CRITICAL THERAPEUTICS INC
Form 10-Q
May 12, 2008

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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, 2008

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period to

Commission File Number: 000-50767

Critical 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.)*
60 Westview Street **Lexington, Massachusetts** *(Address of Principal Executive Offices)*	**02421** *(Zip Code)*

(781) 402-5700
(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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o (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, 2008, the registrant had 43,479,198 shares of Common Stock, $0.001 par value per share, outstanding.

CRITICAL THERAPEUTICS, INC.

FORM 10-Q

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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 our proposed merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone, including the expected timetable for completing the transaction; our future sales and marketing efforts for ZYFLO CR™ (zileuton) extended-release tablets, or ZYFLO CR; possible therapeutic benefits and market acceptance of ZYFLO CR; the progress and timing of our drug development programs and related trials; the efficacy of our drug candidates; and our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, target, may, plan, project, should, 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: the ability to consummate the proposed transaction with Cornerstone; our ability to successfully market and sell ZYFLO CR, including the success of our co-promotion arrangement with Dey, L.P., a wholly-owned subsidiary of Mylan Inc., or DEY; our ability to transition our management team effectively; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO CR; patient, physician and third-party payor acceptance of ZYFLO CR as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO CR or ZYFLO® (zileuton tablets) immediate-release formulation of zileuton, or ZYFLO; our heavy dependence on the commercial success of ZYFLO CR; our ability to maintain regulatory approvals to market ZYFLO CR; the success of our co-promotion agreement with DEY for PERFOROMIST™ (formoterol fumarate) Inhalation Solution, or PERFOROMIST; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; our ability to maintain compliance with NASDAQ listing standards; conducting 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 obtain the substantial additional funding required to conduct our development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc., a wholly-owned subsidiary of AstraZeneca PLC; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO CR, our discoveries and drug candidates. These and other risks are described in greater detail below under the caption Risk Factors in Part II, Item 1A. 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, except as may be required by law, 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. In particular, unless otherwise stated or the context otherwise requires, we have prepared this quarterly report on Form 10-Q as if we were going to remain a standalone, independent company. If we consummate the merger with Cornerstone, the descriptions of our strategy, future operations and financial position, future revenues, projected costs and prospects and the plans and objectives of management in this quarterly report on Form 10-Q may no longer

be applicable.

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Item 1. *Financial Statements*

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2008	December 31, 2007
	(Unaudited) (In thousands)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 20,239	$ 33,828
Accounts receivable, net	1,280	1,273
Amount due under collaboration agreements		31
Inventory, net	9,666	5,599
Prepaid expenses and other	1,839	2,174
Total current assets	33,024	42,905
Fixed assets, net	869	1,151
Other assets	287	868
Total assets	$ 34,180	$ 44,924
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	$	$ 370
Current portion of accrued license fees	1,860	1,838
Current portion of deferred co-promotion fees	1,880	1,880
Accounts payable	6,566	5,283
Accrued expenses	5,620	7,154
Total current liabilities	15,926	16,525
Long-term portion of accrued license fees, less current portion	1,775	1,754
Long-term portion of deferred co-promotion fees, less current portion	9,353	9,554
Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, par value $0.001; authorized 5,000,000 shares; no shares issued and outstanding		
Common stock, par value $0.001; authorized 90,000,000 shares; issued and outstanding 42,805,348 shares at March 31, 2008 and December 31, 2007	43	43
Additional paid-in capital	209,247	208,420
Accumulated deficit	(202,151)	(191,372)
Accumulated other comprehensive loss	(13)	

Total stockholders equity	7,126	17,091
Total liabilities and stockholders equity	$ 34,180	$ 44,924

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2008	2007
	(Unaudited)	
	(In thousands except share and per share data)	
Revenues:		
Net product sales	$ 3,333	$ 2,894
Revenue under collaboration agreements		601
Total revenues	3,333	3,495
Costs and expenses:		
Cost of products sold	1,825	741
Research and development	5,364	2,918
Sales and marketing	3,878	1,982
General and administrative	3,214	3,055
Total costs and expenses	14,281	8,696
Operating loss	(10,948)	(5,201)
Other income (expense):		
Interest income	218	590
Interest expense	(49)	(39)
Total other income	169	551
Net loss	$ (10,779)	$ (4,650)
Net loss per share	$ (0.25)	$ (0.11)
Basic and diluted weighted-average common shares outstanding	42,805,348	42,456,700

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended March 31,	
	2008	2007
	(Unaudited)	
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (10,779)	$ (4,650)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	115	166
Amortization of premiums on short-term investments and other	43	3
Gain on sale of fixed assets	(108)	(8)
Stock-based compensation expense	827	1,042
Changes in assets and liabilities:		
Accounts receivable	(7)	70
Amount due under collaboration agreements	31	619
Inventory	(4,067)	(574)
Prepaid expenses and other	503	6
Accounts payable	1,283	74
Accrued expenses	(1,534)	(987)
Deferred collaboration revenue and fees		2,430
Deferred product revenue		(1,178)
Deferred co-promotion fees	(201)	
Net cash used in operating activities	(13,894)	(2,987)
Cash flows from investing activities:		
Proceeds from sale of investment	400	
Proceeds from sale of fixed assets	276	26
Purchases of fixed assets	(1)	
Net cash provided by investing activities	675	26
Cash flows from financing activities:		
Proceeds from exercise of stock options		181
Repayments of long-term debt and capital lease obligations	(370)	(278)
Net cash used in financing activities	(370)	(97)
Net decrease in cash and cash equivalents	(13,589)	(3,058)
Cash and cash equivalents at beginning of period	33,828	48,388

Cash and cash equivalents at end of period	$ 20,239	$ 45,330
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 9	$ 42

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

(1) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Critical Therapeutics, Inc. and its subsidiary (the Company), and have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The Company believes that all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation, have been included. The information included in this quarterly report on Form 10-Q should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and footnotes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission (the SEC).

Operating results for the three-month periods ended March 31, 2008 and 2007 are not necessarily indicative of the results for the full year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these financial statements include certain judgments regarding revenue recognition, product returns, inventory valuation, accrued and prepaid expenses and valuation of stock-based compensation.

Management s Plans and Proposed Transaction

In November 2007, the Company s board of directors announced that it was reviewing a range of strategic alternatives that could result in potential changes to the Company s current business strategy and future operations. As a result of its strategic alternatives process, on May 1, 2008, the Company and Neptune Acquisition Corp., a wholly owned subsidiary of the Company (the Transitory Subsidiary), entered into an Agreement and Plan of Merger (the Merger Agreement) with Cornerstone BioPharma Holdings, Inc. (Cornerstone). This is further discussed in Note 11, Subsequent Events. Under the Merger Agreement, the Transitory Subsidiary will be merged with and into Cornerstone (the Merger), with Cornerstone continuing after the Merger as the surviving corporation and a wholly owned subsidiary of the Company. If the Merger is completed, at the effective time of the Merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of the Company s common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone s common stock will be assumed by the Company and become options and warrants to purchase the Company s common stock. The Merger Agreement provides that in the Merger the Company will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of the Company s common stock, subject to adjustment as a result of a contemplated reverse stock split of the Company s common stock to occur in connection with the Merger.

Going Concern Assumption

The Company has experienced significant operating losses in each year since its inception in 2000, including net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. The Company had net losses of $10.8 million in the three months ended March 31, 2008 and $4.7 million in the three months ended March 31, 2007. As of March 31, 2008, the Company had an accumulated deficit of approximately $202 million. For the year ended December 31, 2007 and the three

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

months ended March 31, 2008, the Company recorded $11.0 million and $3.3 million, respectively, of revenue from the sale of ZYFLO® (zileuton) tablets (ZYFLO) and ZYFLO CR® (zileuton) extended-release tablets (ZYFLO CR) and has not recorded revenue from any other product.

Although the size and timing of its future operating losses are subject to significant uncertainty, the Company expects its operating losses to continue over the next several years as it funds its development programs, markets and sells ZYFLO CR and prepares for the potential commercial launch of its product candidates and may never achieve profitability. Since the Company s inception, it has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from its collaborators, MedImmune, Inc. (MedImmune) and Beckman Coulter, Inc. (Beckman Coulter), license fees from Innovative Metabolics, Inc. (IMI), payments from DEY under its zileuton co-promotion agreement and revenue from sales of ZYFLO CR and ZYFLO.

For the quarter ended March 31, 2008, the Company s net cash used in operating activities was $13.9 million. Based on our current operating plans, the Company believes that our available cash and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations for the foreseeable future. If the Company s existing resources are insufficient to satisfy its liquidity requirements, either under its current operating plan or any new operating plan it may adopt, it may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to the Company on acceptable terms or at all.

These matters raise substantial doubt about the Company s ability to continue as a going concern and, therefore, the Company may be unable to realize its assets and discharge its liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts nor to amounts and classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

Recent Accounting Pronouncements

In November 2007, the Financial Accounting Standards Board s (FASB) Emerging Issues Task Force (EITF) issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* (EITF 07-01). EITF 07-01 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 (made to) other collaborators based on other applicable generally accepted accounting principles (GAAP) or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer or analogous relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 to have a material impact on its financial statements and results of operations.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods

to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on the Company s financial statements and results of operations.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 141(R), *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,* 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, such 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 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact the Company if it is party to a business combination after the pronouncement has been adopted.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest 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 Company does not expect the adoption of SFAS 160 to have a material impact on its financial statements and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* (SFAS 159). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company s financial statements and results of operations, as the Company has not elected to measure any financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. FAS 157-2 (FSP 157-2) that defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company was required to adopt the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008 and has included the now expanded disclosures in Note 3. The Company is currently evaluating the effect FSP 157-2 will have on its financial statements and results of operations.

(2) Revenue Recognition

Revenue Recognition

The Company recognizes revenue in accordance with the SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101) as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. The Company s revenue is currently derived from product sales of its commercially marketed products, ZYFLO CR and ZYFLO, and its collaboration and

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

license agreements. The collaboration and license agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties. In addition, the Company s product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

Net product sales. The Company sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies. The Company commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. The Company authorizes returns for damaged products and exchanges for expired products in accordance with its return goods policy and procedures, and has established allowances for such amounts at the time of sale. The Company is obligated to accept from customers the return of products that are within six months of their expiration date or up to 12 months beyond their expiration date. The Company recognizes revenue from product sales in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, which requires the amount of future returns to be reasonably estimated at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and estimated chargebacks from distributors and prompt payment and other discounts.

The Company establishes allowances for estimated product returns, rebates and chargebacks primarily based on several factors, including the actual historical product returns, the Company s estimate of inventory levels of the Company s products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

The Company s estimates of product returns, rebates and chargebacks require management s subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, chargebacks and other discounts exceed the estimates the Company made at the time of sale, its financial position, results of operations and cash flows would be negatively impacted.

As of March 31, 2008 and 2007, the Company s allowances for ZYFLO CR and ZYFLO product returns were $286,000 and $138,000, respectively. Prior to the first quarter of 2007, the Company deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors and pharmacies until units were dispensed through patient prescriptions, as the Company was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, the Company began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties as sufficient history existed to make such estimates. In connection with this change in estimate, the Company recorded an increase in net product sales in the three months ended March 31, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000. The Company recorded $2.6 million in net product sales of ZYFLO CR in the first quarter of 2008. The Company anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return used for ZYFLO. As a result, the Company recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns. In the first quarter of 2008, primarily as a result of stronger than expected ZYFLO prescriptions, the Company reduced its product return reserve for ZYFLO by $440,000.

Revenue under collaboration and license agreements. Under the Company s collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone

payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in the Company s statements of operations when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company s collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

development of the product. For example, a delay or acceleration of the performance period by the Company s collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with the Company, the Company does not recognize revenues in excess of cumulative cash collections.

Under the Company s license agreement with IMI, the Company licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. Under the agreement with IMI, the Company received an initial license fee of $500,000 in cash and IMI junior preferred stock valued at $500,000 in connection with IMI s first financing. However, under its license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute (The Feinstein Institute), the Company was obligated to pay The Feinstein Institute $100,000 of this cash payment and IMI junior preferred stock valued at $100,000. The Company included in revenue under collaboration and license agreements in 2007 the $1.0 million total license fee that the Company received from IMI and included the payments of $100,000 in cash and IMI junior preferred stock valued at $100,000 that the Company made to The Feinstein Institute in research and development expenses. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay the Company $1.0 million, excluding a $200,000 payment that the Company would be obligated to pay The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by IMI and its affiliates.

On March 14, 2008, the Company sold the 400,000 shares of junior preferred stock issued to it by IMI in May 2007 in connection with IMI s first financing for an aggregate purchase price of $400,000. The Company sold these shares of junior preferred stock to two investors which had previously participated in IMI s first financing. The purchase price is subject to adjustments if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than the price they paid the Company.

