CORNERSTONE THERAPEUTICS INC
Form 10-Q
August 05, 2010

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

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

For the Quarterly Period Ended June 30, 2010

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 o 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 þ	Non-accelerated filer o (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 July 30, 2010, the registrant had 25,629,504 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 plan to cease manufacturing and distributing at the end of 2010; the possibility that the Food and Drug Administration, or FDA, will take enforcement action against us or one or more of our marketed drugs that do not have FDA-approved marketing applications prior to the end of 2010; patient, physician and third-party payor acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products with FDA-approved marketing applications; our ability to obtain FDA approval to market and sell our products under development; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail in Part I Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission, or SEC, on March 4, 2010. Any material changes to the risk factors disclosed in the annual report are discussed below in Part II Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this quarterly report on Form 10-Q represent our views only as of the date of this quarterly report on Form 10-Q and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make.

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ITEM 1. ***FINANCIAL STATEMENTS***

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

	June 30, 2010 (Unaudited)	December 31, 2009 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 46,446	$ 18,853
Accounts receivable, net	14,176	16,548
Inventories, net	20,132	18,106
Prepaid and other current assets	2,681	4,808
Deferred income tax asset	5,227	3,507
Total current assets	88,662	61,822
Property and equipment, net	1,415	1,312
Product rights, net	119,616	126,806
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Other assets	154	113
Total assets	$ 223,116	$ 203,322
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 5,363	$ 7,172
Accrued expenses	27,869	23,703
Current portion of license agreement liability	1,158	1,019
Current portion of capital lease	10	10
Income taxes payable	2,560	1,606
Deferred revenue	10,822	
Total current liabilities	47,782	33,510
License agreement liability, less current portion	1,341	1,341
Capital lease, less current portion	33	39
Deferred income tax liability	3,853	4,564
Total liabilities	53,009	39,454
Commitments and contingencies, Note 6		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding	25	25

Common stock $0.001 par value, 90,000,000 shares authorized; 25,429,504 and 25,022,644 shares issued and outstanding as of June 30, 2010 and December 31, 2009, respectively		
Additional paid-in capital	159,371	157,745
Retained earnings	10,711	6,098
Total stockholders equity	170,107	163,868
Total liabilities and stockholders equity.	$ 223,116	$ 203,322

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

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CORNERSTONE THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net revenues	$ 28,465	$ 24,993	$ 64,871	$ 55,698
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	8,153	2,901	14,972	6,102
Selling, general and administrative	12,814	11,656	25,239	20,837
Royalties	2,648	5,651	7,246	11,942
Research and development	1,795	1,188	2,701	2,350
Amortization of product rights	3,595	510	7,190	1,021
Total costs and expenses	29,005	21,906	57,348	42,252
(Loss) income from operations	(540)	3,087	7,523	13,446
Other expenses:				
Interest expense, net	(9)	(42)	(10)	(114)
Total other expenses	(9)	(42)	(10)	(114)
(Loss) income before income taxes	(549)	3,045	7,513	13,332
Benefit from (provision for) income taxes	149	(1,307)	(2,900)	(5,279)
Net (loss) income	$ (400)	$ 1,738	$ 4,613	$ 8,053
Net (loss) income per share, basic	$ (0.02)	$ 0.14	$ 0.18	$ 0.67
Net (loss) income per share, diluted	$ (0.02)	$ 0.13	$ 0.18	$ 0.60
Weighted-average common shares, basic	25,405,165	12,166,989	25,377,575	12,095,764
Weighted-average common shares, diluted	25,405,165	13,584,314	25,997,175	13,486,956

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

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

	Six Months Ended June 30, 2010	2009
Cash flows from operating activities		
Net income	$ 4,613	$ 8,053
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	7,365	1,131
Provision for prompt payment discounts	2,049	1,574
(Recovery of) provision for inventory allowances	(367)	568
Stock-based compensation	655	852
Benefit from deferred income taxes	(2,431)	(1,425)
Changes in operating assets and liabilities:		
Accounts receivable	323	(2,723)
Inventories	(1,659)	(1,339)
Prepaid expenses and other assets	2,086	(2,285)
Accounts payable	(1,809)	(2,445)
Accrued expenses	4,305	4,216
Income taxes payable	954	(435)
Deferred revenue	10,822	
Net cash provided by operating activities	26,906	5,742
Cash flows from investing activities		
Proceeds from sale of marketable securities		300
Purchase of property and equipment	(278)	(136)
Net cash (used in) provided by investing activities	(278)	164
Cash flows from financing activities		
Proceeds from exercise of common stock options	516	271
Excess tax benefit from stock-based compensation	455	
Principal payments on capital lease obligation	(6)	(4)
Net cash provided by financing activities	965	267
Net increase in cash and cash equivalents	27,593	6,173
Cash and cash equivalents as of beginning of period	18,853	9,286
Cash and cash equivalents as of end of period	$ 46,446	$ 15,459

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

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CORNERSTONE THERAPEUTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Nature of Operations

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

Principles of Consolidation

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

Interim Financial Statements

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

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

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

Reclassifications

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

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company s consolidated financial statements include certain judgments regarding revenue recognition, product rights, inventory valuation, accrued expenses and stock-based compensation. Actual results could differ from those estimates or assumptions.

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Concentrations of Credit Risk and Limited Suppliers

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

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from any of these sources could have a material adverse effect on the Company s business, financial position and results of operations. During the six months ended June 30, 2010, one supplier individually accounted for 65% of the Company s total inventory purchases during this period. There were no amounts due to this supplier as of June 30, 2010.

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 or chain drug stores. The following tables list the Company s customers that individually comprise greater than 10% of total gross product sales for the three and six months ended June 30, 2010 and 2009 or 10% of total accounts receivable as of June 30, 2010 and December 31, 2009:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010 Gross Product Sales	2009 Gross Product Sales	2010 Gross Product Sales	2009 Gross Product Sales
Cardinal Health, Inc.	32%	34%	39%	35 %
McKesson Corporation	37	36	33	35
AmerisourceBergen Drug Corporation	25	18	21	17
Total	94%	88%	93%	87%

	June 30, 2010 Accounts Receivable	December 31, 2009 Accounts Receivable
Cardinal Health, Inc.	38%	26%
McKesson Corporation	25	37
AmerisourceBergen Drug Corporation	28	24
Total	91%	87%

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains cash deposits with a federally insured bank that may at times exceed federally insured limits. Certain funds in excess of the federally insured limits are held in sweep investment accounts

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

Accounts Receivable

The Company typically requires its customers to remit payments within the first 30 or 60 days, depending on 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

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of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

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

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

	June 30, 2010	December 31, 2009
Trade accounts receivable	$ 14,564	$ 16,932
Less allowance for prompt payment discounts	(388)	(384)
Accounts receivable, net	$ 14,176	$ 16,548

Inventories

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

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

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

	June 30, 2010	December 31, 2009
Raw materials	$ 7,638	$ 5,597
Work in process	306	2,007
Finished goods:		
Pharmaceutical products trade	10,413	9,962
Pharmaceutical products samples	2,512	2,342
Total	20,869	19,908
Inventory allowances	(737)	(1,802)
Inventories, net	$ 20,132	$ 18,106

Revenue Recognition

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Gross product sales	$ 44,140	$ 34,792	$ 99,108	$ 73,703
Sales allowances	(15,680)	(9,799)	(34,256)	(18,242)
Net product sales	28,460	24,993	64,852	55,461
Royalty agreement revenues	5		19	237
Net revenues	$ 28,465	$ 24,993	$ 64,871	$ 55,698

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Net Product Sales

Product Sales. The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated. As of June 30, 2010, the Company had $10.8 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

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

Rebates. The liability for managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each contract. The liability for Medicaid and Medicare rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state.

