CORNERSTONE THERAPEUTICS INC
Form 10-Q
May 07, 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 March 31, 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 *(Address of Principal Executive Offices)*	**27518** *(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 May 1, 2009, the registrant had 12,499,102 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 and risks relating to our ability to realize anticipated synergies and cost savings from our merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma; 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 obtain and maintain regulatory approvals to market and sell our products that 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 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 future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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ITEM 1. ***FINANCIAL STATEMENTS***

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

	March 31, 2009 (Unaudited)	December 31, 2008 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,736	$ 9,286
Marketable securities		300
Accounts receivable, net	16,981	13,660
Inventories, net	12,840	11,222
Prepaid expenses	1,985	1,081
Deferred income tax asset	2,839	2,428
Total current assets	45,381	37,977
Property and equipment, net	979	895
Product rights, net	17,191	17,702
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Deposits	46	46
Total assets	$ 76,866	$ 69,889
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 8,723	$ 10,288
Accrued expenses	20,088	19,052
Current portion of license agreement liability	2,654	2,543
Current portion of capital lease	9	
Income taxes payable	3,580	2,937
Total current liabilities	35,054	34,820
Long-term liabilities:		
License agreement liability, less current portion	2,313	2,313
Capital lease, less current portion	47	
Deferred income tax liability	3,457	3,330
Total long-term liabilities	5,817	5,643
Total liabilities	40,871	40,463
Commitments and contingencies, Note 11		
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; 12,023,747 shares issued and outstanding as of March 31, 2009 and December 31, 2008, respectively	12	12
Additional paid-in capital	33,773	33,519
Retained earnings / (accumulated deficit)	2,210	(4,105)
Total stockholders equity	35,995	29,426
Total liabilities and stockholders equity	$ 76,866	$ 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 March 31,	
	2009	**2008**
Net revenues	$ 30,705	$ 9,445
Costs and expenses:		
Cost of product sales (exclusive of amortization of product rights)	3,201	565
Sales and marketing	5,395	3,908
Royalties	6,291	1,245
General and administrative	3,760	1,523
Research and development	1,162	98
Amortization of product rights	511	739
Other charges	26	
Total costs and expenses	20,346	8,078
Income from operations	10,359	1,367
Other expenses:		
Interest expense, net	(72)	(379)
Total other expenses	(72)	(379)
Income before income taxes	10,287	988
Provision for income taxes	(3,972)	(319)
Net income	$ 6,315	$ 669
Net income per share, basic	$ 0.53	$ 0.11
Net income per share, diluted	$ 0.48	$ 0.10
Weighted-average common shares, basic	12,023,747	5,934,496
Weighted-average common shares, diluted	13,114,505	6,837,122

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)

	Three Months Ended March 31,	
	2009	**2008**
Cash flows from operating activities		
Net income	$ 6,315	$ 669
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	564	758
Change in allowance for prompt payment discounts	63	15
Change in allowance for inventory obsolescence	77	(32)
Stock-based compensation	254	84
Benefit for deferred income taxes	(284)	
Changes in operating assets and liabilities:		
Accounts receivable	(3,384)	609
Inventories	(1,695)	(824)
Prepaid expenses	(904)	(169)
Accounts payable	(1,565)	(5)
Accrued expenses	1,147	807
Income taxes payable	643	281
Net cash provided by operating activities	1,231	2,193
Cash flows from investing activities		
Advances to related parties		(13)
Proceeds from sale of marketable securities	300	
Purchase of property and equipment	(79)	(15)
Purchase of product rights		(1,000)
Collection of deposits		10
Net cash provided by / (used in) investing activities	221	(1,018)
Cash flows from financing activities		
Proceeds from line of credit		4,000
Principal payments on line of credit		(5,000)
Principal payments on capital lease obligation	(2)	
Net cash used in financing activities	(2)	(1,000)
Net increase in cash and cash equivalents	1,450	175
Cash and cash equivalents as of beginning of period	9,286	241
Cash and cash equivalents as of end of period	$ 10,736	$ 416
Supplemental disclosure of cash flow information		

Cash paid during the period for interest	$	3	$	24
Cash paid during the period for income taxes	$	3,613	$	38
Supplemental schedule of non-cash investing and financing activities				
Purchase of equipment under capital lease obligation	$	58	$	

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 market. Key elements of the Company s strategy are to in-license or acquire rights to under-promoted, patent-protected, branded respiratory 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 market; and maintain and strengthen the intellectual property position of the Company s currently marketed products, newly acquired products and product candidates.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc., a Delaware corporation, and its wholly owned subsidiaries: Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma), a Delaware corporation; Cornerstone BioPharma, Inc., a Nevada corporation; Aristos Pharmaceuticals, Inc., a Delaware corporation; and CTI Securities Corporation, a Massachusetts corporation. 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, which was filed with the Securities and Exchange Commission on March 26, 2009.

CTI Securities Corporation was dissolved effective December 31, 2008. All significant intercompany accounts and transactions have been eliminated in consolidation.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

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 various financial institutions and are monitored against the Company s investment policy, which limits concentrations of investments in individual securities and issuers.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from 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 months ended March 31, 2009 and 2008, and all customers that comprise more than 10% of total accounts receivable and such customers aggregate percentage of the Company s total

accounts receivable as of March 31, 2009 and December 31, 2008:

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	Three months ended March 31,	
	2009 Gross Product Sales	2008 Gross Product Sales
Cardinal Health, Inc.	36%	31%
McKesson Corporation	34%	44%
Amerisource Bergen Drug Corporation	16%	17%
Total	86%	92%

	March 31, 2009 Accounts Receivable	December 31, 2008 Accounts Receivable
Cardinal Health, Inc.	39%	35%
McKesson Corporation	29%	32%
Amerisource Bergen Drug Corporation	9%	16%
Total	77%	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 federally insured banks that may at times exceed federally insured limits. As of March 31, 2009 and December 31, 2008, the Company had balances of $0 and $1.3 million, respectively, in excess of federally insured limits.

Marketable Securities

Marketable securities as of December 31, 2008 consisted primarily of auction rate securities. The auction rate securities are of investment-grade quality and have an original maturity date greater than 90 days and can 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 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 March 31, 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 periods ending March 31, 2009 or March 31, 2008.

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

	March 31, 2009	December 31, 2008
Trade accounts receivable	$ 16,534	$ 13,289
Royalties receivable	134	427
Other receivables	678	246
Total accounts receivable	17,346	13,962
Less allowance for prompt payment discounts	(365)	(302)
Accounts receivable, net	$ 16,981	$ 13,660

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 net trade inventories as of March 31, 2009 and December 31, 2008 (in thousands):

		March 31, 2009	December 31, 2008
Raw materials		$ 7,508	$ 6,393
Work in process		1,540	1,832
Finished goods:			
Pharmaceutical products	trade	3,472	3,182
Pharmaceutical products	samples	1,074	492
Total		13,594	11,899
Inventory allowances		(754)	(677)
Inventories, net		$ 12,840	$ 11,222

Property and Equipment

The Company records property and equipment at cost. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred. The Company depreciates its property and equipment over the estimated useful lives of the assets ranging from three to seven years using the straight-line method. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lives of the underlying leases. Amortization expense for leasehold improvements has been included in depreciation expense in these consolidated financial statements.

The following table represents property and equipment as of March 31, 2009 and December 31, 2008 (in thousands):

	Useful Life (Years)	March 31, 2009	December 31, 2008
Computers and software	3 5	$ 398	$ 365
Machinery and equipment	3 7	193	113
Furniture and fixtures	5 7	533	523
Leasehold improvements	Lesser of lease term or 7	96	82
Total		1,220	1,083
Less accumulated depreciation		(241)	(188)
Property and equipment, net		$ 979	$ 895

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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 March 31,	
	2009	2008
Gross product sales	$ 38,912	$ 10,470
Sales allowances	(8,443)	(1,470)
Net product sales	30,469	9,000
Royalty agreement revenue	236	445
Net revenues	$ 30,705	$ 9,445

New Accounting Pronouncements

In April 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position Financial Accounting Standard (FSP FAS) 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). In developing assumptions about renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for entity-specific factors. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The adoption of FSP FAS 142-3 on January 1, 2009 did not have a material impact on the Company s consolidated financial statements.

In November 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF 07-1 on January 1, 2009 did not have a material impact on the Company s consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141(R)). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations* (SFAS 141), some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination so that users of the entity s financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008. The provisions of SFAS 141(R) will impact the Company s financial statements if the Company is a party to a business combination on or after January 1, 2009. In addition, for periods beginning on or after January 1, 2009, SFAS 141(R) requires the Company to report the impact of certain adjustments to valuation allowances on deferred tax assets acquired in business combinations occurring prior to January 1, 2009 as adjustments to income tax expense rather than as adjustments to goodwill.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160). SFAS 160 requires entities to report non-controlling minority

interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. The adoption of SFAS 160 on January 1, 2009 did not have a material impact on the Company s consolidated financial statements.

NOTE 3: MERGER

On October 31, 2008, the Company completed the merger whereby the Company, which was then known as Critical Therapeutics, Inc. (Critical Therapeutics), merged (through a transitory subsidiary) with Cornerstone BioPharma (the Merger), which was accounted for in accordance with SFAS 141. The Company s reasons for the Merger included, among other things, the following considerations: the opportunity to expand the Company 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 accounted for as a reverse acquisition in accordance with GAAP. Accordingly, Critical Therapeutics assets and liabilities were recorded as of the Merger closing date at their estimated fair values.

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A summary of the purchase price is as follows (in thousands):

Fair value of Critical Therapeutics shares outstanding	$ 23,479
Acquiring company transaction costs incurred	1,753
Purchase price	$ 25,232

Under the purchase method of accounting, the total purchase price is allocated to the 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 is allocated to goodwill.

The allocation of the total purchase price, as shown above, to the 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 are as follows (in thousands):

Cash and cash equivalents	$ 3,871
Accounts receivable	2,302
Inventory	6,300
Prepaid expenses and other current assets	701
Fixed assets	315
Other assets	40
Intangible assets:	
Product rights	11,500
Acquired in-process research and development	1,900
Goodwill	13,231
Assumed liabilities	(14,928)
Total	$ 25,232

The amount allocated to acquired inventory has been attributed to the following categories (in thousands):

Raw materials	$ 5,314
Work in process	393
Finished goods	593
Total	$ 6,300

In accordance with SFAS 141, the estimated fair value of raw materials was determined based on their replacement cost. The estimated fair values of work in process and finished goods were determined by estimating the selling prices of those goods less the costs of disposal, a reasonable profit allowance and, with respect to work in process, the costs of completion.

The amount allocated to acquired identifiable intangible assets has been attributed to the following categories (in thousands):

ZYFLO CR® product rights	$ 11,500
Alpha-7 program	1,900
Total	$ 13,400

The estimated fair value attributed to the ZYFLO CR product rights was determined based on a discounted forecast of the estimated net future cash flows to be generated from the ZYFLO CR product rights and is estimated to have a 7.2 year useful life from the closing date of the Merger.

The amount allocated to in-process research and development for the alpha-7 program represents an estimate of the fair value of purchased in-process technology for this research program that, as of the closing date of the Merger, had not reached technological feasibility and had no alternative future use. The alpha-7 program is the only Critical Therapeutics research program that had advanced to a stage of development where management believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed.

The estimated fair value of in-process research and development related to the alpha-7 program was determined based on a discounted forecast of the estimated net future royalties from the anticipated out- licensing of this program considering the estimated probability of technical success and Food and Drug Administration (FDA) approval. Following the closing of the Merger, the amount allocated to the alpha-7 program was immediately charged to research and development expenses.

NOTE 4: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance as of March 31, 2009 and December 31, 2008 was $13.2 million and relates to the Merger. No amount of the goodwill balance at March 31, 2009 will be deductible for income tax purposes.

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Intangible Assets

The following table represents intangible assets as of March 31, 2009 and December 31, 2008 (in thousands):

	March 31, 2009	December 31, 2008
Product rights	$ 26,730	$ 26,730
Less accumulated amortization	(9,539)	(9,028)
Product rights net	$ 17,191	$ 17,702

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of March 31, 2009, ranged from seven to nine years. As of March 31, 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 six years. Amortization expense for the quarters ended March 31, 2009 and 2008 was $511,000 and $739,000, respectively.

Future estimated amortization expense (excluding the rights related to products expected to be launched) subsequent to March 31, 2009 is as follows (in thousands):

2009	$ 1,531
2010	2,042
2011	2,031
2012	2,025
2013	2,025
Thereafter	4,437
	$ 14,091

NOTE 5: LINE OF CREDIT

In April 2005, the Company obtained financing under a bank line of credit for up to $4.0 million. Interest is due monthly with all outstanding principal and interest due on maturity. The initial maturity of the line of credit was April 2006 and thereafter was successively renewed on an annual basis on each maturity date. Amounts outstanding under the line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 3.25% as of March 31, 2009.

Because the Company s borrowing base under the line of credit exceeded $4.0 million as of March 31, 2009 and December 31, 2008, the full amount of the line of credit was available for borrowings and the issuance of letters of credit on each of these dates. As of March 31, 2009, 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 6: STOCK-BASED COMPENSATION

Stock Option Activity

The following table summarizes the Company s stock option activity during the quarter ended March 31, 2009 under all of the Company s stock-based compensation plans:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2009	2,437,572	$ 5.45
Granted		
Forfeited	(83,672)	4.14
Expired	(182,153)	39.54
Outstanding at March 31, 2009	2,171,747	2.64
Vested or expected to vest at March 31, 2009	2,155,588	2.64
Exercisable March 31, 2009	1,255,031	$ 2.77

There were no options issued or exercised during the three months ended March 31, 2009.

As of March 31, 2009, the aggregate intrinsic value of options outstanding and exercisable was $5.2 million and $3.5 million, respectively. As of March 31, 2008, the aggregate intrinsic value of options outstanding and exercisable was $1.8 million and $1.1 million, respectively.

As of March 31, 2009 and 2008, there was approximately $1.6 million and $1.0 million, respectively, of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.19 and 2.84 years, respectively.

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Restricted Stock Activity

As of March 31, 2009 and 2008, there were 475,355 and 51,039 restricted common shares outstanding, respectively.

There were no issuances or vesting of restricted stock during the three months ended March 31, 2009 and 2008.

As of March 31, 2009 and 2008, the intrinsic value of the restricted stock outstanding was $1.9 million and $143,000, respectively.

As of March 31, 2009, there was approximately $1.6 million of total unrecognized compensation cost related to unvested restricted stock issued under the Company s equity compensation plans, which is expected to be recognized over a weighted-average period of 3.32 years.