At March 31, 2008, the Company s accounts receivable balance of $1.3 million was net of allowances of $30,000. At December 31, 2007, the Company s accounts receivable balance of $1.3 million was net of allowances of $29,000.

(3) Cash Equivalents and Investments

The Company considers all highly-liquid investments with original maturities of three months or less when purchased to be cash equivalents.

At March 31, 2008, the Company held $287,000 in auction rate security with a AAA credit rating upon purchase. The Company has been informed that there is insufficient demand at auction for these security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. The Company has classified its $287,000 in auction rate security as a long-term investment and has included the amount in other assets on the Company s accompanying balance sheet. The unrealized gain (loss) during the period is recorded as an adjustment to stockholders equity. The cost of the debt securities, if any, is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period.

As a result of the adoption of SFAS 157 as of January 1, 2008, the Company is now required to provide additional disclosures as part of its financial statements.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

inputs are unobservable inputs based on the Company s own assumptions used to measure assets and liabilities at fair value. A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of March 31, 2008 (in thousands):

		Fair Value Measurements at March 31, 2008 Using		
	Total Carrying Value at March 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available for sale securities:				
U.S. government-backed securities	$ 3,561	$ 3,561	$	$
Commercial paper	1,199		1,199	
Auction rate security	287			287
Total assets measured at fair value	$ 5,047	$ 3,561	$ 1,199	$ 287

U.S. government-backed securities and commercial paper are valued using a market approach based upon the quoted market prices of identical instruments when available or other observable inputs such as trading prices of identical instruments in inactive markets. Scheduled maturity dates of U.S. government-backed securities and commercial paper as of March 31, 2008, had original maturities of less than 90 days and therefore investments were classified as cash and cash equivalents.

The Company s auction rate security instrument is classified as an available for sale security and reflected at fair value. However, due to recent events in credit markets, the auction for this security failed during first quarter of 2008. Therefore, the fair value of this security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of March 31, 2008. This analysis considers, among other items, the collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows and the expectation of the next time the security is expected to have a successful auction.

As a result of the temporary decline in fair value for the Company s auction rate security, which the Company attributes to liquidity issues rather than credit issues, it has recorded an unrealized loss of $13,000 to accumulated other comprehensive income.

(4) Research and License Agreements

In December 2003, the Company entered into an agreement to in-license the controlled-release formulation and the injectable formulation of zileuton from Abbott Laboratories and entered into an agreement with a subsidiary of SkyePharma PLC (SkyePharma), to in-license the controlled-release technology relating to zileuton from SkyePharma. Under these agreements, the Company is required to make milestone payments for successful completion of the technology transfer, filing and approval of the product in the United States and commercialization of the product. In May 2007, the Company received approval by the FDA of the new drug application (NDA) for ZYFLO CR. As a result of the FDA approval, the Company paid $3.1 million under these agreements in June 2007, and accrued an additional $1.8 million and $1.7 million that will be due on the first and second anniversary, respectively, of the FDA s approval of ZYFLO CR. The amounts due on the first and second anniversary of the FDA s approval were accrued at the present value of the total $3.8 million owed, and the accretion of the discount is included in interest expense. The $3.1 million paid as a result of the FDA approval of ZYFLO CR and the accrued $1.8 million and $1.7 million that will be due on the first and second anniversary, respectively, of the FDA s approval of ZYFLO CR were included in the Company s research and development expenses in the second quarter of 2007. For the three months ended March 31, 2008, the Company recorded interest expense of $43,000 related to the accretion of the discount.

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(5) Inventory

Inventory is stated at the lower of cost or market, with cost determined under the first-in, first-out (FIFO) method. As of March 31, 2008, the Company held $9.7 million in inventory to be used for commercial sales related to its commercial product, ZYFLO CR. The Company analyzes its inventory levels quarterly and records reserves for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. At March 31, 2008, the Company had an inventory reserve of $1.2 million. The inventory reserve relates to certain batches that did not meet the Company s product release specifications for ZYFLO CR. Inventory consisted of the following at March 31, 2008 and December 31, 2007, respectively (in thousands):

	March 31, 2008	December 31, 2007
Raw material	$ 6,301	$ 2,587
Work in process	4,197	3,062
Finished goods	361	766
Total inventory	10,859	6,415
Less: reserve	(1,193)	(816)
Inventory, net	$ 9,666	$ 5,599

Risk and uncertainties. The Company currently purchases zileuton active pharmaceutical ingredient (API) for its commercial requirements for ZYFLO CR from a single source. In addition, the Company currently contracts with single parties for the manufacture of uncoated ZYFLO CR tablets and for the coating and packaging of ZYFLO CR tablets. The disruption or termination of the supply of the API, a significant increase in the cost of the API from this single source or the disruption or termination of the manufacturing of the commercial product would have a material adverse effect on the Company s business, financial position and results of operations.

(6) Comprehensive Loss

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying condensed consolidated statements of operations for the three months ended March 31, 2008 and 2007, and comprehensive loss is the unrealized gain (loss) on investments for the period. Total comprehensive loss was $10.8 million and $4.6 million for the three months ended March 31, 2008 and 2007, respectively. The unrealized gain (loss) on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet.

(7) Stock-Based Compensation

All stock-based awards are accounted for at their fair market value in accordance with SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)) and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock option activity for the three-month period ended March 31, 2008 was as follows:

	Number of Shares	2008 Weighted-Average Exercise Price Per Share
Outstanding January 1	5,020,903	$ 4.20
Granted	12,000	0.90
Exercised		
Cancelled	(888,119)	3.66
Outstanding March 31	4,144,784	$ 4.31
Vested and Expected to Vest March 31	3,759,083	$ 4.34
Exercisable March 31	2,514,974	$ 4.75

The weighted-average remaining contractual term and the aggregate intrinsic value for options outstanding at March 31, 2008 were 6.2 years and $6,000, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options exercisable at March 31, 2008 were 4.9 years and $6,000, respectively. The weighted-average exercise price and the number of options vested or expected to vest at March 31, 2008 were 5.9 years and $6,000, respectively. There were no options exercised during the three months ended March 31, 2008.

The total fair value of the shares vested and unexercised and expensed during the three months ended March 31, 2008 was $168,000. As of March 31, 2008, there was $4.9 million of total unrecognized compensation expense related to unvested share-based compensation awards granted under the Company s stock plans, which is expected to be recognized over a weighted-average period of 2.0 years.

The Company anticipates recording additional stock-based compensation expense of $2.0 million in the remaining three quarters of 2008, $2.0 million in 2009 and $828,000 thereafter relating to the amortization of unrecognized compensation expense as of March 31, 2008. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

Option valuation models require the input of highly subjective assumptions. The Company has computed the impact under SFAS 123(R) for options granted using the Black-Scholes option-pricing model for the three months ended March 31, 2008 and 2007. The Company increased its expected volatility assumption for the three months ended March 31, 2008 to 73% from 66% in the corresponding period of 2007. The rate is based on the Company s actual historical volatility since its initial public offering. The expected life of options granted was estimated using the simplified method calculation as prescribed by SEC Staff Accounting Bulletin No. 110. The assumptions used and weighted-average information are as follows:

	Three Months Ended March 31,	
	2008	**2007**
Risk free interest rate	2.8%	4.6%
Expected dividend yield	0%	0%
Expected forfeiture rate	10.6%	10.2%
Expected life	6.25 years	6.25 years
Expected volatility	73%	66%
Weighted-average fair value of options granted equal to fair value	$ 0.60	$ 1.35

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(8) Basic and Diluted Loss per Share

Basic and diluted net loss per common share is calculated by dividing the net loss by the weighted-average number of unrestricted common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because the effects of potentially dilutive securities are anti-dilutive for all periods presented. Anti-dilutive securities that are not included in the diluted net loss per share calculation aggregated 12,027,341 and 12,908,520 as of March 31, 2008 and 2007, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of March 31, 2008 and 2007.

(9) Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with research and development activities relating to its existing product candidates as well as discovery efforts relating to potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company s fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company s products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately $29.9 million as of March 31, 2008. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in the Company s clinical trials and timing of the development of the Company s product candidates. As of March 31, 2008, the Company had $25,000 and $1.7 million included in prepaid expenses and accrued expenses, respectively, related to its research and development agreements on the accompanying condensed consolidated balance sheet. These research and development expenses are accounted for as such costs are incurred. In addition, as of March 31, 2008, the Company had $3.6 million in accrued license fees representing the net present value of the Company s milestone obligations due on the first and second anniversary of the FDA s approval of ZYFLO CR. In addition, at March 31, 2008, the Company accrued approximately $1.1 million in contractual costs as a result of the Company s termination of a Phase IV clinical trial for ZYFLO CR. These accrued license fees and termination costs are included in the accompanying condensed consolidated balance sheet.

In addition, on August 20, 2007, the Company entered into an agreement with Jagotec AG, a subsidiary of SkyePharma PLC, under which Jagotec agreed to manufacture and supply bulk uncoated tablets of ZYFLO CR to the Company for commercial sale. The Company previously had contracted with Jagotec for the manufacture of ZYFLO CR for clinical trials and regulatory review. Under the terms of the prior agreement, the Company and Jagotec had agreed to negotiate a commercial manufacturing agreement for ZYFLO CR. SkyePharma has guaranteed the performance by Jagotec of all obligations under the commercial manufacturing agreement. The Company has agreed to purchase minimum quantities of ZYFLO CR during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, the Company has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, 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. The Company also entered into a manufacturing and supply agreement with Rhodia Pharma Solutions, which was assigned to Shasun Pharma Solutions Ltd. (Shasun), for commercial production of the API for ZYFLO and ZYFLO CR, subject to specified limitations, through December 31, 2009. Under this

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

agreement, the Company committed to purchase minimum amounts of API in the first quarter of 2008. In addition, the Company has agreed to purchase specified quantities of API in 2008 and 2009 with a portion subject to the right of cancellation with a termination fee. The API purchased from Shasun currently has a shelf-life of 36 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. As of March 31, 2008, no reserves have been recorded for purchase commitments.

In May 2007, the Company entered into a three year manufacturing services agreement with Patheon Pharmaceuticals Inc. (Patheon), under which Patheon agreed to coat, conduct quality control and quality assurance and stability testing and package commercial supplies of ZYFLO CR in tablet form. Under this agreement, the Company is responsible for supplying uncoated ZYFLO CR tablet cores to Patheon. The Company has agreed to purchase at least 50% of its requirements for such manufacturing services for ZYFLO CR for sale in the United States from Patheon each year for the term of the agreement.

In addition, in accordance with its co-promotion agreement with Dey, L.P. (DEY), a subsidiary of Mylan, Inc., the Company has entered into advertising and promotional contracts related to its marketing support for ZYFLO CR. The estimated amount that may be incurred in the future under these agreements totals approximately $7.3 million as of March 31, 2008.

The Company is also party to a number of agreements that require it to make milestone payments, royalty payments on net sales of the Company s products and payments on sublicense income received by the Company. In addition, from time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not a party to any pending material litigation or other material legal proceedings and was not a party to any such litigation or proceedings during any of the periods presented.

(10) DEY Co-Promotion and Marketing Services Agreements

On March 13, 2007, the Company entered into an agreement with DEY under which the Company and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and ZYFLO CR in the United States, together with the Company.

Under the co-promotion agreement, DEY paid the Company a non-refundable upfront payment of $3.0 million in March 2007, a milestone payment of $4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of $5.0 million in December 2007 following the commercial launch of ZYFLO CR. Under the co-promotion agreement, the Company will pay DEY a commission on quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. From the date DEY began detailing ZYFLO through the commercial launch of ZYFLO CR, the commission rate was 70%, following the commercial launch of ZYFLO CR in September 2007 through December 31, 2010, the commission rate is 35% and from January 1, 2011 through December 31, 2013, the commission rate is 20%. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by the parties.

The Company has deferred the $12 million in aggregate payments received to date and is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will be offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. The Company records all ZYFLO and ZYFLO CR sales generated by the combined sales force and records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses.

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For the three months ended March 31, 2008, approximately $200,000 was amortized from the deferred co-promotion fees representing the amount earned by DEY during this period.

On June 25, 2007, the Company entered into a definitive agreement with DEY to jointly promote DEY s product PERFOROMIST™ (formoterol fumarate) Inhalation Solution (PERFOROMIST), for the treatment of chronic obstructive pulmonary disease, or COPD. In October 2007, the Company announced that it commercially launched PERFOROMIST with DEY. Under the agreement, DEY agreed to pay the Company a commission on retail sales of PERFOROMIST above a specified baseline. The agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties.

(11) Subsequent Events

Proposed Merger with Cornerstone BioPharma Holdings, Inc.

