CORNERSTONE THERAPEUTICS INC
Form 10-Q
November 03, 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 September 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 October 31, 2011, the registrant had 26,023,644 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; the adverse impact of returns of previously sold inventory; patient, physician and third-party payer 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)

	September 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 81,541	$ 50,945
Accounts receivable, net	17,080	76,476
Inventories, net	12,295	15,174
Prepaid and other current assets	5,322	5,111
Income tax receivable	2,204	197
Deferred income tax asset	4,535	6,599
Total current assets	122,977	154,502
Property and equipment, net	1,691	1,486
Product rights, net	99,051	112,328
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Long-term accounts receivable		7,866
Other assets	834	687
Total assets	$ 237,822	$ 290,138
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 9,674	$ 7,671
Accrued expenses	43,395	46,599
License agreement liability	1,489	1,368
Current portion of capital lease	88	83
Current portion of deferred revenue	2,338	37,616
Total current liabilities	56,984	93,337
Capital lease, less current portion	79	146
Deferred revenue, less current portion		19,578
Deferred income tax liability	3,838	4,679
Total liabilities	60,901	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; 25,796,934 and 25,472,963 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	26	25
Additional paid-in capital	162,572	160,106
Retained earnings	14,323	12,267
Total stockholders equity	176,921	172,398
Total liabilities and stockholders equity	$ 237,822	$ 290,138

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

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF INCOME
(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenues	$ 25,180	$ 27,932	$ 83,216	$ 92,803
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	8,355	7,742	22,933	22,714
Selling, general and administrative	11,239	12,850	36,113	38,089
Royalties	1,605	2,600	6,250	9,846
Research and development	199	1,047	1,372	3,748
Amortization of product rights	3,591	3,595	13,277	10,785
Total costs and expenses	24,989	27,834	79,945	85,182
Income from operations	191	98	3,271	7,621
Other expenses:				
Interest expense, net	(38)	(37)	(121)	(47)
Other expense, net		(25)		(25)
Total other expenses	(38)	(62)	(121)	(72)
Income before income taxes	153	36	3,150	7,549
(Provision for) benefit from income taxes	(36)	728	(1,094)	(2,172)
Net income	$ 117	$ 764	$ 2,056	$ 5,377
Net income per share, basic	$ 0.00	$ 0.03	$ 0.08	$ 0.21
Net income per share, diluted	$ 0.00	$ 0.03	$ 0.08	$ 0.21
Weighted-average common shares, basic	25,782,481	25,430,785	25,646,455	25,395,506
Weighted-average common shares, diluted	26,331,700	26,056,928	26,223,317	26,017,288

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)

	Nine Months Ended September 30,	
	2011	**2010**
Cash flows from operating activities		
Net income	$ 2,056	$ 5,377
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	11,146	11,070
Provision for prompt payment discounts	2,781	2,909
Provision for inventory allowances	339	199
Loss on sale of property and equipment		25
Impairment of product rights	2,500	
Stock-based compensation	1,586	970
Benefit from (provision for) deferred income taxes	1,223	(1,419)
Changes in operating assets and liabilities:		
Accounts receivable	56,615	(2,206)
Inventories	2,540	(1,855)
Prepaid expenses, long-term accounts receivable and other assets	7,508	1,523
Accounts payable	2,003	2,172
Accrued expenses and license agreement liability	(3,083)	5,087
Income taxes receivable	(2,007)	(2,597)
Deferred revenue	(54,856)	9,195
Net cash provided by operating activities	30,351	30,450
Cash flows from investing activities		
Proceeds from sale of property and equipment		2
Purchase of property and equipment	(574)	(361)
Purchase of product rights		(250)
Net cash used in investing activities	(574)	(609)
Cash flows from financing activities		
Proceeds from exercise of common stock options	368	538
Excess tax benefit from stock-based compensation	513	467
Principal payments on capital lease obligation	(62)	(27)
Net cash provided by financing activities	819	978
Net increase in cash and cash equivalents	30,596	30,819
Cash and cash equivalents as of beginning of period	50,945	18,853
Cash and cash equivalents as of end of period	$ 81,541	$ 49,672

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 health care providers through the Company s respiratory sales force and to hospital-based health care 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 nine-month periods ended September 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 of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from any of these sources could have a material adverse effect on the

Company s business, financial position and results of operations. During the nine months ended September 30, 2011, one supplier accounted for 89% of the Company s total inventory purchases. Amounts due to this supplier represented approximately 46% of total accounts payable as of September 30, 2011.

