CORNERSTONE THERAPEUTICS INC
Form 10-Q
May 04, 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 March 31, 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 April 30, 2010, the registrant had 25,602,028 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; 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; 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)

	March 31, 2010 (Unaudited)	December 31, 2009 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 27,536	$ 18,853
Accounts receivable, net	19,854	16,548
Inventories, net	21,366	18,106
Prepaid and other current assets	3,021	4,808
Deferred income tax asset	3,938	3,507
Total current assets	75,715	61,822
Property and equipment, net	1,365	1,312
Product rights, net	123,211	126,806
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Other assets	154	113
Total assets	$ 213,714	$ 203,322
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 8,132	$ 7,172
Accrued expenses	25,884	23,703
Current portion of license agreement liability	1,089	1,019
Current portion of capital lease	10	10
Income taxes payable	2,900	1,606
Total current liabilities	38,015	33,510
License agreement liability, less current portion	1,341	1,341
Capital lease, less current portion	36	39
Deferred income tax liability	4,257	4,564
Total liabilities	43,649	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		
Common stock $0.001 par value, 90,000,000 shares authorized; 25,389,528 and 25,022,644 shares issued and outstanding as of March 31, 2010 and	25	25

December 31, 2009, respectively		
Additional paid-in capital	158,929	157,745
Retained earnings	11,111	6,098
Total stockholders equity	170,065	163,868
Total liabilities and stockholders equity	$ 213,714	$ 203,322

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

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

	Three Months Ended March 31,	
	2010	**2009**
Net revenues	$ 36,406	$ 30,705
Costs and expenses:		
Cost of product sales (exclusive of amortization of product rights)	6,819	3,201
Selling, general and administrative	12,425	9,181
Royalties	4,598	6,291
Research and development	906	1,162
Amortization of product rights	3,595	511
Total costs and expenses	28,343	20,346
Income from operations	8,063	10,359
Other expenses:		
Interest expense, net	(1)	(72)
Total other expenses	(1)	(72)
Income before income taxes	8,062	10,287
Provision for income taxes	(3,049)	(3,972)
Net income	$ 5,013	$ 6,315
Net income per share, basic	$ 0.20	$ 0.53
Net income per share, diluted	$ 0.19	$ 0.48
Weighted-average common shares, basic	25,349,677	12,023,747
Weighted-average common shares, diluted	25,951,952	13,114,505

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)

	Three Months Ended March 31,	
	2010	**2009**
Cash flows from operating activities		
Net income	$ 5,013	$ 6,315
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	3,678	564
Provision for prompt payment discounts	1,144	63
(Recovery of) provision for inventory obsolescence	(457)	77
Stock-based compensation	280	254
Benefit from deferred income taxes	(738)	(284)
Changes in operating assets and liabilities:		
Accounts receivable	(4,450)	(3,384)
Inventories	(2,803)	(1,695)
Prepaid expenses and other assets	1,746	(904)
Accounts payable	960	(1,565)
Accrued expenses	2,251	1,147
Income taxes payable	1,294	643
Net cash provided by operating activities	7,918	1,231
Cash flows from investing activities		
Proceeds from sale of marketable securities		300
Purchase of property and equipment	(136)	(79)
Net cash (used in) provided by investing activities	(136)	221
Cash flows from financing activities		
Proceeds from exercise of common stock options	483	
Excess tax benefit from stock-based compensation	421	
Principal payments on capital lease obligation	(3)	(2)
Net cash provided by (used in) financing activities	901	(2)
Net increase in cash and cash equivalents	8,683	1,450
Cash and cash equivalents as of beginning of period	18,853	9,286
Cash and cash equivalents as of end of period	$ 27,536	$ 10,736