As described in Note 1, Basis of Presentation, on May 1, 2008, the Company, the Transitory Subsidiary and Cornerstone entered into the Merger Agreement. If the Merger is completed, at the effective time of the Merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of our common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone s common stock will be assumed by the Company and become options and warrants to purchase the Company s common stock. The Merger Agreement provides that in the Merger the Company will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of the Company s common stock, subject to adjustment as a result of a contemplated reverse stock split of the Company s common stock to occur in connection with the Merger. Immediately following the effective time of the Merger, Cornerstone s stockholders will own approximately 70 percent, and the Company s current stockholders will own approximately 30 percent, of the Company s common stock, after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to the Company s outstanding options and warrants. The exchange ratio per share of Cornerstone s common stock will be based on the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger and will not be calculated until that time.

The consummation of the Merger is subject to a number of closing conditions, including the approval of both the Company s stockholders and Cornerstone s stockholders, approval by NASDAQ of the Company s application for re-listing of its common stock in connection with the Merger, the continued availability of its products and other customary closing conditions. The Company is targeting a closing of the transaction in the fourth quarter of 2008.

Immediately prior to the effective time of the Merger, the Company has agreed to effect a reverse stock split of its common stock whereby each issued and outstanding share of its common stock will be reclassified and combined into a fractional number of shares of common stock. The reverse stock split ratio is to be mutually agreed upon by the Company and Cornerstone. The reverse stock split is necessary so that as of the effective time of the Merger the Company will satisfy the minimum bid price requirement pursuant to NASDAQ s initial listing standards.

The Merger Agreement provides for the payment of a termination fee of $1.0 million by each of the Company and Cornerstone to the other party in specified circumstances in connection with the termination of the Merger Agreement. In addition, in specified circumstances in connection with termination of the Merger Agreement, the Company has

agreed to reimburse Cornerstone for up to $150,000 in expenses and Cornerstone has agreed to reimburse the Company for up to $100,000 in expenses.

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

May 2008 Restructuring Plan

As part of its efforts to reduce its operating expenditures, on May 8, 2008, the Company announced that it eliminated six positions, or approximately 8% of the Company s workforce. The headcount reduction primarily affects the Company s research and development group. The Company expects to consider further reductions in its headcount in additional areas of its business in the future in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on the Company s business needs and financial resources.

In connection with the implementation of its May 8, 2008 restructuring plan, the Company expects to record a charge of approximately $540,000 of severance benefits in the second quarter of 2008.

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Item 2. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

You should read the following discussion together with our financial statements and accompanying notes included in this quarterly report and our audited financial statements included in our annual report on Form 10-K for the year ended December 31, 2007, which is on file with the SEC. 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 and risks 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

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory and inflammatory diseases linked to the body s inflammatory response. Our marketed product is ZYFLO CR, an extended-release formulation of zileuton, which the FDA approved in May 2007 for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. We began selling ZYFLO CR in the United States in September 2007. In January 2008, we requested and received from the FDA a waiver from the requirement to provide six-months notice to cease manufacturing of the immediate-release formulation of zileuton. As a result, we ceased manufacturing and supplying ZYFLO to the market in February 2008. In addition, we are developing an injectable formulation of zileuton, or zileuton injection.

On May 1, 2008, we entered into an agreement and plan of merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone. If the merger is completed, at the effective time of the merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of our common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone s common stock will be assumed by us and become options and warrants to purchase our common stock. The merger agreement provides that, in the merger, we will issue to Cornerstone stockholders, and assume Cornerstone options and warrants, that will represent, an aggregate of approximately 101.5 million shares of our common stock, subject to adjustment as a result of a contemplated reverse stock split of our common stock to occur in connection with the merger. Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70 percent, and our current stockholders will own approximately 30 percent, of our common stock, after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to our outstanding options and warrants. The exchange ratio per share of Cornerstone s common stock will be based on the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger and will not be calculated until that time.

The consummation of the merger is subject to a number of closing conditions, including the approval of both our stockholders and Cornerstone s stockholders, approval by NASDAQ of our application for re-listing of our common stock in connection with the merger, the continued availability of our products and other customary closing conditions. We are targeting a closing of the transaction in the fourth quarter of 2008.

Immediately prior to the effective time of the merger, we have agreed to effect a reverse stock split of our common stock based on a ratio to be mutually agreed upon by us and Cornerstone. The reverse stock split is necessary so that as of the effective time of the merger we will satisfy the minimum bid price requirement pursuant to NASDAQ s initial listing standards.

Until the closing of our transaction, we will continue our commercial and development activities in accordance with our existing business strategy with an increased focus on managing our cash position. Unless otherwise stated or the context otherwise requires, we have prepared this quarterly report on Form 10-Q as if we were going to remain a standalone, independent company. If we consummate the merger with Cornerstone, many of the forward-looking statements in this quarterly report would no longer be applicable.

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On April 21, 2008, we received notification from the NASDAQ Listings Qualifications Department that for the prior 30 consecutive business days the bid price of our common stock on The NASDAQ Global Market had closed below the minimum $1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5). In accordance with NASDAQ Marketplace Rule 4450(e)(2), we have 180 calendar days, or until October 20, 2008 to regain compliance with NASDAQ s minimum bid price requirement.

Financial Operations Overview

On March 13, 2007, we entered into an agreement with Dey, L.P., or DEY, a subsidiary of Mylan Inc., under which we and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion agreement, DEY paid us a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement, a milestone payment of $4.0 million following approval by the FDA of the NDA for ZYFLO CR and a milestone payment of $5.0 million following our commercial launch of ZYFLO CR. Under the co-promotion agreement, we record all quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, up to $1.95 million and pay DEY a commission on quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million.

In the quarters ended December 31, 2007 and March 31, 2008, we recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that cannot be released into our commercial supply chain because they did not meet our product release specifications. In conjunction with our three third-party manufacturers for zileuton API, tablet cores and coating and release, we have initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. We have incurred and expect to continue to incur significant costs in connection with our investigation. In April 2008, pending the completion of the investigation, we placed 12 additional batches of the core tablets of ZYFLO CR on a quality assurance hold. We are currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR that may be released for commercial supply. If our Supply chain issues continue this could impact the level of commercial supply of ZYFLO CR available for sale and, if not corrected, prevent us from supplying any further product to our wholesale distributors. If the supply issues are not resolved in the near term, we expect that our existing inventory of ZYFLO CR should support our current level of sales to wholesale distributors through mid-July 2008. If we do not have a sufficient commercial supply of ZYFLO CR available, we may decide to reinitiate the marketing and supply of ZYFLO to the market. In April 2008, we began to reinitiate manufacture of ZYFLO in order to have a supply of ZYFLO available if we decide it is necessary to reinitiate marketing and supply of ZYFLO to the market.

We established reserves of approximately $571,000 in the fourth quarter of 2007 and $622,000 in the first quarter of 2008 for batches that did not meet our product release specifications. If we are not able to manufacture ZYFLO CR at a commercially acceptable cost and level of supply, we could experience cash flow difficulties and additional financial losses. Depending on the outcome of the investigation, we may not be able to obtain reimbursement from any of our third-party manufacturers for existing or additional batches of ZYFLO CR that do not meet our product release specifications. Under our merger agreement with Cornerstone, it is a condition to Cornerstone s obligation to consummate the merger that either ZYFLO CR or ZYFLO must be available and ready for purchase by third-party wholesalers or retailers during the period prior to the closing of the merger, other than during any period not exceeding 30 consecutive days.

As we move forward with our proposed merger with Cornerstone, we are continuing to focus on conserving cash resources and have begun to take steps to reduce spending on development programs and personnel. On May 8, 2008, as part of this effort, we announced that we had eliminated six positions, or approximately 8% of our workforce. The headcount reductions primarily affect our research and development group. We expect to consider further reductions in headcount in additional areas of our business in the future in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on our business needs and financial resources.

In connection with the implementation of the May 8, 2008 reduction in our workforce, we expect to record a charge of approximately $540,000 of severance benefits in the second quarter of 2008. We will record

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the restructuring charges in accordance with Statement of Financial Accounting Standards No., or SFAS, 146, *Accounting for Costs Associated with Exit or Disposal Activities.*

On June 25, 2007, we entered into a definitive agreement with DEY to jointly promote DEY s product PERFOROMIST™ (formoterol fumarate) Inhalation Solution, or PERFOROMIST, for the treatment of chronic obstructive pulmonary disease, or COPD. Under the agreement, DEY granted us a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. In October 2007, after expanding our sales force to over 40 representatives, we announced that we commercially launched PERFOROMIST with DEY. Under the agreement, DEY pays us a commission on retail sales of PERFOROMIST above a specified baseline.

In addition, we are developing zileuton injection initially for add-on use in emergency room or urgent care centers for acute asthma patients. In August 2006, we announced results from our Phase I/II clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of zileuton injection in patients with asthma. We initiated a Phase II clinical trial in October 2007 with zileuton injection in asthma patients and completed the clinical phase of this trial in February 2008.

We are also developing other product candidates directed towards reducing the potent inflammatory response that we believe is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. The inflammatory response occurs following stimuli such as infection or trauma. Our product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body s inflammatory response.

We are conducting preclinical work in our alpha-7 program. We believe the successful development of a small molecule product candidate targeting the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, we have selected a lead compound that is currently in development and which we are continuing to advance, with the goal of filing an investigational new drug application, or IND. In addition, we continue to seek collaborations with other pharmaceutical companies for our alpha-7 program.

We are collaborating with MedImmune, Inc., a subsidiary of AstraZeneca PLC, on the development of monoclonal antibodies directed toward a cytokine called high mobility group box protein 1, or HMGB1, which we believe may be an important target for the development of products to treat diseases mediated by the body s inflammatory response. In addition, we are collaborating with Beckman Coulter, Inc. on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1. Under this collaboration, MedImmune paid us initial fees of $10.0 million in late 2003 and $2.5 million in early 2004. In addition, MedImmune agreed to pay us $125,000 in 2007, $1.0 million in 2006, $2.75 million in 2005 and $1.5 million in 2004 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program.

In January 2007, we entered into an exclusive license agreement with Innovative Metabolics, Inc., or IMI, under which we licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. In May 2007, under the agreement with IMI, we received an initial license fee of $500,000 in cash and IMI junior preferred stock valued at $500,000 in connection with IMI s first financing. However, under our license agreement with The Feinstein Institute for Medical Research, formerly known as The North Shore-Long Island Jewish Research Institute, or The Feinstein Institute, we were obligated to pay The Feinstein Institute $100,000 of this cash

payment and IMI junior preferred stock valued at $100,000. We included in revenue under collaboration and license agreements in 2007 the $1.0 million total license fee that we received from IMI and included in research and development expenses the payments of $100,000 in cash and IMI junior preferred stock valued at $100,000 that we made to The Feinstein Institute. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay us $1.0 million, excluding a $200,000 payment that we would be obligated to pay The Feinstein Institute, upon

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full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by IMI and its affiliates. In March 2008, we sold the remaining 400,000 shares of junior preferred stock to two investors, which had participated in IMI s first financing, for an aggregate purchase price of $400,000. The purchase price is subject to adjustment if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than they paid us.

On January 16, 2008, we entered into a sublease with Microbia Precision Engineering, Inc., or Microbia. We entered into the sublease in connection with the negotiated termination of our lease with ARE 60 WESTVIEW, LLC, or ARE, and the negotiation of a new lease between ARE and Microbia for the same premises. Pursuant to the terms of the sublease, we are subleasing from Microbia a portion of the current premises occupied by us in Lexington, Massachusetts totaling approximately 11,298 square feet effective March 1, 2008.

On March 2, 2008, Frank E. Thomas resigned as our President and Chief Executive Officer effective March 31, 2008 and as a member of our board of directors effective March 2, 2008. On March 4, 2008, we announced that our board of directors appointed Trevor Phillips, Ph.D. as our President and Chief Executive Officer effective April 1, 2008 and elected Dr. Phillips as a member of our board of directors effective March 4, 2008.

Since our inception, we have incurred significant losses each year. We had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. We had net losses of $10.8 million in the three months ended March 31, 2008 and $4.7 million in the three months ended March 31, 2007. As of March 31, 2008, we had an accumulated deficit of approximately $202 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue over the next several years as we fund our development programs, market and sell ZYFLO CR and prepare for the potential commercial launch of our product candidates. Since our inception, we have raised proceeds to fund our operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, license fees from IMI, payments from DEY under our zileuton co-promotion agreement and revenues from sales of ZYFLO and ZYFLO CR.

Revenues. From our inception on July 14, 2000 through the third quarter of 2005, we derived all of our revenues from license fees, research and development payments and milestone payments that we have received from our collaboration and license agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, we began selling, and recognizing revenue from ZYFLO. In September 2007, we began selling, and recognizing revenue from ZYFLO CR. In 2007, we also recorded license revenue from our license agreement with IMI.

Cost of Products Sold. Cost of products sold consists of manufacturing, distribution and other costs related to our commercial products, ZYFLO and ZYFLO CR. In addition, it includes royalties to third parties related to ZYFLO and ZYFLO CR and any reserves established for excess or obsolete inventory. Most of our manufacturing and distribution costs are paid to third-party manufacturers. However, there are some internal costs included in cost of products sold, including salaries and expenses related to managing our supply chain and for certain quality assurance and release testing costs.

