CORNERSTONE THERAPEUTICS INC
Form 10-Q
August 11, 2009

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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, 2009

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

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

As of August 7, 2009, the registrant had 24,800,676 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, 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, target, will, 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, including difficulties relating to the manufacture of ZYFLO CR® tablets; 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 that do have FDA-approved marketing applications; 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 products under development 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. 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. 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, 2008 filed with the Securities and Exchange Commission, or SEC, on March 26, 2009. Any material changes to those 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 that we may make or enter into, except that in particular circumstances as specifically indicated we may address the potential impact of our transaction with Chiesi Farmaceutici S.p.A., or Chiesi.

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ITEM 1. ***FINANCIAL STATEMENTS***

CORNERSTONE THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	June 30, 2009 (Unaudited)	December 31, 2008 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 15,459	$ 9,286
Marketable securities		300
Accounts receivable, net	14,136	12,987
Inventories, net	11,993	11,222
Prepaid and other current assets	3,296	1,754
Deferred income tax asset	3,512	2,428
Total current assets	48,396	37,977
Property and equipment, net	979	895
Product rights, net	16,681	17,702
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Other assets	789	46
Total assets	$ 80,114	$ 69,889
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 7,843	$ 10,288
Accrued expenses	24,554	19,052
Current portion of license agreement liability	1,257	2,543
Current portion of capital lease	10	
Income taxes payable	2,502	2,937
Total current liabilities	36,166	34,820
License agreement liability, less current portion	2,313	2,313
Capital lease, less current portion	44	
Deferred income tax liability	2,989	3,330
Total liabilities	41,512	40,463
Commitments and contingencies, Note 9		
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; 12,402,509 and 12,023,747 shares issued and outstanding as of June 30, 2009 and December 31, 2008, respectively	12	12
Additional paid-in capital	34,642	33,519
Retained earnings (accumulated deficit)	3,948	(4,105)
Total stockholders equity	38,602	29,426
Total liabilities and stockholders equity	$ 80,114	$ 69,889

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

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CORNERSTONE THERAPEUTICS INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net revenues	$ 24,993	$ 14,067	$ 55,698	$ 23,512
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	2,901	933	6,102	1,498
Sales and marketing	6,524	3,626	11,919	7,534
Royalties	5,651	3,559	11,942	4,804
General and administrative	5,127	2,288	8,887	3,811
Research and development	1,188	507	2,350	605
Amortization of product rights	510	109	1,021	848
Other charges	5	27	31	27
Total costs and expenses	21,906	11,049	42,252	19,127
Income from operations	3,087	3,018	13,446	4,385
Other expenses:				
Interest expense, net	(42)	(343)	(114)	(722)
Total other expenses	(42)	(343)	(114)	(722)
Income before income taxes	3,045	2,675	13,332	3,663
Provision for income taxes	(1,307)	(520)	(5,279)	(839)
Net income	$ 1,738	$ 2,155	$ 8,053	$ 2,824
Net income per share, basic	$ 0.14	$ 0.36	$ 0.67	$ 0.48
Net income per share, diluted	$ 0.13	$ 0.31	$ 0.60	$ 0.41
Weighted-average common shares, basic	12,166,989	5,934,496	12,095,764	5,934,496
Weighted-average common shares, diluted	13,584,314	6,864,243	13,486,956	6,851,107

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

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CORNERSTONE THERAPEUTICS INC.

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

	Six Months Ended June 30,	
	2009	**2008**
Cash flows from operating activities		
Net income	$ 8,053	$ 2,824
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	1,131	886
Provision for prompt payment discounts	1,574	491
Provision for inventory obsolescence	568	(43)
Stock-based compensation	852	169
Benefit for deferred income taxes	(1,425)	
Changes in operating assets and liabilities:		
Accounts receivable	(2,723)	(6,671)
Inventories	(1,339)	(618)
Prepaid expenses and other assets	(2,285)	2,123
Accounts payable	(2,445)	1,062
Accrued expenses	4,216	2,781
Income taxes payable	(435)	786
Net cash provided by operating activities	5,742	3,790
Cash flows from investing activities		
Advances to related parties		(19)
Proceeds from sale of marketable securities	300	
Purchase of property and equipment	(136)	(16)
Purchase of product rights		(1,750)
Collection of deposits		15
Payment of deposits		(32)
Net cash provided by (used in) investing activities	164	(1,802)
Cash flows from financing activities		
Proceeds from exercise of common stock options	271	
Proceeds from line of credit		5,500
Principal payments on line of credit		(7,250)
Principal payments on notes payable		(460)
Principal payments on capital lease obligation	(4)	
Net cash provided by (used in) financing activities	267	(2,210)
Net increase (decrease) in cash and cash equivalents	6,173	(222)
Cash and cash equivalents as of beginning of period	9,286	241

Cash and cash equivalents as of end of period	$ 15,459	$ 19

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 under-promoted, patent-protected, branded respiratory or related 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 force which is focused on the respiratory and related 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 condensed 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 condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The Company believes that it has included all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of these financial statements. The consolidated balance sheet at December 31, 2008 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, 2008, and these financial statements should be read in connection with those financial statements.

Operating results for the three and six-month periods ended June 30, 2009 and 2008 are not necessarily indicative of the results for the full year.

Reclassifications

Royalties and other receivables, which were previously included in accounts receivable, net, are included in prepaid and other current assets and other assets, respectively, in the accompanying condensed consolidated balance sheets. Depreciation expense, which was previously included in amortization and depreciation, is included in general and administrative expenses in the accompanying condensed consolidated statements of income. These reclassifications had no effect on stockholders equity or 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 condensed 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.

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.

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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 these sources could have a material adverse effect on the Company s business, financial position and results of operations.

The Company sells primarily to large national wholesalers, which in turn, may resell the product to smaller or regional wholesalers, retail pharmacies or chain drug stores. The following tables list all of the Company s customers that individually comprise greater than 10% of total gross product sales and their aggregate percentage of the Company s total gross product sales for the three and six months ended June 30, 2009 and 2008, and all customers that comprise more than 10% of trade accounts receivable and such customers aggregate percentage of the Company s trade accounts receivable as of June 30, 2009 and December 31, 2008:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009 Gross Product Sales	2008 Gross Product Sales	2009 Gross Product Sales	2008 Gross Product Sales
Cardinal Health, Inc.	34%	38%	35%	35%
McKesson Corporation	36%	29%	35%	35%
AmerisourceBergen Drug Corporation	18%	16%	17%	16%
Total	88%	83%	87%	86%

	June 30, 2009 Accounts Receivable	December 31, 2008 Accounts Receivable
Cardinal Health, Inc.	20%	35%
McKesson Corporation	37%	32%
AmerisourceBergen Drug Corporation	19%	16%
Total	76%	83%

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. The majority of funds in excess of the federally insured limits are held in sweep investment accounts collateralized by the securities in which the funds are invested. As of June 30, 2009 and December 31, 2008, the Company had balances of $34,000 and $1.3 million, respectively, in excess of federally insured limits held in non-investment accounts.

Marketable Securities

Marketable securities as of December 31, 2008 consisted of auction rate securities. The auction rate securities were of investment-grade quality and had an original maturity date greater than 90 days and could be sold within one year. The Company recorded its investments in marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115). The classification of marketable securities is generally determined at the date of purchase. The Company s marketable securities are classified as available-for-sale and reported at fair value with unrealized losses recognized net of tax in other comprehensive income (loss). Gains and losses on sales of investments in marketable securities, which are computed based on specific identification of the adjusted cost of each security, are included in investment income at the time of the sale.

In February 2009, the Company sold its investment in the auction rate securities for $300,000, which was the carrying value of the securities.

Accounts Receivable

The Company typically requires customers of branded and generic products to remit payments within 31 days and 61 days, respectively. In addition, the Company offers wholesale distributors a prompt payment discount as an

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incentive to remit payment within the first 30 days after the invoice date for branded products and 60 days after the invoice date for generic products. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company s wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of June 30, 2009 or December 31, 2008. 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 month periods ending June 30, 2009 and June 30, 2008.

The following table represents accounts receivable, net, as of June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009	December 31, 2008
Trade accounts receivable	$ 14,461	$ 13,289
Less allowance for prompt payment discounts	(325)	(302)
Accounts receivable, net	$ 14,136	$ 12,987

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 June 30, 2009 and December 31, 2008 (in thousands):

		June 30, 2009	December 31, 2008
Raw materials		$ 6,391	$ 6,393
Work in process		1,923	1,832
Finished goods:			
Pharmaceutical products	trade	3,621	3,182
Pharmaceutical products	samples	769	492
Total		12,704	11,899
Inventory allowances		(711)	(677)
Inventories, net		$ 11,993	$ 11,222

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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,	
	2009	2008	2009	2008
Gross product sales	$ 34,792	$ 17,621	$ 73,703	$ 28,091
Sales allowances	(9,799)	(3,896)	(18,242)	(5,366)
Net product sales	24,993	13,725	55,461	22,725
Royalty agreement revenue		342	237	787
Net revenues	$ 24,993	$ 14,067	$ 55,698	$ 23,512

NOTE 3: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance as of June 30, 2009 and December 31, 2008 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). The Merger was accounted for under the purchase method of accounting in accordance with SFAS No. 141, *Business Combinations*. 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. 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, 2009 will be deductible for income tax purposes.

Product Rights

The following table represents product rights, net, as of June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009	December 31, 2008
Product rights	$ 26,730	$ 26,730
Less accumulated amortization	(10,049)	(9,028)
Product rights, net	$ 16,681	$ 17,702

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of June 30, 2009, ranged from seven to nine years. As of June 30, 2009, 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, if approved, is targeted to be in late 2010 or early 2011) over an estimated useful life of approximately 14 years. The weighted-average amortization period for the Company s product rights related to its currently marketed products is approximately eight years.

NOTE 4: LINE OF CREDIT

In April 2005, the Company obtained financing under a bank line of credit for up to $4.0 million. Interest was due monthly with all outstanding principal and interest due on maturity. The initial maturity of the line of credit was April 2006 and the line of credit thereafter was successively renewed on an annual basis on each maturity date.

Amounts outstanding under the line of credit bore interest at a variable rate equal to the Wall Street Journal prime rate.