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 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 month period ended March 31, 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 income, are included in selling, general and administrative expenses in the accompanying consolidated statements of income. 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 three months ended March 31, 2010, one supplier individually accounted for 69% of the Company s total inventory purchases during this period. Amounts due to this supplier represented approximately 16% of total accounts payable as of March 31, 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 table lists the Company s customers that individually comprise greater than 10% of total gross product sales for the three months ended March 31, 2010 and 2009 or 10% of total accounts receivable as of March 31, 2010 and December 31, 2009:

	Three Months Ended March 31,	
	2010 Gross Product Sales	2009 Gross Product Sales
Cardinal Health, Inc.	45%	36%
McKesson Corporation	30	34
AmerisourceBergen Drug Corporation	18	16
Total	93%	86%

	March 31, 2010 Accounts Receivable	December 31, 2009 Accounts Receivable
Cardinal Health, Inc.	45%	26%
McKesson Corporation	34	37
AmerisourceBergen Drug Corporation	14	24
Total	93%	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 31 or 61 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 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

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establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of March 31, 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 months ended March 31, 2010 or 2009.

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

	March 31, 2010	December 31, 2009
Trade accounts receivable	$ 20,346	$ 16,932
Less allowance for prompt payment discounts	(492)	(384)
Accounts receivable, net	$ 19,854	$ 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 writes down 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 March 31, 2010 and December 31, 2009 (in thousands):

	March 31, 2010	December 31, 2009
Raw materials	$ 6,688	$ 5,597
Work in process	760	2,007
Finished goods:		
Pharmaceutical products trade	11,846	9,962
Pharmaceutical products samples	2,719	2,342
Total	22,013	19,908
Inventory allowances	(647)	(1,802)
Inventories, net	$ 21,366	$ 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 March 31,	
	2010	2009
Gross product sales	$ 54,968	$ 38,912

Sales allowances	(18,576)	(8,443)
Net product sales	36,392	30,469
Royalty agreement revenues	14	236
Net revenues	$ 36,406	$ 30,705

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

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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 or when future product returns can be reasonably estimated.

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 commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial 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 three 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).

NOTE 3: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance as of March 31, 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 March 31, 2010 will be deductible for income tax purposes.

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Product Rights

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

	March 31, 2010	December 31, 2009
Product rights	$ 141,949	$ 141,949
Less accumulated amortization	(18,738)	(15,143)
Product rights, net	$ 123,211	$ 126,806

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of March 31, 2010, ranged from approximately five to ten years. As of March 31, 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 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):

	March 31, 2010	December 31, 2009
Accrued product returns	$ 10,626	$ 10,962
Accrued rebates	1,846	1,013
Accrued price adjustments and chargebacks	6,386	3,503
Accrued compensation and benefits	1,935	2,486
Accrued royalties	4,712	5,547
Accrued expenses, other	379	192
Total accrued expenses	$ 25,884	$ 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 525,200 and 366,884 stock options granted and exercised, respectively, during the three months ended March 31, 2010.

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

	Three Months Ended March 31, 2010
Estimated dividend yield	0.0%
Expected stock price volatility	80%

Risk-free interest rate	2.27-2.60%
Expected life of option (in years)	5.00
Weighted-average fair value per share	$ 3.49

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

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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 March 31, 2010, the aggregate intrinsic value of options outstanding and exercisable was $5.8 million and $5.0 million, respectively.

As of March 31, 2010, there was $3.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 3.29 years.

Restricted Stock

During the three months ended March 31, 2010, no shares of restricted stock were issued or vested. As of March 31, 2010, there were 212,500 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 3.37 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 March 31,	
	2010	**2009**
Employee	$ 255	$ 252
Non-employee	25	2
Total	$ 280	$ 254

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 $336,000 and $208,000 for the three months ended March 31, 2010 and 2009, respectively.

Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $27.7 million as of March 31, 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 March 31, 2010, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $9.7 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 March 31, 2010 and 2009, total royalty expenses were $4.6 million and $6.3 million, respectively. Certain of these royalty agreements also require minimum annual payments, which have

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been included in royalty expense on the consolidated statements of income. Pursuant to these agreements, the Company is obligated to pay future minimum royalties of $7.5 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 $42.2 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 March 31, 2010, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $467,000.

