.1 million, or 176%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010, primarily due to the November 2010 withdrawal from the market of our propoxyphene/acetaminophen products, which included BALACET 325, APAP 325 and APAP 500. We voluntarily withdrew these products in response to the FDA s actions requiring the withdrawal of the branded versions of propoxyphene, specifically Darvon, Darvon-N and Darvocet-N. Net product sales for these products during the six months ended June 30, 2010 were $5.1 million, whereas we had no product sales from these products during the six months ended June 30, 2011. During the six months ended June 30, 2011, we also recorded returns in excess of our original estimates related to these products resulting in an additional $3.9 million decrease in net product sales.

Costs and Expenses

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Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $9.7 million and $7.2 million for the six months ended June 30, 2011 and 2010, respectively) decreased $0.4 million, or 3%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Six Months Ended June 30,		Change	
	2011	2010	$	%
Net product sales	$ 57,939	$ 64,852	$ (6,913)	(11)%
Cost of product sales (exclusive of amortization of product rights)	14,578	14,972	(394)	(3)
Gross profit	$ 43,361	$ 49,880	$ (6,519)	(13)%
Gross margin	75%	77%		

Gross margin of net product sales for the six months ended June 30, 2011 decreased two percentage points compared to the six months ended June 30, 2010. This decrease was due to a relatively higher percentage of our total net product sales during the first six months of 2011 derived from products that have lower gross margins, specifically CUROSURF, higher costs related to certain of our promotional efforts for our anti-infective products and additional product return reserves.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $365,000, or 1%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This decrease was primarily due to decreases in market research and co-promotion expenses for our propoxyphene/acetaminophen products, which were withdrawn from the market in November 2010. These decreases were partially offset by an increase in co-promotion expense for ALLERX Dose Pack family of products, regulatory fees for CUROSURF, post-marketing stability expenses and a Risk Evaluation and Mitigation Strategy (REMS) study for FACTIVE.

Royalty Expenses. Royalty expenses decreased $2.6 million, or 36%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This decrease was primarily due to lower net product sales of the HYOMAX and propoxyphene/acetaminophen products, partially offset by royalties relating to FACTIVE.

Research and Development Expenses. Research and development expenses decreased $1.5 million, or 57%, during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. This decrease is due primarily to a reduction in expenses related to CRTX 067 and the timing of our product development expenses, which remains consistent with our development plan. Our product development expenses for particular product candidates vary significantly from period to period depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given reporting period.

Amortization of Product Rights. Amortization of product rights increased $2.5 million, or 35%, during the six months ended June 30, 2011 compared to six months ended June 30, 2010. During the six months ended June 30, 2011, we made the decision to not pursue several product development projects that no longer align with our strategic focus and wrote off $2.5 million of related capitalized product rights.

Provision for Income Taxes

The provision for income taxes was $1.1 million for the six months ended June 30, 2011 compared to $2.9 million for the six months ended June 30, 2010. Our effective tax rates for the six months ended June 30, 2011 and 2010 were 35.3% and 38.6%, respectively. The decrease in the effective tax rate was primarily due to an increase in our net operating loss usage for the six months ended June 30, 2011.

Reconciliation of Non-GAAP Financial Measures

To supplement the consolidated financial statements presented in accordance with GAAP, we use non-GAAP measures of certain components of financial performance. These non-GAAP measures include non-GAAP operating income, non-GAAP net income and

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non-GAAP net income per diluted share. Our management regularly uses supplemental non-GAAP financial measures to understand, manage and evaluate our business and make operating and compensation decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from similarly titled non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. The additional non-GAAP financial information presented herein should be considered in conjunction with, and not as a substitute for or superior to the financial information presented in accordance with GAAP (such as operating income, net income and earnings per share) and should not be considered measures of our liquidity. These non-GAAP measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

The non-GAAP financial measures reflect adjustments for stock-based compensation expense and amortization of product rights. We exclude these expenses from our non-GAAP measures because we believe that their exclusion provides an additional means to assess the extent to which our efforts and execution of our strategy are reflected in our operating results. In particular, stock-based compensation expense is excluded primarily because it is a non-cash expense that is determined based on subjective assumptions. Product rights amortization is excluded because it is not reflective of the cash-settled expenses incurred related to product sales. Our management believes that these non-GAAP measures, when shown in conjunction with the corresponding GAAP measures, enhance investors and management s overall understanding of our current financial performance and our prospects for the future.