Because the Company s borrowing base under the line of credit exceeded $4.0 million as of December 31, 2008, the full amount of the line of credit was available for borrowings and the issuance of letters of credit on that date. As

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of December 31, 2008, the Company had no borrowings outstanding and had issued letters of credit totaling $68,000, resulting in $3.9 million of available borrowing capacity.

Effective May 4, 2009, the Company exercised its right to terminate its bank line of credit. There were no penalties associated with the early termination of the line of credit.

NOTE 5: ACCRUED EXPENSES

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

	June 30, 2009	December 31, 2008
Accrued product returns	$ 8,734	$ 5,043
Accrued rebates	1,996	884
Accrued price adjustments and chargebacks	5,142	4,307
Accrued compensation and benefits	2,289	2,507
Accrued royalties	6,285	6,259
Accrued expenses, other	108	52
Total accrued expenses	$ 24,554	$ 19,052

NOTE 6: STOCK-BASED COMPENSATION

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,	
	2009	2008	2009	2008
Employee	$ 576	$ 83	$ 828	$ 164
Non-employee	22	2	24	5
Total	$ 598	$ 85	$ 852	$ 169

The following table shows the amount of total stock-based compensation expense recognized by income statement classification (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
General and administrative	$ 528	$ 63	$ 781	$ 125
Sales and marketing	70	22	71	44
Total	$ 598	$ 85	$ 852	$ 169

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 293,833 and 288,028 stock options granted and exercised, respectively, during the six months ended June 30, 2009.

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The following table shows the assumptions used to value stock option granted during the six months ended June 30, 2009:

	Six Months Ended June 30, 2009
Estimated dividend yield	0.0%
Expected stock price volatility	75%
Risk-free interest rate	2.46-2.85%
Expected life of option (in years)	4.84
Weighted-average fair value per share	$ 4.33

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, 2009, the aggregate intrinsic value of options outstanding and exercisable was $16.5 million and $8.9 million, respectively.

As of June 30, 2009, there was $2.1 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.51 years. On July 28, 2009, the Company completed its strategic transaction with Chiesi Farmaceutici S.p.A. (Chiesi) (see Note 10). As a result, certain unvested stock options will accelerate, which is expected to impact the weighted-average period of compensation cost recognition.

Restricted Stock

During the six months ended June 30, 2009, 120,000 and 90,734 shares of restricted stock were issued and vested, respectively. As of June 30, 2009, there were 445,133 restricted common shares outstanding and approximately $1.8 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 3.38 years. On July 28, 2009, the Company completed its strategic transaction with Chiesi (see Note 10). As a result, certain unvested restricted stock will accelerate, which is expected to impact the weighted-average period of compensation cost recognition.

NOTE 7: INCOME TAXES

The Company computes an estimated annual effective tax rate for interim financial reporting purposes in accordance with the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 18, *Accounting for Income Taxes in Interim Periods, an interpretation of APB Opinion No. 28*. The Company s effective tax rate for the three and six months ended June 30, 2009 is 42.9% and 39.6%, respectively. The Company s effective tax rate for the three and six months ended June 30, 2008 was 19.4% and 22.9%, respectively. The increase in the effective tax rate when comparing the three and six months ended June 30, 2009 to the three and six months ended June 30, 2008 is due primarily to the release of the valuation allowance against the Company s deferred tax assets during the first quarter of 2008. Upon release of the valuation allowance, the Company fully utilized its net operating losses carryforwards, thereby reducing total income tax expense for the three and six month periods ending June 30, 2008.

The estimated annual effective tax rate for the year ending December 31, 2009 includes a benefit of approximately 2% related to a reduction in the valuation allowance offsetting deferred tax assets. As of the date of the Merger, Critical Therapeutics had approximately $64.0 million in deferred tax assets, primarily relating to net operating loss (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 2009 is approximately $277,000 and has

been recorded as a reduction to tax expense. The Company has not established any other valuation allowances.

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The Company implemented FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, which is an interpretation of SFAS No. 109*, Accounting for Income Taxes,* effective January 1, 2007. As of June 30, 2009, 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, 2009. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next twelve months.

The Company recognizes annual interest and penalties related to uncertain tax positions as operating expenses in its statements of income. For the three and six months ended June 30, 2009, the Company recognized no interest or penalties related to uncertain tax positions in the statements of income.

The 2005 through 2008 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, 2009.

NOTE 8: NET INCOME PER SHARE

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Numerator:				
Net income	$ 1,738	$ 2,155	$ 8,053	$ 2,824
Denominator:				
Weighted-average common shares, basic	12,166,989	5,934,496	12,095,764	5,934,496
Dilutive effect of stock options, warrants and restricted stock	1,417,325	929,747	1,391,192	916,611
Weighted-average common shares, diluted	13,584,314	6,864,243	13,486,956	6,851,107
Net income per share, basic	$ 0.14	$ 0.36	$ 0.67	$ 0.48
Net income per share, diluted	$ 0.13	$ 0.31	$ 0.60	$ 0.41
Anti-dilutive weighted-average shares	911,574		1,060,005	

On July 28, 2009, the Company completed its strategic transaction with Chiesi, which would have materially changed the number of common shares and potential common shares outstanding as of June 30, 2009 had it occurred on or before June 30, 2009 (see Note 10).

NOTE 9: COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its facilities, certain equipment and automobiles under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes rent expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Rent expense was approximately $226,000 and $120,000 for the three months ended June 30, 2009 and 2008, respectively, and $434,000 and $249,000 for the six monthly ended June 30, 2009 and 2008, respectively.

Royalties

The Company has contractual obligations to pay royalties to the former owners of certain product rights that have been acquired by or licensed to the Company, some of which are described in Note 15 to the Company s consolidated financial statements included in the Company s annual report on Form 10-K for the year ended December 31, 2008. These royalties are based on a percentage of net sales of the particular licensed product.

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In August 2006, the Company entered into an agreement with Pharmaceutical Innovations, LLC (Pharmaceutical Innovations) for an exclusive license to a U.S. patent and know-how to manufacture, package, market and distribute various day-night products. In exchange for these rights, the Company was required to pay Pharmaceutical Innovations a special royalty of 8.5% of initial net sales of day-night products up to a total of $250,000. The Company paid this special royalty in the years ended December 31, 2006 and 2007. In addition, the Company is obligated to pay royalties based on a percentage of the products annual net sales. The royalty rate increases as the annual net sales increase. Minimum annual royalties are $300,000 per year under this agreement during the life of the licensed patent based on the products currently marketed by the Company. The Company exceeded the minimum annual royalty during the years ended December 31, 2007 and 2008.

On July 1, 2001, the Company acquired from The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) (The Feinstein Institute), an exclusive worldwide license, under patent rights and know-how controlled by The Feinstein Institute relating to a cytokine called HMGB1, to make, use and sell products covered by the licensed patent rights and know-how. As partial consideration for the license, among other things, the Company agreed to make payments to The Feinstein Institute ranging from $50,000 to $275,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how, in each case upon the achievement of specified development and regulatory milestones for the applicable licensed product. As of December 31, 2008, none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales. In the event of no product sales, the Company will be required to pay minimum annual royalties of $15,000 in years 2009 through 2011 and $75,000 in years 2012 through the expiration of the patent in 2023.

The Company also has entered into two sponsored research and license agreements with The Feinstein Institute, one agreement in July 2001 related to identifying inhibitors and antagonists of HMGB1 and related proteins and a second agreement in January 2003 in the field of cholinergic anti-inflammatory technology, including alpha-7. Under the terms of these agreements, the Company acquired an exclusive worldwide license to make, use and sell products covered by the patent rights and know-how arising from the sponsored research. In connection with the July 2001 sponsored research and license agreement, the Company agreed to make payments to The Feinstein Institute ranging from $50,000 to $200,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how. In connection with the January 2003 sponsored research and license agreement, the Company agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. The Company also agreed to make aggregate milestone payments to The Feinstein Institute of up to $1.5 million in both cash and shares of the Company s common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. As of June 30, 2009, none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales. Under the January 2003 sponsored research and license agreement, the Company agreed to pay minimum annual royalties beginning in 2008 to The Feinstein Institute, regardless of whether the Company sells any licensed products, of $100,000 in 2008, which minimum annual royalties amount will increase by $50,000 annually to a maximum of $400,000 in 2014, with a minimum annual royalty payment of $400,000 thereafter payable through the expiration of the patent in 2023.

Supply Agreements

Concentrations

The Company purchases inventory from pharmaceutical manufacturers. During the three and six months ended June 30, 2009, two vendors accounted for 51% and 42% of the Company s inventory purchases, respectively. During the three and six months ended June 30, 2008, two vendors accounted for 56% and 44% of the Company s inventory purchases, respectively. Three inventory vendors accounted for 29% and 25% of the Company s accounts payable as of June 30, 2009 and December 31, 2008, respectively. As of June 30, 2009 and December 31, 2008, the Company had outstanding purchase orders related to inventory totaling approximately $8.0 million and $4.3 million, respectively.

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Vintage

The Company has entered into an agreement with Vintage Pharmaceuticals, LLC (Vintage) to exclusively manufacture BALACET® 325, as well as our generic formulations of propoxyphene napsylate and acetaminophen, APAP 325 and APAP 500, for prices established by the agreement, subject to renegotiation at each anniversary date. The agreement expires in July 2010 and may be renewed for subsequent one-year terms.

Meiji

In connection with the license agreement with Meiji Seika Kaisha, Ltd. (Meiji) dated October 12, 2006, as described in Note 15 to the Company s consolidated financial statements included in the Company s annual report on Form 10-K for the year ended December 31, 2008, Meiji is the Company s exclusive supplier of cefditoren pivoxil and, through October 2018, of SPECTRACEF® 400 mg so long as Meiji is able to supply 100% of the Company s requirements for SPECTRACEF 400 mg. Additionally, Meiji will be a non-exclusive supplier of SPECTRACEF 200 mg through October 2018. The Company is required to purchase from Meiji combined amounts of the API cefditoren pivoxil, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg exceeding $15.0 million for the first year beginning October 2008, $20.0 million for year two, $25.0 million for year three, $30.0 million for year four and $35.0 million for year five. If the Company does not meet its minimum purchase requirement in a given year, the Company must pay Meiji an amount equal to 50% of the shortfall in that year. The Company expects to exceed the minimum purchase requirements. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

Shasun

Shasun Pharma Solutions (Shasun) manufactures all of the Company s commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005. The Company has committed to purchase zileuton API from Shasun in the amounts of $5.8 million in 2009 and $1.6 million in 2010, respectively, which are in excess of the Company s minimum purchase requirements. The agreement will expire on the earlier of the date on which the Company has purchased a specified amount of the API for zileuton or December 31, 2010. The agreement will automatically extend for successive one-year periods after December 31, 2010, unless Shasun provides the Company with 18-months prior written notice of cancellation.