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 March 31, 2010, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $3.0 million.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement.

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. In cooperation with the licensor of the patent, the Company intends to vigorously pursue its claims and to vigorously defend against any counterclaims that might be asserted.

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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 month periods ended March 31, 2010 and 2009 was 37.8% and 38.6%, respectively.

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 March 31, 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 months ended March 31, 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 income. For the three months ended March 31, 2010, the Company recognized no interest or penalties related to uncertain tax positions in the statements of income.

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 March 31, 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 $7.2 million for the three months ended March 31, 2010. As of March 31, 2010, the Company had prepaid inventory of $268,000 due from Chiesi and accounts payable of $1.3 million due to Chiesi.

NOTE 9: NET INCOME PER SHARE

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

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

	Three Months Ended March 31,	
	2010	2009
Numerator:		
Net income	$ 5,013	$ 6,315
Denominator:		
Weighted-average common shares, basic	25,349,677	12,023,747
Dilutive effect of stock options, warrants and restricted stock	602,274	1,090,758
Weighted-average common shares, diluted	25,951,952	13,114,505
Net income per share, basic	$ 0.20	$ 0.53
Net income per share, diluted	$ 0.19	$ 0.48
Anti-dilutive weighted-average shares	1,393,338	390,024

NOTE 10: SUBSEQUENT EVENTS

The Company has evaluated all events or transactions that occurred after March 31, 2010. The Company did not have any material recognizable or nonrecognizable subsequent events.

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. 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, unbranded and authorized generic versions of products that have or had limited intellectual property protection, which we refer to as our legacy products. We consider these products to be non-strategic because we expect the sales of these products to show a downward trend over the long term. We are therefore refocusing our efforts on growing our revenues from strategic specialty products. We believe that if we can successfully implement our refocused strategy we will be able to offset declines in other product sales and deliver more consistent long-term earnings growth for our stockholders. Our performance for the three months ended March 31, 2010 reflects our new focus as the proportion of our sales generated by strategic specialty products increased over the same period in the prior year.

At the same time, we continued to generate revenues during the three months ended March 31, 2010 from sales of legacy products that exceeded our expectations. These products include our ALLERX(R) Dose Pack products, our HYOMAX(R) products and our propoxyphene/acetaminophen products. These additional sales generated significant cash, which we intend to use to fund future growth in our areas of strategic focus.

First Quarter 2010 Highlights

The following is a summary of key financial results and certain non-financial results achieved for the three months ended March 31, 2010:

Our net revenues for the quarter increased 19% to $36.4 million over the three months ended March 31, 2009, of which the percentage of revenue derived from strategic specialty products increased from 29% to 48%;

Our legacy products made a significant contribution of approximately $18.8 million of net revenue;

Our selling, general and administrative costs declined to 34% of net revenue for the three months ended March 31, 2010 compared to the 36% for the three months ended December 31, 2009; and

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Our cash and cash equivalents increased $8.7 million or 46% to $27.5 million at March 31, 2010 compared to $18.9 million at December 31, 2009.

Sales of some of our products fluctuate with the seasonality of the cough/cold season, and our strong financial performance during the first quarter of 2010 was consistent with our historical performance in the first quarter of prior annual periods. We do not believe that our product sales for the three months ended March 31, 2010 are indicative of the results we expect for the remaining nine 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 implement our strategy of 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;

Cash generation from continued sales of our legacy products;

Acquisition of rights to available and profitable new respiratory and related products with intellectual property protection;