Stock-Based Compensation Expense

During the three months ended March 31, 2009 and 2008, the Company recorded approximately $252,000 and $81,000 in employee stock-based compensation expense and $2,000 and $3,000 in non-employee stock-based compensation expense, respectively, based on the total grant date fair value of shares vested. During the three months ended March 31, 2009, $253,000 and $1,000 of the stock-based compensation expense was charged against general and administrative and sales and marketing costs, respectively. During the three months ended March 31, 2008, $62,000 and $22,000 of the stock-based compensation expense was charged against general and administrative and sales and marketing costs, respectively.

NOTE 7: NET INCOME PER SHARE

The Company computes net income per share in accordance with SFAS No. 128, *Earnings per Share* (SFAS 128). Under the provisions of SFAS 128, basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding. 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 then outstanding. 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 reconciles the numerator and denominator used to calculate diluted net income per share (in thousands, except share data):

	Three Months Ended March 31,	
	2009	**2008**
Numerator:		
Net income	$ 6,315	$ 669
Denominator:		
Weighted-average common shares, basic	12,023,747	5,934,496
Dilutive effect of stock options, warrants and restricted stock	1,090,758	902,626
Weighted-average common shares, diluted	13,114,505	6,837,122

For the three months ended March 31, 2009 and 2008, there were 390,024 and zero, respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive.

NOTE 8: LEASES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles under non-cancelable leases expiring at various dates through 2016. Rent expense was $208,000 and $129,000 for the three months ended March 31, 2009 and 2008, respectively.

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Future minimum aggregate payments under non-cancelable lease obligations as of March 31, 2009 are as follows (in thousands):

Year Ending	Operating Leases	Capital Leases
2009	$ 456	$ 12
2010	377	15
2011	348	15
2012	343	15
2013	383	15
Thereafter	976	2
Total minimum lease payments	$ 2,883	74
Less amount representing interest		(18)
Present value of future minimum lease payments		56
Less current portion		(9)
Long-term portion		$ 47

NOTE 9: ACCRUED EXPENSES

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

	March 31, 2009	December 31, 2008
Accrued product returns	$ 6,161	$ 5,043
Accrued rebates	1,266	884
Accrued price adjustments and chargebacks	4,661	4,307
Accrued compensation and benefits	1,491	2,507
Accrued royalties	6,375	6,259
Accrued expenses, other	134	52
Total accrued expenses	$ 20,088	$ 19,052

NOTE 10: INCOME TAXES

As discussed in Note 1, the Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc., Cornerstone BioPharma, Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc.

SFAS No. 109, *Accounting for Income Taxes* and APB Opinion No. 28, *Interim Financial Reporting* generally require that for interim periods results of operations are to be computed using an effective tax rate method that requires estimates of annual ordinary income and other tax preference items.

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The provision for income taxes includes the following (in thousands):

	Three Months Ended March 31,	
	2009	2008
Current:		
Federal	$ 3,679	$ 260
State	577	59
Total	4,256	319
Deferred:		
Federal	(252)	
State	(32)	
Total	(284)	
Total tax provision	$ 3,972	$ 319

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets as of March 31, 2009 and December 31, 2008 are as follows (in thousands):

	March 31, 2009	December 31, 2008
Current:		
Deferred tax assets:		
Accounts receivable, net	$ 141	$ 116
Inventories, net	397	400
Accrued expenses	2,931	2,542
Total current deferred tax assets	3,469	3,058
Deferred tax liabilities:		
Acquired intellectual property	(630)	(630)
Net current deferred tax assets	$ 2,839	$ 2,428
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	$ 61,610	$ 61,888
Deferred compensation	259	293
Product license rights, net	280	315
Tax credits	1,900	1,900
Valuation allowance	(63,510)	(63,788)
Total noncurrent deferred tax assets	539	608

Deferred tax liabilities:		
Acquired intellectual property	(3,783)	(3,783)
Property and equipment, net	(213)	(155)
Total noncurrent deferred tax liabilities	(3,996)	(3,938)
Net deferred tax liability noncurrent	(3,457)	(3,330)
Total net deferred tax liability	$ (618)	$ (902)

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Income taxes computed at the statutory federal income tax rate of 35% are reconciled to the provision for income taxes as follows:

	Three Months Ended March 31	
	2009	2008
United States federal tax at statutory rate	$ 3,498	$ 336
State taxes (net of federal benefit)	451	42
Nondeductible expenses	104	66
Other	197	(34)
Decrease in valuation allowance	(278)	(91)
Provision for income taxes	$ 3,972	$ 319

The Company s acquisition of Critical Therapeutics in 2008 resulted in certain additional deferred tax assets, including assets from federal net operating loss carryforwards (NOLs), state net economic loss carryforwards (NELs), and federal tax credits. The Company determined that it was more likely than not that utilization of these assets would not occur. This determination was based on the limitations on the utilization of NOLs and tax credits imposed by Section 382 and 383, respectively, of the Internal Revenue Code (the Code). Sections 382 and 383 of the Code impose limitations on a corporation s ability to utilize its NOLs and tax credits, respectively, if it experiences an ownership change. Therefore, the $63.5 million of deferred tax assets resulting from these NOLs and tax credits are offset by a full valuation allowance. The reversal of the valuation allowance that relates to the Company s use of these deferred tax assets for the period ended March 31, 2009 was recorded as a reduction of tax expense.

As of March 31, 2009, the Company has federal NOLs of approximately $162.2 million that begin to expire in the year 2021, state NEL s of approximately $154.0 million that begin to expire in 2009 and federal tax credits of approximately $1.9 million that begin to expire in 2021. The Company maintains a valuation allowance with respect to the entire amount of these loss carryforwards and tax credit carryforwards.

Critical Therapeutics filed Form 3115 as an attachment to its 2007 tax return, a period that preceded the date of acquisition by the Company. This filing requested a change in Critical Therapeutics method of accounting, for tax purposes only, of the cost of certain acquired intangible assets. The Company, as the successor to Critical Therapeutics, could be impacted by the requested change, if granted. The requested change would result in capitalization of certain previously-deducted costs, with subsequent amortization of the amounts so capitalized. The initial adjustment would be reflected as an increase to taxable income over four taxable years, including periods of less than one year. The filing required permission from the Internal Revenue Service and a signed agreement from the taxpayer indicating receipt of that permission prior to the taxpayer reflecting the change for tax purposes; this permission has not been received by the Company or acknowledged by the Company. Accordingly, the Company has not reflected any impact from the requested change in its results of operations.

NOTE 11: COMMITMENTS AND CONTINGENCIES

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.

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

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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 and expects to do so in the year ending December 31, 2009.

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 identify 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 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. 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. The required minimum annual royalty for the year ended December 31, 2008 was paid by Critical Therapeutics prior to the completion of the merger.

Supply Agreements

Concentrations

The Company purchases inventory from pharmaceutical manufacturers. During the three months ended March 31, 2009, two vendors accounted for 59% of the Company s inventory purchases. During the three months ended March 31, 2008, one vendor accounted for 39% of the Company s inventory purchases. Three vendors accounted for 24% and 25% of the Company s accounts payable as of March 31, 2009 and December 31, 2008, respectively. As of March 31, 2009 and December 31, 2008, the Company had outstanding purchase orders related to inventory totaling approximately $7.3 million and $4.3 million, respectively.

Vintage

The Company has entered into an agreement with Vintage Pharmaceuticals, LLC (Vintage) to exclusively manufacture BALACET® 325, 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.

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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 manufacture 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 Company expects to exceed the minimum purchase requirements. 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.

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 agreement. The agreement s current term extends to September 15, 2009, 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.

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

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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.

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.

Other Co-promotion Agreements

In February 2006, the Company signed a co-promotion agreement with Ascend Therapeutics, Inc. (Ascend) to provide detailing of a product to a specific physician population. As compensation, the Company paid a fee for detailing the product equal to 50% of net sales. This agreement was terminated in March 2008 at no additional cost to the Company.

In March 2007 and June 2007, the Company entered into co-promotion agreements, as amended, with SJ Pharmaceuticals, LLC (SJ Pharmaceuticals) to co-promote the Company s ALLERX® Dose Pack products and SPECTRACEF products, respectively. Under these agreements, the Company pays SJ Pharmaceuticals fees based on a percentage of the net profits of the products sold above a specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. The Company terminated its ALLERX Dose Pack co-promotion agreement with SJ Pharmaceuticals effective December 31, 2008. In connection with that termination, the Company is obligated to pay SJ Pharmaceuticals a termination fee on a quarterly basis for six months following termination equal to the average amount paid per month during the final six months preceding the termination date. The Company recorded the entire amount of the termination fee in accrued expenses in the accompanying consolidated balance sheet as of December 31, 2008. On February 25, 2009, SJ Pharmaceuticals terminated the SPECTRACEF co-promotion agreement effective April 24, 2009. Neither SJ Pharmaceuticals nor the Company is required to pay the other party any termination fee in connection with the termination.

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. Like the ALLERX Dose Packs co-promotion agreement with SJ Pharmaceuticals that the Company terminated, the Company s co-promotion agreement with Atley Pharmaceuticals is subject to sunset fees that requires the Company to pay additional fees for up to one year in the event of certain defined terminations of the agreement.

Settlements

Adams Respiratory Therapeutics, Inc.

In October 2004, the Company and a related party, Carolina Pharmaceuticals, Inc., were named as co-defendants in litigation brought by Adams Respiratory Therapeutics, Inc. (Adams) that alleged trademark infringement, false advertising and unfair competition claims and sought damages and injunctive relief. The Company vigorously defended these allegations and filed various counterclaims. In January 2005, Adams and the Company entered into an agreement under which in February 2005 the Company received all of the rights to the ALLERX products held by Adams and Adams received all of the rights to the Humibid® family of products held by the Company. Additionally, the parties released each other from all claims and damages in the above mentioned lawsuit. The agreement required the Company to assume the financial responsibility for the first $1.0 million of returned Humibid product that was sold by the Company prior to February 15, 2005 and returned to Adams during the 18-month period beginning February 15, 2005. Conversely, Adams was financially responsible for the first $1.0 million of ALLERX product returns for the same 18-month period. After the 18-month period or the $1.0 million threshold is met, the agreement provided that Adams would have the responsibility for all Humibid product returns whether sold by the Company or Adams. In connection with this agreement, Adams is obligated to pay the Company a royalty ranging from 1% to 2% of net Humibid sales for a period of three years after February 15, 2005 with a minimum annual royalty of $50,000.

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In 2006, a major wholesaler indicated that it was in possession of a significant amount of Humibid prescription inventory. Adams filed a complaint alleging that the Company and Carolina Pharmaceuticals, Inc. did not disclose the outstanding inventory in accordance with the prior agreement and are therefore financially responsible for the returns. The Company and Carolina Pharmaceuticals, Inc. believed they were not liable for these returns under the agreement and filed a counterclaim. Since all Humibid prescription products were sold by Carolina Pharmaceuticals, Inc., the Company did not accrue any amounts related to this claim.

In May 2008, the Company settled the dispute with Adams. The agreement provides that all parties to the settlement are to be released from all legal claims made prior to January 2008 and that the Company and Carolina Pharmaceuticals, Inc. would pay to Reckitt Benckiser Inc., the parent of Adams, $1.5 million in three installments to be paid as follows: $500,000 by June 20, 2008; $500,000 by June 30, 2008; and $500,000 by September 30, 2008. In exchange, the Company is released from all liabilities. All amounts were paid by September 30, 2008 as required. The Company paid $290,000 of the final $500,000 installment and the balance of $210,000 was paid by Carolina Pharmaceuticals, Inc.

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 has concluded that valid arguments exist for distinguishing the claims of the Company s patents over the references cited in the requests for re-examination.

In an unrelated action, another pharmaceutical company filed suit in November 2008 against the Company in the U.S. District Court for the District of Maryland seeking, among other things, a declaratory judgment that the second patent is invalid. Because no monetary relief has been requested in this action, no amount has been accrued in these consolidated financial statements. In cooperation with the licensor, the Company intends to vigorously defend against the declaratory judgment claim and to vigorously pursue appropriate counterclaims.

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its then current directors in the Court of Chancery of the State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George*, Case No. 4039, Court of Chancery, State of Delaware. The plaintiff, which claimed to be one of Critical Therapeutics stockholders, brought the lawsuit on its own behalf, and sought certification of the lawsuit as a class action on behalf of all of Critical Therapeutics then current stockholders, except the defendants and their affiliates. The complaint alleged, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint sought, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they then existed, (ii) invalidating the provisions of the proposed merger that purportedly improperly limited the effective exercise of the defendants continuing fiduciary duties, (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties, (iv) in the event the proposed merger was consummated, rescinding it and setting it aside or awarding rescissory damages, (v) awarding compensatory damages against defendants, jointly and severally, and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, Critical Therapeutics and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that Critical Therapeutics would make certain additional disclosures to Critical Therapeutics stockholders, which are contained in a supplement to the proxy statement/prospectus that was mailed to Critical Therapeutics stockholders. After the completion of certain confirmatory discovery by counsel to the plaintiff, as contemplated by the memorandum of understanding, the parties entered into a stipulation and agreement of compromise, settlement and release on November 24, 2008. On December 3, 2008, the court entered a scheduling order preliminarily approving class treatment of the case and setting a briefing and hearing schedule to consider the proposed settlement of the case. On December 23, 2008, the Company caused a court-approved notice of pendency of class action, proposed class action determination, proposed settlement of class action, settlement hearing and right to appear to be mailed to all persons that held Critical Therapeutics stock during the period May 1, 2008 through October 31, 2008, other than the defendants and their affiliates. On February 26, 2009, the court approved the settlement resolving all of the claims that were or could have been brought in the action being settled, including all claims relating to the Merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the court awarded plaintiff s counsel $175,000 for attorneys fees and expenses to be paid by the Company, which was accrued as of December 31, 2008.

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Product 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 March 31, 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.

As of March 31, 2009, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $1.5 million.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments ranging from three to 24 months of salary, benefits and, with respect to certain executives, bonuses, upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. No amount has been accrued for severance as of March 31, 2009 or 2008.

NOTE 12: SUBSEQUENT EVENTS

On May 6, 2009, the Company entered into a series of agreements for a strategic transaction, which is subject to approval by the Company s stockholders, with Chiesi Farmaceutici SpA (Chiesi) whereby the Company will receive gross proceeds of $15.5 million in cash, an exclusive license for the U.S. commercial rights to Chiesi s CUROSURF® product and a right of first offer on all drugs Chiesi intends to market in the United States. The Company s license agreement with Chiesi, which includes the right of first offer, 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. Pursuant to this transaction, the Company will issue to Chiesi 11.9 million shares of common stock. Additionally, the Company s president and chief executive officer and its executive vice president of manufacturing and trade have 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 will enter into lockup and right of first refusal agreements with Chiesi with respect to their shares of common stock in the Company and will be entitled to receive certain equity incentives from the Company.

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 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 Risk Factors in Part II, Item 1A of this quarterly report on Form 10-Q.