Research and Development Expenses. Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, regulatory costs, including user fees paid to the FDA, milestone payments to third parties, costs related to the development of our approved new drug application, or NDA, for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of our medical affairs and medical

information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, we record manufacturing expenses associated with a product as

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cost of products sold rather than as research and development expenses. We expense research and development costs and patent related costs as they are incurred. Because of our ability to utilize resources across several projects, many of our research and development costs are not tied to any particular project and are allocated among multiple projects. We record direct costs on a project-by-project basis. We record indirect costs in the aggregate in support of all research and development. Development costs for clinical stage programs such as zileuton injection tend to be higher than earlier stage programs such as our HMGB1 and alpha-7 programs due to the costs associated with conducting late stage clinical trials and large-scale manufacturing.

We expect that research and development expenses relating to our portfolio will fluctuate depending primarily on the timing and outcomes of clinical trials, related manufacturing initiatives and milestone payments to third parties and the results of our decisions based on these outcomes. We expect to incur additional expenses over the next several years for clinical trials related to our product development candidates, including zileuton injection and alpha-7. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we scale up production of zileuton injection for later stages of clinical development. We initiated a Phase IV clinical trial in July 2007 related to ZYFLO CR to examine its potential clinical benefits in the current patient treatment setting. In March 2008, we discontinued the trial because of patient enrollment that was significantly slower than we had anticipated. At March 31, 2008, we accrued $1.1 million related to costs to terminate the clinical trial. These costs are included in research and development expenses for the three months ended March 31, 2008. As a result of the FDA s approval of the NDA for ZYFLO CR in May 2007, we made milestone payments totaling $3.1 million and accrued at present value an additional $3.5 million related to milestone obligations due on the first and second anniversary of the FDA s approval. We included these milestone payments and accruals in research and development expenses in our results for the second quarter of 2007 and included the accretion of the discount related to the present value of the milestone obligations in interest expense.

Sales and Marketing Expenses. Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, managed care and our sales operations functions, as well as other costs related to ZYFLO CR and ZYFLO. We also incurred marketing and other costs related to our launch of ZYFLO CR in September 2007. Other costs included in sales and marketing expenses include sales and marketing costs related to our co-promotion and marketing agreement, cost of product samples of ZYFLO CR and ZYFLO, promotional materials, market research and sales meetings. We expect to continue to incur sales and marketing costs associated with enhancing our sales and marketing functions and maintaining our increased sales force to support ZYFLO CR. In addition, under our co-promotion agreement with DEY, we have deferred the $12.0 million in aggregate upfront and milestone payments that we received in 2007. We are amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will offset some or all of the co-promotion fees paid to DEY for promoting ZYFLO CR and ZYFLO in future periods under the agreement. We expect to record all ZYFLO CR and ZYFLO sales generated by the combined sales force and record any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments in sales and marketing.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, legal, business development, information technology and human resource functions. Other costs included in general and administrative expenses include certain facility and insurance costs, including director and officer liability insurance, as well as professional fees for legal, consulting and accounting services.

Critical Accounting Policies

The 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 accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments 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.

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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 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 this quarterly report on Form 10-Q. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, product returns, inventory, accrued expenses, short-term investments, stock-based compensation and income taxes described below fit the definition of critical accounting estimates.

Revenue Recognition. We sell ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return purchased product. We commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. We recognize revenue from product sales in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, or SFAS No. 48, which requires the amount of future returns to be reasonably estimated. We recognize product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and estimated chargebacks from distributors and prompt payment and other discounts.

Prior to the first quarter of 2007, we deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as we were unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, based on our product return experience since we launched ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as sufficient history existed to make such estimates. In connection with this change in estimate, we recorded an increase in net product sales in 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000 and was reported in our results for the first quarter of 2007. We anticipate that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. As a result, we recognize revenue for sales of ZYFLO CR upon shipment to third parties and record a reserve for potential returns from these third parties based on our product returns experience with ZYFLO and other factors.

Under our collaboration agreements with MedImmune and Beckman Coulter, we are entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in our statements of operations when earned. We must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by our collaborators with us. We recognize these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. Because MedImmune and Beckman Coulter can each cancel its agreement with us, we do not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of our operations because, in each case, the adjustment is limited to the cash received.

Under our license agreement with IMI, we included in revenue from collaboration and license agreements in the second quarter of 2007 a $1.0 million initial license fee that we received from IMI and included in research and

development expenses a related $100,000 cash payment and IMI preferred stock payment valued at $100,000 that we made to The Feinstein Institute.

Product Returns. Consistent with industry practice, we offer customers the ability to return products during the six months prior to, and the 12-months after, the product expires. At the time of its commercial

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launch in October 2005, we began shipping ZYFLO with an expiration date of 12 months. Since our launch of ZYFLO, we have extended ZYFLO s expiration date from 12 months to 24 months as of March 31, 2008. In September 2007, we launched ZYFLO CR, which currently has an expiration date of 18 months. We anticipate that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. We may 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, 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. As a result of this ongoing evaluation, our product return reserve is $286,000 as of March 31, 2008, which is comprised of a product return reserve of approximately $177,000 for ZYFLO and $109,000 for ZYFLO CR. Our allowance for ZYFLO product returns includes $165,000 of product in our distribution channel that we do not expect to be dispensed through prescriptions in the second quarter of 2008 as a result of our decision to cease promotion of ZYFLO in February 2008. In the first quarter of 2008, as a result of stronger than expected ZYFLO prescriptions, we reduced our product return reserve for ZYFLO by $440,000.

Inventory. 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. We determine the estimated useful life of our inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of March 31, 2008, inventory consists of zileuton active pharmaceutical ingredient, or API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. 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 our expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At March 31, 2008, we had an inventory reserve of $1.2 million. The inventory reserve includes $571,000 recorded in the fourth quarter of 2007 and $622,000 recorded in the first quarter of 2008 relating to batches that did not meet our product release specifications for ZYFLO CR. As of March 31, 2008, we had $9.7 million in inventory net of the inventory reserve. We expect our inventory levels to decrease in the second and third quarters of 2008.

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 service as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include professional service fees, such as fees paid to lawyers and accountants, rebates to third parties, including government programs such as Medicaid or private insurers, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical materials, license fees in connection with the achievement of milestones and restructuring charges.

In connection with rebates, our estimates are based on our estimated mix of sales to various third-party payors, which either contractually or statutorily are entitled to certain discounts off our listed price of ZYFLO and ZYFLO CR. In the event that our sales mix to certain third-party payors is different from our estimates, we may be required to pay higher or lower total rebates than we have estimated. In connection with service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed; however, certain service providers invoice us based upon milestones in our agreements with them. In the event that we do not identify certain costs that we have begun to incur or we under or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which

certain services commence, the level of services performed on or before a given date and the cost of such services are often

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subject to judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Investments. Investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. We record any unrealized gain (loss) during the year as an adjustment to stockholders equity unless we determine that the unrealized gain (loss) is not temporary. We adjust the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because we have determined that the unrealized gain (loss) on our investments have been temporary, we have not recorded any impairment losses since inception.

It is our intent to hold our investments until such time as we intend to use them to meet the ongoing liquidity needs of our operations. However, if the circumstances regarding an investment or our liquidity needs were to change, such as a change in an investment s external credit rating, we would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses. At March 31, 2008, we held $287,000 in auction rate securities. In February 2008, we were informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. We have classified our investment in auction rate securities as a long-term investment and have included the amount in other assets on our balance sheet.

Stock-Based Compensation. We apply the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the modified prospective application method, which requires us to recognize compensation cost for granted, but unvested awards (upon adoption), new awards and awards modified, repurchased, or cancelled after adoption under the fair value method.

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 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.

The two factors that most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted by us under SFAS 123(R) and the Emerging Issues Task Force 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*, or EITF 96-18, requires fair value estimates of the equity instrument granted. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. 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 stock options and warrants granted to employees or non-employees, we estimate the fair value of the equity instruments based upon the consideration of factors that we deem to be relevant at the time using cost, market or income approaches to such valuations.

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and

accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of March 31, 2008, we had federal and state tax net operating loss carryforwards of approximately $172 million, which expire beginning in 2021 and 2008, respectively. We also have research and experimentation credit carryforwards of approximately $1.9 million as of March 31, 2008, which expire beginning in 2021. We have recorded a full valuation allowance as an offset against these otherwise

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recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of a net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

We did not recognize any accrued interest and penalties related to unrecognized tax benefits, as no amounts would be due as a result of our net tax loss carryforward. Our policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. Tax years for 2000 to 2007 remain subject to examination for federal and numerous state jurisdictions. The primary state tax jurisdiction to which we are subject is the Commonwealth of Massachusetts.

Results of Operations

Three Months Ended March 31, 2008 and 2007

Revenues

Revenue from Product Sales. We recognized revenue from product sales of ZYFLO CR and ZYFLO of $3.3 million in the three months ended March 31, 2008, compared to $2.9 million from product sales of ZYFLO in the three months ended March 31, 2007. The increase in product revenue is primarily attributable to a 49% increase in prescription volume, a 11.3% price increase in ZYFLO s and ZYFLO CR s wholesale acquisition price over the corresponding period in 2007 and a $440,000 reduction in our product return reserve for ZYFLO as a result of stronger than expected ZYFLO prescriptions. In addition, in the three months ended March 31, 2007, we recorded a $953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. On January 1, 2007, based on our product return experience since our launch of ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as we are now able to estimate product returns.

Revenue under Collaboration Agreements. We did not recognize any collaboration revenue in the three months ended March 31, 2008. We recognized $601,000 in collaboration revenue in the three months ended March 31, 2007. Collaboration revenue for the three months ended March 31, 2007 was primarily due to the recognition of $400,000 of deferred revenue recognized under our collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with our HMGB1 program. Collaboration revenue also included approximately $201,000 related to a portion of the $12.5 million of initial fees MedImmune paid to us that we recognized over the duration of the contract and the $5.3 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through March 31, 2007. At March 31, 2008, we had no deferred collaboration revenue and had completed the research term of our agreement with MedImmune. Our revenue recognized from existing collaborations for the remainder of 2008 is likely to decline substantially compared to corresponding periods in 2007 because we have now recognized all of the revenue that we previously deferred. Going forward, our revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under our existing agreements, or will be dependent upon us entering into new collaboration agreements.

Costs and Expenses

Cost of Products Sold. Cost of products sold in the three months ended March 31, 2008 was $1.8 million, compared to $741,000 in the three months ended March 31, 2007. Gross margin was 45% for the three months ended March 31, 2008 and 74% for the three months ended March 31, 2007. Cost of products sold in the three months ended March 31, 2008 consisted of the expenses associated with manufacturing ZYFLO CR and distributing ZYFLO and ZYFLO CR, royalties to Abbott and SkyePharma related to ZYFLO

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and ZYFLO CR and reserves established for excess or obsolete inventory. Cost of products sold in the three months ended March 31, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. As a result of our change in estimates relating to recognition of ZYFLO sales, we recorded an additional $166,000 in cost of products sold in the three months ended March 31, 2007. We recorded inventory reserves of $609,000 for the three months ended March 31, 2008. The write-offs in 2008 resulted from certain batches of ZYFLO CR that did not meet our product release specifications. We did not record any inventory reserves during the three months ended March 31, 2007. As a result of our commercial launch of ZYFLO CR in September 2007, our gross margins, excluding write-offs, will likely decrease as a result of an increase in cost of products sold related to ZYFLO CR due to the more complex manufacturing process and supply chain for ZYFLO CR and additional royalty obligations to Abbott and to SkyePharma for utilization of its controlled-release technology. This likely decrease could be offset, in part, by an increase in our wholesale acquisition price of ZYFLO CR and our ability to spread some of our fixed costs associated with managing our supply chain over a larger revenue base in 2008.

Research and Development Expenses. Research and development expenses in the three months ended March 31, 2008 were $5.4 million, compared to $2.9 million in the three months ended March 31, 2007, an increase of approximately $2.5 million, or 84%. This increase was primarily due to higher expenses associated with our ZYFLO CR Phase IV and zileuton injection clinical trials, offset, in part, by lower expenses associated with our alpha-7 and HMGB1 preclinical programs.

The following table summarizes the primary components of our research and development expenses for the three months ended March 31, 2008 and 2007:

	Three Months Ended March 31,	
	2008	2007
	(In thousands)	
Zileuton (ZYFLO and ZYFLO CR)	$ 3,254	$ 1,335
Zileuton injection	1,046	156
Alpha-7	593	833
HMGB1		119
General research and development expenses	233	235
Stock-based compensation expense	238	240
Total research and development expenses	$ 5,364	$ 2,918

The following summarizes the expenses associated with our primary research and development programs:

Zileuton (ZYFLO and ZYFLO CR). During the three months ended March 31, 2008, we incurred $3.3 million in expenses related to our orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $1.3 million during the three months ended March 31, 2007, a 144% increase. This increase was primarily due to a $2.2 million increase in clinical, manufacturing and consulting costs related to our Phase IV clinical trial for ZYFLO CR. This increase was partially offset by a $267,000 reduction in salaries and other personnel related costs as a result of our December 2006 restructuring and a reduction in associated facilities and overhead costs.