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

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. The Company has initiated voucher programs for its promoted products whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts. The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 or 60 days after the invoice date depending on the products purchased (see Accounts Receivable above).

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NOTE 3: GOODWILL AND INTANGIBLE ASSETS

Goodwill

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

Product Rights

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

	June 30, 2010	December 31, 2009
Product rights	$ 141,949	$ 141,949
Less accumulated amortization	(22,333)	(15,143)
Product rights, net	$ 119,616	$ 126,806

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of June 30, 2010, ranged from approximately five to ten years. As of June 30, 2010, the Company had $3.1 million of product rights related to products it expects to launch in the future. The Company expects to begin amortizing these rights upon the commercial launch of the first product using these rights, which is expected to be shortly after regulatory approval of such first product. The rights will be amortized over the estimated useful lives of the new products. The weighted-average amortization period for the Company s product rights related to its currently marketed products is approximately nine years.

NOTE 4: ACCRUED EXPENSES

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

	June 30, 2010	December 31, 2009
Accrued product returns	$ 12,772	$ 10,962
Accrued rebates	2,531	1,013
Accrued price adjustments and chargebacks	7,126	3,503
Accrued compensation and benefits	2,194	2,486
Accrued royalties	2,770	5,547
Accrued expenses, other	476	192
Total accrued expenses	$ 27,869	$ 23,703

NOTE 5: STOCK-BASED COMPENSATION

Stock Options

The Company currently uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and

subjective variables. These variables include the Company s expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

There were 648,950 and 394,360 stock options granted and exercised, respectively, during the six months ended June 30, 2010.

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

	Six Months Ended June 30, 2010
Estimated dividend yield	0.0%
Expected stock price volatility	80%
Risk-free interest rate	1.83-2.20%
Expected life of option (in years)	5.00
Weighted-average fair value per share	$3.89

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for the stock options is based on the Company s historical volatility from July 1, 2004 through the month of grant, and on the historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. 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 of the stock options granted was estimated based on the historical exercise patterns over the option lives while considering employee exercise strategy and cancellation behavior.

As of June 30, 2010, the aggregate intrinsic value of options outstanding and exercisable was $4.9 million and $4.4 million, respectively.

As of June 30, 2010, there was $3.6 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 3.07 years.

Restricted Stock

During the six months ended June 30, 2010, no shares of restricted stock were issued and 12,500 shares vested. As of June 30, 2010, there were 200,000 restricted common shares outstanding and $1.1 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 3.14 years.

Stock-Based Compensation Expense

The following table shows the approximate amount of total stock-based compensation expense recognized for employees and non-employees based on the total grant date fair value of shares vested (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Employee	$ 366	$ 576	$ 621	$ 828
Non-employee	9	22	34	24
Total	$ 375	$ 598	$ 655	$ 852

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 $370,000 and $226,000 for the three months ended June 30, 2010 and 2009, respectively, and approximately $707,000 and $434,000 for the six months ended June 30, 2010 and 2009, respectively.

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Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $20.9 million as of June 30, 2010, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management s estimates. As of June 30, 2010, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $11.5 million.

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or licensors of certain product rights that have been acquired by or licensed to the Company, some of which are described in Note 7 to the Company s consolidated financial statements included in the Company s annual report on Form 10-K for the year ended December 31, 2009. These royalties are typically based on a percentage of net sales of the particular licensed product. For the three months ended June 30, 2010 and 2009, total royalty expenses were $2.6 million and $5.7 million, respectively and $7.2 million and $11.9 million, respectively, for the six months ended June 30, 2010 and 2009. Certain of these royalty agreements also require minimum annual payments, which have been included in royalty expense on the consolidated statements of operations. Pursuant to these agreements, the Company is obligated to pay future minimum royalties of $7.2 million.

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 $58.7 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 consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

As of June 30, 2010, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $354,000.

Co-Promotion and Marketing Services Agreements

The Company has entered into a co-promotion and marketing service agreement and co-promotion agreements 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 agreements, 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 agreements are also subject to sunset fees that require the Company to pay additional fees for up to one year in the event of certain defined terminations of these agreements.

As of June 30, 2010, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.7 million.

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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 prior to receiving any severance payments.

Legal Proceedings

In 2008, the U.S. Patent and Trademark Office (USPTO) ordered a re-examination of a patent licensed to the Company that covers one or more of the Company s day-night products. In June 2009, the USPTO examiner issued an office action, rejecting claims of the patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims, in view of the patents and publications cited. In August 2009, the patent owner filed an amendment to the claims and a request for reconsideration of the office action issued in June 2009. If the USPTO re-examination examiner maintains one or more of the USPTO rejections of the claims of the patent, the patent owner may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If the Board of Patent Appeals thereafter affirms the examiner s rejections, the patent owner could take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the patent with narrowed claims. The further proceedings involving the patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the patent. The Company s intellectual property counsel believes that valid arguments exist for distinguishing the claims of the Company s patent over the references cited in the request for re-examination.

NOTE 7: INCOME TAXES

The Company computes an estimated annual effective tax rate for interim financial reporting purposes. The estimated annual effective tax rate is used to compute the tax expense or benefit related to ordinary income or loss. Tax expense or benefit related to all other items is individually computed and recognized when the items occur. The Company s effective tax rate for the three and six months ended June 30, 2010 was 27.1% and 38.6%, respectively. The Company s effective tax rate for the three and six months ended June 30, 2009 was 42.9% and 39.6%, respectively. The significant variance in the rate for the three months ended June 30, 2010 compared to the three months ended June 30, 2009 is primarily due to an increase in the estimated permanent differences used in calculation of the estimated annual effective tax rate as of June 30, 2010 compared to March 31, 2010. The increase in the estimated annual rate caused a reduction in the benefit from income taxes for the three months ended June 30, 2010.

The estimated annual effective tax rate for the year ending December 31, 2010 includes a benefit of approximately 4% 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 NOL carryforwards 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 2010 is approximately $277,000 and has been recorded as a reduction to tax expense. The Company has not established any other valuation allowances.

As of June 30, 2010, the Company has no unrecognized tax benefits, including those that would affect the effective tax rate. There were no changes in unrecognized tax positions for the three or six months ended June 30, 2010. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next twelve months.

The Company recognizes any annual interest and penalties related to uncertain tax positions as operating expenses in its statements of operations. For the three and six months ended June 30, 2010, the Company recognized no interest or penalties related to uncertain tax positions in the statements of operations.

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The 2006 through 2009 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 as of June 30, 2010.

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 $4.6 million and $11.8 million for the three and six months ended June 30, 2010, respectively. As of June 30, 2010, the Company had prepaid inventory of $268,000 due from Chiesi and no amounts payable to Chiesi.