Overview

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 market. Our commercial strategy is to in-license or acquire rights to non-promoted or underperforming, patent-protected, branded pharmaceutical products, or late stage product candidates, and then maximize their potential value and competitive position by promoting the products using our sales and marketing capabilities and applying various life cycle management techniques to extend the period we can sell the product and related derivative products. We currently market our products only in the United States.

On October 31, 2008, Critical Therapeutics, Inc., or Critical Therapeutics, and 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. Following the closing of the merger, former Cornerstone BioPharma stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of our common stock, after giving effect to shares issuable pursuant to outstanding options and warrants held by Cornerstone BioPharma s stockholders immediately prior to the effective time of the merger, but without giving effect to any shares issuable pursuant to options and warrants held by Critical Therapeutics stockholders immediately prior to the effective time of the merger. 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.

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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. 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 and DECONSAL® have generated the most net revenues to date for us. Of our marketed products that we do not promote, only our BALACET 325 and APAP 325 products 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 generic 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 relating to APAP 500. Under this agreement, which we terminated effective December 31, 2008, Pliva sold APAP 500 that was 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 determine 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.

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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.

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, for the three months ended March 31, 2009, we have continued to incur additional legal, accounting and related costs relating to our October 2008 merger.

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.

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Critical Accounting Estimates

Management s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements requires our management to make estimates and assumptions that affect our reported assets and liabilities, revenues and expenses and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on our financial condition or operating performance is material.

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2008. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We believe that our estimates relating to revenue recognition, product rights, inventory, accrued expenses and stock-based compensation described below fit the definition of critical accounting estimates.

Revenue Recognition

Net Product Sales

Product Sales. We recognize revenue from our product sales in accordance with Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists*, or SFAS 48, upon transfer of title, which occurs when product is received by our customers. We sell our products primarily to large national wholesalers, which have the right to return the products they purchase. Under SFAS 48, we are required to reasonably estimate the amount of future returns at the time of revenue recognition. We recognize product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts.

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

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

Price Adjustments and Chargebacks. Our estimates of price adjustments and chargebacks are based on our estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the listed prices of our products. We make these judgments based on the facts and circumstances known to us in accordance with GAAP. In the event that the sales mix to third-party payors is different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we have estimated.

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Special Promotional Programs. From time to time, we offer certain promotional incentives to our customers for our products, and we expect that we will continue this practice in the future. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. We account for these programs in accordance with Emerging Issues Task Force, or EITF, Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. We have initiated three voucher programs for SPECTRACEF whereby we offer a point-of-sale subsidy to retail consumers. We estimate our liability for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to us by a third-party claims processing organization and actual redemption rates for our completed programs. The first program expired on December 31, 2008. The second and third programs are still ongoing, and we have no present intention to cancel these programs. We account for the costs of these special promotional programs as price adjustments.

Prompt Payment Discounts. We typically require customers of branded and generic products to remit payments within 31 days and 61 days, respectively. In addition, we offer wholesale distributors a prompt payment discount as an incentive to remit payment within the first 30 days after the date of our invoice for branded products and 60 days after the date of our invoice 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 our wholesale distributors typically take the prompt payment discount, we accrue 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. We do not anticipate that future changes to our estimates of prompt payment discounts will have a material impact on our net revenue.

The following table provides a summary of activity with respect to our sales allowances (in thousands):

	Product Returns	Rebates	Price Adjustments and Chargebacks	Prompt Payment Discounts
Balance at December 31, 2008	$ 5,043	$ 884	$ 4,307	$ 302
Current provision related to sales in current period	1,931	790	4,029	827
Current provision related to sales made in prior periods	865			
Payments and credits	(1,678)	(408)	(3,675)	(764)
Balance at March 31, 2009	$ 6,161	$ 1,266	$ 4,661	$ 365

Expense recognized for product returns was $2.8 million and $1.1 million for the three months ended March 31, 2009 and 2008, respectively, representing 7% and 10% of gross product sales for the three months ended March 31, 2009 and 2008, respectively. Expense recognized for product returns related to current period provisions were $1.9 million for the three months ended March 31, 2009, or 5% of gross product sales. Expense recognized for product returns related to changes in estimates prior to the three months ended March 31, 2009 were $865,000 million and related primarily to product returns of ZYFLO CR and SPECTRACEF.

Expense recognized for rebates was $790,000 and $101,000 in for the three months ended March 31, 2009 and 2008, respectively, representing approximately 2% and 1% of gross product sales for the three months ended March 31, 2009 and 2008, respectively. The increase in rebates is primarily due to the overall increase in sales and our entry into additional supplemental Medicaid rebate programs after March 31, 2008.

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Expense recognized for price adjustments and chargebacks was $4.0 million and $104,000 for the three months ended March 31, 2009 and 2008, respectively, representing approximately 10% and 1% of gross product sales for the three months ended March 31, 2009 and 2008, respectively. This increase was primarily due to $1.4 million and $1.6 million of increases in price adjustments and chargebacks, respectively, related to the launch of our generic products, which typically have higher levels of price adjustments and chargebacks than branded products. Price adjustments were also increased by $866,000 due to the costs of additional SPECTRACEF point-of-sale voucher programs for retail customers that we launched after July 31, 2008 and by $106,000 due to increases in price adjustments and chargebacks related to our branded products.

Expense recognized for prompt payment discounts was $827,000 and $201,000 for the three months ended March 31, 2009 and 2008, respectively, representing approximately 2%of gross product sales for each of the quarters ended March 31, 2009 and 2008.

Royalty Agreement Revenues

We receive royalties under license agreements with a number of third parties that sell products to which we have rights. The license agreements provide for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensees and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. We maintain regular communication with our licensees to gauge the reasonableness of our estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

Product Rights

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins. We evaluate our product rights annually to determine whether a revision to their useful lives should be made. This evaluation is based on our management s projection of the future cash flows associated with the products. At March 31, 2009, we had an aggregate of $17.2 million in capitalized product rights, which we expect to amortize over a period of seven to fourteen years.

Inventory

Inventory consists 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. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and write 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. As of March 31, 2009, we had $13.6 million in inventory and an inventory reserve of $754,000. The inventory reserve includes provisions for inventory that management believes will become short-dated before being sold. Short-dated inventory is inventory that has not expired yet, but which wholesalers or pharmacies refuse to purchase because of its near-term expiration date.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate certain expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in our

consolidated financial statements. Examples of estimated expenses for which we accrue include product development expenses; reserves for product returns; rebates to third parties, including private insurers and government programs such as Medicaid; royalties owed to third-parties on sales of products; interest owed on debt instruments; and compensation and benefits for employees.

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Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the prospective application method, which requires us to recognize compensation cost for all awards granted or modified after January 1, 2006. Awards outstanding at January 1, 2006 continue to be accounted for using the accounting principles originally applied to the award. The expense associated with stock-based compensation is recognized on a straight-line basis over the service period of each award.

Prior to the adoption of SFAS 123(R), we recognized employee stock-based compensation expense using the intrinsic value method, which measures stock-based compensation expense as the amount at which the market price of the stock at the date of grant exceeds the exercise price. Because the exercise price for options awarded to employees is equal to the fair value at the grant date, we did not recognize compensation expense for stock options granted to employees prior to 2006.

We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123(R). We use the Black-Scholes-Merton option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

Accounting for equity instruments granted by us under SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, requires us to estimate the fair value of the equity instruments granted. If our estimates of the fair value of these equity instruments are too high or too low, stock-based compensation expense will be overstated or understated, respectively. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, we use the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most compensatory stock options and warrants granted to employees and non-employees, our board of directors determines fair value contemporaneously with the issuance or grant.

The two factors that most affect stock-based compensation are the estimate of the underlying fair value of our common stock and the estimate of the stock price volatility. Prior to the completion of the merger on October 31, 2008, Cornerstone BioPharma s board of directors determined the underlying fair value of Cornerstone BioPharma s common stock (which was exchanged in the merger for shares of our common stock) based on Cornerstone BioPharma s results of operations; the book value of its stock; its available cash, assets and financial condition; its prospects for growth; the economic outlook in general and the condition and outlook of the pharmaceutical industry in particular; its competitive position in the market; the market price of stocks of corporations engaged in the same or similar line of business that are actively traded in a free and open market, either on an exchange or over-the-counter; positive or negative business developments since the board s last determination of fair value; and such additional factors that it deemed relevant at the time of the grant or issuance.

For example, in addition to the factors enumerated above, Cornerstone BioPharma s board of directors specifically considered the following in making its determination of fair value. With respect to the grants on March 16, 2007, May 24, 2007, September 14, 2007 and December 5, 2007, Cornerstone BioPharma s financial performance was improving due to growing product sales, relatively strong gross margins, and leveraging of its sales force and fixed overhead. With respect to the grants made on October 31, 2008, the date of the merger, Cornerstone BioPharma s board of directors considered the fair market value of Critical Therapeutics common stock.

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Following the completion of the merger, our board of directors determines the underlying fair value of our common stock based on the market price of our common stock as traded on the NASDAQ Capital Market.

Results of Operations

Comparison of the Three Months Ended March 31, 2009 and 2008

Net Revenues

The following table sets forth a summary of our net revenues for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,			
	2009	**2008**	**Change ($)**	**Change (%)**
	(In thousands, except percentages)			
Net Product Sales				
ALLERX 10 Dose Pack/ALLERX 30 Dose Pack	$ 6,712	$ 3,266	$ 3,446	105%
ALLERX Dose Pack DF/ALLERX Dose Pack DF 30	1,970	1,167	803	69%
ALLERX Dose Pack PE/ALLERX Dose Pack PE 30	2,211	2,099	112	5%
SPECTRACEF	3,717	182	3,535	1942%
BALACET 325	929	2,145	(1,216)	(57%)
HYOMAX	8,560		8,560	NA
ZYFLO CR and ZYFLO (1)	5,313		5,313	NA
Other currently marketed products	1,057	141	916	650%
Total Net Product Sales	30,469	9,000	21,469	239%
Royalty Agreement Revenues	236	445	(209)	(47%)
Net Revenues	$ 30,705	$ 9,445	$ 21,260	225%

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

Net Product Sales. Net product sales were $30.5 million for the three months ended March 31, 2009, compared to $9.0 million for the three months ended March 31, 2008, an increase of approximately $21.5 million, or 239%. This increase was primarily due to:

- $8.6 million in net product sales of the HYOMAX line of products, the first of which was launched in May 2008;
- a $4.4 million increase in net product sales of the ALLERX Dose Pack family of products, primarily due to increased sales volume and price increases on all ALLERX Dose Pack products;
- $3.5 million in net product sales of SPECTRACEF during the first three months of 2009, which was attributable to the launch of our SPECTRACEF 400 mg product in November 2008;

a $1.2 million decrease in Balacet net product sales resulting from the July 2008 launch of our generic equivalent product, the net product sales of which amount to $708,000 for the three months ended March 31, 2009 and are included in Other currently marketed products in the table above; and

$5.3 million in net product sales of ZYFLO CR and ZYFLO during the first three months of 2009. As noted above, our historical financial results during the first three months of 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 were $236,000 for the three months ended March 31, 2009, compared to $445,000 for the three months ended March 31, 2008, a decrease of approximately $209,000, or 47%. This decrease was primarily due to a net decrease in royalty agreement revenues based on the underlying volume of sales pursuant to our license agreements with third parties.

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Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $511,000 and $739,000 for the three months ended March 31, 2009 and 2008, respectively) was $3.2 million for the three months ended March 31, 2009, compared to $565,000 for the three months ended March 31, 2008, an increase of approximately $2.6 million, or 466%. Gross margin (exclusive of amortization of product rights of $511,000 and $739,000 for the three months ended March 31, 2009 and 2008, respectively) was 90% and 94% for the three months ended March 31, 2009 and 2008, respectively. Cost of product sales in the first three months of 2009 and 2008 consisted primarily of the expenses associated with manufacturing and distributing products, including shipping and handling costs, and reserves established for excess or obsolete inventory. The decrease in our gross margin was primarily due to the increased sales contribution of ZYFLO CR and the SPECTRACEF products, which typically have lower gross margins than our other products. We recorded inventory write-offs of $130,000 for the three months ended March 31, 2009 and a reversal of previously recognized obsolescence expense of $9,000 for the three months ended March 31, 2008. 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 $5.4 million for the three months ended March 31, 2009, compared to $3.9 million for the three months ended March 31, 2008, an increase of approximately $1.5 million, or 38%. This increase was primarily due to the following:

a $776,000 increase in co-promotion expenses primarily relating to ZYFLO CR;

a $314,000 increase in labor and benefits related costs that was primarily due to the reorganization of our commission-based sales force in May 2008, whereby we consolidated all of our sales functions under one national sales director, reduced the size of our sales force, and began compensating all of our sales professionals with salaries;

a $127,000 increase in travel related expenses; and

a $122,000 increase in consulting expense primarily relating to increased market research.

Royalty Expenses. Royalty expenses were $6.3 million for the three months ended March 31, 2009, compared to $1.2 million for the three months ended March 31, 2008, an increase of approximately $5.1 million, or 405%. This increase was primarily due to the launch of our HYOMAX line of 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.

General and Administrative Expenses. General and administrative expenses were $3.8 million for the three months ended March 31, 2009, compared to $1.5 million for the three months ended March 31, 2008, an increase of approximately $2.3 million, or 147%. This increase was primarily due to the following:

$1.0 million increase related to legal and accounting costs, much of which relates to increased requirements as a result of becoming a public company;

$0.6 million increase in labor and benefits related employee expenses and travel-related expenses due to our growth;

$198,000 increase in FDA regulatory related fees; and

$192,000 increase in product liability and other insurance related costs.

Research and Development Expenses. Research and development expenses were $1.2 million for the three months ended March 31, 2009, compared to $98,000 for the three months ended March 31, 2008, an increase of approximately $1.1 million, or, 1086%. 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.

Research and development expenses of $954,000 were incurred during the three months ended March 31, 2009 for the manufacturing of non-GMP and GMP batches of CRTX 067 and CRTX 069, product candidates for the treatment of cough and for the conduct of two bioequivalence studies related to these product candidates.

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Amortization of Product Rights. Amortization of product rights was $511,000 for the three months ended March 31, 2009, compared to $739,000 for the three months ended March 31, 2008, a decrease of approximately $228,000, or 31%. This decrease was primarily due to the BALACET product rights becoming fully amortized as of March 31, 2008.

Other Charges. Other charges were $26,000 for the three months ended March 31, 2009, compared to $0 for the three months ended March 31, 2008, an increase of approximately $26,000. This increase was primarily due to settlement of litigation.