The non-GAAP measures are subject to inherent limitations because (1) they do not reflect all of the expenses associated with the results of operations as determined in accordance with GAAP and (2) the exclusion of these expenses involved the exercise of judgment by management. Even though we have excluded stock-based compensation expense and amortization of product rights from the non-GAAP financial measures, stock-based compensation is an integral part of our compensation structure and the acquisition of product rights is an important part of our business strategy.

The following tables reconcile our non-GAAP measures to the most directly comparable GAAP financial measures (in thousands, except share and per share data):

	For the three months ended June 30,		For the six months ended June 30,	
	2011	2010	2011	2010
GAAP income (loss) from operations	$ 540	$ (540)	$ 3,080	$ 7,523
Add: stock-based compensation	505	375	884	655
Add: amortization of product rights	6,092	3,595	9,686	7,190
Non-GAAP income from operations	$ 7,137	$ 3,430	$ 13,650	$ 15,368
GAAP net income (loss)	$ 197	$ (400)	$ 1,939	$ 4,613
Add: stock-based compensation	505	375	884	655
Add: amortization of product rights	6,092	3,595	9,686	7,190
Less: tax effects related to above items[1]	(3,987)	(1,077)	(3,731)	(3,028)
Non-GAAP net income	$ 2,807	$ 2,493	$ 8,778	$ 9,430
GAAP net income (loss) per share, diluted	$ 0.01	$ (0.02)	$ 0.07	$ 0.18
Non-GAAP net income per share, diluted	$ 0.11	$ 0.10	$ 0.34	$ 0.36

Shares used in diluted net income (loss) per share calculation:				
GAAP net income (loss)	26,246,073	25,405,165	26,167,997	25,997,176
Non-GAAP net income	26,246,073	26,042,093	26,167,997	25,997,176

1 Tax effects for the three months ended June 30, 2011 and 2010 are calculated using effective tax rates of 60.4% and 27.1% respectively. Tax effects for the six months ended June 30, 2011 and 2010 are calculated using effective tax rates of 35.3% and 38.6% respectively.

Liquidity and Capital Resources

Sources of Liquidity

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We require cash to meet our operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products and payments on our license agreement liability. To date, we have funded our operations primarily from product sales, royalty agreement revenues and the investment from Chiesi. As of June 30, 2011, we had $92.8 million in cash and cash equivalents.

Cash Flows

The following table provides information regarding our cash flows (in thousands):

	Six Months Ended June 30,	
	2011	**2010**
Cash provided by (used in):		
Operating activities	$ 41,459	$ 26,906
Investing activities	(333)	(278)
Financing activities	722	965
Net increase in cash and cash equivalents	$ 41,848	$ 27,593

Net Cash Provided By Operating Activities

Our primary sources of operating cash flows are product sales. Our primary uses of cash in our operations are for funding working capital, selling, general and administrative expenses and royalties.

Net cash provided by operating activities for the six months ended June 30, 2011 reflected our net income of $1.9 million, adjusted by non-cash expenses totaling $13.0 million and changes in accounts receivable, inventories, deferred revenue, income taxes payable, accrued expenses and other operating assets and liabilities totaling $26.6 million. Non-cash items included amortization and depreciation of $7.4 million, impairment of product rights of $2.5 million, changes in allowances for prompt payment discounts and inventory obsolescence totaling $1.8 million, stock-based compensation of $884,000 and changes in deferred income tax of $468,000. Accounts receivable decreased by $48.6 million from December 31, 2010 to June 30, 2011, primarily due to collections of receivables in connection with the December 2010 distribution of ALLERX and HYOMAX products. Inventories decreased by $1.4 million from December 31, 2010 to June 30, 2011, primarily due to reductions in CUROSURF finished product and the active pharmaceutical ingredient and work-in-process for ZYFLO CR and ZYFLO. Prepaid expenses, long-term accounts receivable and other assets decreased by $9.0 million, primarily due to the decrease of long-term accounts receivable, amortization of regulatory fees and changes to our voucher programs. Accounts payable increased by $1.4 million from December 31, 2010 to June 30, 2011, primarily due to an increase in our voucher program payments and timing of other payables. Accrued expenses and license agreement liability decreased by $7.9 million from December 31, 2010 to June 30, 2011, primarily due to a decrease in accrued price adjustments and chargebacks as well as a decrease in the bonus accrual. Deferred revenue decreased by $24.7 million from December 31, 2010 to June 30, 2011 as revenue was recognized based on prescriptions filled for our ALLERX Dose Pack and HYOMAX products. Income taxes receivable increased by $1.2 million from December 31, 2010 to June 30, 2011 due to changes in our estimated taxable income for the year ending December 31, 2011.