NOTE 9: NET (LOSS) INCOME PER SHARE

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Numerator:				
Net (loss) income	$ (400)	$ 1,738	$ 4,613	$ 8,053
Denominator:				
Weighted-average common shares, basic	25,405,165	12,166,989	25,377,575	12,095,764
Dilutive effect of stock options, warrants and restricted stock		1,417,325	619,601	1,391,192
Weighted-average common shares, diluted	25,405,165	13,584,314	25,997,175	13,486,956
Net income per share, basic	$ (0.02)	$ 0.14	$ 0.18	$ 0.67
Net income per share, diluted	$ (0.02)	$ 0.13	$ 0.18	$ 0.60
Anti-dilutive weighted-average shares	3,108,184	911,574	1,549,444	1,060,005

NOTE 10: SUBSEQUENT EVENTS

The Company has evaluated all events or transactions that occurred after June 30, 2010. The Company did not have any material recognizable subsequent events. However, the Company had two nonrecognizable subsequent events. On August 3, 2010, the Company licensed to Targacept, Inc. (Targacept) the worldwide rights to develop and commercialize products targeting the alpha-7 receptor using technology that we originally licensed from the Feinstein Institute for Medical Research. Under the terms of the agreement, the Company will receive an upfront payment of $1.5 million and is eligible for success-based milestone payments of up to $74.9 million, depending on which of two specified lead compounds is progressed by Targacept. The potential milestone payments are comprised of $1.1 million to $1.4 million through Phase 2 clinical proof of concept, $9.5 million to $18.5 million in later-stage pre-commercialization milestones and $35.0 million to $55.0 million in sales-based milestones. In addition, the Company is eligible for an unlimited number of lower success-based milestone payments if other compounds are developed which are covered by the licensed patents. Cornerstone will also receive low single digit royalties based on any future net sales of products developed using the licensed technology.

During the quarter the Company continued discussions with the FDA regarding both its expedited review of CRTX 067, the Company s generic 10 mg chlorpheniramine polistirex/8 mg hydrocodone polistirex suspension product

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candidate, and the development plan for its allergy product candidate, CRTX 070. The Company also notified the FDA of its decision to cease manufacturing and distribution of its marketed unapproved products by the end of 2010. The Company believes that this reinforces the Company s commitment to its strategy and positions the Company well to obtain FDA approval for its pipeline products. The Company does not anticipate that this decision will materially impact the expected sales of these products in 2010. During the second quarter of 2010, revenues from sales of certain of these products were deferred due to the inability to reasonably estimate returns. If this trend continues during the remainder of 2010, revenue from additional sales of these products would be recorded when the risk of product returns has been substantially eliminated. Accordingly, net revenues would be recognized when the product is sold to the end-user based upon prescriptions filled. Sales of these products would therefore be reflected in the consolidated financial statements after 2010 for the duration of the product shelf life, or until channel inventory has been exhausted, whichever is shorter.

NOTE 11: RECENT ACCOUNTING PRONOUNCEMENTS

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

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

The following discussion is designed to provide a better understanding of our unaudited consolidated financial statements, including a brief discussion of our business and products, key factors that impact our performance and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our unaudited consolidated financial statements and the related notes included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q and the consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our annual report on Form 10-K for the year ended December 31, 2009. 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 II Item 1A. Risk Factors of this quarterly report on Form 10-Q.

Executive Overview

Strategy

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products for the respiratory and related markets.

Our long-term commercial strategy is to in-license or acquire rights to strategic specialty products with sustainable growth potential. These products consist of non-promoted or underperforming, patent or trade secret protected branded pharmaceutical products that we can promote through our respiratory and hospital sales forces. Consistent with our respiratory-focused strategy, we are also developing late-stage cough/cold product candidates to enhance our presence in the respiratory market.

We have historically derived a large part of our revenues from branded or branded generic versions of products that have or had limited intellectual property protection, which we refer to as our legacy products. Some of these legacy products are marketed without approved new drug applications, or NDAs, or abbreviated new drug applications, or ANDAs. We do not consider any of our legacy products to be part of our long term strategy.

We are continuing our efforts to grow revenues from strategic specialty products with sustainable growth potential. In order to focus our resources on these efforts, we are winding down our manufacturing and distribution of marketed unapproved products and divesting our valuable but non-core technologies. We believe that if we implement our strategy successfully, we can offset declines in marketed unapproved product sales and deliver more consistent long-term earnings growth for our stockholders. Our performance for the six months ended June 30, 2010 reflects the execution of our strategy as the proportion of our sales generated by strategic specialty products increased over the same period in the prior year.

Second Quarter 2010 Highlights

The following is a summary of key financial results achieved for the three months ended June 30, 2010, as well as certain key non-financial achievements that reflect the continuing strides we are taking to transform the company and attain our goals:

- Our net revenues for the quarter increased 14% to $28.5 million during the three months ended June 30, 2010 compared to the three months ended June 30, 2009, of which the percentage of revenue derived from strategic specialty products increased from 20% to 64%;

- Our cash and cash equivalents increased $27.6 million or 146% to $46.4 million at June 30, 2010 compared to $18.9 million at December 31, 2009;

- We continued to enhance our pipeline by advancing development of CRTX 067, our generic 10 mg chlorpheniramine polistirex/8 mg hydrocodone polistirex suspension product candidate;

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We reacquired, for no cost, all development and commercial rights to our high-mobility group box protein 1 (HMGB-1) protein-related technology from MedImmune, LLC for which we will actively pursue opportunities for divestiture;

We licensed to Targacept, Inc. the worldwide rights to develop and commercialize a product targeting the alpha-7 receptor using technology that we originally licensed from the Feinstein Institute for Medical Research, or the Feinstein Institute; and

We entered into a product development collaboration agreement with Alitair Pharmaceuticals, Inc., or Alitair, to leverage Alitair intellectual property in the development of CRTX 072, one of our cough/cold product candidates, and other products to treat respiratory diseases.

Sales of some of our products fluctuate with the seasonality of the cough/cold season, which primarily results in higher revenues in our first and fourth quarters of the year. We do not believe that our product sales for the six months ended June 30, 2010 are indicative of the results we expect for the remaining six months of 2010. However, we will continue to focus on growing sales of all of our strategic products, even during the periods when demand for certain of those products is customarily lower.

Opportunities and Trends

During the remainder of 2010, we plan to continue to deliver on our strategy of developing our core strategic business and expanding our pipeline, while decreasing our focus on marketed unapproved products, and divesting our non-core technologies.

During the quarter we continued our discussions with the FDA regarding both the expedited review of CRTX 067, our generic 10 mg chlorpheniramine polistirex/8 mg hydrocodone polistirex suspension product candidate, and the development plan for our allergy product candidate, CRTX 070. We also notified the FDA of our decision to cease manufacturing and distribution of our marketed unapproved products by the end of 2010. We believe that this reinforces our commitment to our strategy and positions us well to obtain NDA and ANDA approvals for our pipeline products. At the same time, we believe we are well positioned to manage this transition as we expect to begin to generate revenues from our lead pipeline product in 2011. Following the discontinuance of our marketed unapproved products, the only legacy products we will continue to manufacture and distribute will be our propoxyphene/acetaminophen products, which we market subject to approved NDAs or ANDAs.