We anticipate that our research and development expenses related to our ZYFLO CR program for 2008 will consist primarily of costs related to our Phase IV clinical trial for ZYFLO CR, which we discontinued in March 2008. In addition, we expect to continue to incur research and development expenses to maintain and operate our medical affairs, medical information and pharmacovigilance functions in support of ZYFLO CR.

Zileuton Injection. During the three months ended March 31, 2008, we incurred $1.0 million in expenses related to our zileuton injection program, compared to $156,000 during the three months ended March 31, 2007, a 571% increase. This increase was primarily due to costs related to our Phase II clinical

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trial for zileuton injection, which began in October 2007. We expect to incur additional costs associated with the development of zileuton injection during the second quarter of 2008 as we complete the analysis of the data and prepare to report the results of our Phase II clinical trial. We currently expect to seek a collaborator for our injection program to develop and commercialize a possible product candidate.

Alpha-7. During the three months ended March 31, 2008, we incurred $593,000 in expenses related to our alpha-7 program, compared to $833,000 during the three months ended March 31, 2007, a 29% decrease. This decrease was primarily due to a reduction in the number of employees working on the program and a reduction in associated facilities and overhead costs . We anticipate that the research and development expenses for our alpha-7 program will not grow substantially in the remainder of 2008, as we expect increased costs related to preclinical studies conducted by third parties to advance our lead molecule to be offset by the reduced number of employees working on this program. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. We currently expect to seek a collaborator for our alpha-7 program to develop and commercialize possible product candidates prior to human clinical trials. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the product candidate we choose to develop, the clinical indications developed, the development strategy adopted, and the terms of a collaboration, if we are able to enter into one. As a result, we are unable to estimate the costs or the timing of advancing a small molecule from our alpha-7 program through clinical development.

HMGB1. During the three months ended March 31, 2008, we did not incur any expenses related to our HMGB1 program, compared to $119,000 in expenses during the three months ended March 31, 2007. We have not conducted, and currently do not anticipate conducting, significant research and development activities relating to HMGB1 in 2008. In addition, a larger portion of the expenses in our HMGB1 program will be assumed by MedImmune as the program advances into later stages of preclinical development. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indications developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while any funding received from MedImmune and Beckman Coulter to support our research efforts is included in revenue under collaboration agreements.

Our general research and development expenses, which are not allocated to any specific program, remained consistent in the three months ended March 31, 2008 as compared to the three months ended March 31, 2007. Our general research and development expenses, which are incurred in support of all of our research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses. In addition, our stock-based compensation expense remained consistent in the three months ended March 31, 2008, compared to the three months ended March 31, 2007.

Sales and Marketing. Sales and marketing expenses for the three months ended March 31, 2008 were $3.9 million, compared to $2.0 million for the three months ended March 31, 2007. The $1.9 million increase was primarily attributable to a $765,000 increase in salary and other employee related costs of employees performing sales and marketing functions, an increase of approximately $1.4 million related to promotional materials, advertising and other costs associated with ZYFLO CR that we incurred to support our co-promotion agreement with DEY and an increase of approximately $200,000 in co-promotion fees paid to DEY in accordance our co-promotion agreement. These increases were partially offset by a decrease of $534,000 related to amortization of our deferred sales and marketing expense. The number of employees performing sales and marketing functions increased to 49 employees at March 31, 2008 from 26 employees at March 31, 2007. We expect that our sales and marketing costs will decrease during the remainder of 2008 as we focus on conserving cash resources.

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General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2008 were $3.2 million, compared to $3.1 million for the three months ended March 31, 2007. The increase was primarily due to an increase of $324,000 in legal fees primarily related to our review of strategic alternatives and an increase of $208,000 related to the additional bonus paid in February 2008 in accordance with our agreement with our former President and Chief Executive Officer. These increases were offset, in part, by a decrease of $232,000 in advisory fees paid in connection with the signing of our agreement with DEY in the first quarter of 2007 and a decrease of $190,000 in stock-based compensation. The number of employees performing general and administrative functions was 13 employees at March 31, 2008 and 14 employees at March 31, 2007. We expect that our general and administrative expenses will increase during the remainder of 2008 compared to corresponding periods in 2007 as we incur professional fees relating to our proposed merger with Cornerstone.

Other Income. Interest income for the three months ended March 31, 2008 was $218,000, compared to $590,000 for the three months ended March 31, 2007. The decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to $49,000 for the three months ended March 31, 2008 and $39,000 for the three months ended March 31, 2007. Interest expense primarily relates to the accretion of the discount on our accrued first and second anniversary milestone payments owed to Abbott and SkyePharma as a result of the FDA approval of the NDA for ZYFLO CR and borrowings under our loan with Silicon Valley Bank for capital expenditures.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have raised proceeds to fund our operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from our collaboration, license and co-promotion agreements, the exercise of stock options, and revenues from sales of ZYFLO and ZYFLO CR. As of March 31, 2008, we had $20.5 million in cash, cash equivalents and investments. We have invested our cash and cash equivalents primarily in highly liquid, interest-bearing, investment grade securities in accordance with our established corporate investment policy.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid us initial fees of $12.5 million and an additional $5.4 million through March 31, 2008 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program. As of March 31, 2008, we had completed the research term of our agreement with MedImmune.

Under our collaboration with MedImmune, we may receive additional payments upon the achievement of research, development and commercialization milestones up to a maximum of $124.0 million, after taking into account payments we are obligated to make to The Feinstein Institute on milestone payments we receive from MedImmune.

Under our co-promotion agreement with DEY, we received a non-refundable upfront payment of $3.0 million in March 2007, a milestone payment of $4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of $5.0 million in December 2007 following commercial launch of ZYFLO CR.

Credit Agreement with Silicon Valley Bank. We have financed the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment, software licenses and the completion of leasehold improvements through advances under a credit agreement with Silicon Valley Bank, which was most

recently modified as of January 6, 2006. As of March 31, 2008, we had repaid all outstanding debt owed to Silicon Valley Bank and had no borrowing capacity available under the modified credit agreement or any other credit agreement. We are currently considering financing alternatives to fund capital expenditures in the future.

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Funding Requirements

We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. We had net losses of $10.8 million in the three months ended March 31, 2008 and $4.7 million in the three months ended March 31, 2007. As of March 31, 2008, we had an accumulated deficit of approximately $202 million. We expect that we will continue to incur substantial losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts. As a result, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. We have prepared our financial statements on the assumption that we will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about our ability to continue as a going concern may 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, creditors, suppliers and employees.

We expect to devote substantial resources to support the marketing of ZYFLO CR and to fund the development of our product candidates. We have not made, and do not expect to make, a significant investment in capital expenditures in 2008. We expect to fund any capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Our funding requirements will depend on numerous factors, including:

the ongoing costs of the marketing of ZYFLO CR;

the scope, costs and results of our clinical trials of ZYFLO CR and zileuton injection;

the amount and timing of sales and returns of ZYFLO CR and ZYFLO;

the costs of ongoing sales, marketing and manufacturing activities for ZYFLO CR;

the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;

the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, IMI or future collaborators or licensees;

the timing, receipt and amount of sales and royalties, if any, from our product candidates;

continued progress in our research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under our license agreements;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

the cost of obtaining and maintaining licenses to use patented technologies;

potential acquisition or in-licensing of other products or technologies;

our ability to establish and maintain additional collaborative or co-promotion arrangements; and

the ongoing time and costs involved in corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act of 2002.

Other than payments that we may receive from our collaboration with MedImmune, sales of ZYFLO CR represent our only sources of cash flows and revenue. In addition to the foregoing factors, we believe that our ability to access external funds will depend upon market acceptance of ZYFLO CR, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to successfully commercialize ZYFLO CR. Based on our operating plans, we believe that our available cash

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and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations into the first quarter of 2009.

For the three months ended March 31, 2008, our net cash used for operating activities was $13.9 million and we had minimal capital expenditures. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Under our merger agreement with Cornerstone, any financing transaction would require Cornerstone s consent. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. Such equity securities may have rights and preferences superior to those of the holders of our common stock. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products, which we would otherwise pursue on our own.

Contractual Obligations

We have summarized in the table below our fixed contractual obligations as of March 31, 2008.

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than One Year**	**One to Three Years**	**Three to Five Years**	**More Than Five Years**
			(In thousands)		
Manufacturing and clinical trial agreements	$ 19,810	$ 12,304	$ 7,104	$ 402	$
Research and license agreements	10,054	2,052	2,706	924	4,372
Marketing costs	7,344	2,094	5,250		
Lease obligations	434	434			
Consulting agreement and other	60	60			
Total contractual cash obligations	$ 37,702	$ 16,944	$ 15,060	$ 1,326	$ 4,372

The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. On August 20, 2007, we entered into an agreement with Jagotec, under which Jagotec agreed to manufacture and supply bulk ZYFLO CR tablet cores for commercial sale. We have agreed to purchase minimum quantities of ZYFLO CR tablet cores during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, we have agreed to purchase specified amounts of our requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless we provide Jagotec with 24-months prior written notice of termination or Jagotec provides us with 36-months prior written notice of termination. In addition, we have the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents us from

importing, exporting or selling ZYFLO CR. We also may terminate the agreement upon six-months advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and we determine to permanently cease commercialization of ZYFLO CR. Likewise, we may terminate the agreement upon 12-months advance notice if we intend to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, we have agreed to purchase quantities of ZYFLO CR tablets that are subject to binding forecasts.

In addition, we entered into a manufacturing and supply agreement with Rhodia Pharma Solutions Ltd. for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. On

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September 30, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions Ltd., sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions Ltd., or Shasun. Under this agreement, we committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and the first quarter of 2008. In addition, we have agreed to purchase specified quantities of API in 2008 and 2009 with a portion subject to the right of cancellation with a termination fee. The API purchased from Shasun currently has a minimum shelf-life of 36 months.

The amounts listed for research and license agreements represent our fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that we may be required to pay under our license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an IND to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of our products in various countries.

We are party to a number of agreements that require us to make milestone payments. In particular, under our license agreement with Abbott Laboratories for zileuton, we agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones relating to zileuton, including the completion of the technology transfer from Abbott to us, filing and approval of a product in the United States and specified minimum net sales of licensed products. Through March 31, 2008, we have made aggregate milestone payments of $7.8 million to Abbott under our license agreements related to ZYFLO and ZYFLO CR. In addition, under our license agreement with SkyePharma, through its subsidiary Jagotec, for ZYFLO CR, we agreed to make aggregate milestone payments of up to $6.6 million upon the achievement of various development and commercialization milestones. Through March 31, 2008, we have made aggregate milestone payments of $3.0 million to SkyePharma under our agreement. In May 2007, we received FDA approval of the NDA for ZYFLO CR. Included in the amounts listed for research and license agreements are the combined first and second anniversary milestone payments for the FDA s approval of ZYFLO CR due to Abbott and SkyePharma totaling $3.8 million.

The amounts listed for marketing costs represent advertising and promotional commitments under our co-promotion agreement with DEY related to our marketing support for ZYFLO CR.

The amounts listed for lease obligations represent the amount we owe under our facility, computer and vehicle lease agreements under both operating and capital leases.

The amounts listed for consulting agreements are for fixed payments due to our scientific and business consultants.

The amounts shown in the table do not include royalties on net sales of our products and payments on sublicense income that we may owe as a result of receiving payments under our collaboration or license agreements.

The amounts listed for research and license agreements, consulting agreements and manufacturing and clinical trial agreements include amounts that we owe under agreements that are subject to cancellation or termination by us under various circumstances, including a material uncured breach by the other party, minimum notice to the other party or payment of a termination fee.

The amounts listed in the table above do not include payment of a termination fee of $1.0 million or the reimbursement of expenses of up to $150,000 that we could be obligated to pay to Cornerstone in specified circumstances in connection with the termination of the merger agreement with Cornerstone.

We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While our purchase commitment for API from Shasun exceeds our current forecasted demand in 2008, we expect that any excess API purchased in 2007, 2008 and 2009 under our agreement with Shasun will

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be used in commercial production batches in 2008, 2009 and 2010 and sold before it requires retesting. Therefore, no reserve for this purchase commitment has been recorded as of March 31, 2008.