Other Expenses

Interest Expense, Net. Net interest expense was $72,000 for the three months ended March 31, 2009, compared to $378,000 for the three months ended March 31, 2008, a decrease of approximately $306,000, or 81%. This decrease 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 $4.0 million for the three months ended March 31, 2009, compared to $319,000 for the three months ended March 31, 2008. The increase in the provision for income taxes was due to an $9.3 million increase in income before income taxes. Our effective tax rate was 39% for the three months ended March 31, 2009 and 32% for the three months ended March 31, 2008. The increase in the effective rate primarily relates to the utilization of the Company s net operating loss carryforward during the period ended March 31, 2008. As the deferred tax asset associated with this net operating loss was offset by a valuation allowance prior to utilization, the release of this valuation allowance as of March 31, 2008 reduced the effective tax rate for the period. For the period ending March 31, 2009, the only net operating loss carry forward remaining was that which was acquired pursuant to the Merger and is subject to an annual IRC Section 382 limitation.

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 our debt. 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 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 March 31, 2009, we had $10.7 million in cash and cash equivalents and $3.9 million in borrowing availability under the Paragon line of credit. There were no borrowings on the line of credit during the three months ended March 31, 2009. Effective May 4, 2009, we exercised our right to terminate the Paragon line of credit.

Cash Flows

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

	Three Months Ended March 31,	
	2009	**2008**
Cash provided by (used in):		
Operating activities	$ 1,231	$ 2,193
Investing activities	221	(1,018)
Financing activities	(2)	(1,000)
Net increase in cash and cash equivalents	$ 1,450	$ 175

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 three months ended March 31, 2009 reflected our net income of $6.3 million, adjusted by non-cash expenses totaling $674,000 and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $5.8 million. Non-cash items primarily included amortization and depreciation of $564,000, stock-based compensation of $254,000 and changes in deferred income tax of $284,000. Accounts receivable increased by $3.4 million from December 31, 2008 to March 31, 2009, primarily due to increased net product sales, including increased sales of generic products, which have longer payment terms.

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Inventories increased by $1.7 million from December 31, 2008 to March 31, 2009, primarily due to the purchase of ZYFLO CR inventory in the first quarter of 2009. Prepaid expenses increased by $904,000, primarily due to voucher programs and prepayments in respect of future zileuton API purchases. Accounts payable decreased by $1.6 million from December 31, 2008 to March 31, 2009, primarily due to decreased payables for manufacturing, product development and marketing expenses. Accrued expenses increased by $1.1 million from December 31, 2008 to March 31, 2009, primarily due to increased royalties, rebates and chargebacks resulting from increased product sales, offset, in part, by a decrease in accrued interest due to the conversion of the Carolina Note and payment of accrued interest in connection with our merger. Income taxes payable (exclusive of income taxes payable assumed in the merger) increased by $643,000 from December 31, 2008 to March 31, 2009.

Net cash provided by operating activities for the three months ended March 31, 2008 reflected our net income of $669,000, adjusted by non-cash expenses totaling $825,000 and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities totaling $699,000. Non-cash items included amortization and depreciation of $758,000 and stock-based compensation of $84,000.

Net Cash Used in Investing Activities

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

Net cash used in investing activities for the three months ended March 31, 2008 primarily reflected net advances to related parties of $13,000, the purchase of product rights for $1.0 million and the purchase of property and equipment of $15,000, offset, in part, by net proceeds received from the net collection of deposits of $10,000.

Net Cash Used in Financing Activities

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

Net cash used in financing activities for the three months ended March 31, 2008 reflected net payments on the Paragon line of credit of $1.0 million.

Funding Requirements

We expect to continue to incur significant development and commercialization expenses as we seek FDA approval for the SPECTRACEF line extensions, CRTX 068 and CRTX 062, advance the development of our other product candidates, including CRTX 058, our product candidate for the treatment of symptoms of allergic rhinitis, and CRTX 067 and CRTX 069, our product candidates for the treatment of cough; seek regulatory approvals for our product candidates that successfully complete clinical testing; 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;

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

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives, which may not be available on acceptable terms, if at all.

As of March 31, 2009, we had approximately $10.7 million of cash and cash equivalents on hand and borrowing availability of $3.9 million under the Paragon line of credit. 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. 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.

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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 price-level changes 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 2: Summary of Significant Accounting Policies in Part I, Item 1 in 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 March 31, 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 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 March 31, 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 a result of 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 filed with the SEC on March 26, 2009.

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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 has initiated a comprehensive assessment of our internal control over financial reporting, which to date has 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. The assessment of our internal control over financial reporting is not complete, and, accordingly, our management may identify additional material weaknesses as part of its assessment. We expect the assessment process to be completed during the second quarter of 2009.

Also as discussed in our annual report on Form 10-K for the year ended December 31, 2008, in connection with the assessment, our Audit Committee and our president and chief executive officer have previously directed our management to particularly review the expertise, training and sufficiency of our finance and accounting personnel so that we can take appropriate steps to remediate the presently identified material weakness, as well as any further steps necessary to remediate any additional material weaknesses identified as part of the assessment, promptly after we complete the assessment. As part of that review, our management is also assessing the impact on our internal control over financial reporting of the resignation of Chenyqua M. Baldwin, our Vice President, Finance, Chief Accounting Officer and Controller, which is expected to become effective on or about May 6, 2009. We expect that the duties and responsibilities currently being performed by Ms. Baldwin will be reassigned to other current or 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 March 31, 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*

In November 2006, we were named as a defendant in an action filed in New York County, New York by Adams Respiratory Therapeutics, Inc., or Adams, captioned *Adams Respiratory Therapeutics, Inc. (f/k/a Adams Laboratories, Inc.) v. Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals, Inc.*, Supreme Court of the State of New York, New York County, Index No. 603969/2006. The complaint alleged breach of contract concerning a settlement agreement between Adams and us dated January 14, 2005. The complaint also alleged claims concerning the settlement agreement for failure to pay the agreed amount, fraudulent misrepresentation and negligent misrepresentation. We filed an answer to the complaint in which we denied the material allegations of the complaint and asserted counterclaims against Adams for breach of contract concerning the settlement agreement. Following mediation in March 2008, we reached an agreement with Adams to settle all matters, which resulted in the execution of a new settlement agreement in May 2008. We and Carolina Pharmaceuticals, Inc. completed payment of the $1.5 million settlement amount to Reckitt Benckiser Inc., the parent of Adams, on or about September 30, 2008, and the litigation was dismissed with prejudice on October 6, 2008.

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 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 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. 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,

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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 August 21, 2008, the USPTO determined that a substantial new question of patentability was raised by the patents and publications cited by Vision. We will have 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. If the re-examination examiner in the USPTO rejects claims of the 372 Patent, Pharmaceutical Innovations may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If Pharmaceutical Innovations does not receive relief from the Board of Patent Appeals, Pharmaceutical Innovations could file a further appeal to the U.S. Court of Appeals for the Federal Circuit or could institute 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. We intend to defend our interests vigorously against the counterclaims asserted by Vision.

On May 15, 2008, the USPTO sent written notice to us that a cancellation proceeding had been initiated by Bausch & Lomb, Incorporated, or Bausch & Lomb, against the ALLERX trademark registration. The petition to cancel filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We are currently engaged in settlement discussions with Bausch & Lomb concerning a refinement of the product description in the ALLERX trademark registration to distinguish it from the product marketed by Bausch & Lomb under the Alrex trademark. We responded to the TTAB on June 24, 2008, opposing the claims in the Bausch & Lomb cancellation petition, while concurrently continuing to seek settlement of the cancellation proceeding on favorable terms. We could take any of numerous courses of action, including continuing to oppose Bausch & Lomb s claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex trademark or entering into discovery. A final decision by the TTAB could take several years.

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against us and each of our then current directors in the Court of Chancery of the State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George*, Case No. 4039, Court of Chancery, State of Delaware. The plaintiff, which claimed to be one of our stockholders, brought the lawsuit on its own behalf, and sought certification of the lawsuit as a class action on behalf of all stockholders of Critical Therapeutics, except the defendants and their affiliates. The complaint alleged, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint sought, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they then existed, (ii) invalidating the provisions of the proposed merger that purportedly improperly limited the effective exercise of the defendants continuing fiduciary duties, (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties, (iv) in the event the proposed merger was consummated, rescinding it and setting it aside or awarding rescissory damages, (v) awarding compensatory damages against defendants, jointly and severally, and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, we and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that we would make

certain additional disclosures to Critical Therapeutics stockholders, which are contained in a supplement to the proxy statement/prospectus that was mailed to Critical Therapeutics stockholders. After the completion of certain

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confirmatory discovery by counsel to the plaintiff, as contemplated by the memorandum of understanding, the parties entered into a stipulation and agreement of compromise, settlement and release on November 24, 2008. On December 3, 2008, the court entered a scheduling order preliminarily approving class treatment of the case and setting a briefing and hearing schedule to consider the proposed settlement of the case. On December 23, 2008, we caused a court-approved notice of pendency of class action, proposed class action determination, proposed settlement of class action, settlement hearing and right to appear to be mailed to all persons that held Critical Therapeutics stock during the period May 1, 2008 through October 31, 2008, other than the defendants and their affiliates. On February 26, 2009, the court approved the settlement resolving all of the claims that were or could have been brought in the action being settled, including all claims relating to the merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, we paid plaintiff s counsel $175,000 for attorneys fees and expenses that had been awarded by the court.

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 seeks 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 seeks a declaratory judgment that its Allergy DN II and Allergy DN PE products do not infringe the 372 and 816 Patents. Breckenridge also seeks 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 does not request monetary relief. We have not yet responded to Breckenridge s complaint but we intend to defend our interests vigorously against the claims asserted by Breckenridge.

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

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q and the other reports that we file with the SEC, in evaluating Cornerstone Therapeutics and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors include any material changes to and supersede the risk factors previously disclosed in our annual report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 26, 2009.

Risks Relating to Commercialization and Product Acquisitions

We expect to derive substantially all of our revenues from sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products and the propoxyphene/acetaminophen products.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenues from sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products and the propoxyphene/acetaminophen products. If commercial, regulatory or other developments adversely affect our ability to market these products or if demand for these products is reduced, our business, financial condition and operating results could be materially harmed. Until one or more of our product candidates receives FDA approval and is successfully commercialized, the success of our business and operating results will depend substantially on the demand for and continued marketability of these products.

The commercial success of our currently marketed products and any additional products that we successfully develop 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:

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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.

For example, the SPECTRACEF products are indicated for, and we are developing our product candidates CRTX 068 and CRTX 062 for, the treatment of certain respiratory infections. Products used to treat respiratory infections are, from time to time, subject to negative publicity, including with respect to antibiotic resistance and overuse.

In 2008, we experienced supply chain issues in manufacturing ZYFLO CR. If we are unable to manufacture or release ZYFLO CR on a timely and consistent basis, some physicians may prescribe ZYFLO to ensure that their patients with asthma continue to have access to zileuton as a treatment option. ZYFLO, which is dosed four times per day, contains the same zileuton API as ZYFLO CR, which is dosed two tablets twice daily.

Despite being approved by the FDA since 1996, ZYFLO did not achieve broad market acceptance. We experienced difficulty expanding the prescriber and patient bases for ZYFLO, in part, we believe, because it requires dosing of one tablet four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. If any existing negative perceptions about ZYFLO persist, we will have difficulty achieving market acceptance for ZYFLO CR.

In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two tablets twice daily, or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, sales of ZYFLO CR will be limited and our revenues will be adversely affected.

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

Market perceptions about the safety of ZYFLO CR and ZYFLO also 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

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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 company data 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 the company studies it reviewed were not designed to detect those events. The FDA also reviewed clinical trial data to assess other mood and behavioral 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 behavior changes. It is our understanding that other leukotriene modulator manufacturers were asked to make 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 could 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. A Joint Status Report on the Case of Public Citizen v. Food and Drug Administration issued by the United States District Court for the District of Columbia on February 2, 2009 stated that the FDA anticipates that it will issue a final determination approving or denying the citizens petition by May 4, 2009. On January 30, 2009, an FDA Advisory Committee voted 14-to-12 in favor of a phased removal from the market of all drugs containing propoxyphene. If the FDA acts upon the Advisory Committee s recommendation and begins the phased removal of propoxyphene products from the market, product sales of our propoxyphene/acetaminophen products would be eliminated and we would be forced to terminate our co-promotion agreement with Atley Pharmaceuticals, Inc., or Atley Pharmaceuticals.

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 has scheduled a meeting of advisory committees to discuss acetaminophen risk management on June 29 and 30, 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. Any such future policy change could adversely affect our ability to market our propoxyphene/acetaminophen products.

Our strategy of obtaining, through product acquisitions and in-licenses, rights to products and product candidates for our development pipeline and to proprietary drug delivery and formulation technologies for our life cycle management of current products may not be successful.

Part of our business strategy is to acquire rights to FDA-approved products, pharmaceutical product candidates in the late stages of development and proprietary drug delivery and formulation technologies. Because we do not have

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discovery and research capabilities, the growth of our business will depend in significant part on our ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that we believe have significant commercial potential and are consistent with our commercial objectives. However, we may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates and drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities for us, as well as higher acquisition prices. Many of our competitors have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Other factors that may prevent us from licensing or otherwise acquiring suitable products, product candidates or technologies include:

- We may be unable to license or acquire the relevant products, product candidates or technologies on terms that would allow us to make an appropriate return on investment;
- Companies that perceive us as a competitor may be unwilling to license or sell their product rights or technologies to us;
- We may be unable to identify suitable products, product candidates or technologies within our areas of expertise; and
- We may have inadequate cash resources or may be unable to obtain financing to acquire rights to suitable products, product candidates or technologies from third parties.

If we are unable to successfully identify and acquire rights to products, product candidates and proprietary drug delivery and formulation technologies and successfully integrate them into our operations, we may not be able to increase our revenues in future periods, which could result in significant harm to our financial condition, results of operations and prospects.

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, including our sales force, sales management, sales logistics and sales administration, and our marketing department. As of April 30, 2009, our sales force consists of 82 sales representatives. 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 not successful in our efforts to expand our sales force and marketing capabilities, our ability to independently market and promote 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 the product candidate. 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 our products.

We face competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The development and commercialization of drugs is highly competitive. We face competition with respect to our currently marketed products, our current product candidates and any products that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. We face significant competition

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for our currently marketed products. Some of our currently marketed products do not have patent protection and in most cases face generic competition. All of these products face significant price competition from a range of branded and generic products for the same therapeutic indications.

Given that our product development approach is to develop new formulations of existing drugs, some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. For example, our product candidate CRTX 068, which is for the treatment of certain respiratory infections, may not demonstrate sufficient additional clinical benefits to physicians to justify a higher price compared to generic equivalents within the same therapeutic class. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop.

Our patents will not protect our products if competitors devise ways of making products that compete with our products without legally infringing our patents. The Federal Food, Drug and Cosmetic Act, or FDCA, and FDA regulations and policies provide certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications, or ANDAs, for generic substitutes. These same types of exclusivity incentives encourage manufacturers to submit new drug applications, or NDAs, that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as our product and that the generic product is absorbed in the body at the same rate and to the same extent as our product, a comparison known as bioequivalence. Such products would be significantly less costly than our products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit our ability to obtain a return on the investments we have made in those products.

Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates. If NDA approval is received for a new drug containing an API that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, an NDA approval for a new indication or formulation of the drug with the same API, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA for a generic version of such drug for a period of three years from the date of the NDA approval. This three-year exclusivity, however, only covers the innovation associated with the NDA to which it attaches.

The FDCA also provides a five-year period of exclusivity for a drug approved under the first NDA of which no API has previously been approved. If the drug approval for any of our product candidates were blocked by such a period of marketing exclusivity, we would not be able to receive FDA approval until the applicable exclusivity period expired.

Our products compete, and our product candidates, if approved, will compete, principally with the following:

The SPECTRACEF products and CRTX 068 second and third generation cephalosporins, such as Shinogi USA, Inc. s Cedax® (ceftibuten), Lupin Pharmaceuticals, Inc. s Suprax® (cefixime) and generic formulations of Abbott Laboratories , or Abbott, Omnicef® (cefdinir) and GlaxoSmithKline plc s, or GSK, Ceftin® (cefuroxime); macrolides, such as generic formulations of Pfizer Inc. s Zithromax® (azithromycin) and Abbott s Biaxin® (clarithromycin); and quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Levaquin® (levofloxacin) and generic formulations of Bayer Schering AG s Cipro® (ciprofloxacin).

CRTX 062 Suprax and generic formulations of Omnicef and Ceftin.

ZYFLO CR and ZYFLO bronchodilatory drugs, such as Teva Specialty Pharmaceuticals LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering-Plough Corporation s Proventil® HFA (albuterol sulfate) Inhalation Aerosol; LTRAs, such as Merck & Co., Inc. s Singulair® (montelukast sodium); inhaled

corticosteroids, such as GSK s Flovent® Diskus (fluticasone proprionate inhalation powder); and combination products, such as GSK s Advair Diskus® (fluticasone propionate and salmetorol inhalation powder) and AstraZeneca PLC s Symbicort®, a twice-daily asthma therapy combining budesonide, an

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inhaled corticosteroid, and formoterol, a long-acting beta2-agonist. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market.

ALLERX and RESPIVENT Dose Pack Products prescription products, including first generation antihistamine and antihistamine combination products, such as Capellon Pharmaceuticals, Ltd. s, or Capellon, Rescon® (phenylephrine, chlorpheniramine and methscopolamine) and Laser Pharmaceuticals, LLC s Dallergy® (phenylephrine, chlorpheniramine and methscopolamine), and over-the-counter products, such as McNeil-PPC, Inc. s Benadryl® (diphenhydramine) and Schering-Plough Corporation s Chlor-Trimeton® (chlorpheniramine).

HYOMAX Products belladonna and derivative antispasmodics, such as the generic formulations of Alaven Pharmaceutical LLC s Levsin® (hyoscyamine sulfate) and Levbid® (hyoscyamine sulfate) products and of PBM Pharmaceuticals, Inc. s Donnatal® (belladonna alkaloids /phenobarbital); urinary incontinence antispasmodics, such as Pfizer Inc. s Detrol® LA (tolterodine tartrate), Astellas Pharmaceuticals, Inc. and GSK s VESIcare® (solifenacin) and the generic formulations of Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Ditropan® and Ditropan XL® (oxybutynin); and synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma Inc. s Bentyl® (dicyclomine) and Bradley Pharmaceuticals, Inc. s Pamine® (methscopolamine bromide).

BALACET 325, APAP 325 and APAP 500 generic formulations of propoxyphene and acetaminophen, the APIs in BALACET 325, APAP 325 and APAP 500, and many other drugs on the market or in development for the treatment of mild to moderate pain.

CRTX 058 second generation antihistamines, such as Sanofi-Aventis U.S. LLC s Allegra® (fexofenadine); third generation antihistamines, such as UCB, Inc. and Sanofi-Aventis U.S. LLC s Xyzal® (levocetirizine) and Schering-Plough Corporation s Clarinex® (desloratadine); and over-the-counter products such as Benadryl, Chlor-Trimeton, Schering-Plough Corporation s Claritin® (loratadine) and McNeil-PPC, Inc. s Zyrtec® (cetirizine).

CRTX 067 and CRTX 069 various narcotic and non-narcotic antitussives, such as King Pharmaceuticals, Inc. s Tussigon® (hydrocodone and homatropine), Mallinckrodt Brand Pharmaceuticals, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), UCB, Inc. s Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) and generic formulations of Wyeth s Phenergan® with codeine (codeine and promethazine); over-the-counter antitussives, such as Reckitt Benckiser Inc. s Delsym® (dextromethorphan polistirex), Schering-Plough Corporation s Coricidin HBP® Cough & Cold (dextromethorphan and chlorpheniramine); and prescription antitussives, such as Sciele Pharma, Inc. s Rondec® DM Syrup (dextromethorphan, phenylephrine and chlorpheniramine) and Meda Pharmaceuticals Inc. s Tussi-12D® (carbetapentane, pyrilamine and phenylephrine).

Many of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products and thus may be better equipped than us to discover, develop, manufacture and commercialize products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, registering patients for clinical trials and acquiring technologies. Many of our competitors have collaborative arrangements in our target markets with leading companies and research institutions. In many cases, products that compete with our currently marketed products and product candidates have already received regulatory approval or are in late-stage development, have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent

position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely

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affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products noncompetitive. If our product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those product candidates.

As our competitors introduce their own generic equivalents of our generic products, our net revenues from such products are expected to decline.

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

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

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.

A failure to maintain optimal inventory levels could harm our reputation and subject us to financial losses.

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We are obligated to make aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg exceeding specified dollar amounts annually over a five-year period under our supply agreement with Meiji Seika Kaisha, Ltd , or Meiji. Under the agreement, the required annual aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg are $15.0 million for the first year beginning with the commercial launch in October 2008 of SPECTRACEF 400 mg manufactured by Meiji, $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 we do not meet our minimum purchase requirement in a given year, we must pay Meiji an amount equal to 50% of the shortfall in that year.

We are also subject to minimum purchase obligations under supply agreements, which require us to buy inventory of the tablet cores for ZYFLO CR. We have committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec AG, or Jagotec, in each of the four 12-month periods starting May 30, 2008. If ZYFLO CR does not achieve the level of demand we anticipate, we may not be able to use the inventory we are required to purchase. Based on our current expectations regarding demand for ZYFLO CR, we expect that inventory levels could increase substantially in the future as a result of minimum purchase obligations under supply agreements with third-party manufacturers and orders we have submitted to date.

Because accurate product planning is necessary to ensure that we maintain optimal inventory levels, significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If we are required to recognize charges for excess inventories, such charges could have a material adverse effect on our financial condition and results of operations.

In 2008, we experienced difficulties in the supply for ZYFLO CR, including an aggregate of eight batches of ZYFLO CR that could not be released into our commercial supply chain, consisting of one batch of ZYFLO CR that did not meet our product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. We cannot assure you that we will not have similar manufacturing issues in producing ZYFLO CR or our other products in the future.

Our ability to maintain optimal inventory levels also depends on the performance of third-party contract manufacturers. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our products as a result of U.S. Drug Enforcement Administration, or DEA, regulations and because of the limited number of suppliers of hyoscyamine sulfate and methscopolamine nitrate. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. If we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and our brands could be harmed and physicians may be less likely to prescribe our products in the future, each of which could have a material adverse effect on our financial condition, results of operations and cash flows.

If our third-party manufacturers and packagers do not obtain the necessary quota for controlled substances needed to supply us with our products or the quotas are not sufficient, we may be unable to meet commercial demand for the products.

Certain of our products, including ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D, RESPIVENT-D, BALACET 325, APAP 325 and APAP 500, contain controlled substances, which are regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer can manufacture and the amount of API it can use to manufacture those products. We rely on Sovereign, the manufacturer of bulk tablets for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, Legacy and Carton Service, the manufacturers of trade and sample packaging for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, and Vintage, the manufacturer and packager of BALACET 325, APAP 325 and APAP 500, to annually request and obtain from the DEA the quota allocation needed to meet our production requirements. If our manufacturers and packagers are unsuccessful in obtaining quotas, our supply chain for controlled substance products could be at risk.

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If we or our contract manufacturers fail to comply with regulatory requirements for our controlled substance products and product candidates, the DEA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our contract manufacturers and certain of our products and product candidates, including those containing propoxyphene and pseudoephedrine, are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturers must adhere to a number of requirements with respect to our controlled substance products and product candidates, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on prescription refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our currently marketed products, any other products that we successfully develop and the testing of our product candidates in human clinical trials. If we cannot successfully defend against claims that our products or product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products or any products that we may develop;

injury to our reputation;

the withdrawal of clinical trial participants;

the withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to clinical trial participants or patients;

diversion of management time and attention;

loss of revenue; and

inability to commercialize the products that we may develop.

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. A Joint Status Report on the Case of *Public Citizen v. Food and Drug Administration* issued by the United States District Court for the District of Columbia on February 2, 2009 stated that the FDA anticipates that it will issue a final determination approving or denying the citizens petition by May 4, 2009. On January 30, 2009, an FDA Advisory Committee voted 14-to-12 in favor of a phased removal of all drugs containing propoxyphene. Propoxyphene is one of two APIs, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. In addition, 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. While we are not aware of any pending or threatened product liability claims against us related to propxyphene or acetaminophen, we cannot assure you that such claims will not arise in the future.

Our contracts with wholesalers and other customers require us to carry product liability insurance. We have product liability insurance coverage with a $10 million annual aggregate limit and a $10 million individual claim

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limit, and which is subject to a per claim deductible and a policy aggregate deductible. The annual cost of this products liability insurance was approximately $265,000 for the policy year beginning September 13, 2008. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Relating to Product Development and Regulatory Matters

If we are unable to develop safe and efficacious formulations of our product candidates, or our clinical trials for CRTX 062 or our other product candidates are not successful, we may not be able to develop, obtain regulatory approval for and commercialize these product candidates successfully.

Our product candidates are still in various stages of development. Our product development pipeline includes CRTX 068 and CRTX 062, product candidates for the treatment of certain respiratory infections. Our product development pipeline also includes the following three additional product candidates: CRTX 058, a product candidate for the treatment of symptoms of allergic rhinitis; CRTX 067, a product candidate for the treatment of cough; and CRTX 069, also a product candidate for the treatment of cough. All of our product candidates remain subject to pharmaceutical formulation development and clinical testing necessary to obtain the regulatory approvals or clearances required for commercial sale. Depending on the nature of the product candidate, to demonstrate a product candidate s safety and efficacy, we and our collaborators generally must either demonstrate bioequivalence with a drug already approved by the FDA or complete human clinical trials. We may not be able to obtain permission from the FDA, institutional review boards, or IRBs, or other authorities to commence or complete necessary clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance, or cause imposition of burdensome post-approval requirements or limit commercial use if approved or cleared. For example, CRTX 067 and CRTX 069 contain a narcotic, which has been associated with abuse and can lead to serious illness, injury or death if improperly used. Furthermore, we, one of our collaborators, IRBs or regulatory agencies may order a clinical hold or suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, Guidance for Industry issued by the FDA in 2007 regarding, among other things, the design of clinical trials of drug candidates for the treatment of acute bacterial otitis media, noted that investigators or IRBs may consider a placebo-controlled study to be unethical where the trial would involve the withholding of known effective antimicrobial treatment to the placebo control group unless the investigators and IRBs determine that the withholding of known effective treatment would result in no more than a minor increase over minimal risk. The FDA suggested that the ethical dilemma might be bridged by using a superiority study of the investigational antimicrobial compared to a known effective antimicrobial treatment. While the FDA did not absolutely prohibit placebo-controlled trials in such cases, we believe this FDA guidance may make placebo-controlled trials more difficult to design and complete, especially in pediatric populations.

Adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in failure to obtain approval or approval for a narrower indication. If clinical trials fail, our product candidates would not receive regulatory approval or achieve commercial viability.

If clinical trials for our product candidates are delayed, we would be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay the receipt of any revenues from product sales.

We currently expect to commence clinical trials with respect to CRTX 068 in 2009, CRTX 062 in 2010, CRTX 058 in 2009 and CRTX 067 and CRTX 069 in 2009. We cannot predict whether we will encounter problems with

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any of our completed or planned clinical trials that will delay or cause regulatory authorities, IRBs or us to suspend those clinical trials or the analysis of data from such trials.

Any of the following could delay the completion of our planned clinical trials:

- we or FDA, a third party assisting us with product development or an IRB suspending or stopping a clinical trial;
- discussions with the FDA regarding the scope or design of our clinical trials;
- delay in obtaining, or the inability to obtain, required approvals from regulators, IRBs or other governing entities at clinical sites selected for participation in our clinical trials;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, or we may abandon projects that had appeared to be promising;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical investigation;
- serious and unexpected drug-related side effects experienced by participants in past clinical trials for the same or a different indication; or
- exposure of participants to unacceptable health risks.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the seasonality of the disease, the availability of effective treatments for the relevant disease, competing trials with other product candidates and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. In addition, subjects may drop out of clinical trials and thereby impair the validity or statistical significance of the trials.

Delays in patient enrollment and the related increase in costs also could cause us to decide to discontinue a clinical trial prior to completion. For example, in March 2008, we discontinued our Phase IV clinical trial for ZYFLO CR designed to generate data in the current patient treatment setting because patient enrollment was significantly slower than we had anticipated. We initiated the trial in July 2007 and had enrolled only approximately 25% of the patients prior to discontinuing the trial. We had planned to use data from this trial to support ZYFLO CR s market position, and we may have increased difficulty promoting ZYFLO CR to physicians without this data.

We expect to rely on academic institutions and contract research organizations to supervise or monitor some or all aspects of the clinical trials for the product candidates we advance into clinical testing. Accordingly, we have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

Although we have not previously experienced most of the foregoing risks with respect to our clinical trials, as a result of these risks, we or third parties upon whom we rely may not successfully begin or complete our clinical trials in the time periods forecasted, if at all. If the results of our planned clinical trials for our product candidates are not available when we expect or if we encounter any delays in the analysis of data from our clinical trials, we may

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be unable to submit results for regulatory approval or clearance or to conduct additional clinical trials on the schedule that we anticipate.

If clinical trials are delayed, the commercial viability of our product candidates may be reduced. If we incur costs and delays in our programs, or if we do not successfully develop and commercialize our products, our future operating and financial results will be materially affected.

If our clinical trials do not demonstrate safety and efficacy in humans, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Depending upon the nature of the product candidate, obtaining regulatory approval for the sale of our product candidates may require us and our collaborators to fund and conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, uncertain as to outcome and, depending upon the design of the trial, takes several years or more to complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. Similarly, even if clinical trials of a product candidate are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. One or more of our clinical trials could fail at any stage of testing.