Our marketed unapproved products include our ALLERX Dose Pack products and our HYOMAX products and represent approximately $24.1 million of our net revenues for the six months ended June 30, 2010. We do not believe that our decision will materially impact our expected sales of these products in 2010. During the second quarter of 2010, revenues from sales of certain ALLERX products were deferred due to the inability to reasonably estimate returns. If this trend continues during the remainder of 2010, revenue from additional sales of these products would be recorded when the risk of product returns has been substantially eliminated. Accordingly, net revenue would be recognized when the product is sold to the end-user based upon prescriptions filled. Sales of these products would therefore be reflected in our consolidated financial statements after 2010 for the duration of the product shelf life, or until channel inventory has been exhausted, whichever is shorter.

Meanwhile, we are advancing our product pipeline. We continue to expect that our cough product, CRTX 067, will receive marketing approval by the FDA in 2011, and we have advanced our plans to develop CRTX 070, one of our allergy product candidates. Additionally, we anticipate that our relationship with Neos Therapeutics, L.P. and our new product development collaboration with Alitair will result in development of several proprietary, patent protected respiratory products. We also continue to seek out opportunities to acquire respiratory and hospital products to leverage the reach and capability of our sales force.

During the remainder of 2010, we also expect to enter into discussions for the potential divestiture of our HMGB-1 technology which we license from the Feinstein Institute and which is focused on reducing chronic inflammation associated with various medical conditions.

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As a result of winding down our manufacturing and distribution of our marketed unapproved products, enhancing our pipeline and divesting our valuable but non-core technologies, we believe we will be better positioned to develop our strategic specialty products by combining organic growth, strategic acquisitions and product development. As we do so, we will be evaluating our performance with particular reference to the following fiscal and management measures, which we believe will be drivers of our success:

Sales growth of our strategic specialty products through our respiratory and hospital sales forces;

Acquisition of rights to available proprietary respiratory or hospital products with sustainable growth potential;

Progress in the development of our product candidates;

Control of our manufacturing and selling, general and administrative expenses; and

Identification of partners and entry into value-maximizing transactions to divest our non-core technologies.

Results of Operations

Comparison of the Three Months Ended June 30, 2010 and 2009

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

	Three Months Ended June 30,		Change	
	2010	**2009**	**$**	**%**
Net product sales				
CUROSURF	$ 8,619	$	$ 8,619	NM
FACTIVE®	1,206		1,206	NM
SPECTRACEF® product family	307	1,625	(1,318)	(81)%
ZYFLO® product family	8,007	3,490	4,517	129
ALLERX Dose Pack products	5,924	8,551	(2,627)	(31)
HYOMAX product family	1,900	8,841	(6,941)	(79)
Propoxyphene/acetaminophen products	2,497	2,231	266	12
Other products		254	(254)	NM
Total net product sales	28,460	24,992	3,468	14
Royalty agreement revenues	5	1	4	400
Net revenues	28,465	24,993	3,472	14
Cost of product sales (exclusive of amortization of product rights)	8,153	2,901	5,252	181
Selling, general and administrative	12,814	11,656	1,158	10
Royalties	2,648	5,651	(3,003)	(53)
Research and development	1,795	1,188	607	51
Amortization of product rights	3,595	510	3,085	605
(Loss) income from operations	(540)	3,087	(3,627)	(117)
Total other expenses, net	(9)	(42)	33	(79)
(Loss) income before income taxes	(549)	3,045	(3,594)	(118)
Benefit from (provision for) income taxes	149	(1,307)	(1,456)	(111)

Net (loss) income	$ (400)	$ 1,738	$ (2,138)	(123)%
Net (loss) income per share, diluted	$ (0.02)	$ 0.13	$ (0.15)	(115)%
Non-GAAP income from operations (1)	$ 3,430	$ 5,352	$ (1,922)	(36)%
Non-GAAP net income (1)	$ 2,493	$ 3,031	$ (539)	(18)%
Non-GAAP net income per share, diluted (1)	$ 0.10	$ 0.22	$ (0.12)	(55)%

(1) See Reconciliation of Non-GAAP Financial Measures below.

NM Not meaningful.

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Net Revenues

Net Product Sales.

CUROSURF and FACTIVE net product sales were $8.6 million and $1.2 million, respectively, for the three months ended June 30, 2010. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009. We began promoting and selling CUROSURF in September 2009 and began marketing and promoting FACTIVE in October 2009.

SPECTRACEF product family net product sales decreased $1.3 million, or 81%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009, primarily due to lower sales volumes caused by a decline in the branded oral antibiotic market and additional reserves of $1.5 million for potential returns of discontinued product.

ZYFLO CR® and ZYFLO net product sales increased $4.5 million, or 129%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009, primarily due to alignment of our price to market and steady prescription volume.

ALLERX Dose Pack net product sales decreased $2.6 million, or 31%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009, primarily due to the deferral of revenue from sales made during the three months ended June 30, 2010. At June 30, 2010, approximately $10.8 million of revenue was deferred due to the inability to estimate returns for the sales of certain ALLERX Dose Pack products. As a result of recent changes in market dynamics, we are unable to estimate returns due to uncertainty regarding consumer demand, future availability of API and the level of competition. Deferred revenue related to these sales will be recognized as revenue when prescriptions are filled.

HYOMAX net product sales decreased $6.9 million, or 79%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009, primarily due to lower net prices and volume as a result of increased competition from other manufacturers.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $3.6 million and $510,000 for the three months ended June 30, 2010 and 2009, respectively) increased $5.3 million, or 181%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009.

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

	Three Months Ended June 30,		Change	
	2010	**2009**	**$**	**%**
Net product sales	$ 28,460	$ 24,992	$ 3,468	14%
Cost of product sales (exclusive of amortization of product rights)	8,153	2,901	5,252	181
Gross margin	$ 20,307	$ 22,091	$ (1,784)	(8)%
% of net product sales	71%	88%		(17)%

Gross margin as a percentage of net product sales for the three months ended June 30, 2010 decreased 17% compared to the three months ended June 30, 2009 due to a relatively higher portion of our net product sales in the second quarter of 2010 derived from products that have lower gross margins, specifically CUROSURF, partially offset by a decrease in our provision for inventory allowances of $348,000 compared to the second quarter of 2009.

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Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.2 million, or 10%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009. This increase was primarily due to increases in labor and benefits-related costs as a result of the addition of our hospital sales force in September 2009 and its related management team expenses; co-promotion expenses relating to ZYFLO CR and BALACET; travel-related expenses due to the increased number of sales representatives; and consulting expenses relating to increased market research, partially offset by lower legal and consulting expenses in the three months ended June 30, 2010 as compared to the three months ended June 30, 2009 when we incurred significant expenses related to our transaction with Chiesi.

Royalty Expenses. Royalty expenses decreased $3.0 million, or 53%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009. This decrease was primarily due to lower net revenues of the HYOMAX products, partially offset by royalties relating to FACTIVE, which was acquired during the third quarter of 2009, and increased royalties for ZYFLO CR.

Research and Development Expenses. Research and development expenses increased $607,000, or 51%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009. This increase is due to 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 $3.1 million, or 605%, during the three months ended June 30, 2010 compared to the three months ended June 30, 2009. This increase was due to the amortization of CUROSURF and FACTIVE product rights. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009.