Net cash provided by operating activities for the six months ended June 30, 2010 reflected our net income of $4.6 million, adjusted by non-cash expenses totaling $7.3 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $15.0 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2011 reflected the purchase of property and equipment for $333,000.

Net cash used in investing activities for the six months ended June 30, 2010 reflected the purchase of property and equipment for $278,000.

Net Cash Provided by Financing Activities

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Net cash provided by financing activities for the six months ended June 30, 2011 reflected proceeds from common stock option exercises of $311,000 and an excess tax benefit from stock options of $452,000, partially offset by principal payments on capital leases of $41,000.

Net cash provided by financing activities for the six months ended June 30, 2010 reflected proceeds from common stock option exercises of $516,000 and an excess tax benefit from stock options of $455,000, partially offset by principal payments on capital leases of $6,000.

Funding Requirements

Our future capital requirements will depend on many factors, including:

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of June 30, 2011, we had approximately $92.8 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. There have been no material changes outside the ordinary course of business to our contractual obligations during the six months ended June 30, 2011. The following table summarizes our contractual obligations as of June 30, 2011 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 215	$ 50	$ 164	$ 1	$
Operating leases(1)	2,797	349	1,113	1,183	152
Purchase obligations(2)	36,778	18,430	17,880	271	197
Royalty obligations(3)	465	15	150	150	150
Total contractual obligations	$ 40,255	$ 18,844	$ 19,307	$ 1,605	$ 499

(1) Operating leases include minimum payments under leases for our facilities, automobiles and certain equipment. Our total minimum lease payments for the corporate headquarters are $482,000 in 2011 (of which we paid $210,000 during the first six months of 2011), $492,000 in 2012, $536,000 in 2013, $584,000 in 2014 and $751,000 thereafter.

(2) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $26.7 million; clinical trial and research agreements with contract research organizations and consultants of $2.4 million; agreements with providers of marketing analytical services of $7.4 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $313,000.

(3) Royalty obligations include minimum royalty payments due in connection with certain of our agreements.

In addition to the material contractual cash obligations included in the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. We may be required to make additional payments of $38.6 million if all milestones are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets and have not been included in the table above.

Seasonality

Sales of some of our products fluctuate with the seasonality of the respiratory season, which primarily results in higher revenues in our first and fourth fiscal quarters. Accordingly, we do not believe that our product sales for the six months ended June 30, 2011 are indicative of the results we expect for the remaining six months of 2011.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. For information regarding our critical accounting policies and estimates, please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates contained in our Annual Report on Form 10-K for the year ended December

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31, 2010 and Note 2 to our consolidated financial statements contained therein. There have been no material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

As discussed in Note 11 to our consolidated financial statements included in Part I Item 1. Financial Statements of this Quarterly Report on Form 10-Q, there are no recent accounting pronouncements that we have not yet adopted that are expected to have a material impact on our consolidated financial statements.

ITEM 3. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

Interest Rate Risk

Our exposure to market risk is confined to our cash equivalents, all of which have maturities of less than three months and bear and pay interest in U.S. dollars. Since we invest in highly liquid, relatively low yield investments, we do not believe interest rate changes would have a material impact on us.

Our risk associated with fluctuating interest expense is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. We do not have any other instruments with interest rate exposure.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have two development agreements denominated in foreign currencies, Euros and Swiss francs. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of the fluctuations in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the three and six months ended June 30, 2011 and 2010. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

ITEM 4. ***CONTROLS AND PROCEDURES***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of June 30, 2011, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2011, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

There are no material pending legal proceedings to which we are a party or to which any of our property is subject.

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ITEM 1A. ***RISK FACTORS***

We operate in a rapidly changing environment that involves a number of risks that could materially and adversely affect our business, financial condition, prospects, operating results or cash flows. For a detailed discussion of the risk factors that should be understood by any investor contemplating an investment in our stock, please refer to Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010, which was filed with the SEC on March 3, 2011. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K, except as follows:

Risks Relating to Product Development and Regulatory Matters

Some of our pharmaceutical products have been marketed without approved NDAs or ANDAs.