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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 nine months ended September 30, 2011 and 2010 or 10% of total accounts receivable as of September 30, 2011 and December 31, 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011 Gross Product Sales	2010 Gross Product Sales	2011 Gross Product Sales	2010 Gross Product Sales
Cardinal Health, Inc.	38%	38%	39%	39%
McKesson Corporation	34	29	35	32
AmerisourceBergen Drug Corporation	23	25	21	22
Total	95%	92%	95%	93%

	September 30, 2011 Accounts Receivable	December 31, 2010 Accounts Receivable
Cardinal Health, Inc.	35%	50%
McKesson Corporation	22	30
AmerisourceBergen Drug Corporation	41	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 September 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 September 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 three or nine months ended September 30, 2011 or 2010.

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

	September 30, 2011	December 31, 2010
Accounts receivable	$ 17,641	$ 78,491
Less allowance for prompt payment discounts	(561)	(2,015)
Accounts receivable, net	$ 17,080	$ 76,476

The Company has ceased manufacturing and distribution of ALLERX® and HYOMAX®. During 2010, 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. In March 2011 the FDA announced that it intended to take enforcement action against marketed unapproved prescription cough, cold and allergy products shipped on or after August 30, 2011

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(the March 2011 FDA Announcement). During the three months ended September 30, 2011, certain wholesalers requested to return approximately $26.4 million of ALLERX Dose Pack product since they interpreted the March 2011 FDA Announcement to cover distribution of these products by wholesalers. In connection with the expected returns, the Company reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, the Company satisfied $16.7 million of its accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when the Company receives the returned product.

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 September 30, 2011 and December 31, 2010 (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	$ 3,516	$ 5,542
Work in process	497	1,575
Finished goods:		
Pharmaceutical products trade	8,465	8,635
Pharmaceutical products samples	722	1,267
Total	13,200	17,019
Inventory allowances	(905)	(1,845)
Inventories, net	$ 12,295	$ 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Gross product sales	$ 37,873	$ 41,616	$ 133,345	$ 140,724
Sales allowances	(12,695)	(15,206)	(50,228)	(49,462)
Net product sales	25,178	26,410	83,117	91,262
License and royalty agreement revenues	2	1,522	99	1,541
Net revenues	$ 25,180	$ 27,932	$ 83,216	$ 92,803

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

Net Product Sales

Product Sales. The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments,

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chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated.

As of September 30, 2011 and December 31, 2010, the Company had $2.3 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.

During the three months ended September 30, 2011, certain wholesalers indicated that they interpreted the March 2011 FDA Announcement to cover distribution of ALLERX Dose Pack products by wholesalers and requested to return approximately $26.4 million of ALLERX Dose Pack product to the Company. In connection with the expected returns, the Company reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, the Company satisfied $16.7 million of its accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when the Company receives the returned product.

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 payers, 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 payers 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 nine months ended September 30, 2011 were $0 and $75,000, respectively. License agreement revenues were $1.5 million for the three and nine months ended September 30, 2010. In August 2010, in accordance with a license agreement with Targacept, Inc. (Targacept) under which the Company out-licensed certain rights with respect to its alpha-7 receptor technology, the Company received an upfront nonrefundable payment of $1.5 million. The Company is also eligible for success-based milestone payments of up to $74.9 million, depending on which compound is progressed by Targacept.

Royalty agreement revenues are earned under license agreements, which provide for the payment of royalties based on sales of certain licensed products. These revenues are recognized based on product sales that occurred in the relevant period. Royalty agreement revenues for the three months ended September 30, 2011 and 2010 were $2,000 and $22,000, respectively. Royalty agreement revenues for the nine months ended September 30, 2011 and 2010 were $24,000 and $41,000, respectively.

NOTE 3: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance as of September 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 September 30, 2011 will be deductible for income tax purposes.

Product Rights

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

	September 30, 2011			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted - Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 22,418	$ 85,188	10.0
FACTIVE®	7,613	3,242	4,371	4.8
SPECTRACEF®	4,505	2,332	2,173	10.0
ZYFLO®	11,500	4,681	6,819	7.1
CRTX 067	500		500	n/a
Other	75	75		
Total	$ 131,799	$ 32,748	$ 99,051	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 nine months ended September 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 September 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):

	September 30, 2011	December 31, 2010
Accrued product returns	$ 22,190	$ 15,025
Accrued rebates	2,912	3,034
Accrued price adjustments and chargebacks	11,537	21,520
Accrued compensation and benefits	3,113	2,760
Accrued royalties	2,740	3,303
Accrued expenses, other	903	957
Total accrued expenses	$ 43,395	$ 46,599

During the three months ended September 30, 2011, certain wholesalers indicated that they interpreted the March 2011 FDA Announcement to cover distribution of ALLERX Dose Pack products by wholesalers and requested to return approximately $26.4 million of ALLERX Dose Pack product to the Company. In connection with the expected returns, the Company reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, the Company satisfied $16.7 million of its accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when the Company receives the returned product.