Jagotec

Jagotec AG (Jagotec) manufactures all of the Company s bulk, uncoated tablets of ZYFLO CR® pursuant to a manufacturing and supply agreement dated August 20, 2007. The Company has agreed to purchase from Jagotec a minimum of 20.0 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The agreement s initial term extends to May 22, 2012, and will automatically continue thereafter, unless the Company provides Jagotec with 24-months prior written notice of termination or Jagotec provides the Company with 36-months prior written notice of termination.

On June 12, 2009, the Company entered into a letter amendment with Jagotec, which amends the manufacturing and supply agreement dated August 20, 2007. The letter amendment adjusts the pricing terms the Company is obligated to pay Jagotec for the delivery of ZYFLO CR. All other terms of the manufacturing and supply agreement remain in full force and effect.

Patheon

Patheon Pharmaceuticals, Inc. (Patheon) coats, conducts quality control, quality assurance and stability testing and packages commercial supplies of ZYFLO CR for the Company using uncoated ZYFLO CR tablets the Company supplies to Patheon. The Company has agreed to purchase from Patheon at least 50% of the Company s requirements for such manufacturing services for ZYFLO CR for sale in the United States each year during the term of this agreement. The agreement s initial term extends to May 9, 2010, and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon with 12-months prior written notice of termination or Patheon provides the Company with 18-months prior written notice of termination.

Patheon also manufactures all of the Company s ZYFLO® immediate release tablets pursuant to a commercial manufacturing agreement. The Company has agreed to purchase from Patheon at least 50% of the Company s commercial supplies of ZYFLO immediate-release tablets for sale in the United States each year for the term of the

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agreement. The agreement s current term extends to September 15, 2009, and automatically continues for successive one-year periods thereafter, unless the Company provides Patheon with 12-months prior written notice of termination or Patheon provides the Company with 18-months prior written notice of termination.

Sovereign

Sovereign Pharmaceuticals, Ltd. (Sovereign) manufactures all of the Company s requirements of three HYOMAX® products pursuant to an exclusive supply and marketing agreement that the Company entered into in May 2008. Additionally, the Company purchases all of its requirements for HYOMAX DT tablets pursuant to purchase orders it places from time to time with Sovereign, which manufactures and supplies the HYOMAX DT tablets to the Company pursuant to an agreement between Sovereign and Capellon Pharmaceuticals, Ltd. to which the Company is not a party. The Company pays Sovereign its costs to manufacture the HYOMAX products exclusively for the Company, as well as a royalty based on a share of the net profits realized from the sale of the products. The term of the agreement expires in April 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least 90 days prior to the end of the then current term.

Chiesi

Chiesi will manufacture all of the Company s requirements of CUROSURF® pursuant to a license and distribution agreement that the Company entered into on May 6, 2009. Under the license and distribution agreement, Chiesi will license and grant to the Company the exclusive distribution rights to Chiesi s CUROSURF treatment in the United States for a ten-year term. The Company will pay Chiesi the greater of a percentage of net sales price for CUROSURF or the applicable floor price as set forth in the license and distribution agreement. The agreement has a ten-year term and will be renewed for successive one-year terms unless specified prior written notice is given.

DEY Co-Promotion and Marketing Services Agreement

On March 13, 2007, the Company entered into an agreement with Dey, L.P. (DEY), a wholly owned subsidiary of Mylan Inc., under which the Company and DEY agreed to jointly promote ZYFLO CR and ZYFLO. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right to promote and detail ZYFLO CR and ZYFLO in the United States, together with the Company.

Under the co-promotion agreement, DEY paid the Company $12.0 million in non-refundable aggregate payments in 2007 and the Company committed to fund at least $3 million in promotional expenses in 2007. In addition, the Company and DEY each agreed to contribute 50% of approved out-of-pocket promotional expenses during 2008 for ZYFLO CR that are approved by the parties joint commercial committee. From January 1, 2009 through the expiration or termination of the co-promotion agreement, DEY is responsible for the costs associated with its sales representatives and the product samples distributed by its sales representatives, and the Company is responsible for all other promotional expenses related to the products.

Prior to January 1, 2009, the Company paid DEY a co-promotion fee equal to thirty five percent (35%) of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million. Beginning January 1, 2009 through December 31, 2013, the Company has agreed to pay DEY a co-promotion fee equal to the ratio of total prescriptions written by certain pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by the parties.

Atley Co-Promotion Agreement

In April 2007, the Company entered into a co-promotion agreement, as amended, with Atley Pharmaceuticals, Inc. (Atley Pharmaceuticals) to co-promote a prescription pain product beginning July 1, 2007. Under the agreement, the Company pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of the product (as well as an authorized generic equivalent of the product marketed by the Company) above a specified baseline within assigned sales territories. The Company s co-promotion agreement with Atley Pharmaceuticals is

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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 the agreement.

Product and Development Agreements

In August 2006, the Company loaned Neos Therapeutics, L.P. (Neos) $500,000 under a secured subordinated promissory note agreement. In December 2006, the Company entered into a product development agreement with Neos providing the Company with an exclusive license to certain products under development utilizing Neos s patent-pending time release suspension technology. Under the terms of the agreement, the note with Neos was forgiven. The Company has recorded the $500,000 consideration as product rights related to the time release suspension technology. The agreement, as amended and restated in August 2008, requires Neos to develop the first product at its own expense up to a defined milestone. After that milestone is achieved, the Company is required to reimburse Neos 110% of all direct costs incurred and pay $150 per hour for personnel time incurred in the development of the products. The Company will also make milestone payments up to $1.0 million for each product based on specific events. As of June 30, 2009, the Company had not made any milestone payments. Upon commercialization, the Company would also pay Neos royalties based on a percentage of net sales.

In December 2008, the Company entered into an additional development, license and services agreement with Neos to license certain Neos patent-pending technology. Under the agreement, Neos will perform development work on a new product candidate. The Company is required to pay hourly fees for the development work in addition to up to an aggregate of $400,000 in fees.

On July 13, 2009, the Company entered into an asset purchase agreement with Oscient Pharmaceuticals Corporation (Oscient) to purchase, in an auction sale supervised by a bankruptcy court, the license rights to FACTIVE®, a quinolone antibiotic for the treatment of certain respiratory infections. The Company s offer is subject to its being the winning bidder and approval of the court supervising Oscient s bankruptcy proceedings. If the sale to the Company is approved, the Company will pay to Oscient $5.0 million (or such higher amount as the Company may bid at the auction sale) for the product s license rights plus an amount for purchased inventory to be mutually determined prior to closing, and pay a royalty for 5 years based on a percentage of net sales.

As of June 30, 2009, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $1.5 million.

Legal Proceedings

In 2007, 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. Subsequently, in October 2007, the Company filed suit against a pharmaceutical company in the U.S. District Court for the Eastern District of North Carolina alleging infringement of the patent. In November 2007, before a response to the Company s claims was due, the defendant moved to stay the litigation pending the re-examination of the Company s patent. The court granted defendants motion and stayed the litigation pending the re-examination of the patent in February 2008. In cooperation with its licensor, the Company intends to vigorously pursue its claims and to vigorously defend against any counterclaims that might be asserted. Additionally, in June 2008, the defendant requested that the USPTO re-examine a related second patent licensed to the Company by an affiliate of the licensor of the first patent. The USPTO granted this request and ordered a re-examination of the second patent in August 2008. The Company s intellectual property counsel believes that valid arguments exist for distinguishing the claims of the Company s patents over the references cited in the requests for re-examination.

NOTE 10: SUBSEQUENT EVENTS

Effective this quarter, the Company adopted SFAS No. 165, *Subsequent Events* (SFAS 165). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of SFAS 165 did not impact the Company s financial position or results of operations. The Company evaluated all events or transactions that occurred after June 30, 2009 through August 11, 2009, the date the Company issued these financial statements. During this period, the Company did not have any material recognizable subsequent events. However, the Company did have a nonrecognizable subsequent event discussed below.

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On May 6, 2009, the Company entered into a series of agreements for a strategic transaction, subject to approval by the Company s stockholders, with Chiesi, whereby the Company agreed to issue Chiesi approximately 12.2 million shares of common stock in exchange for $15.5 million in cash, an exclusive license for the U.S. commercial rights to Chiesi s CUROSURF product and a two-year right of first offer on all drugs Chiesi intends to market in the United States. The Company s license agreement with Chiesi is for a ten-year initial term and thereafter will be automatically renewed for successive one-year renewal terms, unless earlier terminated by either party upon six months prior written notice. As part of this transaction, the Company s president and chief executive officer and its executive vice president of manufacturing and trade agreed to sell to Chiesi an aggregate of 1.6 million shares of their common stock in the Company and enter into lockup, right of first refusal and option agreements with respect to their remaining shares. In addition, certain of the Company s other executive officers entered into lockup and right of first refusal agreements with Chiesi with respect to their shares of common stock in the Company and are entitled to receive certain equity incentives from the Company. On July 27, 2009, the Company s stockholders approved the Company s issuance of the shares at a special stockholders meeting, and the transaction closed on July 28, 2009. The transaction is considered a change of control as defined in certain employment arrangements between the Company and various employees, which causes the acceleration of vesting of certain stock options and restricted stock held by these employees. The Company has not yet completed its evaluation of the estimated impact of the accelerated vesting on its operating results.

NOTE 11: RECENT ACCOUNTING PRONOUNCEMENTS

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162 (* SFAS 168), to establish the *FASB Accounting Standards Codification* as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles in the United States. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of this standard to have an impact on its financial position or results of operations.

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

You should read the following discussion and analysis of financial condition and results of operations together with our unaudited condensed 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, 2008. 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.

Background

Cornerstone Therapeutics Inc. (Cornerstone, we, our, or us) is a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products primarily for the respiratory and related markets. Our commercial strategy is to in-license or acquire rights to underpromoted, patent-protected, branded respiratory or related pharmaceutical products or late-stage product candidates; implement life cycle management strategies to maximize the potential value and competitive position of our currently marketed products, newly acquired products and product candidates that are currently in development; grow product revenue through our specialty sales force, which is focused on the respiratory and related markets; and maintain and strengthen the intellectual property position of our currently marketed products, newly acquired products and product candidates We currently market our products only in the United States.