At March 31, 2008, we had $9.7 million in inventory. We expect that our inventory levels in the second and third quarters of 2008 will decrease as we have no API purchase commitments in those periods. 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. These differences could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory. For example, we recorded charges of $821,000 in 2007 and $299,000 in 2006 to reserve for excess or obsolete inventory that had an expiration date such that the product was unlikely to be sold. In addition, in the first quarter of 2008, four additional batches of ZYFLO CR tablets did not meet our product release specifications and could not be released into our commercial supply chain. We have initiated an investigation to determine the cause of this issue, but the investigation is ongoing and not yet complete. We are currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR that may be released for commercial supply. These charges were included in cost of products sold in the statements of operations for these periods.

Currently, we purchase our API for commercial requirements for ZYFLO CR from a single source. In addition, we currently contract with a single third party for the manufacture of uncoated ZYFLO CR tablets and with another single third party for the coating and packaging of these tablets. The disruption or termination of the supply of API, a significant increase in the cost of the API from this single source or the disruption or termination of the manufacturing of our commercial products could have a material adverse effect on our business, financial position and results of operations.

Effects of Inflation

Our assets are primarily monetary, consisting primarily of cash, cash equivalents and investments. Because of their liquidity, these assets are not significantly affected by inflation. We also believe that we have intangible assets in the value of our technology. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our consolidated balance sheet. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, 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.

Recent Accounting Pronouncements

In November 2007, the FASB, Emerging Issues Task Force, or EITF, issued No. EITF Issue 07-01, *Accounting for Collaborative Arrangements*, or EITF 07-01. EITF 07-01 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. Further, EITF 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer or analogous relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. We do not expect the adoption of EITF 07-01 to have a material impact on our financial statements and results of operations.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The

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initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on our financial statements and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations,* or 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,* 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, such 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 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact us if we are a party to a business combination after the pronouncement has been adopted.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements an amendment of ARB No. 51,* or 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. We do not expect the adoption of SFAS 160 to have a material impact on our financial statements and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115,* or SFAS 159. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We were required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on our financial statements and results of operations, as we elected not to measure any financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements,* or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. FAS 157-2, or FSP 157-2, that defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. We were required to adopt the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. We are currently evaluating the effect FSP 157-2 will have on our financial statements and results of operations.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, directly or through managed funds, with maturities of two years or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. If

market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2008, we estimate that the fair value of our investment portfolio would decline by approximately $1,000. We could be exposed to losses related to these securities should one of our

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counterparties default. We attempt to mitigate this risk through credit monitoring procedures. We have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. At March 31, 2008, we held approximately $287,000 in auction rate securities with a AAA credit rating upon purchase. In February 2008, we were informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. We have classified our investment in auction rate securities as a long-term investment and included the investment in other assets on our balance sheet.

Item 4. ***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, 2008. 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 Securities and Exchange Commission 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. Our 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, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2008 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.***

Not applicable.

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 Securities and Exchange Commission, in evaluating Critical 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, 2007.

Risks Related to Our Proposed Merger with Cornerstone

If the proposed merger with Cornerstone is not consummated, our business could suffer materially and our stock price could decline.

On May 1, 2008, we entered into an agreement and plan of merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone. If the merger is completed, at the effective time of the merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of our common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone s

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common stock will be assumed by us and become options and warrants to purchase our common stock. The merger agreement provides that in the merger we will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of our common stock, subject to adjustment as a result of a contemplated reverse stock split of our common stock to occur in connection with the merger. Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70 percent, and our current stockholders will own approximately 30 percent, of our common stock, after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to our outstanding options and warrants. The exchange ratio per share of Cornerstone s common stock will be based on the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger and will not be calculated until that time.

The consummation of the merger is subject to a number of closing conditions, including the approval of both our stockholders and Cornerstone s stockholders, approval by NASDAQ of our application for re-listing of our common stock in connection with the merger, the continued availability of our products and other customary closing conditions. We are targeting a closing of the transaction in the fourth quarter of 2008.

If the proposed merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

We have incurred and expect to continue to incur significant expenses related to the proposed merger with Cornerstone. These transaction expenses include investment banking fees and legal and other professional fees. A substantial portion of these fees will be payable by us even if the merger does not close.

The merger agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the merger agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the merger require the consent of Cornerstone. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. If the merger agreement is terminated in the future after we have invested significant time and resources in the transaction process, we will have a limited ability to continue our current operations without obtaining additional financing to fund our operations.

We could be obligated to pay Cornerstone a $1.0 million termination fee and to reimburse Cornerstone for up to $150,000 in expenses in connection with the termination of the merger agreement, depending on the reason for the termination.

Our customers, prospective customers, collaborators and other business partners and investors in general may view the failure to consummate the merger as a poor reflection on our business or prospects.

Some of our suppliers, distributors and other business partners may seek to change or terminate their relationships with us as a result of the proposed merger.

As a result of the proposed merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities.

Our management team may be distracted from day to day operations as a result of the proposed merger with Cornerstone.

The market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed.

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Risks Relating to Our Business

Our business depends heavily on the commercial success of ZYFLO CR.

ZYFLO CR is currently our only commercially marketed product. We commercially launched ZYFLO CR on September 27, 2007. In February 2008, we discontinued the production and marketing of ZYFLO, the immediate-release formulation of zileuton, which we had commercially launched in October 2005. ZYFLO did not achieve broad market acceptance. If we are able to successfully commercialize ZYFLO CR, we expect it will account for a significant portion of our revenues for the foreseeable future. However, we cannot assure you that ZYFLO CR will not suffer the same lack of broad market acceptance that has affected ZYFLO.

Our product candidates are in early clinical and preclinical stages of development and are a number of years away from commercialization. Research and development of product candidates is a lengthy and expensive process. Our early-stage product candidates in particular will require substantial funding for us to complete preclinical testing and clinical trials, initiate manufacturing and, if approved for sale, initiate commercialization. If ZYFLO CR is not commercially successful, we may be forced to find additional sources of funding earlier than we anticipated. If we are not successful in obtaining additional funding on acceptable terms, we may be forced to significantly delay, limit or eliminate one or more of our development or commercialization programs.

If ZYFLO CR does not achieve market acceptance, we may not be able to generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

The commercial success of ZYFLO CR will depend upon its acceptance by the medical community, third-party payors and patients. Physicians will prescribe ZYFLO CR only if they determine, based on experience, clinical data, side effect profiles or other factors, that this product either alone or in combination with other products is appropriate for managing their patient s asthma. We believe that the primary advantage of ZYFLO CR over ZYFLO is ZYFLO CR s more convenient dosing schedule, but this advantage may not result in broad market acceptance of ZYFLO CR, and we may experience the same lack of market acceptance with ZYFLO CR that we have experienced with ZYFLO.

Despite being approved by the FDA since 1996, ZYFLO did not achieve broad market acceptance. During the period between our commercial launch of ZYFLO in October 2005 through February 2008, prescription data for ZYFLO indicates that approximately 5,757 physicians prescribed the product. We recorded revenue from the sale of ZYFLO of $8.7 million for the year ended December 31, 2007 and $711,000 for the three months ended March 31, 2008. We recorded revenue from the sale of ZYFLO CR of $2.3 million for the year ended December 31, 2007 and $2.6 million for the three months ended March 31, 2008. We experienced difficulty expanding the prescriber and patient base for ZYFLO, in part, we believe, because some physicians view ZYFLO as less effective than other products on the market or view its clinical data as outdated and because it requires dosing of one pill 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. In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two pills twice daily, or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, our sales of ZYFLO CR will be limited and our revenues will be adversely affected.

Market perceptions about the safety of ZYFLO may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In

clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO CR can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO CR, based upon its product label, which was approved by the FDA in May 2007.

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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. As a result, many physicians may have negative perceptions about the safety of ZYFLO CR and other zileuton product candidates, which could limit their commercial acceptance. The absence of ZYFLO from the market prior to our commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues. These negative perceptions could carry over to ZYFLO CR.

The position of ZYFLO CR in managed care formularies, which are lists of approved products developed by managed care organizations, or MCOs, may make it more difficult to expand the current market share for this product. In many instances, ZYFLO CR had been relegated to a third-tier status, which typically requires the highest co-pay 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.

If any existing negative perceptions about ZYFLO persist, we will have difficulty achieving market acceptance for ZYFLO CR. If we are unable to achieve market acceptance of ZYFLO CR, we will not generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

If our marketing and sales infrastructure and presence are not adequate or our collaborative marketing arrangements are not successful, our ability to market and sell our products will be impaired.

After reducing the size of our sales force as part of cost reduction programs that we announced in 2006, we then increased the size of our sales force in 2007 in connection with the commercial launch of ZYFLO CR. As of April 30, 2008, our sales force consists of approximately 39 sales representatives. Rebuilding our sales force involved significant time and expense. If we are not successful in our efforts to retain an adequate sales force, our ability to market and sell ZYFLO CR will be impaired.

In March 2007, we entered into a co-promotion agreement with Dey, L.P., a wholly-owned subsidiary of Mylan Inc., or DEY, for the co-promotion of ZYFLO CR and ZYFLO. We cannot predict whether the co-promotion arrangement will lead to increased sales for ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR on September 27, 2007 and for ZYFLO on April 30, 2007. Given the recent initiation of DEY s efforts, the potential success of the co-promotion arrangement is uncertain. Under the co-promotion agreement, we agreed to provide a minimum number of promotional details per month by our sales representatives to a specified group of office-based physicians and other health care professionals for ZYFLO CR. If we are not successful in our efforts to provide the required level of promotional detailing, DEY s co-promotion fee may be increased and DEY may have a right to terminate the co-promotion agreement for ZYFLO CR. For example, if we experience greater than expected turnover of sales representatives, we may have difficulty satisfying our minimum detailing obligations. In February 2008, Mylan Inc., which acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic business, of which DEY was a part, announced that it is pursing strategic alternatives for DEY, including the potential sale of the business. Any decision by DEY or Mylan not to devote sufficient resources to the co-promotion arrangement or any future reductions 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.

On June 25, 2007, as contemplated by the terms of the zileuton co-promotion agreement, we and DEY entered into a separate definitive co-promotion agreement providing for us to co-promote DEY s product PERFOROMIST™ (formoterol fumarate) Inhalation Solution, or PERFOROMIST, for the long-term, twice-daily maintenance treatment of bronchoconstriction for emphysema and chronic bronchitis, which is also known as chronic obstructive pulmonary disease, or COPD. Under the PERFOROMIST co-promotion agreement, DEY agreed to pay us a co-promotion fee based on retail sales of PERFOROMIST and we agreed to provide a minimum number of promotional details per

month by our sales representatives to a specified group of office-based physicians and other health care professionals. If we are not successful in our efforts to provide the required level of promotional detailing for PERFOROMIST, our co-promotion fee may be reduced

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and DEY may have a right to terminate the PERFOROMIST co-promotion agreement. Promoting both ZYFLO CR and PERFOROMIST may be challenging for our sales representatives and may reduce their efficiency, which could negatively impact our revenues.

The amount of any co-promotion fee that DEY pays to us under the PERFOROMIST co-promotion agreement will be limited if PERFOROMIST does not achieve market acceptance. For example, safety concerns relating to PERFOROMIST may harm potential sales. PERFOROMIST belongs to a class of medications known as long-acting beta2-adrenergic agonists, or LABAs, which may increase the risk of asthma-related death. Data from a large placebo-controlled study in the United States comparing the safety of the LABA salmeterol or placebo plus usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding also may apply to formoterol, the active ingredient in PERFOROMIST. For the year ended December 31, 2007 and the three months ended March 31, 2008, we did not receive any co-promotion fees from DEY in connection with the PERFOROMIST co-promotion agreement because the level of quarterly retail sales for PERFOROMIST did not exceed a specified level. In addition, Mylan s sale or potential sale of DEY could lead to a slower launch of PERFOROMIST, negatively impact retail sales of PERFOROMIST and limit the amount of any co-promotion fee that we are entitled to receive from DEY.

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

We are subject to minimum purchase obligations under our supply agreements with our third-party manufacturers, which require us to buy inventory of the zileuton active pharmaceutical ingredient, or API, and tablet cores for ZYFLO CR. 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. As of March 31, 2008, we had $9.7 million in inventory, consisting primarily of tablet cores and API. Based on our current expectations regarding demand for ZYFLO CR, we expect that our inventory levels could increase substantially in the future as a result of our minimum purchase obligations under our supply agreements with third-party manufacturers and orders we have submitted to date. 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, it could have a material adverse effect on our financial condition and results of operations in the period in which we recognize charges for excess inventory.

In the quarters ended December 31, 2007 and March 31, 2008, we recorded an inventory reserve for an aggregate of eight batches of ZYFLO CR that cannot be released into our commercial supply chain because the batches did not meet our product release specifications. We cannot assure you that we will not have similar manufacturing issues in producing ZYFLO CR in the future. If we are unable to manufacture or release ZYFLO CR on a timely and consistent basis, if we fail to maintain an adequate inventory of zileuton API or ZYFLO CR core tablets, if our inventory were to be destroyed or damaged, or if our inventory were to reach its expiration date, patients might not have access to ZYFLO CR, our reputation and our brand could be harmed and physicians may be less likely to prescribe ZYFLO CR in the future. Conversely, if we are unable to sell our inventory in a timely manner, we could experience cash flow difficulties and additional financial losses.