NOTE 5: STOCK-BASED COMPENSATION

Stock Options

The Company 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 755,347 and 273,181 stock options granted and exercised, respectively, during the nine months ended September 30, 2011.

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

	Nine Months Ended September 30, 2011

Estimated dividend yield		0.0%
Expected stock price volatility		80%
Risk-free interest rate		0.79-2.24%
Expected life of option (in years)		5.00
Weighted-average grant date fair value per share of options granted	$	3.87

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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 September 30, 2011, the aggregate intrinsic value of options outstanding and exercisable was $4.7 million and $3.9 million, respectively.

As of September 30, 2011, there was $3.9 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.63 years.

Restricted Stock

During the nine months ended September 30, 2011, 105,000 shares of restricted stock were issued and 50,790 shares vested. As of September 30, 2011, there were 226,710 restricted common shares outstanding and $1.3 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.68 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately $702,000 and $315,000 for the three months ended September 30, 2011 and 2010, respectively and $1.6 million and $970,000 for the nine months ended September 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 $254,000 and $339,000 for the three months ended September 30, 2011 and 2010, respectively, and approximately $843,000 and $1.0 million for the nine months ended September 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 $11.9 million as of September 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 September 30, 2011, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $8.6 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 September 30, 2011 and 2010, total royalty expenses were $1.6 million and $2.6 million, respectively and for the nine months ended September 30, 2011 and 2010, total royalty expenses were $6.3 million and $9.8 million, respectively.

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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 $38.3 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 September 30, 2011, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately $2.2 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 September 30, 2011, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.8 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 September 30, 2011, the Company had $348,000 recorded as accrued severance related to the departure of one of its executive officers.

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 nine months ended September 30, 2011 was 23.5% and 34.7%, respectively. The Company s effective tax rate for the three and nine months ended September 30, 2010 was (2,022.2)% and 28.8%, respectively. The effective rate for the three and nine months ended September 30, 2010 reflected changes in the estimated tax provision related to the year ended December 31, 2009. The changes resulted from an increase in our net operating loss usage generating a tax benefit recognized in the three months ended September 30, 2010.

The estimated annual effective tax rate for the year ending December 31, 2011 includes a benefit of approximately 27.6% 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.

There were no changes in unrecognized tax positions for the nine months ended September 30, 2011. As of September 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.

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

The 2008 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 $5.6 million and $15.2 million for the three and nine months ended September 30, 2011, respectively and $5.1 million and $16.8 million for the three and nine months ended September 30, 2010, respectively. As of September 30, 2011 and December 31, 2010, the Company had accounts payable due to Chiesi of $4.4 million and $2.1 million, respectively.

NOTE 9: NET INCOME PER SHARE

Basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding during each period. Diluted net income per share is computed by dividing net income 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 per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Numerator:				
Net income	$ 117	$ 764	$ 2,056	$ 5,377
Denominator:				
Weighted-average common shares, basic	25,782,481	25,430,785	25,646,455	25,395,506
Dilutive effect of stock options, warrants and restricted stock	549,219	626,143	576,862	621,782
Weighted-average common shares, diluted	26,331,700	26,056,928	26,223,317	26,017,288
Net income per share, basic	$ 0.00	$ 0.03	$ 0.08	$ 0.21
Net income per share, diluted	$ 0.00	$ 0.03	$ 0.08	$ 0.21
Anti-dilutive weighted-average shares	1,438,236	1,448,660	1,525,532	1,515,849

As of September 30, 2011, there were 226,710 shares of unvested restricted stock outstanding that contain non-forfeitable rights to dividends. These securities are considered to be participating securities under the two-class method for determining basic and fully diluted net income per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net income in each of the periods presented, only the treasury stock method has been disclosed.

NOTE 10: SUBSEQUENT EVENTS

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

NOTE 11: RECENT ACCOUNTING PRONOUNCEMENTS

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment* (ASU 2011-08), which amends current guidance to allow a company to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment also improves previous guidance by expanding upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed

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for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company plans to early adopt ASU 2011-08 and does not expect the adoption to have any impact upon its financial position and results of operations.

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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 respiratory, hospital and related specialty markets. We recently articulated our strategic plan which called for building upon our established strategic product base and focusing on therapeutic niches within the respiratory and hospital markets in order to deliver short-term value through increased market penetration and create long-term value by acquiring strategically-aligned products that leverage our existing commercial capabilities.

As part of that plan, we set ourselves the following objectives for 2011:

Increasing the market penetration of our strategic products while maximizing the cash generated by our final sales of marketed unapproved products;

Using this transition period to align our organizational structure to better support a business model built around strategic products;

Identifying acquisition opportunities to boost our inorganic growth;

Focusing our development pipeline to support our strategy; and

Increasing our short-term revenues by launching our generic cough/cold product CRTX 067.