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On October 31, 2008, Critical Therapeutics, Inc., or Critical Therapeutics, and Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma, completed their previously announced merger. Cornerstone BioPharma s reasons for the merger included, among other things, the opportunity to expand Cornerstone BioPharma s respiratory product portfolio, the potential for enhanced future growth and value and the ability to access additional capital. Because former Cornerstone BioPharma stockholders owned, immediately following the merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was treated as a reverse acquisition in accordance with accounting principles generally accepted in the United States, or GAAP. Accordingly, for all purposes, our financial statements for periods prior to the merger reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and our financial statements for all subsequent periods reflect the results of the combined company. In addition, unless specifically noted otherwise, discussions of our financial results throughout this document do not include the historical financial results of Critical Therapeutics (including sales of ZYFLO CR and ZYFLO®) prior to the completion of the merger.

On May 6, 2009, we entered into a series of agreements for a strategic transaction, subject to approval by our stockholders, with Chiesi, whereby we agreed to issue Chiesi approximately 12.2 million shares of common stock in exchange for $15.5 million in cash, an exclusive license for the U.S. commercial rights to Chiesi s CUROSURF® product and a two-year right of first offer on all drugs Chiesi intends to market in the United States. Our license agreement with Chiesi is for a ten-year initial term and thereafter will be automatically renewed for successive one-year renewal terms, unless earlier terminated by either party upon six months prior written notice. As part of this transaction, our president and chief executive officer and our executive vice president of manufacturing and trade agreed to sell to Chiesi an aggregate of 1.6 million of their shares of our common stock and enter into lockup, right of first refusal and option agreements with respect to their remaining shares. In addition, certain of our other executive officers entered into lockup and right of first refusal agreements with Chiesi with respect to their shares of our common stock and are entitled to receive certain equity incentives from us. On July 27, 2009, our stockholders approved our issuance of the shares at a special stockholders meeting, and the transaction closed on July 28, 2009. The transaction is considered a change of control as defined in certain employment arrangements between us and various employees, which causes the acceleration of vesting of certain stock options and restricted stock held by these employees. We have not yet completed our evaluation of the estimated impact of the accelerated vesting on our operating results.

CUROSURF is a natural lung surfactant and a world-leading treatment approved by the FDA for Respiratory Distress Syndrome in premature infants. CUROSURF is currently available in over 60 countries, including the United States and most of Europe, and has been administered to over one million infants since 1992. Respiratory Distress Syndrome affects approximately ten of every 100 premature infants in the United States, or approximately 40,000 babies, each year. Respiratory Distress Syndrome can lead to serious complications and is one of the most common causes of neonatal mortality.

We expect to begin marketing, promoting, and earning revenues from CUROSURF in the third quarter of 2009. There is no assurance that we will achieve the sales level for CUROSURF that was achieved by Chiesi s prior licensee of the U.S. rights to this product.

Current Marketed Products

We currently promote SPECTRACEF®, ZYFLO CR and the ALLERX® Dose Pack family of products. In addition, we have a co-promotion agreement with Dey, L.P., or DEY, for the exclusive co-promotion along with us of ZYFLO CR and ZYFLO. Under the DEY co-promotion agreement, we pay DEY a co-promotion fee equal to the ratio of total prescriptions written by certain pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties. We currently generate revenues from product sales and royalties from the sale of other products that we do not actively promote. Of these, HYOMAX®, BALACET® 325, APAP 500, one of our generic propoxyphene/acetaminophen products, and DECONSAL® have generated the most net revenues to date for us. Of our marketed products that we do not promote, only BALACET 325 and APAP 325, our generic equivalent of BALACET 325, are currently promoted by a third party.

The HYOMAX line of products consists of generic formulations of four antispasmodic medications containing the active pharmaceutical ingredient, or API, hyoscyamine sulfate, an anticholinergic, which may be prescribed for various gastrointestinal disorders. We launched our first HYOMAX product in May 2008. We pay Sovereign Pharmaceuticals, Ltd., or Sovereign, its costs to manufacture the HYOMAX products exclusively for us, as well as a royalty based on a share of the net profits realized from the sale of the products. Although our HYOMAX line of products consists of generic formulations without patent protection, until the second quarter of 2009, this product line experienced limited generic competition. However, we are now experiencing increased market competition with respect to a number of our HYOMAX products, and we may experience additional competition in the future. As competition for our HYOMAX line of products increases, we expect that our market share and the price of our HYOMAX products will decline. The extent of any decline will depend on several factors, including, among others, the number of competitors and the pricing strategy of the new competitors.

In September 2005, we entered into a supply and marketing agreement with Pliva Inc., or Pliva, relating to APAP 500. Under this agreement, which we terminated effective December 31, 2008, Pliva sold APAP 500 that was

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supplied to it by Vintage Pharmaceuticals, LLC, or Vintage, and paid us royalties based on the quarterly net sales of APAP 500.

Financial Operations Overview

Net Revenues

Our net revenues are comprised of net product sales and royalty agreement revenues. We recognize product sales net of estimated allowances for product returns; estimated rebates in connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts. The primary factors that affect our net product sales are the level of demand for our products, unit sales prices and the amount of sales adjustments that we recognize. Royalty agreement revenues consist of royalties we receive under license agreements with third parties that sell products to which we have rights. The primary factors that affect royalty agreement revenues are the demand and sales prices for such products and the royalty rates that we receive on the sales of such products by third parties.

From time to time, we implement price increases on our branded products. Our branded and generic products are subject to rebates, chargebacks and other sales allowances that have the effect of decreasing the net revenues that we ultimately realize from product sales. Our generic products may also be subject to substantial price competition from equivalent generic products introduced by other pharmaceutical companies. Such competition may also decrease our net revenues from the sale of our generic products.

Cost of Product Sales

Our cost of product sales is primarily comprised of the costs of manufacturing and distributing our pharmaceutical products. In particular, cost of product sales includes third-party manufacturing and distribution costs, the cost of API, freight and shipping, reserves for excess or obsolete inventory and labor, benefits and related employee expenses for personnel involved with overseeing the activities of our third-party manufacturers. Cost of product sales excludes amortization of product rights.

We contract with third parties to manufacture all of our products and product candidates. Changes in the price of raw materials and manufacturing costs could adversely affect our gross margins on the sale of our products. Changes in our mix of products sold also will result in variations in our cost of product sales. Accordingly, our management expects gross margins will change as our product mix is altered by changes in demand for our existing products or the launch of new products.

Sales and Marketing Expenses

Our sales and marketing expenses consist of labor, benefits and related employee expenses for personnel in our sales, marketing and sales operations functions; advertising and promotion costs, including the costs of samples; and the fees we pay under our co-promotion agreements to third parties to promote our products, which are based on a percentage of net profits from product sales, determined in accordance with the particular agreement. The most significant component of our sales and marketing expenses is labor, benefits and related employee expenses. We expect that our sales and marketing expenses will increase as we expand our sales and marketing infrastructure to support additional products and product lines and as a result of increased co-promotion fees due to greater product sales.

Royalty Expenses

Royalty expenses include the contractual amounts we are required to pay the licensors from which we have acquired the rights to our marketed products or third-parties to whom we pay royalties under settlement agreements relating to our products. Royalties are generally based on a percentage of the products net sales. With respect to the HYOMAX line of products, royalties are based on a percentage of the net profits earned by us on the sale of the products. Although product mix affects our royalties, we generally expect that our royalty expenses will increase as total net product sales increase.

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General and Administrative Expenses

General and administrative expenses primarily include labor, benefits and related employee expenses for personnel in executive, finance, accounting, business development, information technology, regulatory/medical affairs and human resource functions. Other costs include facility costs not otherwise included in sales and marketing or research and development expenses and professional fees for legal and accounting services. General and administrative expenses also consist of the costs of maintaining and overseeing our intellectual property portfolio, which include the cost of external legal counsel and the mandatory fees of the U.S. Patent and Trademark Office, or USPTO, and foreign patent and trademark offices. General and administrative expense also includes depreciation expense for our property and equipment, which we depreciate over the estimated useful lives of the assets using the straight-line method. We expect that general and administrative expenses will increase as we continue to build the infrastructure necessary to support our commercialization and product development activities and to meet our compliance obligations as a public company. In addition, during the six months ended June 30, 2009, we have continued to incur additional legal, accounting and related costs relating to our October 2008 merger and our strategic transaction with Chiesi.

Research and Development Expenses

Research and development expenses consist of product development expenses incurred in identifying, developing and testing our product candidates and the write-off of in-process research and development expenses related to the alpha-7 program acquired from Critical Therapeutics in connection with our merger. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; expenses incurred under joint development agreements; regulatory costs; costs of contract research and manufacturing; and the cost of facilities used by our product development personnel. We expense product development costs as incurred. We believe that significant investment in product development is important to our competitive position and plan to increase our expenditures for product development to realize the potential of the product candidates that we are developing or may develop.

Our product development expenses reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which we have discontinued development. Additionally, product development expenses include our costs of qualifying new current Good Manufacturing Practice, or cGMP, third-party manufacturers for our products, including expenses associated with any related technology transfer. We do not allocate indirect costs (such as salaries, benefits or other costs related to our accounting, legal, human resources, purchasing, information technology and other general corporate functions) to the research and development expenses associated with individual product candidates. Rather, we include these costs in general and administrative expenses.

Amortization of Product Rights

We capitalize our costs to license product rights from third parties as such costs are incurred and amortize these amounts on a straight-line basis over the estimated useful life of the product or the remaining trademark or patent life. We re-evaluate the useful life of our products on an annual basis to determine whether the value of our product rights assets have been impaired and appropriately adjust amortization to account for such impairment. Amortization of product rights is expected to increase in the future as we begin amortizing product rights related to new products.

Other Charges

Other charges include expenses related to settlements of litigation.