Benefit from (Provision for) Income Taxes

The benefit from income taxes was $149,000 for the three months ended June 30, 2010 compared to a provision for income taxes of $1.3 million for the three months ended June 30, 2009. Our effective tax rates for the three months ended June 30, 2010 and 2009 were 27.1% and 42.9%, respectively. The decrease in the effective tax rate was due primarily to the decrease in nondeductible expenses as a relative percentage of income before taxes.

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Comparison of the Six Months Ended June 30, 2010 and 2009

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

	Six Months Ended June 30,		Change	
	2010	2009	$	%
Net product sales				
CUROSURF	$ 15,716	$	$ 15,716	NM
FACTIVE	3,313		3,313	NM
SPECTRACEF product family	2,284	5,342	(3,058)	(57)%
ZYFLO product family	14,281	8,803	5,478	62
ALLERX Dose Pack products	18,293	19,444	(1,151)	(6)
HYOMAX product family	5,799	17,401	(11,602)	(67)
Propoxyphene/acetaminophen products	5,072	3,868	1,204	31
Other products	94	603	(509)	(84)
Total net product sales	64,852	55,461	9,391	17
Royalty agreement revenues	19	237	(218)	(92)
Net revenues	64,871	55,698	9,173	16
Cost of product sales (exclusive of amortization of product rights)	14,972	6,102	8,870	145
Selling, general and administrative	25,239	20,837	4,402	21
Royalties	7,246	11,942	(4,696)	(39)
Research and development	2,701	2,350	351	15
Amortization of product rights	7,190	1,021	6,169	604
Income from operations	7,523	13,446	(5,923)	(44)
Total other expenses, net	(10)	(114)	(104)	(91)
Income before income taxes	7,513	13,332	(5,819)	(44)
Provision for income taxes	(2,900)	(5,279)	(2,379)	(45)
Net income	$ 4,613	$ 8,053	$ (3,440)	(43)%
Net income per share, diluted	$ 0.18	$ 0.60	$ (0.42)	(70)%
Non-GAAP income from operations (1)	$ 15,368	$ 16,787	$ (1,419)	(8)%
Non-GAAP net income (1)	$ 9,430	$ 10,071	$ (641)	(6)%
Non-GAAP net income per share, diluted (1)	$ 0.36	$ 0.75	$ (0.39)	(52)%

(1) See Reconciliation

of Non-GAAP Financial Measures below.

NM Not meaningful.

Net Revenues

Net Product Sales.

CUROSURF and FACTIVE net product sales were $15.7 million and $3.3 million, respectively, for the six months ended June 30, 2010. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009. We began promoting and selling CUROSURF in September 2009 and began marketing and promoting FACTIVE in October 2009.

SPECTRACEF product family net product sales decreased $3.1 million, or 57%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, primarily due to lower sales volumes caused by a decline in the branded oral antibiotic market and additional reserves of $1.5 million for potential returns of discontinued product.

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ZYFLO CR and ZYFLO net product sales increased $5.5 million, or 62%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, primarily due to alignment of our price to market and steady prescription volume.

ALLERX Dose Pack net product sales decreased $1.2 million, or 6%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, primarily due to the deferral of revenue from sales made during the six months ended June 30, 2010. At June 30, 2010, approximately $10.8 million of revenue was deferred due to the inability to estimate returns for the sales of certain ALLERX Dose Pack products. As a result of recent changes in market dynamics, we are unable to estimate returns due to uncertainty regarding consumer demand, future availability of API and the level of competition. Deferred revenue related to these sales will be recognized as revenue when prescriptions are filled.

HYOMAX net product sales decreased $11.6 million, or 67%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, primarily due to lower net prices and volume as a result of increased competition from other manufacturers.

Net product sales from our propoxyphene/acetaminophen products increased $1.2 million, or 31%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, primarily due to an increase in sales volume.

Royalty Agreement Revenues. Royalty agreement revenues decreased $218,000, or 92%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009, due to the expiration of our supply and marketing agreement with Pliva, Inc., or Pliva, for APAP 500 in December 2008, and partially offset by the addition of FACTIVE royalty revenue. Upon expiration of our agreement with Pliva, we stopped supplying Pliva with inventory; however, Pliva continued to sell existing inventory through the six months ended June 30, 2009.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $7.2 million and $1.0 million for the six months ended June 30, 2010 and 2009, respectively) increased $8.9 million, or 145%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009.

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

	Six Months Ended June 30,		Change	
	2010	2009	$	%
Net product sales	$ 64,852	$ 55,461	$ 9,391	17%
Cost of product sales (exclusive of amortization of product rights)	14,972	6,102	8,870	145
Gross margin	$ 49,880	$ 49,359	$ 521	1%
% of net product sales	77%	89%		(12)%

Gross margin as a percentage of net product sales for the six months ended June 30, 2010 decreased 12% compared to the six months ended June 30, 2009 due to a relatively higher portion of our net product sales during the first six months of 2010 derived from products that have lower gross margins, specifically CUROSURF, partially offset by a decrease in our provision for inventory allowances of $934,000 for the six months ended June 30, 2010 compared to the six months ended June 30, 2009. The decrease in the provision for inventory allowances resulted from adjustments made during the first quarter of 2010 for previously reserved excess inventory that was sold during the six months ended June 30, 2010.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $4.4 million, or 21%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009. This increase was primarily due to increases in labor and benefits-related costs as a result of the growth of our sales force and the

addition of our hospital sales force in September 2009 and its related management team expenses; co-promotion expenses relating to ZYFLO CR and BALACET; travel-related expenses due to the increased number of sales representatives; and consulting expenses relating to increased market research, partially offset by lower legal

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and consulting expenses in the six months ended as of June 30, 2010 as compared to the six months ended June 30, 2009 when we incurred significant expenses related to our transaction with Chiesi.

Royalty Expenses. Royalty expenses decreased $4.7 million, or 39%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009. This decrease was primarily due to lower net revenues of the HYOMAX products, partially offset by royalties relating to FACTIVE, which was acquired during the third quarter of 2009, and increased royalties for ZYFLO CR.

Research and Development Expenses. Research and development expenses increased $351,000, or 15%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009. This increase is due to 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 $6.2 million, or 604%, during the six months ended June 30, 2010 compared to the six months ended June 30, 2009. This increase was due to the amortization of CUROSURF and FACTIVE product rights. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009.

Provision for Income Taxes

The provision for income taxes was $2.9 million for the six months ended June 30, 2010 compared to $5.3 million for the six months ended June 30, 2009. Our effective tax rates for the six months ended June 30, 2010 and 2009 were 38.6% and 39.6%, respectively.

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 decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

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

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization of product rights and acquisition-related expenses. Acquisition-related expenses consist of certain expenses that were incurred in connection with the 2009 transaction with Chiesi. 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, and acquisition-related expenses are excluded because they arise from prior acquisitions and management believes they have no direct correlation to current operating results. 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.

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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, amortization of product rights and acquisition-related expenses from the non-GAAP financial measures, stock-based compensation is an integral part of our compensation structure, the acquisition of product rights is an important part of our business strategy and the transaction with Chiesi resulted in significant cash expenses.