We believe that we continue to make good progress toward these objectives and that if we implement this strategy successfully, we can deliver consistent long-term revenue and earnings growth.

Third Quarter 2011 Highlights

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

Cash and cash equivalents equaled $81.5 million as of September 30, 2011.

Net product sales were $25.2 million and $26.4 million for the three months ended September 30, 2011 and 2010, respectively. Net product sales from strategic products increased $1.6 million, or 9%, for the three months ended September 30, 2011 compared the three months ended September 30, 2011. The percentage of net product sales generated from strategic products increased from 67% for the three months ended September 30, 2010 to 77% for the three months ended September 30, 2011.

When calculated in accordance with accounting principles generally accepted in the United States, or GAAP, income from operations was $191,000 for the three months ended September 30, 2011 compared to $98,000 for the three months ended September 30, 2010. On a GAAP basis, net income for the three months ended September 30, 2011 was $117,000 compared to $764,000 for the three months ended September 30, 2010.

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On a non-GAAP basis, income from operations was $4.5 million for the three months ended September 30, 2011 compared to $4.0 million for the three months ended September 30, 2010. On a non-GAAP basis, net income for the same periods was $3.4 million and $3.8 million, respectively.

In March 2011, the FDA announced that it intended 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 (this announcement is referred to as the March 2011 FDA Announcement). All of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010 and this action did not require the recall or withdrawal of any products. However, during the three months ended September 30, 2011, certain wholesalers indicated that they interpreted the March 2011 FDA Announcement to cover distribution of ALLERX Dose Pack products by wholesalers and requested to return approximately $26.4 million of those products to us. In connection with the expected returns, we reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, we satisfied $16.7 million of our accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when we receive the returned product. We anticipate a future negative impact on our cash flows from these returns of ALLERX Dose Pack product of approximately $6.7 million.

Opportunities and Trends

We continue to execute on our strategic plan, which calls for growing our core CUROSURF® and ZYFLO® franchises and transitioning away from our primary care-focused anti-infective franchise. As called for in our plan, we are sharpening our focus on the specialty and hospital markets. We will continue to focus on growing revenues from our strategic products and expect to cease recognizing revenues from our unapproved products by the end of 2011. We are also increasing our business development efforts to expand our product portfolio. We believe that this approach, combined with the experience and expertise of our management team, positions us well to drive the future growth of our strategic products revenue.

We generate revenue by promoting our products to targeted health care professionals who are hospital-based or whose practices focus on the treatment of respiratory disorders. Primarily, these health care professionals are specialists and, while we also identify and target general practitioners who treat particularly large numbers of patients with respiratory ailments, we have recently realigned our sales force to focus calls on neonatologists and respiratory specialists. As a result, our share of the hospital market for our lead product, Curosurf, has continued to grow, and the percentage of our respiratory products prescribed by specialists continues to increase.

At the same time, our strategic plan calls for migrating away from our primary-care focus particularly in the area of anti-infectives. This migration is due in part to the increased presence of generic products in this sector of the market and is driven by our decision to realign our respiratory sales force to specialists. This has reduced the portion of the total anti-infective prescriber base that we call on, but we have been able to maintain coverage of approximately 90% of the total prescription volume for our brands. As we continue to execute on this initiative we may continue to see a slight decline in prescription levels for our anti-infective products.

In part as a result of this realignment, our strategic products generated $59.0 million in net product sales for the nine months ended September 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 71% 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. This metric will become less significant as our sales of marketed unapproved products wind down during the remainder of 2011, particularly since we believe that recent decisions of our partners in the distribution channel will likely cause us to cease recognizing sales of marketed unapproved products by the end of 2011 due to the quantity of those products that we now believe will be returned.

We have also focused our development pipeline to concentrate on projects that may enhance the life cycle of our ZYFLO products. This includes exploring the potential for using zileuton, the active ingredient in our ZYFLO products, to treat other unmet needs in our areas of therapeutic focus. We have also made organizational changes and

upgraded our master data management system and internal sales and marketing data warehouse, and we expect to deploy a comprehensive business intelligence reporting infrastructure in the near future.

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As we continue to focus on the growth of our existing products and product candidates, we also continue to position ourselves to execute acquisitions that will drive our next phase of growth. We are systematically focusing our efforts on acquiring products or companies whose products will fit strategically with the focus and strengths of our sales force. With the help of our commercial partner, Chiesi Farmaceutici S.p.A., or Chiesi, we believe that we can continue to operate efficiently in challenging economic and industry environments and that we will find opportunities to invest our cash in ways that will drive future growth. We will need to continue to maintain our strategic focus, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships in order to execute our strategy successfully.