If the market is not receptive to our product candidates, we will be unable to generate revenues from sales of these products.

The probability of commercial success of each of our product candidates is subject to significant uncertainty. Factors that we believe will materially affect market acceptance of our product candidates under development include:

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;

the safety, efficacy and ease of administration;

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the therapeutic benefit or other improvement over existing comparable products;

pricing and cost effectiveness;

the ability to be produced in commercial quantities at acceptable costs;

the availability of reimbursement from third-party payors such as state and Federal governments, under programs such as Medicare and Medicaid, and private insurance plans and managed care organizations; and

the extent and success of our sales and marketing efforts.

The failure of our product candidates to achieve market acceptance would prevent us from ever generating meaningful revenues from sales of these product candidates.

We may not be successful in our efforts to advance and expand our portfolio of product candidates.

An element of our strategy is to develop and commercialize product candidates that address large unmet medical needs. We seek to do so through:

preclinical studies to evaluate product candidates;

sponsored research programs with academic and other research institutions and individual doctors, chemists and researchers; and

collaborations with other pharmaceutical or biotechnology companies with complementary clinical development or commercialization capabilities or capital to assist in funding product development and commercialization.

In addition, subject to having sufficient cash and other resources to develop or commercialize additional products, we may seek to in-license or acquire product candidates or approved products. However, we may be unable to license or acquire suitable product candidates or products from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates or approved products include the following:

we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;

companies that perceive us as a competitor may be unwilling to assign or license their product rights to us;

we may be unable to identify suitable products or product candidates within our areas of expertise; and

we may have inadequate cash resources or may be unable to access public or private financing to obtain rights to suitable products or product candidates from third parties.

If we are unable to develop suitable potential product candidates through our preclinical studies, sponsored research programs or by obtaining rights from third parties, we will not be able to increase our revenues in future periods, which could result in significant harm to our financial position and adversely impact our stock price.

We face substantial competition. If we are unable to compete effectively, ZYFLO CR, PERFOROMIST and our product candidates may be rendered noncompetitive or obsolete.

The development and commercialization of new drugs is highly competitive. We will face competition with respect to the development of product candidates and for ZYFLO CR and any other products that we commercialize in the future from pharmaceutical companies, biotechnology companies, specialty

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pharmaceutical companies, companies selling low-cost generic substitutes, academic institutions, government agencies or research institutions.

A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO CR. Many established therapies currently command large market shares in the asthma market, including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in June 2007, AstraZeneca commercially launched in the United States Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a long-acting beta2-agonist.

In the COPD market, PERFOROMIST and zileuton, if we are able to develop it as a treatment for COPD, will face intense competition. COPD patients are currently treated primarily with a number of medications that are indicated for COPD, asthma, or both COPD and asthma. The primary products used to treat COPD are anticholinergics, long-acting beta-agonists and combination long-acting beta-agonists and inhaled corticosteroids. These medications are delivered in various device formulations, including metered dose inhalers, dry powder inhalers and by nebulization. Lung reduction surgery is also an option for COPD patients.

Many therapies for COPD are already well established in the respiratory marketplace, including GlaxoSmithKline s Advair® and Serevent® and Spiriva®, a once-daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer. In April 2007, Sepracor began marketing a direct competitor to PERFOROMIST called Brovana®. Brovana is an isomer of formoterol that is delivered in a nebulized formulation. DEY has sued Sepracor for infringement of DEY s patents, and Sepracor has counterclaimed. Other novel approaches are also in development.

We are also developing an injectable formulation of zileuton, or zileuton injection, for use in the hospital emergency department for the treatment of acute asthma attacks. We may face intense competition from companies seeking to develop new drugs for use in severe acute asthma attacks. For example, Merck & Co., Inc. is conducting clinical trials of an intravenous formulation of its product Singulair®.

If our therapeutic programs directed toward the body s inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc. s Enbrel®, Johnson & Johnson s Remicade®, Bristol-Myers Squibb Company s Orencia®, Abbott Laboratories Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company s Xigris®. Other companies are developing therapies directed towards cytokines. We do not know whether any or all of these products under development will ever reach the market and if they do, whether they will do so before or after our products are approved.

Our competitors products may be safer, more effective, more convenient or more effectively marketed and sold, than any of our products. Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize products;
- more extensive experience than we have in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- competing products that have already received regulatory approval or are in late-stage development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

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 obtain more effective patent protection, than we are able to. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve

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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 obsolete or noncompetitive. If our product candidates are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those product candidates.

If we are unable to retain key personnel and hire additional qualified personnel, we may not be able to achieve our goals.

Our success depends in large part on our ability to attract, retain and motivate qualified management and commercial personnel. We are highly dependent on the principal members of our executive management team. The loss of the services of any one or more of the members of our executive management team would diminish the knowledge and experience that we, as an organization, possess and might significantly delay or prevent the achievement of our research, development or commercialization objectives and could cause us to incur additional costs to recruit replacement executive personnel. We do not maintain key person life insurance on any of the members of our executive management team.

On March 2, 2008, Frank E. Thomas resigned as our President and Chief Executive Officer effective March 31, 2008 and as a member of our board of directors effective March 2, 2008. On March 4, 2008, we announced that our board of directors appointed Trevor Phillips, Ph.D. as President and Chief Executive Officer effective April 1, 2008 and elected Dr. Phillips as a member of our board of directors effective March 4, 2008. Dr. Phillips previously had served as our Chief Operating Officer and Senior Vice President of Operations. In addition to Dr. Phillips, we also depend, in particular, on the continuing services of Thomas P. Kelly, our Chief Financial Officer and Senior Vice President of Finance and Corporate Development, and other members of our executive management team. Since June 1, 2006, we have experienced significant turnover on our executive management team, with five executive officers, including Mr. Thomas, leaving our company and one executive officer joining our company. If we are unsuccessful in transitioning our smaller executive management team to compensate for the loss of Mr. Thomas and these other executives, the achievement of our research, financial, development and commercialization objectives could be significantly delayed or may not occur. In addition, our focus on transitioning to our new management team could divert our management s attention from other business concerns. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs.

Recruiting and retaining qualified commercial personnel, in addition to our executive management team, will also be critical to our success. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, 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 research, development, regulatory approval and commercialization of our product candidates.

We have experienced turnover in our sales and marketing team. For example, we have experienced an increase in the number of voluntary resignations of our sales and marketing personnel after we publicly announced in November 2007 that we were in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. Our announcement of the proposed merger with Cornerstone could have a similar effect. If we are not successful in our efforts to retain qualified sales and marketing personnel, our ability to market and sell ZYFLO CR and our ability to deliver our required level of promotional detailing under our co-promotion agreements with DEY would be impaired.

We have also experienced turnover on our board of directors. For example, we have had eight directors leave our board and three directors join our board since June 1, 2006. We currently have four directors serving on our board. If

our board were to fail to satisfy the requirements of relevant rules and regulations of the Securities and Exchange Commission, or SEC, and The NASDAQ Stock Market, relating to director independence or membership on board committees, this could result in the delisting of our common stock

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from the NASDAQ Stock Market or could adversely affect investors confidence in our company 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 for the second quarter and third quarter of 2007. If we fail to achieve and maintain effective internal control over financial reporting, we could face difficulties in preparing timely and accurate financial reports, which could result in a loss of investor confidence in our reported results and a decline in our stock price.

In connection with the preparation of our financial statements for the second quarter of 2007, we identified a material weakness in our internal control over financial reporting as discussed in Item 9A of our annual report on Form 10-K and as previously reported in our quarterly reports on Form 10-Q for the quarters ended June 30, 2007 and September 30, 2007. As a result of this material weakness, our management concluded that our disclosure controls and procedures were not effective as of either June 30, 2007 or September 30, 2007. We implemented steps to remedy the material weakness, and our management provided an unqualified assessment of our internal controls over financial reporting for the year ended December 31, 2007. There were no material changes in our internal control over financial reporting for the quarter ended March 31, 2008. Any failure or difficulties in maintaining these procedures and controls could cause us to fail to meet our periodic reporting obligations or result in our inability to prevent or detect material misstatements in our financial statements. It is possible that our management may not be able to provide an unqualified assessment of our internal control over financial reporting or disclosure controls and procedures in the future, or be able to provide quarterly certifications that our disclosure controls and procedures are effective. It is also possible that we may identify additional significant deficiencies or material weaknesses in our internal control over financial reporting in the future. Any material weakness, or any remediation thereof that is ultimately unsuccessful, could cause investors to lose confidence in the accuracy and completeness of our financial statements, which in turn could harm our business, lead to a decline in our stock price and restrict our ability to raise additional funds needed for the growth of our business.

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.

We are subject to extensive regulation by Federal and state governments. The laws that directly or indirectly affect our business include, but are not limited to, the following:

Federal Medicare and Medicaid anti-kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under Federal healthcare programs such as the Medicare and Medicaid programs;

other Medicare laws and regulations that establish the requirements for coverage and payment for our products, including the amount of such payments;

the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program, including private payors and, further, requires us to comply with standards regarding privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets;

the Federal False Statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the Federal Food, Drug and Cosmetic Act, which regulates development, manufacturing, labeling, marketing, distribution and sale of prescription drugs and medical devices;

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the Federal Prescription Drug Marketing Act of 1987, which regulates the distribution of drug samples to physicians and other prescribers who are authorized under state law to receive and dispense drug samples;

state and foreign law equivalents of the foregoing;

state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern the sale, distribution, use, administration and prescribing of prescription drugs; and

state laws that prohibit practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the Federal Medicare and Medicaid anti-kickback laws, which may not be limited to government reimbursed items or services.

On January 1, 2006, we became 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.

If our past or present operations are found to be in violation of any of the laws described above or other laws or governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licenses under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims of a violation. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to enforcement action by the FDA. For example, we received a warning letter from the FDA in November 2005 relating to certain promotional material that included an illustration of the mechanism of action for ZYFLO. The FDA asserted that the promotional material incorporating the illustration was false or misleading because it presented efficacy claims for ZYFLO, but failed to contain fair balance by not communicating the risks associated with its use and failing to present the approved indication for ZYFLO. In response to the warning letter, and as requested by the FDA, we stopped disseminating the promotional material containing the mechanism of action and we provided a written response to the FDA. As part of our response, we provided a description of our plan to disseminate corrective messages about the promotional material to those who received this material. We revised the promotional material containing the mechanism of action to address the FDA s concerns regarding fair balance. If our promotional activities fail to comply with the FDA s regulations or guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions, and other penalties and our reputation and the reputation of ZYFLO CR in the market could be harmed.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention from operating our business and damage our reputation or our brands. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change or discontinue our business practices or our existing business practices

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could be challenged as unlawful, which could materially harm our business, financial condition and results of operations.

State pharmaceutical marketing and promotional compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

In recent years, several states, including California, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, as well as the District of Columbia have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs and file periodic reports with the state on sales, marketing, pricing, reporting pricing and other activities. 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 compliance program must establish a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California.

Maine, Minnesota, New Mexico, Nevada, Vermont, West Virginia and the District of Columbia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to healthcare practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and uncertain, and available guidance is limited. We are in the process of identifying the universe of state laws applicable to pharmaceutical companies and are taking steps to ensure that we come into compliance with all such laws. 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.

Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute our existing products.

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at assuring drug safety and monitoring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become more clear. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

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 ZYFLO CR and our other product candidates, together with our general operations, are subject to extensive regulation by Federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company and had approximately 75 employees as of March 31, 2008. We rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented and changing regulatory requirements, it is possible that we may not be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions,

including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

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As a publicly traded company, we are subject to significant legal and regulatory requirements, including the Sarbanes-Oxley Act of 2002 and related regulations, some of which have either only recently become applicable to us or are subject to change. For example, we are incurring additional expenses and devoting significant management time and attention to evaluating our internal control systems in order to allow our management to report on, and our registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that we have implemented do not comply with all of the relevant rules and regulations of the SEC and The NASDAQ Stock Market, we may be subject to sanctions or investigation by regulatory authorities, including the SEC or The NASDAQ Stock Market. This type of action could adversely affect our financial results or investors confidence in our company and our ability to access the capital markets and could result in the delisting of our common stock from the NASDAQ Stock Market. If we fail to develop and maintain adequate controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in our stock price.

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 ZYFLO CR are, and any future sales of our product candidates will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and Federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and we expect there will continue to be, state and Federal legislative and administrative proposals that could limit the amount that state or Federal governments 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, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as MCOs, may adopt their own reimbursement reductions in response to 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 drug product is approved, governmental and private reimbursement 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, including ZYFLO CR, and current reimbursement policies for marketed products may change at any time.