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 March 31, 2010 and 2009

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

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	Three Months Ended March 31,		Change	
	2010	2009	$	%
Net product sales				
CUROSURF	$ 7,097	$	$ 7,097	NM
FACTIVE®	2,107		2,107	NM
SPECTRACEF® product family	1,977	3,717	(1,740)	(47)%
ZYFLO® product family	6,274	5,313	961	18
ALLERX Dose Pack products	12,369	10,893	1,476	14
HYOMAX product family	3,899	8,560	(4,661)	(54)
Propoxyphene/acetaminophen products	2,575	1,637	938	57
Other products	94	349	(255)	(73)
Total net product sales	36,392	30,469	5,923	19
Royalty agreement revenues	14	236	(222)	(94)
Net revenues	36,406	30,705	5,701	19
Cost of product sales (exclusive of amortization of product rights)	6,819	3,201	3,618	113
Selling, general and administrative	12,425	9,181	3,244	35
Royalties	4,598	6,291	(1,693)	(27)
Research and development	906	1,162	(256)	(22)
Amortization of product rights	3,595	511	3,084	604
Income from operations	8,063	10,359	(2,296)	(22)
Total other expenses, net	(1)	(72)	(71)	(99)
Income before income taxes	8,062	10,287	(2,225)	(22)
Provision for income taxes	(3,049)	(3,972)	(923)	(23)
Net income	$ 5,013	$ 6,315	$ (1,302)	(21)%
Net income per share, diluted	$ 0.19	$ 0.48	$ (0.29)	(60)%
Non-GAAP income from operations (1)	$ 11,938	$ 11,435	$ 503	4%
Non-GAAP net income (1)	$ 7,423	$ 6,976	$ 447	6%
Non-GAAP net income per share, diluted (1)	$ 0.29	$ 0.53	$ (0.24)	(45)%

(1) See Reconciliation of Non-GAAP Financial Measures

below.

NM Not meaningful.

Net Revenues

Net Product Sales.

CUROSURF and FACTIVE net product sales were $7.1 million and $2.1 million, respectively, for the three months ended March 31, 2010. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009.

SPECTRACEF product family net product sales decreased $1.7 million, or 47%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009, primarily due to lower sales volumes caused by a decline in the branded oral antibiotic market.

ZYFLO CR® and ZYFLO net product sales increased $961,000, or 18%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009, primarily due to alignment of our price to market and steady prescription volume.

ALLERX Dose Pack net product sales increased $1.5 million, or 14%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009, primarily due to increased volume as a result of improved availability of one of the active pharmaceutical ingredients used to manufacture new product.

HYOMAX net product sales decreased $4.7 million, or 54%, during the three months ended March 31, 2010 compared to the three months ended March 31, 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 $938,000, or 57%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009, primarily due to an increase in sales of APAP 325, our generic formulation of BALACET® 325, and APAP 500. Net product sales for APAP 325 were $1.2 million and $708,000 for the three months ended March 31, 2010 and 2009, respectively. BALACET 325 net revenues declined in the three months ended March 31, 2010 compared to the three months ended March 31, 2009 due to the market share erosion by APAP 325. We expect that APAP 325 will continue to challenge BALACET 325 for market share.

Royalty Agreement Revenues. Royalty agreement revenues decreased $222,000, or 94%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009, due the expiration of our supply and marketing agreement with Pliva, Inc., or Pliva, for APAP 500 in December 2008, 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 three months ended March 31, 2009.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $3.6 million and $511,000 for the three months ended March 31, 2010 and 2009, respectively) increased $3.6 million, or 113%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009.

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

	Three Months Ended March 31,		Change	
	2010	2009	$	%
Net product sales	$ 36,392	$ 30,469	$ 5,923	19%
Cost of product sales (exclusive of amortization of product rights)	6,819	3,201	3,618	113
Gross margin	$ 29,573	$ 27,268	$ 2,305	8%
% of net product sales	81%	89%		(8)%

Gross margin for the three months ended March 31, 2010 decreased eight percentage points compared to the three months ended March 31, 2009 due to a relatively higher portion of our net product sales in the first quarter of 2010 derived from products that have lower gross margins, specifically CUROSURF, partially offset by a reduction in our provision for inventory obsolescence by $457,000 for the three months ended March 31, 2010 to adjust net inventory for previously reserved inventory that we now expect will be sold. For the three months ended March 31, 2009, we increased our provision by $130,000 to reserve for excess or obsolete inventory that, due to its expiration dating, we did not expect would be sold.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $3.2 million, or 35%, during the three months ended March 31, 2010 compared to the three months ended March 31, 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; marketing and promotional spending relating to the launch of FACTIVE and CUROSURF; co-promotion expenses relating to ZYFLO CR; travel-related expenses due to the increased number of sales representatives; and consulting expenses relating to increased market research, partially offset by lower legal expenses.