We expect to submit an NDA to the FDA in 2011 for CRTX 062 for use of this product candidate by children with pharyngitis, tonsillitis or otitis media. All of the preclinical studies and clinical trials of CRTX 062 were conducted previously. We intend to rely on the results of these prior clinical trials to support our NDA for CRTX 062 for certain indications. The previous company conducted its clinical trials of CRTX 062 using a non-inferiority design, meaning that the objective was to demonstrate that the safety and effectiveness of CRTX 062 is not inferior relative to the control drug. However, current FDA guidelines request superiority design clinical trials, meaning that the objective of the clinical trials is to demonstrate that the test drug s safety and effectiveness are superior to the control drug. If the FDA does not permit us to rely on the prior clinical data for CRTX 062, we would be required to repeat some or all of the clinical trials, which would lead to unanticipated costs and delays. Problems with the previous trials, such as incomplete, outdated or otherwise unacceptable data also could cause this NDA to be delayed or rejected.

If we are required to conduct additional clinical trials or other testing of our product candidates in addition to those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for product candidates;
- not be able to obtain marketing approval;
- obtain approval for indications that are not as broad as intended; or
- have the product removed from the market after obtaining marketing approval.

Product development costs also will increase if we experience delays in testing or obtaining approvals. Significant clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. Changes in regulatory approval policies

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during the development period, changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process and may require additional clinical or other data as a condition of reviewing or approving an application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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. Personnel who are no longer with Cornerstone 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 sNDA for SPECTRACEF 400 mg in July 2008 and we launched this product in October 2008. 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.

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

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has historically refrained from taking enforcement action against some marketed, unapproved new drugs. The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. Although the FDA considers all such drugs to require its approval, FDA enforcement against such products as unapproved drugs prioritizes products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA is less likely to exercise enforcement discretion regarding unapproved new drugs if it finds that the marketer and its manufacturers are also allegedly in non-compliance with cGMP requirements. Also, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and could ask or require that the products be removed from the market immediately. Although we may be given the benefit of a grace period to submit a marketing application before the agency would take enforcement action, the time it takes us to complete the necessary clinical trials and submit an NDA or ANDA to the FDA may exceed this time period, which would result in an interruption of sales of our products.

As of April 30, 2009, our only products that are subject to approved NDAs or ANDAs are the SPECTRACEF products, ZYFLO CR, ZYFLO and our propoxyphene/acetaminophen products. All of our other products are marketed in the United States without an FDA-approved marketing application. Our net revenues from the sale of unapproved products were $21.7 million, or 71% of total net revenues, in the quarter ended March 31, 2009, and were $49.8 million, or 77% of total net revenues, in the year ended December 31, 2008.

Our net revenues from sales of the ALLERX Dose Pack products were $10.9 million in the quarter ended March 31, 2009 and $26.4 million in the year ended December 31, 2008. Our net revenues from sales of our HYOMAX products, which we launched beginning in May 2008, were $8.6 million in the quarter ended March 31, 2009 and $23.0 million in the year ended December 31, 2008. If the FDA required us to remove our unapproved products from the market, particularly our ALLERX Dose Pack family of products and our HYOMAX line of products, our

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revenue from product sales would be significantly reduced. For example, when the FDA announced in May 2007 that it was directing that all non-approved extended-release guaifenesin products, including Cornerstone s DECONSAL II product, be removed from the market within 180 days, the FDA noted that Adams was the only company to date that had obtained FDA approval for timed-release products containing guaifenesin. Our net revenues from sales of DECONSAL II were $177,000 in 2007 and $1.2 million in 2006.

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

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by managed care organizations, or MCOs, varies but coverage is similar to other products within the same class of drugs. For example, the SPECTRACEF products are covered by private insurance plans, similar to other marketed, branded cephalosporins. However, the position of ZYFLO CR may make it more difficult to expand the current market share for this product. In most instances, ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, created a new Medicare benefit for prescription drugs. More recently, the Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. In addition, private insurers, such as MCOs, may adopt their own reimbursement reductions in response to federal or state legislation. Any reduction in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product, and the amount for which that product will be reimbursed, are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products may change at any time.

The MMA established a voluntary prescription drug benefit, called Part D, which became effective in 2006 for all Medicare beneficiaries. We cannot be certain that our currently marketed products will continue to be, or any of our product candidates still in development will be, included in the Medicare prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

If we succeed in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates are in the development stage, we do not know whether payors will cover the products and the level of reimbursement, if any, we will receive for these product candidates if they are successfully developed, and we are unable at this time to determine the cost-

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effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of products.

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

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 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 are misleading because they broaden the approved indication for SPECTRACEF, omit risks related to its use, make unsubstantiated superiority claims, overstate the efficacy of SPECTRACEF and make misleading dosing claims. While we no longer use the sales aids reviewed by the FDA, in response to the warning letter, we have 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 will provide a written response to the FDA by May 18, 2009. As part of our response, we will provide a description of our plan to disseminate corrective messages about the promotional material to those who received any 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 NDA 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. 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 by the FDA 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 finished product release 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 have not yet responded to the Form 483 but we intend to take appropriate action to effectively address all 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;

refusal to permit the import or export of our products;

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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.

State and federal pharmaceutical marketing and promotional compliance and reporting requirements may expose us to regulatory and legal action by government authorities.

In recent years, several states, including California, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or file periodic reports with the state on sales and marketing activities and expenditures, including but not limited to, the provision of gifts to healthcare practitioners. For example, a California statute effective July 1, 2005 requires pharmaceutical companies to adopt and post on their public web site a comprehensive compliance program that complies with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals and the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers. In addition, such a compliance program must establish a specific annual dollar limit on gifts or other items given to individual health care professionals in California. Other states have also enacted statutes of varying scope that impose reporting and disclosure requirements on pharmaceutical companies pertaining to drug pricing. Similar legislation is being considered in a number of other states and the U.S. Congress is also considering legislation that would require drug manufacturers to report to the federal government their payments and other transfers of value to physicians.

Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business.

We may be subject to investigations or other inquiries concerning our compliance with reporting obligations under federal health care program pharmaceutical pricing requirements.

There have been a number of government enforcement actions under the federal health care programs, primarily Medicare and Medicaid, against numerous pharmaceutical companies alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated prices, such as average wholesale and best price, which are alleged to have improperly inflated the reimbursements paid by Medicare, state Medicaid programs and other payors to health care providers who prescribed and administered those products or pharmacies that dispensed those products. These actions have been brought by both the federal government and individual states. Failure to comply with these government health care program pharmaceutical pricing requirements may lead to federal or state investigations, criminal or civil liability, exclusion from government health care programs, contractual damages and otherwise materially harm our reputation, business and prospects.

Our corporate compliance and corporate governance programs cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, marketing, sales and reimbursement of our products and product candidates, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States. We are a relatively small company and had approximately 129 employees as of April 30, 2009. We rely heavily on third parties to conduct many important functions. We have developed and instituted a corporate compliance program designed to comply with current best practices for pharmaceutical companies and continue to update the program in response to newly implemented and changing regulatory requirements. However, our compliance program does not and cannot guarantee that we are in compliance with all potentially applicable federal and state regulations. If we fail to comply with any of these regulations, we may be subject to a range of enforcement actions, including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against such actions, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

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We will spend considerable time and money complying with federal and state laws and regulations, and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.

Health care providers, physicians and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. Applicable federal and state health care laws and regulations, include, but are not limited to, the following:

The federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;

The federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds. Penalties include three times the government s damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the False Claims Act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the *qui tam* plaintiff is rewarded with a percentage of the recovery;

Health Insurance Portability and Accountability Act, or HIPAA, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

The Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and

Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws. In some cases, these state laws impose more strict requirements than the federal laws. Some state laws also require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

We are a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the Medicaid rebate program, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law. We are also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. Both the federal government and state governments have initiated investigations into the rebate practices of many pharmaceutical companies to ensure compliance with these rebate programs. Any investigation of our rebate practices could be costly, could divert the attention of our management and could damage our reputation.

Efforts to help ensure that our business arrangements comply with these extensive federal and state health care fraud and abuse laws could be costly. It is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other applicable governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government health care programs and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business is found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusions from government health care programs.

Many aspects of the above-described laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations, which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for

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violation of these laws, even if we successfully defend against the action, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices of our products and impair our ability to derive revenue from our products.

Legislation has been introduced in the United States Congress that, if enacted, would permit more widespread re-importation of FDA-approved drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. While we do not currently sell any of our products outside the United States, legislation or other factors that increase such sales by our direct competitors could adversely affect our pricing and revenues. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from our product sales.

Risks Relating to Our Dependence on Third Parties

We use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates at an acceptable cost, which could result in clinical development and commercialization of product candidates being delayed, prevented or impaired.

We have no manufacturing facilities and rely on third parties to manufacture and supply all of our products. We currently rely on these third parties for the purchase of raw materials and the manufacture and packaging of our products. Many of the agreements we have entered into are exclusive agreements in which the manufacturer is a single-source supplier, preventing us from using alternative sources.

We obtain all of our BALACET 325, APAP 500 and APAP 325 supply from Vintage, which has the exclusive right to supply all of our requirements for these products. Meiji has the exclusive right to supply all of our requirements for cefditoren pivoxil, the API in SPECTRACEF. We also acquire all of our requirements for the SPECTRACEF products from Meiji. We acquire all of our requirements for the HYOMAX line of products and all of the bulk tablets for our ALLERX Dose Pack products from Sovereign. We also have qualified two packagers of the ALLERX product line.

We have contracted with Shasun Pharma Solutions, or Shasun, for commercial production of the zileuton API, subject to specified limitations, through December 31, 2010. Zileuton API is used in our FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in our zileuton injection product candidate. Our only source of supply for zileuton API is Shasun, which manufactures the zileuton API in the United Kingdom. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture API for us.

We have contracted with Jagotec, a subsidiary of SkyePharma PLC, for the manufacture of core tablets for ZYFLO CR for commercial sale. Our only source of supply for the core tablets of ZYFLO CR is Jagotec, which manufactures them in France. We have contracted with Patheon Pharmaceuticals, Inc., or Patheon, to coat and package the core tablets of ZYFLO CR for commercial sale. Patheon is currently our only source of finished ZYFLO CR tablets. We have contracted with Patheon to manufacture ZYFLO tablets for commercial sale. Patheon is currently our only source of finished ZYFLO tablets.

If any of the third-party manufacturers with whom we contract fails to perform their obligations, we may be adversely affected in a number of ways, including the following:

We may not be able to meet commercial demands for our products;

We may be required to cease distribution or issue recalls;

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We may not be able to initiate or continue clinical trials of product candidates that are under development; and

We may be delayed in submitting applications for regulatory approvals for product candidates.

We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If we were required to change manufacturers, we would be required to obtain FDA approval of an sNDA covering the new manufacturing site. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that the products manufactured by the new manufacturer are equivalent to the products manufactured by the current manufacturer, which could take 12 to 18 months or possibly longer. The technical transfer of manufacturing capabilities can be difficult. For example, in the second quarter of 2007, we initiated the qualification process for two new manufacturing sites for the five different tablet formulations that are used in the various AM/PM dosing combinations in the different ALLERX Dose Pack products in order to have additional manufacturing capacity and to mitigate the risks associated with relying on a single supplier. Both facilities initially encountered difficulties in developing stable tablet formulations, which were later resolved. Any delays associated with the approval of an sNDA covering a new manufacturer or conducting additional clinical bioequivalence trials could adversely affect the production schedule or increase our production costs and could ultimately lead to a shortage of supply in the market.

Additionally, FDA regulations restrict the manufacture of penicillin products in the same facility that manufactures a cephalosporin such as the SPECTRACEF products. These restrictions reduce the number of cGMP FDA-approved facilities that are able to manufacture cephalosporins, which could complicate our ability to qualify manufacturers for CRTX 062 and CRTX 068 or quickly qualify a new manufacturer for the SPECTRACEF products.

We also rely on third-party manufacturers to purchase the necessary raw materials to manufacture our products, with the exception of cefditoren pivoxil, the API in SPECTRACEF, which we are required to purchase from Meiji. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our products as a result of DEA regulations and because of the limited number of suppliers of hyoscyamine sulfate and methscopolamine nitrate. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. In addition, supply interruptions or delays could occur that require us or our manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in our raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operation.

In addition, we import the API, tablet cores and finished product for certain of our products from third parties that manufacture such items outside the United States, and we expect to do so from outside the United States in the future. This may give rise to difficulties in obtaining API, tablet cores or finished product in a timely manner as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging. For example, in January 2009, the FDA released draft guidance on Good Importer Practices, which, if adopted, will impose additional requirements on us with respect to oversight of our third-party manufacturers outside the United States. The FDA has stated that it will inspect 100% of API, tablet cores and finished product that is imported into the United States. If the FDA requires additional documentation from third-party manufacturers relating to the safety or intended use of the API or finished product, the importation of the API or finished product could be delayed. While in transit from outside the United States or while stored with our third-party logistics provider, DDN/Obergfel, LLC, or DDN, our API, tablet cores or finished product could be lost or suffer damage, which would render such items unusable. We have attempted to take appropriate risk mitigation steps and to obtain transit or casualty insurance. However, depending upon when the loss or damage occurs, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage.

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We rely on third-party manufacturers for compliance with applicable regulatory requirements. This may increase the risk of sanctions being imposed on us or on a manufacturer of our products or product candidates, which could result in our inability to obtain sufficient quantities of these products or product candidates.

Our third-party manufacturers may not be able to comply with cGMP regulations or other United States regulatory requirements or similar regulatory requirements outside the United States. DEA regulations also govern facilities where controlled substances are manufactured. Our third-party manufacturers are subject to DEA registration requirements and unannounced inspections by the FDA, the DEA, state regulators and similar regulators outside the United States. While we generally negotiate for the right under our long-term manufacturing contracts to periodically audit our third-party manufacturers performance, we do not have control over our third-party manufacturers compliance with these regulations. We cannot assure you that our current quality assurance program is reasonably designed to, or would, discover all instances of non-compliance by our third-party manufacturers with these regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including:

fines;

injunctions;

civil penalties;

the failure of regulatory authorities to grant marketing approval of our product candidates;

delays, suspension or withdrawal of approvals;

suspension of manufacturing operations;

license revocation;

seizures or recalls of products or product candidates;

operating restrictions; and

criminal prosecutions.

Any of these sanctions could significantly and adversely affect supplies of our products and product candidates.

Difficulties relating to the supply chain for ZYFLO CR tablets could significantly inhibit our ability to meet, or prevent us from meeting, commercial demand for the product.