As we conclude 2011 we will 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 our life-cycle management program to expand our zileuton franchise; and

Identification of products that align with our strategy and may represent potential acquisition targets that would contribute to our sustainable growth.

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Results of Operations

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

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

	Three Months Ended September 30,		Change	
	2011	2010	$	%
Net product sales				
CUROSURF	$ 9,347	$ 8,051	$ 1,296	16%
ZYFLO product family	8,316	7,574	742	10
FACTIVE®	763	850	(87)	(10)
SPECTRACEF® product family	882	1,194	(312)	(26)
ALLERX® Dose Pack products	5,437	3,812	1,625	43
HYOMAX® product family	359	2,002	(1,643)	(82)
Other products	74	2,927	(2,853)	(97)
Total net product sales	25,178	26,410	(1,232)	(5)
License and royalty agreement revenues	2	1,522	(1,520)	(100)
Net revenues	25,180	27,932	(2,752)	(10)
Cost of product sales (exclusive of amortization of product rights)	8,355	7,742	613	8
Selling, general and administrative	11,239	12,850	(1,611)	(13)
Royalties	1,605	2,600	(995)	(38)
Research and development	199	1,047	(848)	(81)
Amortization of product rights	3,591	3,595	(4)	NM
Income from operations	191	98	93	95
Total other expenses, net	(38)	(62)	(24)	(39)
Income before income taxes	153	36	117	325
(Provision for) benefit from income taxes	(36)	728	(764)	(105)
Net income	$ 117	$ 764	$ (647)	(85)%
Net income per share, diluted	$ 0.00	$ 0.03	$ (0.03)	(100)%
Non-GAAP income from operations (1)	$ 4,484	$ 4,008	$ 476	12%
Non-GAAP net income (1)	$ 3,400	$ 3,834	$ (434)	(11)%
Non-GAAP net income per share, diluted (1)	$ 0.13	$ 0.15	$ (0.02)	(13)%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.
NM Not meaningful.

Net Revenues

Net Product Sales.

CUROSURF net product sales increased $1.3 million, or 16%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010, primarily due to the timing of sales orders placed by our customers and an increase in price, partially offset by an increase in the estimated fees to be paid to our distributors.

ZYFLO CR® and ZYFLO net product sales increased $742,000, or 10%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. This increase was primarily due to timing of customer purchases and an increase in price, partially offset by an increase in the estimated fees to be paid to our distributors.

FACTIVE net product sales decreased $87,000, or 10%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. This decrease was primarily due to a decrease in sales volume and increase in our estimated rates for product returns and voucher redemption, partially offset by a price increase.

SPECTRACEF product family net product sales decreased $312,000, or 26%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. This decrease was primarily due to a reduction in sales volume.

ALLERX Dose Pack net product sales increased $1.6 million, or 43%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. This increase was primarily due to increased prescription volume, offset by

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an increase in the estimated fees to be paid to our distributors and voucher redemption. During the three months ended September 30, 2011, revenue continued to be recognized as prescriptions were filled instead of at the time of sale. At September 30, 2011, we had deferred revenue of approximately $1.7 million related to previous sales of ALLERX Dose Pack products.

HYOMAX net product sales decreased $1.6 million, or 82%, during the three months ended September 30, 2011 compared to the three months ended September 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 September 30, 2011, we had deferred revenue of approximately $587,000 related to previous sales of HYOMAX products.

Net product sales from other products decreased $2.9 million, or 97%, during the three months ended September 30, 2011 compared to the three months ended September 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 September 30, 2010 were $2.9 million, whereas we had no product sales from these products during the three months ended September 30, 2011.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $3.6 million for each of the three months ended September 30, 2011 and 2010) increased $613,000, or 8%, during the three months ended September 30, 2011 compared to the three months ended September 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 September 30,		Change	
	2011	2010	$	%
Net product sales	$ 25,178	$ 26,410	$ (1,232)	(5)%
Cost of product sales (exclusive of amortization of product rights)	8,355	7,742	613	8
Gross profit	$ 16,823	$ 18,668	$ (1,845)	(10)%
Gross margin	67%	71%		

Gross margin of net product sales for the three months ended September 30, 2011 decreased four percentage points compared to the three months ended September 30, 2010. This decrease was due to a relatively higher percentage of our total net product sales during the three months ending September 30, 2011 derived from products that have lower gross margins, specifically CUROSURF.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.6 million, or 13%, during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. This decrease was primarily due to decreases in our marketing and promotional spending relating to FACTIVE and ZYFLO CR 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 $995,000, or 38%, during the three months ended September 30, 2011 compared to the three months ended September 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 $848,000, or 81%, during the three months ended September 30, 2011 compared to the three months ended September 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.