Royalty Expenses. Royalty expenses decreased $1.7 million, or 27%, during the three months ended March 31, 2010 compared to the three months ended March 31, 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 decreased $256,000, or 22%, during the three months ended March 31, 2010 compared to the three months ended March 31, 2009. This decrease 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 604%, during the three months ended March 31, 2010 compared to the three months ended March 31, 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 $3.0 million for the three months ended March 31, 2010 compared to $4.0 million for the three months ended March 31, 2009. Our effective tax rates for the three months ended March 31, 2010 and 2009 were 37.8% and 38.6%, 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.

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

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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.

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):

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	For the three months ended March 31,	
	2010	2009
GAAP income from operations	$ 8,063	$ 10,359
Add: stock-based compensation	280	254
Add: amortization of product rights	3,595	511
Add: acquisition-related expenses[1]		311
Non-GAAP income from operations	$ 11,938	$ 11,435
GAAP net income	$ 5,013	$ 6,315
Add: stock-based compensation	280	254
Add: amortization of product rights	3,595	511
Add: acquisition-related expenses[1]		311
Less: tax effects related to above items[2]	(1,465)	(415)
Non-GAAP net income	$ 7,423	$ 6,976
GAAP net income per share, diluted	$ 0.19	$ 0.48
Non-GAAP net income per share, diluted	$ 0.29	$ 0.53
Shares used in diluted net income per share calculation:		
GAAP net income	25,951,952	13,114,505
Non-GAAP net income	25,951,952	13,114,505

[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 March 31, 2010 and 2009 are calculated using effective tax rates of 37.8% and 38.6% 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 March 31, 2010, we had $27.5 million in cash and cash equivalents.

Cash Flows

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

	Three Months Ended March 31,	
	2010	**2009**
Cash provided by (used in):		
Operating activities	$ 7,918	$ 1,231
Investing activities	(136)	221
Financing activities	901	(2)
Net increase in cash and cash equivalents	$ 8,683	$ 1,450

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 three months ended March 31, 2010 reflected our net income of $5.0 million, adjusted by non-cash expenses totaling $3.9 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $1.0 million. Non-cash items included amortization and depreciation of $3.7 million, change in allowances for prompt payment discounts and inventory obsolescence of $687,000, stock-based compensation of $280,000 and changes in deferred income tax of $738,000. Accounts receivable increased by $4.5 million from December 31, 2009 to March 31, 2010, primarily due to increased net product sales. Inventories increased by $2.8 million from December 31, 2009 to March 31, 2010, primarily due to purchases of CUROSURF finished product and the active pharmaceutical ingredient, or API, for ZYFLO CR and ZYFLO. Prepaid expenses and other assets decreased by $1.7 million, primarily due to amortization of regulatory fees, usage of prepaid inventory and changes in our voucher programs. Accounts payable increased by $1.0 million from December 31, 2009 to March 31, 2010, primarily due to timing differences. Accrued expenses increased by $2.3 million from December 31, 2009 to March 31, 2010, primarily due to increased rebates as a result of new regulations and chargebacks resulting from increased competition and product sales, partially offset by a decrease in royalties and bonuses. Income taxes payable increased by $1.3 million from December 31, 2009 to March 31, 2010.

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Net cash provided by operating activities for the three months ended March 31, 2009 reflected our net income of $6.3 million, adjusted by non-cash expenses totaling $674,000 and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $5.8 million.