Critical Accounting Estimates

Management s discussion and analysis of financial condition and results of operations are based upon our condensed consolidated financial statements, which 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, 2008 and Note 2 to our condensed consolidated

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financial statements contained therein. There have been no material changes to the critical accounting policies previously disclosed in that report.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2009 and 2008

Net Revenues

The following table sets forth a summary of our net revenues and the presentation of the change from period-to-period (in thousands, except percentages):

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended June 30, 2009 vs. June 30, 2008		Six Months Ended June 30, 2009 vs. June 30, 2008	
	2009	2008	2009	2008	$	%	$	%
Net product sales								
ALLERX 10 Dose Pack/ALLERX 30 Dose Pack	$ 7,879	$ 3,111	$ 14,591	$ 6,377	$ 4,768	153%	$ 8,214	129%
ALLERX Dose Pack DF/ALLERX Dose Pack DF 30	1,161	1,387	3,131	2,554	(226)	(16)	577	23
ALLERX Dose Pack PE/ALLERX Dose Pack PE 30	(488)	1,836	1,722	3,935	(2,324)	(127)	(2,213)	(56)
SPECTRACEF	1,625	1,614	5,342	1,795	11	1	3,547	198
BALACET 325	875	958	1,804	3,103	(83)	(9)	(1,299)	(42)
HYOMAX	8,841	4,473	17,401	4,473	4,368	98	12,928	289
ZYFLO CR and ZYFLO (1)	3,490		8,803		3,490	100	8,803	100
Other currently marketed products	1,610	346	2,667	488	1,264	365	2,179	447
Total net product sales	24,993	13,725	55,461	22,725	11,268	82	32,736	144
Royalty agreement revenues		342	237	787	(342)	(100)	(550)	(70)
Net revenues	$ 24,993	$ 14,067	$ 55,698	$ 23,512	$ 10,926	78%	$ 32,186	137%

(1) Does not include the historical sales of ZYFLO CR and ZYFLO made by Critical Therapeutics.

Net Product Sales. Net product sales were $25.0 million for the three months ended June 30, 2009, compared to $13.7 million for the three months ended June 30, 2008, an increase of approximately $11.3 million, or 82%. For the

six months ended June 30, 2009, net product sales were $55.5 million compared to $22.7 million for the six months ended June 30, 2008, an increase of approximately $32.7 million or 144%.

ALLERX Dose Pack family of products net product sales for the three months ended June 30, 2009 increased by $2.2 million, or 35%, compared to the three months ended June 30, 2008. For the six months ended June 30, 2009, net product sales increased by $6.6 million or 51% compared to the six months ended in June 30, 2008. The growth in product sales was due primarily to a price increase on the entire product family, offset by decreased volume of the ALLERX PE and the ALLERX DF formulations as a result of generic competition.

SPECTRACEF net product sales increased for the three and six months ended June 30, 2009 compared to the three and six months ended June 30, 2008, primarily due to the launch of the SPECTRACEF 400 mg Dose Packs in late 2008.

BALACET 325 net product sales decreased for the three and six months ended June 30, 2009 compared to the three and six months ended June 30, 2008, primarily due to our launch of APAP 325 in July 2008. Net product sales for APAP 325 were $930,000 and $1.6 million for the three and six months ended June 30, 2009, respectively, and are included in net product sales from other currently marketed products.

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HYOMAX net product sales increased for the three and six months ended June 30, 2009 compared to the three and six months ended June 30, 2008, primarily due to timing of the launches of the HYOMAX products during 2008. The first HYOMAX product was launched in May 2008, the second and third in June 2008 and the fourth in July 2008.

ZYFLO CR and ZYFLO net product sales were $3.5 million and $8.8 million for the three and six months ended June 30, 2009, respectively. As noted above, our historical financial results for the three and six months ended June 30, 2008 do not include sales of ZYFLO CR and ZYFLO by Critical Therapeutics prior to the completion of our October 31, 2008 merger.

Royalty Agreement Revenues. Royalty agreement revenues decreased for the three and six months ended June 30, 2009 compared to the three and six months ended June 30, 2008, primarily due the expiration of the supply and marketing agreement for APAP 500 in December 2008. Subsequent to the expiration of the supply and marketing agreement, we began marketing APAP 500. Net product sales for APAP 500 were $425,000 for the three and six months ended June 30, 2009, and are included in other currently marketed products.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $510,000 and $109,000 for the three months ended June 30, 2009 and 2008, respectively) was $2.9 million for the three months ended June 30, 2009, compared to $933,000 for the three months ended June 30, 2008, an increase of approximately $2.0 million, or 211%. Cost of product sales (exclusive of amortization of product rights of $1.0 million and $848,000 for the six months ended June 30, 2009 and 2008, respectively) was $6.1 million for the six months ended June 30, 2009, compared to $1.5 million for the six months ended June 30, 2008, an increase of approximately $4.6 million, or 307%. Cost of product sales consisted primarily of the expenses associated with manufacturing and distributing products, including shipping and handling costs, and reserves established for excess or obsolete inventory.

Gross margin (exclusive of royalty agreement revenues and amortization of product rights) was 88% and 93% for the three months ended June 30, 2009 and 2008, respectively. Gross margin (exclusive of royalty agreement revenues and amortization of product rights) was 89% and 93% for the six months ended June 30, 2009 and 2008, respectively. The decrease in gross margin was primarily due to the increased sales contribution of the ZYFLO product family, the SPECTRACEF product family and HYOMAX, which have lower gross margins than our other products. We recorded inventory write-offs of $483,000 and $534,000 for the three and six months ended June 30, 2009, respectively, and $37,000 and $61,000 for the three and six months ended June 30, 2008, respectively. These adjustments were necessary to adequately state reserves related to excess or obsolete inventory that, due to its expiration dating, would not be sold.

Sales and Marketing Expenses. Sales and marketing expenses were $6.5 million for the three months ended June 30, 2009, compared to $3.6 million for the three months ended June 30, 2008, an increase of $2.9 million, or 80%. Sales and marketing expenses were $11.9 million for the six months ended June 30, 2009, compared to $7.5 million for the six months ended June 30, 2008, an increase of $4.4 million, or 58%. These increases were primarily due to increases in labor and benefits-related costs as a result of the growth of our sales force and management team; advertising and promotional spending relating to the marketing launch of ZYFLO CR in 2009 and SPECTRACEF 400 mg; 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.

Royalty Expenses. Royalty expenses were $5.7 million for the three months ended June 30, 2009, compared to $3.6 million for the three months ended June 30, 2008, an increase of approximately $2.1 million, or 59%. Royalty expenses for the six months ended June 30, 2009 were $11.9 million compared to $4.8 million for the six months ended June 30, 2008 an increase of $7.1 million or 149%. These increases were primarily due to the launches of our four HYOMAX products, the first of which occurred in May 2008; increased net product sales of the ALLERX family of products; and royalties relating to ZYFLO CR and ZYFLO, which were acquired in our October 31, 2008 merger.

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General and Administrative Expenses. General and administrative expenses were $5.1 million for the three months ended June 30, 2009, compared to $2.3 million for the three months ended June 30, 2008, an increase of $2.8 million, or 122%. General and administrative expenses were $8.9 million for the six months ended June 30, 2009, compared to $3.8 million for the six months ended June 30, 2008, an increase of $5.1 million, or 134%. These increases were primarily due increases in labor and benefits-related employee expenses and travel-related expenses due to expansion of our workforce; legal and accounting costs, most of which relate to increased regulatory requirements as a result of our becoming a public company and costs associated with the Chiesi transaction (see Note 10 to our condensed consolidated financial statements); FDA regulatory-related fees; and product liability and other insurance related costs.

Research and Development Expenses. Research and development expenses were $1.2 million for the three months ended June 30, 2009, compared to $507,000 for the three months ended June 30, 2008, an increase of approximately $681,000, or 134%. For the six months ended June 30, 2009, research and development expenses were $2.4 million compared to $605,000 for the six months ended June 30, 2008, an increase of $1.7 million or 288%. These increases were primarily due to the manufacturing of and studies conducted on a product candidate, as well as stability studies for existing products.

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 was $510,000 for the three months ended June 30, 2009, compared to $109,000 for the three months ended June 30, 2008, an increase of approximately $401,000, or 368%. Amortization of product rights in the six months ended June 30, 2009 was $1.0 million compared to $848,000 for the six months ended June 30, 2008, an increase of $173,000 or 20%. These increases were primarily due to the amortization of ZYFLO CR product rights, offset by the BALACET product rights that became fully amortized as of March 31, 2008. ZYFLO CR was added to our product portfolio as a result of our October 31, 2008 merger.

Other Expenses

Interest Expense, Net. Net interest expense was $42,000 and $114,000 for the three and six months ended June 30, 2009, respectively, compared to $343,000 and $722,000 for the three and six months ended June 30, 2008, respectively. The decrease of approximately $301,000 and $608,000 when comparing current periods to prior periods was primarily due to the conversion of our promissory note with Carolina Pharmaceuticals Ltd., or the Carolina Note, into common stock on October 31, 2008 in connection with our merger.

Provision for Income Taxes

The provision for income taxes was $1.3 million and $5.3 million for the three and six months ended June 30, 2009, respectively, compared to $520,000 and $839,000 for the three and six months ended June 30, 2008, respectively. Our effective tax rate for the three and six months ended June 30, 2009 is 42.9% and 39.6%, respectively. Our effective tax rate for the three and six months ended June 30, 2008 was 19.4% and 22.9%, respectively. The increase in the effective tax rate when comparing the three and six months ended June 30, 2009 to the three and six months ended June 30, 2008 is due primarily to the release of the valuation allowance against our deferred tax assets during the first quarter of 2008. Upon release of the valuation allowance, we fully utilized our net operating loss carryforwards, thereby reducing total income tax expense for the three and six month periods ending June 30, 2008.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for working capital, capital expenditures, acquisitions and in-licenses of rights to products and principal and interest payments on any debt we may have outstanding. To date, we have funded our operations primarily from product sales, royalty agreement revenues and borrowings under the Carolina Note and our line of credit with Paragon Commercial Bank, or Paragon. We borrowed $13.0 million under

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the Carolina Note in April 2004. In connection with the closing of our merger, all of the outstanding principal amount of the Carolina Note of approximately $9.0 million was exchanged for 6,064,731 shares of Cornerstone BioPharma s common stock (which was exchanged for 1,443,913 shares of our common stock in the merger). As of June 30, 2009, we had $15.5 million in cash and cash equivalents. There were no borrowings on the Paragon line of credit during the three or six months ended June 30, 2009. Effective May 4, 2009, we exercised our right to terminate the Paragon line of credit. In July 2009, in connection with the consummation of our strategic transaction with Chiesi, among other consideration, we received approximately $15.5 million in cash.