In 2008, we experienced difficulties in the supply chain for ZYFLO CR, including an aggregate of eight batches of ZYFLO CR that could not be released into our commercial supply chain, consisting of one batch of ZYFLO CR that did not meet our product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In conjunction with our three third-party manufacturers for zileuton API, tablet cores and coating and release, we initiated an investigation to determine the cause of this issue and we believe that we have resolved the supply chain issue. Any delays or difficulties associated with our supply chain for ZYFLO CR could adversely affect our production schedule or increase our production costs and could ultimately lead to a shortage of supply in the market. If we are not able to supply ZYFLO CR at a commercially acceptable cost and level, we could experience difficulties in maintaining or increasing market share for ZYFLO CR.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical

investigators, to perform this function. Reliance on these third parties for clinical development activities reduces our

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control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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 products 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 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 advance written notice. DEY also has the right to terminate the co-promotion agreement upon two (2) months prior written notice to us if in any two consecutive calendar quarters we are unable to deliver to DEY at least seventy five percent (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 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.

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The concentration of our product sales to only a few wholesale distributors increases the risk that we will not be able to effectively distribute our products if we need to replace any of these customers, which would cause our sales to decline.

The majority of our sales are to a small number of pharmaceutical wholesale distributors, which in turn sell our products primarily to retail pharmacies, which ultimately dispense our products to the end consumers. Sales to our three primary wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, Inc., or Cardinal Health, and McKesson Corporation, collectively accounted for at least 86% of our gross product sales during 2008.

The loss of any of these wholesaler customers accounts or a material reduction in their purchases could harm our business, financial condition and results of operations if we are unable to enter into agreements with replacement wholesale distributors on commercially reasonable terms. The risk of this occurring is exacerbated by the recent significant consolidation in the wholesale drug distribution industry, including through mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

Our business could suffer as a result of a failure to manage and maintain our distribution network.

We rely on third parties to distribute our products to pharmacies. We have contracted with DDN, a third-party logistics company, for the distribution of our products to wholesalers, retail drug stores, mass merchandisers and grocery stores in the United States.

Our distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. Failure to maintain our third-party contracts or a third party s inability or failure to adequately perform as agreed under its contract with us could negatively impact us. We do not have our own warehouse or distribution capabilities, we lack the resources and experience to establish any of these functions, and we do not intend to establish these functions in the foreseeable future. If we are unable to effectively manage and maintain our distribution network, sales of our products could be severely compromised and our business could be harmed.

We also depend on the distribution abilities of our wholesale customers to ensure that products are effectively distributed throughout the supply chain. If there are any interruptions in our customers ability to distribute products through their distribution centers, our products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution. For example, in the fourth quarter of 2007 and the first quarter of 2008, several Cardinal Health distribution centers were placed on probation by the DEA and were prohibited from distributing controlled substances. Although Cardinal Health had a plan in place to re-route all orders to the next closest distribution center for fulfillment, system inefficiency resulted in a failure to effectively distribute our products to all areas.

If any of the third parties that we rely upon for assistance in researching, developing, manufacturing, promoting and distributing our products and product candidates defaults on or is unable to refinance at maturity its third party indebtedness, our operating performance would be adversely affected.

The full impact of the credit crunch that is currently affecting the national and international credit markets has yet to be fully established and therefore the possibility remains that credit conditions, as well as a slowdown or recession in economic growth, could adversely affect the third parties upon whom we rely for researching, developing, manufacturing, promoting and distributing our products and product candidates. We believe that some of the third parties upon which we rely, including Neos Therapeutics, L.P., or Neos, depend on financing from banks, financial institutions and other third-party financing sources in order to finance their operations. The current economic environment may make it more difficult or impossible for these third parties to obtain additional financing or extend the terms of their current financing. Some of these third parties may be highly leveraged, and if they are unable to service their indebtedness, such failure could adversely affect their ability to maintain their operations and to meet their contractual obligations to us, which may have an adverse effect on our financial condition, results of operations and cash flows.

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We depend on MedImmune and Beckman Coulter and expect to depend on additional collaborators in the future for a portion of our revenues and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of our product candidates. These collaborations may not be successful.

We have entered into and may in the future enter into collaboration arrangements on a selective basis. For example, we have determined as a strategic matter to seek to enter into collaboration arrangements with respect to the development of our alpha-7 product candidates and our zileuton injection product candidate.

We are relying on MedImmune to fund the development of and to commercialize product candidates in our HMGB1 program. We are relying on Beckman Coulter to fund the development and to commercialize diagnostics in our HMGB1 program. Payments due to us under the collaboration agreements with MedImmune and Beckman Coulter are generally based on the achievement of specific development and commercialization milestones that may not be met. In addition, the collaboration agreements entitle us to royalty payments that are based on the sales of products developed and marketed through the collaborations. These future royalty payments may not materialize or may be less than expected if the related products are not successfully developed or marketed or if we are forced to license intellectual property to continue to generate revenues.

Our collaboration agreement with MedImmune generally is terminable by MedImmune at any time upon six-months notice or upon our material uncured breach of the agreement. The parties agreed to work exclusively in the development and commercialization of HMGB1-inhibiting products for a period of four years, and, after such time, we have agreed to work exclusively with MedImmune in the development of HMGB1-inhibiting products for the remaining term of the agreement. If MedImmune were to terminate or breach this arrangement, and we were unable to enter into a similar collaboration agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on our own, the development and commercialization of the HMGB1 program likely would be delayed, curtailed or terminated, which could harm our future prospects.

In June 2007, AstraZeneca PLC completed its acquisition of MedImmune and MedImmune became a wholly owned subsidiary of AstraZeneca. We cannot predict what impact this transaction may have on our HMGB1 collaboration with MedImmune. If MedImmune does not devote sufficient time and resources to our collaboration or changes the focus of its programs, it could delay or prevent the achievement of clinical, regulatory and commercial milestones and prevent us from realizing the potential commercial benefits of the collaboration.

Our license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. If Beckman Coulter were to terminate or materially breach the license agreement, and we were unable to enter into a similar agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on our own, the development and commercialization of a diagnostic based on the detection of HMGB1 likely would be delayed, curtailed or terminated.

In addition, our collaborations with MedImmune and Beckman Coulter and any future third-party collaborative arrangements may not be scientifically or commercially successful. Factors that may affect the success of collaborations include the following:

- Collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product on which they are collaborating with us or that could affect our collaborators commitment to us;

- Reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our collaborators would reduce our revenues, which we expect will be based on a percentage of net sales by collaborators;

- Collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;

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Collaborators may not devote sufficient time and resources to any collaboration with us, which could prevent us from realizing the potential commercial benefits of that collaboration; and

Collaborators may pursue higher priority programs or change the focus of their development programs, which could affect their commitments to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or the commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration of our collaboration agreements would adversely affect us financially and could harm our business reputation.

Risks Relating to Intellectual Property and Licenses

If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.

Our success depends in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products, whether such technology is owned by us or licensed to us by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. We and our licensors may not be able to obtain additional issued patents relating to our respective technology or products. Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the longevity of the patent protection we may have for our products. For example, two United States patents exclusively licensed to us have been challenged by third parties in re-examination proceedings before the USPTO. While we no longer rely on one of the patents to protect any of our products, we believe that the other United States patent being re-examined, the 372 Patent, covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. In addition, Breckenridge filed suit on November 10, 2008, against Cornerstone BioPharma, Inc. in the United States District Court for the District of Maryland seeking, among other things, a declaratory judgment that the 372 Patent is invalid. The re-examination proceedings before the USPTO and the Breckenridge litigation are described in greater detail in our annual report on Form 10-K filed with the SEC on March 26, 2009 under the caption Legal Proceedings in Part I, Item 3. If the USPTO or the United States District Court for the District of Maryland finds that some or all of the claims under the 372 Patent are invalid, our sales of the ALLERX Dose Pack products and our future operating and financial results could be adversely affected. Additionally, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our owned or licensed patents also may not afford protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in our or our licensors issued patents or pending patent applications, or that we or our licensors were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a United States patent application covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. These proceedings are costly and time-consuming, and it is possible that our efforts could be unsuccessful, resulting in a loss of our United States patent protection. In addition, United States patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-provisional filing date. Because the timing for submission of our applications to the FDA for regulatory approval of our product candidates is uncertain and, once submitted, the FDA regulatory process and timing for regulatory approval with respect to our product candidates is unpredictable, our

estimates regarding the

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commercialization dates of our product candidates are subject to change. Accordingly, the length of time, if any, our product candidates, once commercialized, will remain subject to patent protection is uncertain.

Our collaborators and licensors may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, under our license arrangement with Pharmaceutical Innovations for ALLERX Dose Pack and ALLERX Dose Pack PE, Pharmaceutical Innovations generally is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if Pharmaceutical Innovations fails to do so. In addition, both Pharmaceutical Innovations and we have the right to pursue claims against third parties for infringement of the patent rights.

We may not have sufficient resources to bring these actions or to bring such actions to a successful conclusion. Even if we are successful in these proceedings, we may incur substantial cost and divert the time and attention of our management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on our business.

The composition of matter patent for the API in SPECTRACEF and in the SPECTRACEF line extension product candidates expired in April 2009, and the composition of matter patent for the API in ZYFLO CR and ZYFLO will expire in December 2010 and none of our other current products or current product candidates have, or will have, composition of matter patent protection.

Some of our currently marketed products do not have patent protection and in most cases such products face generic competition. In addition, although we own or exclusively license United States patents and patent applications with claims directed to the pharmaceutical formulations of our product candidates, methods of use of our product candidates to treat particular conditions, delivery systems for our product candidates, delivery profiles of our product candidates and methods for producing our product candidates, patent protection is not available for composition of matter claims directed to the APIs of any of our products or product candidates other than ZYFLO CR and ZYFLO. The SPECTRACEF composition of matter United States patent expired in April 2009. The composition of matter United States patent for zileuton that is used in ZYFLO CR and ZYFLO will expire in December 2010.

Because the composition of matter patent for the API in SPECTRACEF expired in April 2009 and for the API in ZYFLO CR and ZYFLO expires in December 2010, competitors will be able to offer and sell products with the same API so long as these competitors do not infringe any other patents that we or third parties hold, including formulation and method of use patents. However, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product s labeling. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit our ability to generate revenue from the sale of our product candidates, if approved for commercial sale. In addition, if a third party were able to design around our formulation and process patents and create a different formulation using a different production process not covered by our patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Trademark protection of our products may not provide us with a meaningful competitive advantage.

We use trademarks on most of our currently marketed products and believe that having distinctive marks is an important factor in marketing those products. Distinctive marks may also be important for any additional products that we successfully develop and commercially market. However, we generally do not expect our marks to provide a meaningful competitive advantage over other branded or generic products. We believe that efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors are, and are likely to continue to be, more important factors in the commercial success of our products and, if approved, our product candidates. For example, physicians and patients may not readily associate our trademark with the applicable product or API. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy if an approved generic is available, resulting in a

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significant loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Competitors also may use marks or names that are similar to our trademarks. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

Competitors may also seek to cancel our similar trademarks based on the competitor s prior use. For example, on May 15, 2008, the USPTO sent written notice to us that Bausch & Lomb filed a cancellation proceeding with respect to the ALLERX registration, 3,384,232 (serial number 77120121), seeking to cancel the ALLERX registration based on Bausch & Lomb s claims that such registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We responded to the TTAB on June 24, 2008 opposing the claims by Bausch & Lomb. On February 10, 2009, the TTAB suspended proceedings for a period of six months to allow the parties to negotiate a possible settlement of the cancellation proceeding. If the settlement discussions do not provide a prior resolution, we could take numerous courses of action, including continuing to oppose the claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex® trademark, or entering into discovery. If the USPTO cancels the ALLERX registration, we will no longer be able use the federal registration symbol in conjunction with our mark, and we may have unexpected costs of repackaging and changing our marketing materials, which could adversely affect sales of the ALLERX Dose Pack products and our future operating and financial results. The cancellation of the registration could also weaken our ability to enforce our rights in the ALLERX trademark against third parties in some circumstances, as we would no longer benefit from certain presumptions that come with a trademark registration. The USPTO cannot issue an injunction against the use of the ALLERX mark, and there currently is no threat pending against us to cease using the ALLERX brand. Nonetheless, if the matter is not settled, the possibility exists that an injunction, and even damages, could be sought against us in a new, separate trademark infringement proceeding in federal or state court by the same plaintiff.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We have acquired intellectual property rights relating to all of our product candidates under license agreements with third parties and expect to enter into additional licenses in the future. These licenses provide us with rights to intellectual property that is necessary for our business. For example, we acquired from Meiji the exclusive United States rights to market, develop and commercialize SPECTRACEF. Pursuant to our agreement with Meiji, we obtained an exclusive license to use know-how and trademarks to commercialize SPECTRACEF and any other pharmaceutical product containing the API cefditoren pivoxil in the United States.

Our existing licenses impose, and we expect that future licenses will impose, various obligations related to development and commercialization activities, milestone and royalty payments, sublicensing, patent protection and maintenance, insurance and other similar obligations common in these types of agreements. For example, we have entered into an agreement with Neos and Coating Place, Inc., or Coating Place, directed to commercialization of certain combination products, which obligates us to use commercially reasonable efforts to carry out development and regulatory activities within timelines specified in such development agreement. Under this agreement, we are obligated to use commercially reasonable efforts to develop and commercially launch such products in the United States as soon as practicable, and thereafter to maximize sales of such licensed product in the United States. If we fail to comply with these obligations or otherwise breach the license agreement, Neos or Coating Place may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any product that is covered by the licensed patents. Even if we contest any such termination or claim and are ultimately successful, we could suffer adverse consequences to our operations and business interests.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect our unpatented proprietary information in part by confidentiality agreements with our current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential

information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential

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information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets may otherwise become known or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, our competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business will be adversely affected.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently issue and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if such claims are successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims or to avoid potential claims, we or our potential future collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. For example, our MedImmune collaboration agreement provides that a portion of the royalties payable to us by MedImmune for licenses to our intellectual property may be offset by amounts paid by MedImmune to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in our revenues. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO, regarding intellectual property rights with respect to our products and technology. The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Many of our employees were previously employed at other pharmaceutical or biotechnology companies, including competitors or potential competitors. We try to ensure that our employees do not use the proprietary information or know-how of others in their work for us. However, we may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed the intellectual property, trade secrets or other proprietary information of any such employee s former employer. We may be required to engage in litigation to defend against these claims. Even if we are successful in such litigation, the litigation could result in substantial costs to us and/or be distracting to our management. If we fail to defend or are unsuccessful in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Risks Relating to Financial Results

We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our product development or commercialization efforts.

We have incurred and expect to continue to incur significant development expenses in connection with our ongoing activities, particularly as we conduct clinical trials for product candidates. In addition, we incur significant commercialization expenses related to our currently marketed products for sales, marketing, manufacturing and

distribution. We expect these commercialization expenses to increase in future periods if we are successful in

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obtaining FDA approval to market our product candidates CRTX 068, CRTX 062 and CRTX 058. We have used, and expect to continue to use, revenue from sales of our marketed products to fund a significant portion of the development costs of our product candidates and to expand our sales and marketing infrastructure. However, we may need substantial additional funding for these purposes and may be unable to raise capital when needed or on acceptable terms, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

As of March 31, 2009, we had approximately $10.7 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and revenue from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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

- the level of product sales from 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 chooses 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.