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Provision for Income Taxes

The provision for income taxes was $36,000 for the three months ended September 30, 2011 compared to a benefit from income taxes of $728,000 for the three months ended September 30, 2010. Our effective tax rates for the three months ended September 30, 2011 and 2010 were 23.5% and (2,022.2)%, respectively. The effective rate for the three months ended September 30, 2010 reflected changes in the estimated tax provision related to the year ended December 31, 2009. The changes resulted from an increase in our net operating loss usage generating a tax benefit recognized in the three months ended September 30, 2010.

Comparison of the Nine Months Ended September 30, 2011 and 2010

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

	Nine Months Ended September 30,		Change	
	2011	2010	$	%
Net product sales				
CUROSURF	$ 25,402	$ 23,767	$ 1,635	7%
ZYFLO product family	22,313	21,855	458	2
FACTIVE	5,227	4,163	1,064	26
SPECTRACEF product family	6,051	3,478	2,573	74
ALLERX Dose Pack products	26,191	22,105	4,086	18
HYOMAX product family	1,770	7,801	(6,031)	(77)
Other products	(3,837)	8,093	(11,930)	(147)
Total net product sales	83,117	91,262	(8,145)	(9)
License and royalty agreement revenues	99	1,541	(1,442)	(94)
Net revenues	83,216	92,803	(9,587)	(10)
Cost of product sales (exclusive of amortization of product rights)	22,933	22,714	219	1
Selling, general and administrative	36,113	38,089	(1,976)	(5)
Royalties	6,250	9,846	(3,596)	(37)
Research and development	1,372	3,748	(2,376)	(63)
Amortization of product rights	13,277	10,785	2,492	23
Income from operations	3,271	7,621	(4,350)	(57)
Total other expenses, net	(121)	(72)	49	68
Income before income taxes	3,150	7,549	(4,399)	(58)
Provision for income taxes	(1,094)	(2,172)	(1,078)	(50)
Net income	$ 2,056	$ 5,377	$ (3,321)	(62)%
Net income per share, diluted	$ 0.08	$ 0.21	$ (0.13)	(62)%
Non-GAAP income from operations (1)	$ 18,134	$ 19,376	$ (1,242)	(6)%
Non-GAAP net income (1)	$ 11,757	$ 13,750	$ (1,993)	(14)%
Non-GAAP net income per share, diluted (1)	$ 0.45	$ 0.53	$ (0.08)	(15)%

(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 $1.6 million, or 7%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010, primarily due to increases in sales volume and price, partially offset by an increase in the estimated fees to be paid to our distributors.

ZYFLO CR and ZYFLO net product sales increased $458,000, or 2%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Excluding the impact of an additional reserve of $1.2 million for potential returns of short-dated product on net product sales for the nine months ended September 30, 2010, net product sales decreased approximately $741,000 during the nine months ended September 30, 2011. This decrease was primarily due to the timing of customer purchases and an increase in the estimated fees to be paid to our distributors, partially offset by an increase in price.

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FACTIVE net product sales increased $1.1 million, or 26%, during the nine months ended September 30, 2011 compared to the nine months ended September 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 $2.6 million, or 74%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Excluding the impact of an additional reserve of $1.6 million for potential returns of discontinued product on net product sales for the nine months ended September 30, 2010, net product sales increased approximately $1.0 million during the nine months ended September 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 $4.1 million, or 18%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Excluding the impact of an additional reserve of $3.4 million for product returns in excess of our estimates during the nine months ended September 30, 2010, net product sales increased approximately $700,000 during the nine months ended September 30, 2011. This increase was due to increased prescription volume. At September 30, 2011, we had deferred revenue of approximately $1.7 million related to previous sales of our ALLERX Dose Pack products.

HYOMAX net product sales decreased $6.0 million, or 77%, during the nine months ended September 30, 2011 compared to the nine months ended September 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 September 30, 2011, we had deferred revenue of approximately $587,000 related to previous sales of HYOMAX products.

Net product sales from our other products decreased $11.9 million, or 147%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010, primarily due to our November 2010 withdrawal from the market of our propoxyphene/acetaminophen products. Net product sales for these products during the nine months ended September 30, 2010 were $8.0 million, whereas we had no product sales from these products during the nine months ended September 30, 2011. During the nine months ended September 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

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $13.3 million and $10.8 million for the nine months ended September 30, 2011 and 2010, respectively) increased $219,000, or 1%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

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

	Nine Months Ended September 30,		Change	
	2011	**2010**	**$**	**%**
Net product sales	$ 83,117	$ 91,262	$ (8,145)	(9)%
Cost of product sales (exclusive of amortization of product rights)	22,933	22,714	219	1
Gross profit	$ 60,184	$ 68,548	$ (8,364)	(12)%
Gross margin	72%	75%		

Gross margin of net product sales for the nine months ended September 30, 2011 decreased three percentage points compared to the nine months ended September 30, 2010. This decrease was due to a relatively higher percentage of our total net product sales during the first nine months of 2011 derived from products that have lower gross margins, specifically CUROSURF.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $2.0 million, or 5%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. This decrease was primarily due to decreases in market research, samples and advertising costs for the ZYFLO and FACTIVE product families, as well as co-promotion expenses related to our propoxyphene/acetaminophen products, which were withdrawn from the market in November 2010.