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

	For the three months ended June 30,		For the six months ended June 30,	
	2010	2009	2010	2009
GAAP (loss) income from operations	$ (540)	$ 3,087	$ 7,523	$ 13,446
Add: stock-based compensation	375	598	655	852
Add: amortization of product rights	3,595	510	7,190	1,021
Add: acquisition-related expenses[1]		1,157		1,468
Non-GAAP income from operations	$ 3,430	$ 5,352	$ 15,368	$ 16,787
GAAP net (loss) income	$ (400)	$ 1,738	$ 4,613	$ 8,053
Add: stock-based compensation	375	598	655	852
Add: amortization of product rights	3,595	510	7,190	1,021
Add: acquisition-related expenses[1]		1,157		1,468
Less: tax effects related to above items[2]	(1,077)	(972)	(3,028)	(1,323)
Non-GAAP net income	$ 2,493	$ 3,031	$ 9,430	$ 10,071
GAAP net (loss) income per share, diluted	$ (0.02)	$ 0.13	$ 0.18	$ 0.60
Non-GAAP net income per share, diluted	$ 0.10	$ 0.22	$ 0.36	$ 0.75
Shares used in diluted net (loss) income per share calculation:				
GAAP net (loss) income	25,405,165	13,584,314	25,997,175	13,486,956
Non-GAAP net income	26,042,093	13,584,314	25,997,175	13,486,956

[1] Acquisition-related expenses include legal, accounting

and related costs that resulted from or were incurred in connection with the Chiesi transaction.

[2] Tax effects for the three months ended June 30, 2010 and 2009 are calculated using effective tax rates of 27.1% and 42.9% respectively. Tax effects for the six months ended June 30, 2010 and 2009 are calculated using effective tax rates of 38.6% and 39.6% 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, the investment from Chiesi and borrowings under a related party note payable and our previous line of credit, which we terminated in May 2009. As of June 30, 2010, we had $46.4 million in cash and cash equivalents.

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Cash Flows

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

	Six Months Ended June 30,	
	2010	**2009**
Cash provided by (used in):		
Operating activities	$ 26,906	$ 5,742
Investing activities	(278)	164
Financing activities	965	267
Net increase in cash and cash equivalents	$ 27,593	$ 6,173

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 inventories and other costs of product sales, selling, general and administrative expenses and royalties.

Net cash provided by operating activities for the six months ended June 30, 2010 reflected our net income of $4.6 million, adjusted by non-cash expenses totaling $7.3 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $15.0 million. Non-cash items included amortization and depreciation of $7.4 million, change in allowances for prompt payment discounts and inventory of $1.7 million, stock-based compensation of $655,000 and changes in deferred income tax of $2.4 million. Accounts receivable decreased by $323,000 from December 31, 2009 to June 30, 2010, primarily due to timing of net product sales and customer payments. Inventories increased by $1.7 million from December 31, 2009 to June 30, 2010, primarily due to purchases of CUROSURF, ZYFLO CR and ZYFLO finished product and the active pharmaceutical ingredient, or API, for ZYFLO CR and ZYFLO. Prepaid expenses and other assets decreased by $2.1 million, primarily due to amortization of regulatory fees and insurance, usage of prepaid inventory and changes in our voucher programs. Accounts payable decreased by $1.8 million from December 31, 2009 to June 30, 2010, primarily due to timing differences. Accrued expenses increased by $4.3 million from December 31, 2009 to June 30, 2010, primarily due to increased rebates as a result of new laws, specifically the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act of 2010, and wholesale and contract fees resulting from increased competition and product sales, partially offset by a decrease in royalties. Deferred revenue increased $10.8 million from December 31, 2009 to June 30, 2010, due to sales that were deferred due to the inability to estimate product returns. Income taxes payable increased by $954,000 from December 31, 2009 to June 30, 2010.

Net cash provided by operating activities for the six months ended June 30, 2009 reflected our net income of $8.0 million, adjusted by non-cash expenses totaling $2.7 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $5.0 million.

Net Cash (Used in) Provided By Investing Activities

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

Net cash provided by investing activities for the six months ended June 30, 2009 reflected the net proceeds from the sale of marketable securities of $300,000, partially offset by the purchase of property and equipment for $136,000.

Net Cash Provided by Financing Activities

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

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Net cash provided by financing activities for the six months ended June 30, 2009 reflected proceeds from common stock option exercises of $271,000, partially offset by principal payments on capital leases of $4,000.

Funding Requirements

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

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

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Our only committed external source of funds is borrowing availability under the line of credit we entered into in January 2010. We may borrow up to $5.0 million under our line of credit subject to certain conditions. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of June 30, 2010, we had approximately $46.4 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. There have been no material changes outside the ordinary course of business to our contractual obligations during the six months ended June 30, 2010. The following table summarizes our contractual obligations as of June 30, 2010 (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 56	$ 8	$ 31	$ 17	$
Operating leases(1)	3,261	298	1,087	1,125	751
Purchase obligations(2)	43,335	21,542	17,255	4,538	
Royalty obligations(3)	7,200	200	1,150	1,050	4,800
Other long-term liabilities(4)	2,750	1,250	1,500		
Total contractual obligations	$ 56,602	$ 23,298	$ 21,023	$ 6,730	$ 5,551

(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 $400,000 in 2010, $482,000 in 2011, $492,000 in 2012, $536,000 in 2013 and $1.3 million thereafter.

(2) Purchase obligations include fixed or minimum payments under

manufacturing and supply agreements with third-party manufacturers of $32.4 million; clinical trial and research agreements with contract research organizations and consultants of $354,000; agreements with providers of marketing analytical services of $2.8 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $7.8 million.

(3) Royalty obligations include minimum royalty payments due in connection with our agreements with Pharmaceutical Innovations and The Feinstein Institute.

(4) Other long-term liabilities include principal and interest due under our

license agreement liability with Meiji Seika Kaisha, Ltd.					

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 $58.7 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.

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, 2009 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.

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Recent Accounting Pronouncements

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

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

Interest Rate Risk

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

Our risk associated with fluctuating interest expense is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. The interest rates on our existing long-term debt borrowings are fixed and as a result, interest due on borrowings are not impacted by changes in market-based interest rates. If amounts are drawn down on our line of credit during 2010, we will be exposed to interest rate risk. The line of credit bears a variable interest rate equal to the prime rate published by the Wall Street Journal with a floor of 5%. Given the amount of borrowing availability we have under the line of credit, we do not believe that interest rate changes would have a material impact on us.

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 changes in these exchange rates related to these contracts was immaterial to our consolidated financial statements for the three and six months ended June 30, 2010 and 2009. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of June 30, 2010, our management 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 (the Exchange Act). Based upon that evaluation, our Chief Executive Officer, also acting as our interim Chief Financial Officer, concluded that, as of June 30, 2010, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer, also acting as our interim Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Not applicable.

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PART II OTHER INFORMATION

ITEM 1. *LEGAL PROCEEDINGS*

Prior to March 2008, we used a different formulation for ALLERX 10 Dose Pack and ALLERX 30 Dose Pack that we believe was protected under claims in U.S. patent number 6,270,796, or the 796 Patent. In 2007, the U.S. Patent and Trademark Office, or the USPTO, ordered a re-examination of the 796 Patent as a result of a third-party request for ex parte re-examination.