The terms of any additional capital funding that we require may not be favorable to us or our stockholders.

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. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any agreements governing debt or equity financing may also contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

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We have incurred significant losses and may incur losses in the future.

Critical Therapeutics experienced significant operating losses in each year from its inception in 2000 until its merger with Cornerstone BioPharma, and Cornerstone BioPharma experienced operating losses from its inception in 2004 and has only been profitable beginning in 2007. As a combined company, we may be unable to sustain and increase our profitability, even if we are able to commercialize additional products. To date, we have financed our operations primarily with revenue from product sales and borrowings. We have devoted substantially all of our efforts to:

establishing a sales and marketing infrastructure;

acquiring marketed products, product candidates and related technologies;

commercializing marketed products; and

developing product candidates, including conducting clinical trials.

We expect to continue to incur significant development and commercialization expenses as we:

seek FDA approval for our product candidates CRTX 068 and CRTX 062;

advance the development of our other product candidates, including CRTX 058, CRTX 067 and CRTX 069;

seek regulatory approvals for product candidates that successfully complete clinical testing; and

expand our sales force 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.

For us to sustain and increase our profitability, we believe that we must succeed in commercializing additional drugs with significant market potential. This will require us to be successful in a range of challenging activities, including:

successfully completing clinical trials of our product candidates;

obtaining and maintaining regulatory approval for these product candidates; and

manufacturing, marketing and selling those products for which we may obtain regulatory approval.

We may never succeed in these activities and may never generate revenue that is sufficient to sustain or increase profitability on a quarterly or annual basis. Any failure to sustain and increase profitability could impair our ability to raise capital, expand our business, diversify our product offerings or continue operations.

If the estimates that we make, or the assumptions upon which we rely, in preparing our financial statements prove inaccurate, the actual results may vary from those reflected in our projections.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders deficit, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated chargebacks, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product s historical experience adjusted to reflect known changes in the factors that impact such reserves. Actual sales allowances may exceed our estimates for a

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variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. We cannot assure you, therefore, that any of our estimates, or the assumptions underlying them, will be correct.

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We have a short operating history. Cornerstone BioPharma commenced active operations in 2004. Excluding ZYFLO CR and ZYFLO, Cornerstone acquired most of its currently marketed products and product candidates through two licensing transactions, one for the ALLERX Dose Pack products in February 2005 and the other for SPECTRACEF in October 2006, after these products were already being marketed by other companies. Excluding approvals to market ZYFLO CR and ZYFLO obtained by Critical Therapeutics personnel who are no longer with Cornerstone and the approval for SPECTRACEF 400 mg, for which the FDA approved Cornerstone s sNDA in July 2008 and which we launched in October 2008, we have not received approval from the FDA for any of our products or demonstrated our ability to obtain regulatory approval for any drugs that we have developed or are developing. In addition, we have not demonstrated our ability to initiate sales and marketing activities for successful commercialization of a newly approved product. As a relatively new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

Our operating results are likely to fluctuate from period to period.

We anticipate that there may be fluctuations in our future operating results. Potential causes of future fluctuations in our operating results may include:

- new product launches, which could increase revenues but also increase sales and marketing expenses;
- acquisition activity;
- one-time charges, such as for inventory expiration or product quality issues;
- increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional development;
- changes in the competitive, regulatory or reimbursement environment, which could decrease revenues or increase sales and marketing, product development or compliance costs;
- unexpected product liability or intellectual property claims and lawsuits;
- significant payments, such as milestones, required under collaboration, licensing and development agreements before the related product candidate has received FDA approval;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the dependence on a small number of products for a significant portion of net revenues and net income; and
- price erosion and customer consolidation.

Additionally, the ongoing integration of the Cornerstone BioPharma and Critical Therapeutics businesses following our merger could cause disruptions to our ongoing operations and be distracting to our management, which could cause fluctuations in our operating results. We may never fully realize the benefits or synergies from the merger that we have anticipated. If we are unable to successfully integrate our business operations following the consummation of the merger, our results of operations and financial condition could be materially and adversely affected.

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Risks Relating to Employee Matters and Managing Growth

If we fail to attract and retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.

Recruiting and retaining highly qualified scientific, technical and managerial personnel and research partners will be critical to our success. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals and contract manufacturing, will place additional requirements on our management, operational and financial resources. These demands may require us to hire additional personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the development, regulatory approval and commercialization of our product candidates. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to us.

We depend to a great extent on the principal members of our management and scientific staff. The loss of the services of any of our key personnel, in particular, Craig Collard, President and Chief Executive Officer, Brian Dickson, M.D., Chief Medical Officer, and David Price, Executive Vice President of Finance and Chief Financial Officer, might significantly delay or prevent the achievement of our development and commercialization objectives and could cause us to incur additional costs to recruit replacements. Each member of our executive management team may terminate his employment at any time. We do not maintain key person life insurance with respect to any of our executives. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs.

We may experience turnover amongst our board of directors. If our board were to fail to satisfy the requirements of relevant rules and regulations of the SEC and NASDAQ relating to director independence or membership on board committees, this could result in the delisting of our common stock from NASDAQ or could adversely affect investors confidence in us and our ability to access the capital markets. If we are unable to attract and retain qualified directors, the achievement of our corporate objectives could be significantly delayed or may not occur.

We identified a material weakness in our internal control over financial reporting as of December 31, 2008 that has not yet been effectively remediated. 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, as a result of this material weakness, our chief executive officer and chief financial officer concluded that, as of March 31, 2009, our disclosure controls and procedures were not effective. While we are in the process of identifying the measures needed to remedy this material weakness, we may not be successful in remediating this material weakness. In addition, 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. 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, 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

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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.

Our management will be required to devote substantial time to comply with public company regulations.

As a public company, we will incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and NASDAQ, impose various requirements on public companies, including with respect to corporate governance practices. Some of our management and other personnel do not have substantial experience complying with the requirements applicable to public companies and will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that our management maintain adequate disclosure controls and procedures and internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and, as applicable, our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require us to incur substantial accounting and related expenses and expend significant management efforts. We may need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404. Moreover, if we are not able to comply with the requirements of Section 404, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our financial reporting could be unreliable and misinformation could be disseminated to the public.

Any failure to develop or maintain effective internal control over financial reporting or difficulties encountered in implementing or improving our internal control over financial reporting could harm our operating results and prevent us from meeting our reporting obligations. Ineffective internal controls also could cause our stockholders and potential investors to lose confidence in our reported financial information, which would likely have a negative effect on the trading price of our common stock. In addition, investors relying upon this misinformation could make an uninformed investment decision, and we could be subject to sanctions or investigations by the SEC, NASDAQ or other regulatory authorities, or to stockholder class action securities litigation.

Risks Relating to Common Stock

Our stock price is subject to fluctuation, which may cause an investment in our stock to suffer a decline in value.

The market price of our common stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- the results of current and any future clinical trials;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the results and timing of regulatory reviews relating to the approval of product candidates;

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the initiation of material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights;

failure of any product candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect research and development expenditures;

the results of clinical trials conducted by others on products that would compete with our product candidates;

issues in manufacturing our product candidates or any approved products;

the loss of key employees;

the introduction of technological innovations or new commercial products by our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of our common stock;

changes in the structure of health care payment systems; and

period-to-period fluctuations in our financial results.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our financial condition, results of operations and reputation.

If we fail to continue to meet all applicable continued listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist our common stock, the market liquidity and market price of our common stock could decline.

Our common stock is currently listed on The NASDAQ Capital Market. In order to maintain that listing, we must satisfy minimum financial and other listing requirements. If we fail to continue to meet all applicable listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist our common stock, an active trading market for our common stock may not be sustained and the market price of our common stock could decline. If an active trading market for our common stock is not sustained, it will be difficult for our stockholders to sell shares of our common stock without further depressing the market price of our common stock or at all. A delisting of our common stock also could make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

If our quarterly results of operations fluctuate, this fluctuation may subject our stock price to volatility, which may cause an investment in our stock to suffer a decline in value.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which are not within our control, could subject our operating results and stock price to volatility, including:

variations in the amount and timing of sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products due to changes in product pricing, changes in the prevalence of disease conditions from quarter to quarter or other factors;

the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;

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the availability and timely delivery of a sufficient supply of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the amount of rebates, discounts and chargebacks to wholesalers, Medicaid, federal and state healthcare programs, and MCOs related to the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the amount and timing of product returns for the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

achievement of, or the failure to achieve, milestones under our development agreement with MedImmune, our license agreement with Beckman Coulter and, to the extent applicable, other licensing and collaboration agreements;

the results of ongoing and planned clinical trials of our product candidates;

production problems occurring at our third-party manufacturers;

the results of regulatory reviews relating to the development or approval of our product candidates; and

general and industry-specific economic conditions that may affect our research and development expenditures.

Due to the possibility of significant fluctuations, we do not believe that quarterly comparisons of our operating results will necessarily be indicative of our future operating performance. If our quarterly operating results fail to meet the expectations of stock market analysts and investors, the price of our common stock may decline.

If significant business or product announcements by us or our competitors cause fluctuations in our stock price, an investment in our stock may suffer a decline in value.

The market price of our common stock may be subject to substantial volatility as a result of announcements by us or other companies in our industry, including our collaborators. Announcements that may subject the price of our common stock to substantial volatility include announcements regarding:

our operating results, including the amount and timing of sales of our products, including the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the availability and timely delivery of a sufficient supply of our products, including the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

Our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;

the results of discovery, preclinical studies and clinical trials by us or our competitors;

the acquisition of technologies, product candidates or products by us or our competitors;

the development of new technologies, product candidates or products by us or our competitors;

regulatory actions with respect to our product candidates or products or those of our competitors; and

significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

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Insiders have substantial control and could delay or prevent a change in corporate control, including a transaction in which our stockholders could sell or exchange their shares for a premium.

As of March 31, 2009, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 51.6% of our outstanding common stock. As a result, our directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the company s management and affairs. Accordingly, this concentration of ownership may harm the value of the company s common stock by:

delaying, deferring or preventing a change in control;

impeding a merger, consolidation, takeover or other business combination; or

discouraging a potential acquirer from making an acquisition proposal or otherwise attempting to obtain control.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or frustrate attempts by our stockholders to change our management or board of directors and hinder efforts by a third party to acquire a controlling interest in our company.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, anti-takeover provisions include provisions in our bylaws and certificate of incorporation providing that, except as otherwise required by law, special meetings of the stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president (if the president is different than the chief executive officer) or the board of directors, and that stockholders may not take action by written consent and provisions in our bylaws providing for the classification of the board of directors. Additionally, the board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of the common stock are subject to the rights of the holders of any preferred stock that the company issues. As a result, our issuance of preferred stock could cause the market value of the common stock to decline and could make it more difficult for a third party to acquire a majority of our outstanding voting stock.

Delaware law also prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. The board of directors may use this provision to prevent changes in management. Also, under applicable Delaware law, the board of directors may adopt additional anti-takeover measures in the future.

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

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

Not applicable.

Issuer Purchases of Equity Securities

During the first quarter of 2009, we did not purchase any shares of our common stock.

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ITEM 3. ***DEFAULTS UPON SENIOR SECURITIES***

Not applicable.

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

None.

ITEM 5. ***OTHER INFORMATION***

Entry into a Material Definitive Agreement.

Pursuant to an agreement entered into on March 13, 2007 with DEY, a subsidiary of Mylan, as subsequently amended on June 25, 2007 by amendment 1, we and DEY agreed to jointly co-promote ZYFLO and, if approved by the FDA, ZYFLO CR. Under the co-promotion agreement, we granted DEY an exclusive right to promote and detail ZYFLO and ZYFLO CR in the United States, together with us and our affiliates, for asthma and, subject to FDA approval, other respiratory conditions. On May 4, 2009, we and DEY agreed to further amend the co-promotion agreement by amendment 2. The co-promotion agreement, as amended, is described below.

Both we and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In addition, DEY has agreed to provide a minimum number of details per month for ZYFLO CR in the second position to certain pulmonary specialists, or PUDs. Under the amendment, our former obligation to provide a minimum number of details per month for ZYFLO CR in the first position has been eliminated. We 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 we are responsible for all other promotional expenses related to the products.

Prior to January 1, 2009, we 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, in order to tie DEY s co-promotion fee more closely to prescriptions written by the PUDs it is detailing, we have agreed to pay DEY a co-promotion fee equal to the ratio of total prescriptions written by PUDs 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 has a term expiring on December 31, 2013, which may be extended by mutual agreement of DEY and us. Beginning on March 31, 2012, either DEY or we may terminate the co-promotion agreement with six months advance written notice. DEY also has the right to terminate the co-promotion agreement upon two (2) months prior written notice to us if we experience certain supply shortages. First, DEY may terminate if in any two consecutive calendar quarters we are unable to deliver to DEY at least seventy five percent (75%) of the ZYFLO CR samples forecast by DEY for such quarters. Second, DEY may terminate at any time if commercial supplies of ZYFLO CR remain on back order for more than one calendar quarter. In addition to these supply-related events, 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 million.

DEY and Mylan have agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of: (i) one year after expiration or termination of the co-promotion agreement, or (ii) March 31, 2012. However, if an unauthorized generic product to ZYFLO CR that is AB-rated by the FDA is introduced by a third party, DEY and Mylan will no longer be held to any non-competition obligation. On the other hand, if an unauthorized generic product to ZYFLO that is AB-rated by the FDA is introduced by a third party, DEY and Mylan would not be subject to the non-competition obligations with respect to ZYFLO only. If we decide to launch an authorized generic of ZYFLO CR or ZYFLO, DEY and Mylan will have the exclusive right to market the authorized generic version of such product. DEY and Mylan also will not be subject to these non-competition obligations if DEY terminates the co-promotion agreement either because ZYFLO CR cumulative net sales for any four consecutive calendar quarters after January 1, 2009 of ZYFLO CR are less than $20 million or upon the occurrence of a material uncured breach by us.

Amendment 2 to the co-promotion agreement is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q, and we refer you to such exhibit for the complete terms of amendment 2 to the co-promotion agreement, which are incorporated herein by reference.

Termination of a Material Definitive Agreement

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

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ITEM 6. ***EXHIBITS***

The following exhibits are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K:

Exhibit No.	Description
10.1+	Amendment No. 2, dated May 4, 2009, to Co-Promotion and Marketing Services Agreement between DEY, L.P. and Cornerstone Therapeutics Inc. dated March 13, 2007.
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.

+ Confidential treatment requested as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.

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SIGNATURES

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

CORNERSTONE THERAPEUTICS INC.

Date: May 7, 2009

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

Date: May 7, 2009

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

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