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These decreases were partially offset by an increase in co-promotion expense for ZYFLO CR and 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 $3.6 million, or 37%, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. This decrease was primarily due to lower net product sales of the HYOMAX and propoxyphene/acetaminophen products, partially offset by increased royalties relating to FACTIVE.

Research and Development Expenses. Research and development expenses decreased $2.4 million, or 63%, during the nine months ended September 30, 2011 compared to the nine months ended September 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 23%, during the nine months ended September 30, 2011 compared to nine months ended September 30, 2010. During the nine months ended September 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 nine months ended September 30, 2011 compared to $2.2 million for the nine months ended September 30, 2010. Our effective tax rates for the nine months ended September 30, 2011 and 2010 were 34.7% and 28.8%, respectively. The effective rate for the nine months ended September 30, 2010 reflected changes in the estimated tax provision related to the year ended December 31, 2009. The changes resulted from an increase in our net operating loss usage generating a tax benefit recognized in the three months ended September 30, 2010.

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 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 net income 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.

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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 September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
GAAP income from operations	$ 191	$ 98	$ 3,271	$ 7,621
Add: stock-based compensation	702	315	1,586	970
Add: amortization of product rights	3,591	3,595	13,277	10,785
Non-GAAP income from operations	$ 4,484	$ 4,008	$ 18,134	$ 19,376
GAAP net income	$ 117	$ 764	$ 2,056	$ 5,377
Add: stock-based compensation	702	315	1,586	970
Add: amortization of product rights	3,591	3,595	13,277	10,785
Less: tax effects related to above items(1)	(1,010)	(840)	(5,162)	(3,382)
Non-GAAP net income	$ 3,400	$ 3,834	$ 11,757	$ 13,750
GAAP net income per share, diluted	$ 0.00	$ 0.03	$ 0.08	$ 0.21
Non-GAAP net income per share, diluted	$ 0.13	$ 0.15	$ 0.45	$ 0.53
Shares used in diluted net income per share calculation:				
GAAP net income	26,331,700	26,056,928	26,223,317	26,017,288
Non-GAAP net income	26,331,700	26,056,928	26,223,317	26,017,288

(1) Tax effects for the three months ended September 30, 2011 and 2010 are calculated using effective tax rates of 23.5% and 21.5% respectively. Tax effects for the nine months ended September 30, 2011 and 2010 are calculated using effective tax rates of 34.7% and 28.8% respectively.

Liquidity and Capital Resources

Sources of Liquidity

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 September 30, 2011, we had $81.5 million in cash and cash equivalents.

In connection with the March 2011 FDA Announcement, during the three months ended September 30, 2011, certain wholesalers indicated that they interpreted the March 2011 FDA Announcement to cover distribution of ALLERX Dose Pack products by wholesalers and requested to return approximately $26.4 million of ALLERX Dose Pack product to us. In connection with the expected returns, we reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, we satisfied $16.7 million of our accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when we receive the returned product. We anticipate a future negative impact on our cash flows from these returns of ALLERX Dose Pack products of

approximately $6.7 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2011	**2010**
Cash provided by (used in):		
Operating activities	$ 30,351	$ 30,450
Investing activities	(574)	(609)
Financing activities	819	978
Net increase in cash and cash equivalents	$ 30,596	$ 30,819

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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 nine months ended September 30, 2011 reflected our net income of $2.1 million, adjusted by non-cash expenses totaling $19.6 million and changes in accounts receivable, inventories, deferred revenue, income taxes payable, accrued expenses and other operating assets and liabilities totaling $8.7 million. Non-cash items included amortization and depreciation of $11.1 million, impairment of product rights of $2.5 million, changes in allowances for prompt payment discounts and inventory obsolescence totaling $3.1 million, stock-based compensation of $1.6 million and changes in deferred income tax of $1.2 million. Accounts receivable decreased by $56.6 million from December 31, 2010 to September 30, 2011, primarily due to collections of receivables and expected returns of our 2010 sales of ALLERX Dose Pack and HYOMAX products. Inventories decreased by $2.5 million from December 31, 2010 to September 30, 2011, primarily due to reductions in ZYFLO CR and ZYFLO active pharmaceutical ingredient and samples, partially offset by a reduction in inventory allowances due to write-offs of ALLERX Dose Pack and ZYFLO CR sample inventory. Prepaid expenses, long-term accounts receivable and other assets decreased by $7.5 million, primarily due to the decrease of long-term accounts receivable and long-term deferred cost of product sales. Accounts payable increased by $2.0 million from December 31, 2010 to September 30, 2011, primarily due to timing of payments. Accrued expenses and license agreement liability decreased by $3.1 million from December 31, 2010 to September 30, 2011, primarily due to a decrease in accrued price adjustments and chargebacks as well as a decrease in the bonus accrual, partially offset by an increase in accrued product returns. Deferred revenue decreased by $54.9 million from December 31, 2010 to September 30, 2011 due to expected product returns and revenue that was recognized based on prescriptions filled for our ALLERX Dose Pack and HYOMAX products. Income taxes receivable increased by $2.0 million from December 31, 2010 to September 30, 2011 due to a decrease in our estimated taxable income for the year ending December 31, 2011.