In proceedings before a re-examination examiner in the USPTO, the examiner rejected claims of the 796 Patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims. The 796 Patent owner, J-Med Pharmaceuticals, Inc., or J-Med, appealed to the USPTO Board of Patent Appeals and Interferences, or Board of Patent Appeals, on June 13, 2008, seeking reversal of the examiner s rejections. On the same date, J-Med filed additional documents with the USPTO for review by the examiner. The examiner responded with an advisory action, withdrawing several of the rejections, but maintaining other rejections. An appeal brief was filed on August 18, 2008, a supplemental appeal brief was filed on May 7, 2009 and a reply brief was filed on January 25, 2010. The examiner did not reverse her prior rejections and, on April 13, 2010, the re-examination was docketed to the Board of Patent Appeals. The appeal will be heard by the Board of Patent Appeals on August 4, 2010. After reviewing the statements of appeal, the Board of Patent Appeals can take various actions, including affirming or reversing the examiner s rejections in whole or part, or introducing new grounds of rejection of the 796 Patent claims. If the Board of Patent Appeals thereafter affirms the examiner s rejections, J-Med can take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 796 Patent with narrowed claims. The further proceedings involving the 796 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 796 Patent.

On June 13, 2008, counsel for Vision Pharma, LLC, or Vision, filed in the USPTO a request for re-examination of certain claims under U.S. patent number 6,843,372, or the 372 Patent, which we believe covers our current formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, as well as ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Our counsel reviewed the request for re-examination and the patents and publications cited by counsel for Vision, and our counsel have concluded that valid arguments exist for distinguishing the claims of the 372 Patent over the references cited in the request for re-examination. On June 18, 2009, the USPTO examiner issued an office action, rejecting claims of the 372 Patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims, in view of the patents and publications cited by Vision. On August 18, 2009, the patent owner, Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations, filed an amendment to the claims and a request for reconsideration of the office action issued on June 18, 2009. If the USPTO re-examination examiner maintains one or more of the USPTO rejections of the claims of the 372 Patent, Pharmaceutical Innovations may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If the Board of Patent Appeals thereafter affirms the examiner s rejections, Pharmaceutical Innovations could take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 372 Patent with narrowed claims. The further proceedings involving the 372 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 372 Patent.

On May 15, 2008, the TTAB issued written notice to us indicating that Bausch & Lomb, Incorporated, or Bausch & Lomb, had initiated a cancellation proceeding (Cancellation No. 92049358) against U.S. Reg. No. 3,384,232. The petition for cancellation filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark, that the ALLERX mark so resembles Bausch & Lomb s Alrex® trademark as to cause confusion as to the source of goods sold under ALLERX mark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We timely filed an answer to Bausch & Lomb s petition for cancellation, disputing claims made in such petition and raising various defenses. Discovery requests were issued to Bausch & Lomb in January 2009, but cancellation proceedings were suspended by the TTAB on February 10, 2009 for six months and on July 29, 2009 for an additional three months upon indication that the parties were engaged in settlement negotiations. Motions for Suspension on Consent were filed by the parties on November 6, 2009 requesting 90 day suspension and

on February 2, 2010 for an additional 90 days suspension. These motions were granted. The current suspension of cancellation proceedings expires on August 7, 2010. We are currently engaged in

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settlement discussions with Bausch & Lomb to resolve the dispute on favorable terms. If settlement is not reached, then proceedings will resume, and a final decision by the TTAB could take several years.

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, 2009, which was filed with the SEC on March 4, 2010.

There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K, except as follows:

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act, or Affordable Care Act. On March 30, 2010, the President signed H.R. 4872, the Healthcare and Education Reconciliation Act of 2010, or Reconciliation Act, which included a package of fixes to the Affordable Care Act as well as additional elements to reform healthcare in the United States. We refer to the Affordable Care Act and the Reconciliation Act as Health Care Reform.

The passage of Health Care Reform is expected to result in a transformation of the delivery and payment for healthcare services in the U.S. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that will improve patients ability to obtain and maintain health insurance. Such measures include the elimination of lifetime caps, no rescission of policies, and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to our products.

However, a number of provisions contained in Health Care Reform may adversely affect reimbursement for our products. In 2010, the new law will increase the minimum basic Medicaid rebate for brand name prescription drugs from 15.1% to 23.1%, increase the minimum basic Medicaid rebate for generic drugs from 11% to 13%, require pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees, potentially increase the additional Medicaid rebate calculation for line extensions of oral solid dosage forms of innovator products and expand the entities eligible for 340B pricing and the revision of the average manufacturer price definition to remove certain classes of trade.

Health Care Reform also requires drug manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap, also known as the donut hole. The legislation also provides a $250 payment to Part D beneficiaries who reach the coverage gap during 2010, and mandates the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020. Moreover, Health Care Reform reduces Part D premium subsidies for higher-income beneficiaries, expands medication therapy management requirements, and makes a number of other revisions to Part D program requirements. The elimination of the coverage gap may result in greater access to our products for Part D beneficiaries.

The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2011). Substantial new provisions affecting compliance also have been added, which may require us to modify the manner in which we advertise, promote and the distribute product samples to health care practitioners.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including regulations that will be issued to implement provisions of Health Care Reform. Health Care Reform and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

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Some of our specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs.

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has practiced enforcement discretion against some marketed, unapproved new drugs 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, or cGMPs requirements. Also, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and the FDA could at any time ask or require that the products be removed from the market immediately.

In November 2009, we reported that as a result of an inspection of one of our contract manufacturers facilities we had received a warning letter from the FDA alleging that Deconsal CT (phenylephrine hydrochloride, pyrilamine maleate) chewable tablets and Deconsal DM (phenylephrine hydrochloride, pyrilamine maleate, dextromethorphan hydrobromide) chewable tablets were new drugs lacking an approved application and as such should not be introduced into interstate commerce. We responded to the warning letter by advising the FDA that although we did not admit its allegations, we had not sold any Deconsal CT products since July 2009 and had not sold any Deconsal DM products since January 2009, and do not intend to manufacture, or have manufactured, any further lots of these products.

In accordance with our overall business strategy, we have recently informed the FDA that we have decided to discontinue manufacturing and distribution of all of our marketed unapproved products, including our ALLERX Dose Pack products and our HYOMAX line of products, as of December 31, 2010. Our decision does not limit the FDA s enforcement authority and there is no certainty that the FDA will not seek to require the withdrawal of these products before December 31, 2010.