Net Cash (Used in) Provided By Investing Activities

Net cash used in investing activities for the three months ended March 31, 2010 reflected the purchase of property and equipment for $136,000.

Net cash provided by investing activities for the three months ended March 31, 2009 reflected the net proceeds from the sale of marketable securities of $300,000, partially offset by the purchase of property and equipment for $79,000.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2010 reflected proceeds from common stock option exercises of $483,000 and an excess tax benefit from stock options of $421,000, partially offset by principal payments on capital leases of $3,000.

Net cash used in financing activities for the three months ended March 31, 2009 reflected principal payments on capital leases of $2,000.

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.

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As of March 31, 2010, we had approximately $27.5 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. There have been no material changes outside the ordinary course of business to our contractual obligations during the three months ended March 31, 2010. The following table summarizes our contractual obligations as of March 31, 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	$ 59	$ 12	$ 31	$ 16	$
Operating leases(1)	3,419	507	1,041	1,120	751
Purchase obligations(2)	45,482	23,162	18,141	4,179	
Royalty obligations(3)	7,500	500	1,150	1,050	4,800
Other long-term liabilities(4)	2,750	1,250	1,500		
Total contractual obligations	$ 59,210	$ 25,431	$ 21,863	$ 6,365	$ 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 $27.7 million; clinical trial and research agreements with contract research organizations and consultants of $467,000; agreements with providers of marketing analytical services of $3.0 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $14.3 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 $42.2 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.

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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.

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 one supplier contract denominated in Euros which will expire during 2010. Unfavorable fluctuations in the dollar-to-Euro exchange rate could have a negative impact on our financial statements. The impact of the change in the exchange rate related to this contract was immaterial to our consolidated financial statements for the three months ended March 31, 2010 and 2009. We do not believe a fluctuation in the dollar-to-Euro exchange rate 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 March 31, 2010, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of March 31, 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 and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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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 March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Not applicable.

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 Board of Patent Appeals will act on the case and 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.

In February 2008, we filed a notice of opposition before the Trademark Trial and Appeal Board, or TTAB, in relation to Application No. 77/226,994 filed in the USPTO by Vision, seeking registration of the mark VisRx. The opposition proceeding is captioned *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, Opposition No. 91182604. In April 2008, Vision filed an answer and counterclaims in which it requested cancellation of our U.S. Registration

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Nos. 3,384,232 (covering the mark ALLERX for use in connection with anti-allergy, antihistamine and decongestant preparations) and 2,448,112 (covering the mark ALLERX for use in connection with dietary and nutritional supplements). Vision did not request monetary relief. On October 29, 2009, we reached an agreement with Vision to settle the opposition proceeding, which provided for dismissal with prejudice of our opposition to Vision s application for registration of the mark VisRx; dismissal without prejudice of Vision s counterclaim seeking cancellation of U.S. Registration No. 3,384,232; and voluntary cancellation of U.S. Registration No. 2,448,112. A stipulation memorializing the agreed resolution of the opposition proceeding and an application for voluntary cancellation of U.S. Reg. No. 2,448,112 were filed with the TTAB on October 29, 2009. The USPTO ordered the cancellation on March 11, 2010.

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 May 30, 2010. We are currently engaged in 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.

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: May 4, 2010	/s/ Craig Collard Craig Collard *President and Chief Executive Officer* *(Principal Executive Officer)*
Date: May 4, 2010	/s/ David Price David Price *Executive Vice President, Finance and Chief Financial Officer* *(Principal Financial Officer)*
Date: May 4, 2010	/s/ Ira Duarte Ira Duarte *Director of Accounting* *(Principal Accounting Officer)*

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EXHIBIT INDEX

Exhibit No.	Description
10.1+	Amendment No. 2, dated January 28, 2010, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003.
10.2+	Amendment No. 2, entered into on January 28, 2010 and effective as of November 16, 2009, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006.
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.