Net cash provided by operating activities for the nine months ended September 30, 2010 reflected our net income of $5.4 million, adjusted by non-cash expenses totaling $13.8 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $11.3 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2011 reflected the purchase of property and equipment for $574,000.

Net cash used in investing activities for the nine months ended September 30, 2010 reflected the purchase of property and equipment for $361,000, purchase of product rights of $250,000 and proceeds from sale of property and equipment of $2,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2011 reflected proceeds from common stock option exercises of $368,000 and an excess tax benefit from stock options of $513,000, partially offset by principal payments on capital leases of $62,000.

Net cash provided by financing activities for the nine months ended September 30, 2010 reflected proceeds from common stock option exercises of $538,000 and an excess tax benefit from stock options of $467,000, partially offset by principal payments on capital leases of $27,000.

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;

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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 September 30, 2011, we had approximately $81.5 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.

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 nine months ended September 30, 2011. The following table summarizes our contractual obligations as of September 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	$ 183	$ 25	$ 157	$ 1	$
Operating leases(1)	2,650	180	1,135	1,183	152
Purchase obligations(2)	27,703	8,883	18,352	271	197
Total contractual obligations	$ 30,536	$ 9,088	$ 19,644	$ 1,455	$ 349

(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 $346,000 during the first nine 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 $20.5 million; clinical trial and research agreements with contract research

organizations and consultants of $2.2 million; agreements with providers of marketing analytical services of $4.8 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $174,000.

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 $38.3 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.

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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 three months ended September 30, 2011 are indicative of the results we expect for the remaining three 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 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

See Note 11 to our consolidated financial statements included in Part I Item 1. Financial Statements of this Quarterly Report on Form 10-Q, for a description of recent accounting pronouncements, including expected dates of adoption and estimated effects, if any, 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 nine months ended September 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 September 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 the Exchange Act. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 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

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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 September 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.

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 intended 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 had already been manufactured and shipped prior to December 31, 2010, and this action did not require the recall or withdrawal of any products. However, during the three months ended September 30, 2011, certain wholesalers indicated that they interpreted the March 2011 FDA Announcement to cover distribution of ALLERX Dose Pack products by wholesalers. They requested to return approximately $26.4 million of ALLERX Dose Pack product to us. In connection with the expected returns, we reclassified $26.4 million of deferred revenue and related accrued expenses to accrued product returns. During September 2011, we satisfied $16.7 million of our accrued product return liability for ALLERX Dose Pack returns by disbursing cash of $5.7 million and reducing accounts receivable by $11.0 million. Approximately $3.0 million of accounts receivable related to previously deferred sales of ALLERX Dose Packs remains recorded on the consolidated balance sheet as of September 30, 2011 and will be reversed (along with the associated accrued product return liability) when we receive the returned product. We anticipate a future negative impact on our cash flow from these returns of ALLERX Dose Pack product will be approximately $6.7 million. Deferred revenue is recognized as revenue when product is sold through to the end user based on prescriptions filled. To estimate the product sold through to end users, we rely on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers. If actual prescriptions filled differ from our estimates, there may be additional

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inventory in the channel subject to return. Accordingly, we may be required to accept additional returns of ALLERX Dose Pack product and issue refunds in excess of our deferred revenues, which could have a material adverse effect on our financial condition, results of operations, cash balance 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 payers, 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 payers often implement similar reimbursement policies as government payers. 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 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 payers 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.

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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: November 3, 2011	/s/ Craig Collard Craig Collard *Chief Executive Officer* *(Principal Executive Officer)*
Date: November 3, 2011	/s/ Vincent T. Morgus Vincent T. Morgus *Executive Vice President,* *Finance and Chief Financial Officer* *(Principal Financial Officer)*
Date: November 3, 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	Executive Employment Agreement between the Registrant and Kenneth R. McBean dated September 6, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated August 30, 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 the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 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.