Cash Flows

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

	Six Months Ended June 30,	
	2009	**2008**
Cash provided by (used in):		
Operating activities	$ 5,742	$ 3,790
Investing activities	164	(1,802)
Financing activities	267	(2,210)
Net increase (decrease) in cash and cash equivalents	$ 6,173	$ (222)

Net Cash Provided By Operating Activities

Our primary sources of operating cash flows are product sales and royalty agreement revenues. Our primary uses of cash in our operations are for inventories and other costs of product sales, sales and marketing expenses, royalties, general and administrative expenses and interest.

Net cash provided by operating activities for the six months ended June 30, 2009 reflected our net income of $8.1 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. Non-cash items included amortization and depreciation of $1.1 million, change in allowances for prompt payment discounts and inventory obsolescence of $2.1 million, stock-based compensation of $852,000 and changes in deferred income tax of $1.4 million. Accounts receivable increased by $1.2 million from December 31, 2008 to June 30, 2009, primarily due to increased net product sales. Inventories increased by $805,000 from December 31, 2008 to June 30, 2009, primarily due to the purchase of ZYFLO CR, HYOMAX and ALLERX finished goods inventory and HYOMAX API, offset by decreased purchases of raw materials (other than HYOMAX API). Prepaid expenses and other assets increased by $2.3 million, primarily due to voucher programs and prepayments on purchases of API not yet received into inventory. Accounts payable decreased by $2.5 million from December 31, 2008 to June 30, 2009, primarily due to decreased payables related to the 2008 merger, manufacturing, product development and marketing expenses. Accrued expenses increased by $4.2 million from December 31, 2008 to June 30, 2009, primarily due to increased returns, royalties, rebates and chargebacks resulting from increased product sales, offset, in part, by a decrease in accrued bonus. Income taxes payable (exclusive of income taxes payable assumed in the merger) decreased by $435,000 from December 31, 2008 to June 30, 2009.

Net cash provided by operating activities for the six months ended June 30, 2008 reflected our net income of $2.8 million, adjusted by non-cash expenses totaling $1.5 million and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities totaling $537,000. Non-cash items included amortization and depreciation of $886,000, change in allowances for prompt payment discounts and inventory obsolescence of $448,000 and stock-based compensation of $169,000.

Net Cash Provided by (Used in) Investing Activities

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

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Net cash used in investing activities for the six months ended June 30, 2008 primarily reflected net advances to related parties of $19,000, the purchase of product rights for $1.8 million, the purchase of property and equipment of $16,000 and net payments for deposits of $17,000.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2009 reflected proceeds from common stock option exercises of $271,000.

Net cash used in financing activities for the six months ended June 30, 2008 reflected net payments on the Paragon line of credit and the Carolina Note of $1.8 million and $460,000, respectively.

Funding Requirements

We expect to continue to incur significant development and commercialization expenses as we seek FDA approval for CRTX 068 and CRTX 062; advance the development of our other product candidates, including CRTX 058 and CRTX 069; seek regulatory approvals for our product candidates that successfully complete clinical testing, such as CRTX 067; and expand our sales team and marketing capabilities to prepare for the commercial launch of future products, subject to FDA approval. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts. Accordingly, we will need to increase our revenues to be able to sustain and increase our profitability on an annual and quarterly basis. There is no assurance that we will be able to do so. Our failure to achieve consistent profitability could impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

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, which may not be available on acceptable terms, if at all.

As of June 30, 2009, we had approximately $15.5 million of cash and cash equivalents on hand. Effective May 4, 2009, we exercised our right to terminate our line of credit with Paragon. There were no penalties associated with the early termination of the line of credit. In July 2009, in connection with the consummation of our strategic

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transaction with Chiesi, we received approximately $15.5 million in cash, an exclusive license for the U.S. commercial rights to Chiesi s CUROSURF product and a two-year right of first offer on all drugs Chiesi intends to market in the United States.

In July 2009, we also entered into an asset purchase agreement with Oscient Pharmaceuticals Corporation, or Oscient, to purchase, in an auction sale supervised by a bankruptcy court, the license rights to FACTIVE®, a quinolone antibiotic for the treatment of certain respiratory infections. If we are the winning bidder and our offer is approved by the bankruptcy court, we will be required to pay Oscient $5.0 million (or such higher amount as we may bid at the auction sale) for the product s license rights plus an amount for purchased inventory to be mutually determined prior to closing.

Based on our current operating plans, we believe that our existing cash and cash equivalents and revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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.

Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception. We expect our cost of product sales and other operating expenses will change in the future in line with periodic inflationary changes in price levels. Because we intend to retain and continue to use our property and equipment, we believe that the incremental inflation related to the replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources. While our management generally believes that we will be able to offset the effect of cost inflation by adjusting our product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse affect on our financial condition, results of operations and cash flows.

Recent Accounting Pronouncements

See Note 11: Recent Accounting Pronouncements in *Part I Item 1. Financial Statements* of this quarterly report on Form 10-Q for a description of recent accounting pronouncements, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements.

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

Not required for smaller reporting companies.

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

Not applicable.

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2009. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other

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procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level as we have not conducted necessary testing to confirm the material weakness in our internal control over financial reporting described in our annual report on Form 10-K for the year ended December 31, 2008 has been effectively remediated.

Changes in Internal Control Over Financial Reporting

As discussed in our annual report on Form 10-K for the year ended December 31, 2008, our management initiated a comprehensive assessment of our internal control over financial reporting. As of March 31, 2009, management identified a material weakness related to our lack of a sufficient number of personnel in our accounting and finance department with appropriate accounting knowledge and experience to record our financial results in conformity with GAAP, which prevents us from being able to timely and effectively close our books at the end of each interim and annual period. While we believe that we have taken the appropriate actions to remediate the material weakness as of June 30, 2009, with the expansion of our accounting and finance department and remediation of related disclosure controls, we have not conducted necessary testing to confirm that the material weakness has been effectively remediated. Additionally, our assessment of our internal control over financial reporting is not complete; accordingly, our management may identify additional material weaknesses as part of its assessment. We expect the assessment process to be completed during the third quarter of 2009.

Chenyqua M. Baldwin, our Vice President, Finance, Chief Accounting Officer and Controller, resigned effective May 7, 2009. As part of the expansion of our accounting and finance department, Ms. Baldwin s duties and responsibilities were reassigned among our Chief Financial Officer and other existing and newly hired personnel in our finance and accounting department.

Except as noted above, there was no change 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, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 USPTO ordered a re-examination of the 796 Patent as a result of a third-party request for ex parte re-examination. We and J-Med Pharmaceuticals, Inc., or J-Med, the licensor of the 796 Patent, have asserted infringements of the 796 Patent in litigation with each of Everton Pharmaceuticals, LLC, or Everton, Breckenridge Pharmaceutical, Inc., or Breckenridge, and Vision Pharma, LLC, or Vision, and manufacturers and related parties of each, alleging that those parties had infringed the 796 Patent by making, using, selling, offering for sale or importing into the United States pharmaceutical products intended as generic equivalents to the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack protected under claims in the 796 Patent. Everton and Breckenridge entered into settlement agreements in January 2007 and July 2007, respectively, and agreed to cease selling the infringing products. In October 2007, we and J-Med filed an action in the U.S. District Court for the Eastern District of North Carolina against Vision and Nexgen Pharma, Inc. captioned *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Vision Pharma, LLC and Nexgen Pharma, Inc.*, No. 5:07-CV-00389-F. In this action, we and J-Med alleged that the product known as VisRx infringes the 796 Patent. On November 19, 2007, we and J-Med

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filed an amended complaint asserting claims against Vision s principals, Sander Busman, Thomas DeStefano and Michael McAloose. On November 30, 2007, defendants moved to stay the litigation pending the re-examination of the 796 Patent. The Court granted defendants motion and stayed the litigation pending the re-examination of the 796 Patent on February 15, 2008.

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. 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, and a supplemental appeal brief was filed on May 7, 2009. If the examiner does not reverse his prior rejections, then 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 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 ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, 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. We anticipate having the opportunity, in coordination with the patent owner, Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations, to present substantive arguments supporting the patentability of the claims issued in the 372 Patent in a response to the office action. 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 to Notice of Opposition and Counterclaims in which it requested cancellation of U.S. Registrations No. 3,384,232 and 2,448,112 for the mark ALLERX owned by us. Vision did not request monetary relief. We responded to Vision s counterclaims on May 16, 2008. Discovery is ongoing in this proceeding with respect to Vision s counterclaims. We intend to defend our interests vigorously against the counterclaims asserted by Vision.

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 the ALLERX trademark registration (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® mark 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. The suspension of cancellation proceedings will

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expire on November 10, 2009. We are currently engaged in settlement discussions with Bausch & Lomb to resolve the dispute on favorable terms. We have agreed with Bausch & Lomb to request a further suspension of cancellation proceedings if settlement is not concluded before November 10, 2009. If settlement is not reached, then proceedings will resume, and a final decision by the TTAB could take several years.

On November 10, 2008, we were named as a defendant in an action filed by Breckenridge in the United States District Court for the District of Maryland captioned *Breckenridge Pharmaceutical, Inc. v. Cornerstone BioPharma, Inc., J-Med Pharmaceuticals, Inc. and Allan M. Weinstein*, No. 8:08-CV-02999-DKC. Breckenridge sought a declaratory judgment that the 372 Patent and U.S. Patent No. 6,651,816, or the 816 patent, are invalid. The 372 Patent is licensed to us by Pharmaceutical Innovations, an affiliate of J-Med. We do not have an interest in the 816 Patent. Breckenridge also sought a declaratory judgment that its Allergy DN II and Allergy DN PE products do not infringe the 372 and 816 Patents. Breckenridge also sought a declaratory judgment that our claimed copyrights in the product informational inserts for ALLERX DF and ALLERX PE are invalid and/or not infringed by the product informational inserts for Allergy DN II and Allergy DN PE. Breckenridge did not request monetary relief. Breckenridge voluntarily dismissed the action without prejudice on May 11, 2009.

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

We operate in a rapidly changing environment that involves a number of risks. The following discussion highlights some of these risks and others are discussed elsewhere in this report. These and other risks 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 investment in our stock, please refer to Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2008, which was filed with the SEC on March 26, 2009.