Even though the Federal Food, Drug and Cosmetic Act requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has exercised its discretion to permit older legacy, unapproved drugs to remain on the market temporarily by employing a risk-based enforcement policy. Although the FDA considers all such drugs to require its approval, the FDA s enforcement policy prioritizes unapproved products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA is more likely to bring an enforcement action with respect to an unapproved drug if it finds that the marketer and its manufacturers are also allegedly in non-compliance with current Good Manufacturing Practices (cGMPs) requirements.

In accordance with our overall business strategy, we have discontinued manufacturing and distribution of all of our marketed unapproved products, including our ALLERX Dose Pack products and our HYOMAX line of products. Our decision does not limit the FDA s enforcement authority and the FDA may seek to require the withdrawal of these products while revenue is still being recognized based off wholesaler and distributor pull-through.

In March 2011, the FDA announced that it intends to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011. All of our marketed unapproved products have already been manufactured and shipped; furthermore, this action does not require the recall or withdrawal of any products. However, it is impossible to predict the impact that the FDA s announcement may have on the market for products such as ALLERX, and certain of our partners in the distribution channel may choose to return some of our ALLERX products to us before the expiration of their shelf life. At June 30, 2011, approximately $31.4 million of revenue from sales of ALLERX remain deferred due to our inability to estimate returns. If we are required to accept a large amount of returns of ALLERX products and to issue refunds in respect of them, this may result in our not being able to recognize some or all of our deferred revenues, which could have a material adverse effect on our financial condition, results of operations, cash balances and cash flows.

For the years ended December 31, 2009 and 2010, our ALLERX Dose Pack products and our HYOMAX line of products generated $59.9 million and $37.4 million of net product sales, respectively. We may not be able to replace these revenues with revenues from our strategic products. If we are not able to replace these product revenues, our discontinuance of these products could have a material adverse effect on our business, financial condition and results of operations and cash flows.

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of our products.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical products. Furthermore, private payors often implement similar reimbursement policies as government payors. For a discussion of the more important pharmaceutical pricing and reimbursement issues applicable to us, please see the Pharmaceutical Pricing and Reimbursement section of Item 1. Business and Item 1A. Risk Factors Risks Related to Financial Results of our Annual Report on Form 10-K for the year ended December 31, 2010.

For example, in June 2011, we were informed by the Centers for Medicare and Medicaid Services that our two timed release dosage forms of HYOMAX would no longer be eligible for inclusion in the Medicaid Drug Rebate program. Since we have ceased manufacturing and distribution of these products, we did not exercise our right to contest this determination. We are unable to predict

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whether this action will affect sales of HYOMAX that remain in the distribution channel. Further legislative or administrative acts that reduce or discontinue reimbursement for our products could adversely impact our business. Any reduction or discontinuance in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product, and the amount for which that product will be reimbursed, are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products may change at any time.

We cannot be certain that our currently marketed products will continue to be, or any of our product candidates still in development will be, included in the Medicare Part D prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

If we succeed in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates are in the development stage, we do not know whether payors will cover the products and the level of reimbursement, if any, we will receive for these product candidates if they are successfully developed, and we are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of our products and product candidates. Moreover, Health Care Reform includes funding for comparative effectiveness research and the establishment of committees, such as the Independent Payment Advisory Board, to analyze different payment systems (including bundled payments) and recommend payment reform and other cost-containment measures, which all could reduce reimbursement for our products.

If the reimbursement we receive for any of our product candidates is inadequate in light of its development and other costs, our ability to realize profits from the affected product candidate would be limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

ITEM 6. *EXHIBITS*

The exhibits listed in the accompanying exhibit index are filed as part of this Quarterly Report on Form 10-Q, and such exhibit index is incorporated by reference herein.

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SIGNATURES

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

CORNERSTONE THERAPEUTICS INC.

Date: August 4, 2011

/s/ Craig Collard
Craig Collard
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 4, 2011

/s/ Vincent T. Morgus
Vincent T. Morgus
Executive Vice President,
Finance and Chief Financial Officer
(Principal Financial Officer)

Date: August 4, 2011

/s/ Ira Duarte
Ira Duarte
Director, Accounting and Financial
Planning and Analysis
(Principal Accounting Officer)

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EXHIBIT INDEX

Exhibit No.	Description
10.1	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted on or after May 19, 2011).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-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 Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-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 Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Cornerstone Therapeutics Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Operations, (iii) the Unaudited Consolidated Statements of Cash Flows, and (iv) Notes to Unaudited Consolidated Financial Statements, tagged as blocks of text.

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.