In the first half of 2009 and 2010, our ALLERX Dose Pack products and our HYOMAX line of products generated $36.8 million and $24.1 million of net revenue, respectively. Once we have discontinued these products, there is no guarantee that we will be able to replace these revenues with revenues from our strategic specialty products. If we are not able to replace these product revenues, this discontinuance could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

If we fail to comply with regulatory requirements for our products or if we experience unanticipated problems with them, the FDA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our products, our contract manufacturers and other partners are subject to comprehensive regulation by the FDA. These requirements include submissions of safety and other post-marketing information; record-keeping and reporting; annual registration of manufacturing facilities and listing of products with the FDA; ongoing compliance with cGMP regulations; and requirements regarding advertising, promotion and the distribution of samples to physicians and related recordkeeping. For example, we received a warning letter from the FDA s Division of Drug Marketing, Advertising and Communications on June 22, 2010 relating to certain promotional and labeling material for our ZYFLO CR extended release tablets. The FDA asserted that our ZYFLO CR webpage was false and misleading because it presented efficacy claims for ZYFLO CR, but failed to contain certain risk information associated with the product, and that certain promotional material was false or misleading because it omitted important information about the risks associated with the use of ZYFLO CR, made unsubstantiated superiority claims and omitted material facts. Additionally, the FDA stated that the web page and promotional material were disseminated with an outdated version of the FDA-approved product labeling for ZYFLO CR. Although we did not admit and in fact denied some of FDA s allegations, as part of our response and in connection with the close out of this matter, we ceased dissemination of the relevant promotion materials, disabled and revised the web page, retrieved and destroyed the relevant promotional materials and updated our procedures regarding promotional material and labeling.

We will also disseminate updated messaging to the recipients of the aforementioned

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promotional materials. If our promotional activities fail to comply with the FDA s regulations and guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions and other penalties, and, if so, our business and reputation could be harmed.

Under the Food and Drug Administration Amendments Act of 2007, or FDAAA, the FDA is also authorized, among other things, to require the submission of REMS with NDAs, or post-approval upon the discovery of new safety information, to monitor and address potential product safety issues. The FDAAA also grants the FDA the authority to mandate labeling changes in certain circumstances and establishes requirements for registering and disclosing the results of clinical trials. For example, as part of the REMS for FACTIVE, the FDA required the packaging to be revised to include a boxed warning and a medication guide. The FDA also requires us to periodically submit a REMS assessment for FACTIVE to evaluate whether the REMS are sufficient to inform patients of the serious risks associated with their use. Completion of the REMS assessment could be costly and time consuming.

The manufacturers and the manufacturing facilities used to make our products and product candidates are also subject to comprehensive regulatory requirements. While we generally negotiate for the right under our long-term manufacturing contracts to periodically audit our third-party manufacturers performance, we do not have control over our third-party manufacturers compliance with applicable regulations. We cannot assure you that our current quality assurance program is reasonably designed to, or would, discover all instances of non-compliance by our third-party manufacturers with these regulations. For instance, the FDA inspected one of our contract manufacturer s facilities in 2009 and as a result of alleged failure of the manufacturer to comply with cGMPs, the FDA issued a warning letter to the manufacturer. Companies, including us, whose products were cited in the manufacturer s warning letter were issued warning letters for separate allegations.

The FDA periodically inspects sponsors, marketers and manufacturers for compliance with these requirements. On March 24, 2010, the FDA issued us a Notice of Inspectional Observations, or Form 483, in connection with a March 2010 inspection of our cGMPs. The Form 483 stated that our processes related review of batch specific documentation, analytical information, deviations and investigations prior to releasing finished product for distribution; our validation assessment procedure; and our documentation related to product complaints, the resultant investigations and close out are areas of possible non-compliance with FDA regulations. We responded to the FDA on May 5, 2010 and have taken actions to address each of the observations identified by the FDA in the Form 483 as quickly as practicable.

If the FDA makes additional inspectional observations in other inspections or if the FDA is not satisfied with the corrective actions we take in response to the Form 483, we could be subject to further FDA action, including sanctions. We may also be subject to sanctions as a result of discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with applicable regulatory requirements. Possible sanctions include the following:

withdrawal of the products from the market;

restrictions on the marketing or distribution of such products;

restrictions on the manufacturers or manufacturing processes;

warning letters;

refusal to approve pending applications or supplements to approved applications that we submit;

recalls;

fines;

suspension or withdrawal of regulatory approvals;

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refusal to permit the import or export of our products;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

Any of these actions could have a material adverse effect on our business, financial condition and results of operations.

Our patents may be challenged by ANDA applicants.

If a drug is claimed to be covered by an unexpired patent that the NDA holder has listed with the FDA, an ANDA applicant must certify in a so-called paragraph IV certification that the patent is invalid, unenforceable or not infringed by the product that is the subject of the ANDA. If the holder of the NDA sues the ANDA applicant within 45 days of being notified of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of a court decision favorable to the ANDA applicant or the expiration of 30 months.

For example, on May 30, 2008, Orchid Healthcare, a Division of Orchid Chemicals & Pharmaceuticals Ltd., or Orchid, filed an ANDA seeking approval for a generic version of FACTIVE. In the application, Orchid certified that certain of the FDA-listed patents covering FACTIVE are invalid and/or will not be infringed by Orchid s manufacture, importation, use or sale of the product for which Orchid submitted its ANDA. The certification did not include a certification with respect to U.S. Patent No. 5,633,262, which is listed in the Orange Book as covering FACTIVE and expires in June 2015. We are evaluating whether to commence litigation in response to Orchid s Paragraph IV certification.

While Orchid received tentative approval by the FDA for their ANDA on July 2, 2010, they will not be permitted to launch the generic version until expiry of U.S. Patent No. 5,633,262 in June 2015.

As our competitors introduce their own pharmaceutical and/or therapeutic equivalents of our products, our net revenues from such products are expected to decline.

Product sales of pharmaceutical and/or therapeutic equivalents often follow a particular pattern over time based on regulatory and competitive factors. The first company to introduce an equivalent of a branded product is often able to capture a substantial share of the market. However, as other companies introduce competing equivalent products, the first entrant s market share, and the price of its equivalent product, will typically decline. The extent of the decline generally depends on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. It is possible that competitors to our ANDA, or generic, products have already begun the process of developing and obtaining FDA approval for competitive products. Our inability to introduce generic equivalents to our branded products or our withdrawal of existing products from the market due to increased competition would have a material adverse effect on our financial condition and results of operations.

For example, in the generic drug industry, when a company is the first to introduce a generic drug, the pricing of the generic drug is typically set based on a discount from the published price of the equivalent branded product. Other generic manufacturers or a manufacturer contracted to market an authorized generic to the brand may enter the market and, as a result, the price of the drug may decline significantly. In such event, we may in our discretion provide our customers a credit with respect to the customers remaining inventory for the difference between our new price and the price at which we originally sold the product to our customers. There are circumstances under which we may, as a matter of business strategy, not provide price adjustments to certain customers and, consequently, we may lose future sales to competitors.

ITEM 6. ***EXHIBITS***

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

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SIGNATURES

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

CORNERSTONE THERAPEUTICS INC.

Date: August 5, 2010

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

Date: August 5, 2010

/s/ Ira Duarte
Ira Duarte
Director of Accounting
(Principal Accounting Officer)

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EXHIBIT INDEX

Exhibit No.	Description
10.1	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted on or after May 20, 2010).
10.2	Termination Agreement between MedImmune LLC, and Cornerstone Therapeutics Inc. effective June 1, 2010.
10.3+	Addendum, dated May 31, 2010, to Amended and Restated Products Development Agreement between Neos Therapeutics, L.P. and Cornerstone Therapeutics Inc. dated August 27, 2008.
10.4	Cornerstone Therapeutics Inc. 2004 Stock Incentive Plan, as Amended and Restated May 20, 2010 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 20, 2010).
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.

+ Portions of the exhibit have been omitted pursuant to a request for confidential treatment, which portions have been separately filed with the Securities and Exchange Commission.