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

Concerns regarding the safety profile of ZYFLO CR and ZYFLO may limit the market acceptance of ZYFLO CR.

Market perceptions about the safety of ZYFLO CR and ZYFLO may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO CR can elevate liver enzyme levels, its product labeling, which was approved by the FDA in May 2007, contains the recommendation that periodic liver function tests be performed on patients taking ZYFLO CR. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO CR and any other zileuton product candidates that we successfully develop and commercialize, which could limit their commercial acceptance.

In March 2008, the FDA issued an early communication regarding an ongoing safety review of the leukotriene montelukast relating to suicide and other behavior-related adverse events. In that communication, the FDA stated that it was also reviewing the safety of other leukotriene medications. On May 27, 2008, we received a request from the FDA that we gather and provide to the FDA data from the clinical trial database to evaluate behavior-related adverse events for ZYFLO and ZYFLO CR. On January 13, 2009, the FDA announced that the company studies it reviewed do not show any association between these drugs that act through the leukotriene pathway (for example, montelukast, zafirlukast and zileuton) and suicide, although the FDA noted that these studies were not designed to detect those events. The FDA also reviewed clinical trial data to assess other mood-related and behavior-related adverse events related to such drugs. On April 23, 2009, the FDA requested that we add wording to the precaution section of the ZYFLO CR and ZYFLO labeling to include post-marketing reports of sleep disorders and neuropsychiatric events. It is our understanding that other leukotriene modulator manufacturers were asked to make

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similar changes. There is a risk that this labeling change may cause physicians and other members of the health care community to prefer competing products without such labeling over ZYFLO CR and ZYFLO, which would cause sales of these products to suffer.

Concerns regarding the potential toxicity and addictiveness of propoxyphene and the known liver toxicity of acetaminophen may limit market acceptance of our propoxyphene/acetaminophen products or cause the FDA to remove these products from the market.

Periodically, there is negative publicity related to the potential toxicity and addictiveness of propoxyphene. Propoxyphene is one of two APIs, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. For example, the consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. The FDA denied the citizen petition on July 7, 2009 stating that despite serious concerns about propoxyphene, the benefits of using the medication for pain relief outweighed its safety risks. However, the FDA is also requiring our propoxyphene/acetaminophen products, along with other propoxyphene products, to include additional labeling in the boxed warning to address the risk of overdose and to develop an FDA-approved medication guide that must be given to all patients who take our propoxyphene/acetaminophen products. There is a risk that this labeling change may cause physicians and other members of the health care community to prefer competing products without such labeling over the propoxyphene/acetaminophen products, which would cause sales of these products to suffer.

In December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. The FDA convened a public advisory committee meeting to discuss acetaminophen risk management in June 2009. The FDA could act on these concerns by changing its policies with respect to acetaminophen as a single ingredient and in combination with opioid products. While the docket for this meeting will remain open for comment until September 30, 2009, the FDA at any time could change policy which could adversely affect our ability to market our propoxyphene/acetaminophen products.

Our limited experience in obtaining regulatory approvals could delay, limit or prevent such approvals for our product candidates.

We have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this process. We acquired the rights to most of our currently marketed products and product candidates through four licensing transactions, two related to ZYFLO CR and ZYFLO in 2003 and 2004, respectively; one for the ALLERX Dose Pack products in February 2005; and one for SPECTRACEF in October 2006. In connection with our strategic transaction with Chiesi, Chiesi granted us the exclusive U.S. rights to distribute CUROSURF. Personnel who are no longer employed by us obtained approval to market ZYFLO and ZYFLO CR in the United States from the FDA in September 2005 and May 2007, respectively. The FDA approved our supplemental new drug application for SPECTRACEF 400 mg in July 2008, and we launched this product in October 2008. In July 2009, we filed a regulatory submission with the FDA for CRTX 067, an antitussive product. We do not have other experience gaining FDA approval of product candidates.

Our limited experience in this regard could delay or limit approval of our product candidates if we are unable to effectively manage the applicable regulatory process with either the FDA or foreign regulatory authorities. In addition, significant errors or ineffective management of the regulatory process could prevent approval of a product candidate, especially given the substantial discretion that the FDA and foreign regulatory authorities have in this process.

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 and our products 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

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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, or DDMAC, on May 4, 2009 relating to two sales aids that we formerly used to promote SPECTRACEF. The FDA asserted that the sales aids were misleading because they broadened the approved indication for SPECTRACEF, omitted risks related to its use, made unsubstantiated superiority claims, overstated the efficacy of SPECTRACEF and made misleading dosing claims. While we no longer use the sales aids reviewed by the FDA, in response to the warning letter, we initiated a review of all of our current SPECTRACEF promotional materials for deficiencies similar to those identified by the FDA in the warning letter to ensure that we take effective action to immediately cease and avoid the future dissemination of such deficient promotional materials. As requested by the FDA, we provided written responses to the FDA on May 18, 2009 and July 8, 2009. As part of our responses, we provided a description of our plan to disseminate corrective messages to the recipients of the deficient promotional materials. We plan to incorporate appropriate revisions into new SPECTRACEF promotional materials and to work with FDA s DDMAC to address their stated concerns. If we were to receive any additional warning letters, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions and other penalties, and our reputation in the market could be harmed.

The manufacturer and the manufacturing facilities used to make our products and product candidates are also subject to comprehensive regulatory requirements. The FDA periodically inspects sponsors, marketers and manufacturers for compliance with these requirements. Additional, potentially costly, requirements may apply to specific products as a condition of FDA approval or subsequent regulatory developments. For example, as part of the approval of the new drug application for ZYFLO CR in May 2007, the FDA required us to conduct a pediatric clinical trial of ZYFLO CR as a post-approval commitment and report the results to the FDA by June 2010. A waiver from this obligation was requested from the FDA on January 7, 2008, for which no response has been received. If we do not successfully begin and complete this clinical trial in the time required by the FDA, our ability to market and sell ZYFLO CR may be hindered, and our business may be harmed as a result.

On April 28, 2009, the FDA issued us a Notice of Inspectional Observations, or Form 483, in connection with an inspection of our ZYFLO CR regulatory procedures it conducted during April 2009. The Form 483 stated that our processes related to ZYFLO CR for review of batch specific documentation, analytical information, deviations and investigations prior to releasing finished product for distribution; our staffing levels relating to quality assurance and controls; and our late filing of a ZYFLO CR Field Alert Report are areas of possible non-compliance with FDA regulations. We responded to the FDA on May 7, 2009 and intend to take appropriate action to effectively address each of the observations identified by the FDA in the Form 483 as quickly as practicable.

If the FDA makes additional inspectional observations, 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:

- 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.

If we fail to manage successfully our product acquisitions, our ability to develop our product candidates and expand our product pipeline may be harmed.

Our failure to address adequately the financial, operational or legal risks of our product acquisitions or in-license arrangements could harm our business. These risks include:

the overuse of cash resources;

higher than anticipated acquisition costs and expenses;

potentially dilutive issuances of equity securities;

the incurrence of debt and contingent liabilities, impairment losses and/or restructuring charges;

the assumption of or exposure to unknown liabilities;

the development and integration of new products that could disrupt our business and occupy our management s time and attention;

the inability to preserve key suppliers or distributors of any acquired products; and

the acquisition of products that could substantially increase our amortization expenses.

If we are unable to successfully manage our product acquisitions, our ability to develop new products and expand our product pipeline may be limited, and we could suffer significant harm to our financial condition, results of operations and prospects.

For example, we have entered into a ten-year license and distribution agreement with Chiesi for CUROSURF. Even though CUROSURF is currently marketed in the United States, there can be no assurance that that our pre-acquisition due diligence identified all possible issues that may arise with respect to this product. In addition, Chiesi may face difficulties in transferring the product rights and product inventory to us from the current U.S. licensee. There is no assurance that the net sales of CUROSURF will be sufficient to offset the net income per share impact of increased amortization expense and the dilutive effect of the shares issued to Chiesi in the strategic transaction that closed on July 28, 2009.

If we are unable to attract, hire and retain qualified sales and marketing personnel, the commercial opportunity for our products and product candidates may be diminished.

We have built a commercial organization, consisting of our sales department, which includes our sales force and our sales management, sales logistics and sales administration personnel, as well as our marketing department. As of July 31, 2009, our sales force consists of 81 sales representatives. As part of our acquisition of the U.S. distribution rights for CUROSURF, we anticipate adding sales representatives and support staff dedicated to marketing and promoting the product. We may not be able to attract, hire, train and retain qualified sales and marketing personnel to augment our existing capabilities in the manner or on the timeframe that we plan. If we are unsuccessful in our efforts to expand our sales force and marketing capabilities, our ability to independently market and promote our products and any product candidates that we successfully bring to market will be impaired. In such an event, we would likely need to establish a collaboration, co-promotion, distribution or other similar arrangement to market and sell our products and product candidates. However, we might not be able to enter into such an arrangement on favorable

terms, if at all. Even if we are able to effectively expand our sales force and marketing capabilities, our sales force and marketing teams may not be successful in commercializing and promoting our products.

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The commercial success of our currently marketed products and any additional products that we successfully develop or bring to market depends on the degree of market acceptance by physicians, patients, health care payors and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, health care payors and others in the medical community. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be able to sustain or increase our profitability. The degree of market acceptance of our products, including our product candidates, if approved for commercial sale, will depend on a number of factors, including:

the prevalence and severity of the products side effects;

the efficacy and potential advantages of the products over alternative treatments;

the ability to offer the products for sale at competitive prices, including in relation to any generic or re-imported products or competing treatments;

the relative convenience and ease of administration of the products;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the perception by physicians and other members of the health care community of the safety and efficacy of the products and competing products;

the availability and level of third-party reimbursement for sales of the products;

the continued availability of adequate supplies of the products to meet demand;

the strength of marketing and distribution support;

any unfavorable publicity concerning us, our products or the markets for these products, such as information concerning product contamination or other safety issues in the markets for our products, whether or not directly involving our products;

regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products; and

changes in intellectual property protection available for the products or competing treatments.

We rely on third parties to market and promote some products, and these third parties may not successfully commercialize these products.

We may seek to enter into co-promotion arrangements to enhance our promotional efforts and, therefore, sales of our products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management support, we can reach health care providers in areas where we have limited or no sales force representation, thus expanding the reach of our sales and marketing programs.

We also seek to enter into co-promotion arrangements for the marketing of products that are not aligned with our respiratory focus and, therefore, are not promoted by our sales force. For example, in July 2007, Atley Pharmaceuticals began marketing and promoting BALACET 325 to pain specialists and other high prescribers of pain products through a co-promotion agreement. We rely on MedImmune, Inc., or MedImmune, a subsidiary of AstraZeneca PLC, for the commercialization of any of monoclonal antibodies directed toward a cytokine called HMGB1, which we believe may be an important target for the development of products to treat diseases mediated by

the body s inflammatory response, and we plan to rely on Beckman Coulter, Inc., or Beckman Coulter, for the commercialization of any diagnostic assay for HMGB1. We may not be successful in entering into additional

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marketing arrangements in the future and, even if successful, we may not be able to enter into these arrangements on terms that are favorable to us. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, our future revenues may suffer. We rely on DEY to jointly promote and market ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR in October 2007. Both DEY and we may terminate the co-promotion agreement on or after October 1, 2012 with six months prior written notice. DEY also has the right to terminate the co-promotion agreement upon two months prior written notice to us if in any two consecutive calendar quarters we are unable to deliver to DEY at least 75% of the ZYFLO CR samples forecast by DEY for such quarters, or if at any time commercial supplies of ZYFLO CR remain on back order for more than one calendar quarter. In addition, DEY has the right to terminate the co-promotion agreement after January 1, 2010 with two- months prior written notice if ZYFLO CR cumulative net sales for any four consecutive calendar quarters beginning on or after January 1, 2009 are less than $20.0 million. Both parties have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In particular, both parties have agreed to provide a minimum number of details per month for ZYFLO CR.

If DEY were to terminate or breach the co-promotion agreement, and we were unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promote and market ZYFLO CR, then our sales of ZYFLO CR would be limited and we would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. DEY is a subsidiary of Mylan Inc., or Mylan. Mylan acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic business, of which DEY was a part. We cannot predict what impact Mylan s acquisition of DEY may have on our co-promotion arrangement. Any decision by DEY or Mylan not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit our ability to generate significant revenues from product sales. Furthermore, if DEY does not have sufficient sales capabilities, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

We identified a material weakness in our internal control over financial reporting as of December 31, 2008, and we have not conducted the necessary testing to confirm that the measures we have taken have effectively remediated the material weakness. If we fail to achieve and maintain effective internal control over financial reporting and disclosure controls and procedures, we could face difficulties in preparing timely and accurate financial statements and periodic reports, which could result in a loss of investor confidence in the information that we report and a decline in our stock price, and could impair our ability to raise additional funds to the extent needed to meet our future capital requirements.

In connection with the preparation of our financial statements as of and for the year ended December 31, 2008, we identified a material weakness in our internal control over financial reporting as discussed in Item 9A(T), Controls and Procedures, of our annual report on Form 10-K for the year ended December 31, 2008. As discussed in Item 9A(T) of our annual report on Form 10-K for the year ended December 31, 2008 and Part I Item 4A(T). Controls and Procedures of our quarterly report on Form 10-Q for the three months ended March 31, 2009, as a result of this material weakness, our chief executive officer and chief financial officer concluded that, as of December 31, 2008 and March 31, 2009, respectively, our disclosure controls and procedures were not effective. As discussed above in Part I Item 4A(T). Controls and Procedures, we took actions during the three months ended June 30, 2009 that we believe are appropriate to remediate this material weakness but we have not conducted the necessary testing to confirm the material weakness has been effectively remediated. We or our independent registered public accounting firm may identify additional material weaknesses in our internal control over financial reporting in the future, including in connection with our management s ongoing assessment of our internal control over financial reporting, which is discussed in Item 9A(T) of our annual report on Form 10-K for the year ended December 31, 2008 and Part I Item 4A(T). Controls and Procedures of this quarterly report on Form 10-Q. Accordingly, our chief executive officer and chief financial officer concluded that, as of June 30, 2009, our disclosure controls and procedures were not effective.

Any failure or difficulties in promptly and effectively remediating our presently identified material weakness, or any material weaknesses that we or our independent registered public accounting firm may identify in the future,

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could result in our inability to prevent or detect material misstatements in our financial statements and cause us to fail to meet our periodic reporting obligations. As a result, our management may not be able to provide an unqualified assessment of our internal control over financial reporting as of December 31, 2009 or beyond, and our chief executive officer and chief financial officer may not be able to conclude, on a quarterly basis, that our disclosure controls and procedures are effective. In addition, our independent registered public accounting firm may not be able to provide an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2009 or beyond. Any material weakness, or any remediation thereof that is ultimately unsuccessful, could also cause investors to lose confidence in the accuracy and completeness of our financial statements and periodic reports, which in turn could harm our business, lead to a decline in our stock price and impair our ability to raise additional funds to the extent needed to meet our future capital requirements.

ITEM 2. ***UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS***

Recent Sales of Unregistered Securities; Uses of Proceeds From Registered Securities

On May 6, 2009, we entered into a series of agreements for a strategic transaction, subject to approval by our stockholders, with Chiesi, whereby we agreed to issue Chiesi approximately 12.2 million shares of our common stock, par value $0.001 per share, in exchange for $15.5 million in cash, an exclusive license for the U.S. commercial rights to CUROSURF and a two-year right of first offer on all drugs Chiesi intends to market in the United States. Our license agreement with Chiesi is for a ten-year initial term and thereafter will be automatically renewed for successive one-year renewal terms, unless earlier terminated by either party upon six months prior written notice.

On July 27, 2009, our stockholders approved our issuance of the shares at a special stockholders meeting, and the transaction closed on July 28, 2009. We believe that the offer and sale of the shares by us to Chiesi is exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving a public offering. Chiesi is a knowledgeable, sophisticated investor and had access to comprehensive information about us during an extensive due diligence process. In addition, Chiesi agreed to hold the shares for a minimum of 24 months, with certain exceptions.

ITEM 4. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

The following matters were submitted to a vote of our stockholders at our 2009 Annual Meeting of Stockholders held on May 28, 2009 and approved by the requisite vote of stockholders as follows:

1. To elect Christopher Codeanne and Michael Enright to our board of directors to serve as Class II directors, each for a term of three years.

	Number of Shares	
Nominee	For	Withheld
Christopher Codeanne	5,070,978	35,867
Michael Enright	4,973,415	133,430

2. To approve our 2004 Stock Incentive Plan, as amended and restated, to, among other things, increase the number of shares authorized for issuance under the 2004 Stock Incentive Plan, and increase the number of shares that may be granted to a participant in a calendar year.

	Number of Shares		
For	**Against**	**Abstain**	**Broker Non-Vote**
2,581,612	547,543	1,347	1,976,343

3. To ratify our Audit Committee s selection of Grant Thornton LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009.

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Number of Shares		
For	Against	Abstain
5,095,042	4,528	7,275

The number of shares of common stock eligible to vote as of the record date of March 30, 2009 was 6,823,935 shares.

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 11, 2009

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

Date: August 11, 2009

/s/ David Price
David Price
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Fourth Amended and Restated Bylaws of the Registrant dated July 28, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated July 27, 2009).
10.1	Stock Purchase Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 6, 2009; Exhibits A, B, C, D and E thereto incorporated by reference to Exhibits 10.9-10.14, 10.4, 10.3, 10.5 and 10.6, respectively, to the Registrant s Current Report on Form 8-K dated May 6, 2009; and Exhibit H thereto incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.2+	License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.3	Governance Agreement among the Registrant, Chiesi Farmaceutici S.p.A. and, solely with respect to the sections identified therein, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.4	Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.5	Amendment, dated June 26, 2009, to Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated June 26, 2009).
10.6	Registration Rights Agreement between the Registrant and Chiesi Farmaceutici S.p.A. dated May 6, 2009 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.7	Registration Rights Agreement among the Registrant, Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.8	Voting Agreement between the Registrant and Chiesi Farmaceutici S.p.A. dated May 6, 2009 (incorporated by reference to Exhibit 10.7 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.9	Voting Agreement among Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd., Lutz Family Limited Partnership, Brian Dickson, M.D., Joshua Franklin, David Price, Alan Roberts and, solely with respect to Section 2(b)

	thereof, the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.8 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.10+	Letter Amendment, dated June 12, 2009, to Manufacturing and Supply Agreement among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.11+	Amendment No. 1, dated June 16, 2009, to Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 16, 2009).
10.12+	Amendment No. 2, dated May 4, 2009, to Co-Promotion and Marketing Services Agreement between the Registrant and DEY, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009).
10.13	2004 Stock Incentive Plan of the Registrant (as Amended and Restated May 28, 2009) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 28, 2009).

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Exhibit No.	Description
10.14	First Amendment, dated June 18, 2009, to Executive Retention Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated February 8, 2006 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.15	Amended and Restated Executive Employment Agreement between the Registrant and Craig A. Collard dated May 6, 2009 (incorporated by reference to Exhibit 10.9 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.16	Severance Agreement and General Release between the Registrant and Chenyqua Baldwin dated May 7, 2009.
10.17	First Amendment, dated June 12, 2009, to Executive Employment Agreement between Cornerstone BioPharma, Inc. and Brian Dickson dated March 1, 2006 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.18	Amended and Restated Executive Employment Agreement between the Registrant and Brian Dickson dated May 6, 2009 (incorporated by reference to Exhibit 10.12 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.19	Amended and Restated Executive Employment Agreement between the Registrant and Joshua B. Franklin dated May 6, 2009 (incorporated by reference to Exhibit 10.13 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.20	First Amendment, dated June 12, 2009, to Executive Employment Agreement between Cornerstone BioPharma, Inc. and Steven M. Lutz dated March 1, 2006 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.21	Amended and Restated Executive Employment Agreement between the Registrant and Steven M. Lutz dated May 6, 2009 (incorporated by reference to Exhibit 10.10 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.22	Amended and Restated Executive Employment Agreement between the Registrant and David Price dated May 6, 2009 (incorporated by reference to Exhibit 10.11 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.23	Amendment No. 1 to Amended and Restated Executive Employment Agreement, dated June 26, 2009, between the Registrant and David Price (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated June 26, 2009).
10.24	First Amendment, dated June 12, 2009, to Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.25	Separation Letter Agreement and General Release between the Registrant and Scott B. Townsend dated June 5, 2009.

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.