The MMA established a prescription drug benefit that became effective in 2006 for all Medicare beneficiaries. We cannot be certain that ZYFLO CR, 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 MCOs, health maintenance organizations, or HMOs, preferred provider organizations, or PPOs, and private health plans that administer the Medicare drug benefit have the ability to negotiate price and demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, MCOs, HMOs, PPOs, healthcare institutions and other government agencies continue to seek price discounts. Because MCOs, HMOs and PPOs and private health plans will administer the Medicare drug benefit, managed care and private health plans will influence prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for senior citizen and drug programs for people with low incomes, including price or patient reimbursement constraints, restrictions on access to certain products, and bulk purchasing of drugs.

If we succeed in bringing products in addition to ZYFLO CR 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 are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate their

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cost-effectiveness. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for those product candidates if they are successfully developed. If the reimbursement we receive for any of our product candidates is inadequate in light of our 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.

Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, a product liability claim against us could interfere with the development and commercialization of our product candidates or subject us to unanticipated damages or settlement amounts.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing and sale of drugs. If the use of ZYFLO CR, ZYFLO or one or more of our other product candidates harms people, we may be subject to costly and damaging product liability claims. We currently have a $20.0 million annual aggregate limit for insurance covering both product liability claims for ZYFLO CR and ZYFLO and clinical trial liability claims for our product candidates. We may seek additional product liability insurance prior to marketing any of our other product candidates still in development. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that we have not anticipated in our business plans. Any product liability claim against us, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

Risks Relating to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

If we do not obtain the regulatory approvals or clearances required to market and sell our product candidates under development, our business may be unsuccessful.

Neither we nor any of our collaborators may market any of our products or our product candidates under development in the United States, Europe or in any other country without marketing approval from the FDA or the equivalent foreign regulatory agency. ZYFLO CR is currently our only commercial product and can only be marketed in the United States.

The regulatory process to obtain market approval or clearance for a new drug or biologic takes many years, requires expenditures of substantial resources, is uncertain and is subject to unanticipated delays. We have had only limited experience in preparing applications and obtaining regulatory approvals and clearances. Adverse side effects of a product candidate in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve or clear a particular product candidate for any or all indications for use.

The FDA and foreign regulatory agencies have substantial discretion in the drug approval process and can deny, delay or limit approval of a product candidate for a variety of reasons. If we do not receive the required regulatory approval or clearance to market any of our product candidates under development, our ability to generate product revenue and achieve profitability, our reputation and our ability to raise additional capital will be materially impaired.

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If clinical trials for our 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 development and remain subject to clinical testing and regulatory approval or clearance. In order to obtain regulatory approvals or clearances for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. We may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these 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 have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, we, one of our collaborators, institutional review boards, or regulatory agencies may hold, 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, in March 2006, we announced that we had discontinued a Phase II clinical trial of ethyl pyruvate, which we refer to as CTI-01, a small molecule product candidate that we had been developing for prevention of complications that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery. After reviewing the final data from the trial, we decided to discontinue further development of CTI-01. We subsequently terminated, effective in February 2007, the license agreements between us and the University of Pittsburgh and Xanthus Pharmaceuticals, Inc., formerly Phenome Sciences, Inc., related to patent rights related to CTI-01 controlled by University of Pittsburgh and Xanthus.

Preclinical testing and clinical trials of new drug and biologic candidates are lengthy and expensive and the historical failure rate for such candidates is high. We may not be able to advance any more product candidates into clinical trials. Even if we do successfully enter into clinical trials, the results from preclinical testing of a product candidate may not predict the results that will be obtained in human clinical trials. In addition, positive results demonstrated in preclinical studies and clinical trials that we complete may not be indicative of results obtained in additional clinical trials. Clinical trials may take several years to complete, and failure can occur at any stage of testing.

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 a submission or approval for a narrower indication. If clinical trials fail, our product candidates would not become commercially viable.

If clinical trials for our product candidates are delayed, we would be unable to 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 cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards or us to delay or suspend those clinical trials, or delay the analysis of data from our ongoing clinical trials.

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients and volunteers into clinical trials;

lower than anticipated retention rates of patients and volunteers in clinical trials;

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the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing;

insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in ongoing or past clinical trials for the same or a different indication;

serious and unexpected drug-related side effects observed during ongoing or past preclinical studies; or

the placement of a clinical hold on a trial.

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 our 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 of the trial.

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 of patient enrollment that 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 clinical 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.

As a result of these factors, we or third parties on whom we rely may not successfully begin or complete our clinical trials in the time periods we have forecasted, if at all. If the results of our ongoing or planned clinical trials for our product candidates are not available when we expect or if we encounter any delay in the analysis of data from our preclinical studies and clinical trials, we may be unable to submit for regulatory approval or clearance or conduct additional clinical trials on the schedule we currently 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.

Even if we obtain regulatory approvals or clearances, our products and product candidates will be subject to ongoing regulatory requirements and review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose permission to manufacture and distribute our products and the sale of our product candidates could be suspended.

Our products and product candidates are subject to continuing regulatory review after approval, including the review of spontaneous adverse drug experiences and clinical results from any post-market testing required as a condition of approval that are reported after our product candidates become commercially available. The manufacturer and the manufacturing facilities we use to make ZYFLO CR, tablet cores and API and any of our product candidates will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions

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on the product or manufacturer or facility, including withdrawal of the product from the market. Our product promotion and advertising will also be subject to regulatory requirements and continuing FDA review.

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.

Numerous proposals have been made in recent months and years to impose new requirements on drug approvals, expand post-approval requirements, and restrict sales and promotional activities. For example, a new drug application, or NDA, requires that an applicant submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, and federal legislation has been proposed that would require all new drug applicants to submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Additional measures have also been proposed to address perceived shortcomings in the FDA s handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices that some see as excessive or improper. If these or other legal or regulatory changes are enacted, it may become more difficult or burdensome for us to obtain extended or new product approvals, and our current approvals may be restricted or subject to onerous post-approval requirements. Such changes may increase our costs and adversely affect our operations. The ability of us or our partners to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

If we or our third-party manufacturers or service providers fail to comply with applicable laws and regulations, we or they could be subject to enforcement actions, which could adversely affect our ability to market and sell our product candidates and may harm our reputation.

If we or our third-party manufacturers or service providers fail to comply with applicable Federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and hinder market acceptance of our product candidates. These enforcement actions include:

- product seizures;
- voluntary or mandatory recalls;
- suspension of review or refusal to approve pending applications;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- restrictions on, or prohibitions against, marketing our product candidates;
- restrictions on applying for or obtaining government bids;
- fines;
- restrictions on importation of our product candidates;

injunctions; and

civil and criminal penalties.

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Risks Relating to Our Dependence on Third Parties

We depend on DEY to jointly promote and market ZYFLO CR. This co-promotion arrangement may not be successful.

We are relying on DEY to jointly promote and market ZYFLO CR. ZYFLO CR is our only commercially marketed product. Our ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of our co-promotion arrangement with DEY. DEY initiated promotional detailing activities for ZYFLO CR in September 2007 after initiating promotional detailing for ZYFLO in April 2007. We cannot predict if DEY s promotional detailing activities will have a meaningful impact on our revenues from ZYFLO CR.

After September 27, 2010, DEY may terminate the co-promotion agreement with six-months, advance written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months, prior written notice if ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party. 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 particular, both we and DEY have agreed to provide a minimum number of details per month for ZYFLO CR. We also rely on DEY to provide the support of its managed care group to negotiate contracts and engage in other activities with third-party payors for favorable managed care access. This managed care support includes advice and logistical support to us regarding our managed care strategy.

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 promoting and marketing ZYFLO CR, 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. 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 with DEY. For example, in February 2008, Mylan announced that it is pursuing strategic alternatives for DEY, including the potential sale of the business. 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, as a result of difficulty retaining or hiring sales representatives following Mylan s announcement that it is pursuing strategic alternatives for DEY or otherwise, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

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 are relying on MedImmune, Inc., a wholly-owned subsidiary of AstraZeneca PLC, 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. All of our revenues prior to October 2005, when we commercially launched ZYFLO, were derived from our collaboration agreements with MedImmune and Beckman Coulter. Additional payments due to us under the collaboration agreements with MedImmune and Beckman Coulter are generally based on our achievement of specific development and commercialization milestones that we

may not meet. 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

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property from third parties. Accordingly, we cannot predict if our collaborations with MedImmune and Beckman Coulter will continue to generate revenues for us.

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. Under the collaboration agreement, we are obligated to use commercially reasonable, good faith efforts to conduct the collaboration in accordance with rolling three-year research plans that describe and allocate between MedImmune and us responsibility for, among other things, the proposed research, preclinical studies, toxicology formulation activities and clinical studies for that time period. In addition, we and MedImmune 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 our 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 our HMGB1 program likely would be delayed, curtailed or terminated. The delay, curtailment or termination of our HMGB1 program could significantly harm our future prospects.

Our license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party. If Beckman Coulter were to terminate or breach our arrangement, 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 collaborative arrangements that we enter into with third parties may not be scientifically or commercially successful. Factors that may affect the success of our collaborations include the following:

- our 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;

- our 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;

- our 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

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

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.

We intend to enter into collaboration agreements with other parties in the future that relate to our other product candidates, and we are likely to have similar risks with regard to any such future collaborations.

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IMI may not be successful in developing a product under the patent rights and know-how that we licensed to IMI relating to the mechanical and electrical stimulation of the vagus nerve.

We have licensed to Innovative Metabolics, Inc., or IMI, patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. IMI is an early-stage company. We are not involved in IMI s efforts to develop and commercialize a medical device based on the intellectual property that we licensed to IMI. We will receive additional payments under the IMI license only if IMI is successful in achieving full regulatory approval of such a device or receives a royalty, fee or other payment from a third party in connection with a sublicense of its rights under our license agreement.

We rely on third parties to manufacture and supply the zileuton API, ZYFLO CR and our product candidates. We expect to continue to rely on these sole source suppliers for these purposes and would incur significant costs to independently develop manufacturing facilities.

We have no manufacturing facilities and limited manufacturing experience. In order to continue to commercialize ZYFLO CR, develop product candidates, apply for regulatory approvals and commercialize our product candidates, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. We expect to continue to rely on third parties for production of the zileuton API, commercial supplies of ZYFLO CR and preclinical and clinical supplies of our product candidates. These third parties are currently our sole source suppliers, and we expect to continue to rely on them for these purposes for the foreseeable future.

We have contracted with Shasun Pharma Solutions Ltd. 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 product, ZYFLO CR, 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. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged, or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production. 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 AG, a subsidiary of SkyePharma PLC, or SkyePharma, 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 SkyePharma, which manufactures them in France. The manufacture of the core tablets for ZYFLO CR could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

We have contracted with Patheon Pharmaceuticals Inc. to coat and package the core tablets of ZYFLO CR for commercial supplies. Patheon is currently our only source of finished ZYFLO CR tablets. The manufacture of the finished ZYFLO CR tablets could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

We are dependent upon Shasun, Patheon and SkyePharma as sole providers, and will be dependent on any other third parties who manufacture our product candidates, to perform their obligations in a timely manner and in accordance with applicable government regulations. If third-party manufacturers with whom we contract fail 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 ZYFLO CR;

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 our product candidates that are under development; and

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

If Shasun, Patheon or SkyePharma experiences any significant difficulties in their respective manufacturing processes for our products including the zileuton API, ZYFLO CR core tablets or finished product for ZYFLO CR, we could experience significant interruptions in the supply of ZYFLO CR. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity or the scheduling of manufacturing sufficient for our needs at our third-party manufacturing partners, could impair our ability to supply ZYFLO CR at required levels. Such an interruption could cause us to incur substantial costs and impair our ability to generate revenue from ZYFLO CR may be adversely affected.

The zileuton API is manufactured in United Kingdom by Shasun, and we either store the zileuton API at a Shasun warehouse, ship the zileuton API either directly to a contract manufacturer or to a third-party warehouse. For the manufacture of ZYFLO CR, we ship zileuton API to France for manufacturing of core tablets by SkyePharma and we ship core tablets from France to the United States to be coated, packaged and labeled at Patheon. While in transit, our zileuton API and ZYFLO CR core tablets, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment from Shasun, our zileuton API, which is stored in France at SkyePharma or in the United States at Patheon or at third-party warehouse, or our ZYFLO CR core tablets, which are stored at Patheon prior to coating and packaging, and our finished ZYFLO CR products, which are stored at our third-party logistics provider, Integrated Commercialization Solutions, Inc., or ICS, could be lost or suffer damage, which would render them unusable. We have attempted to take appropriate risk mitigation steps and to obtain transit insurance. However, depending on when in the process the zileuton API, ZYFLO CR core tablets or finished product is lost or damaged, 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 to our zileuton API, ZYFLO CR core tablets or finished product.

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 for the zileuton API or ZYFLO CR tablet cores or coating, we would be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that ZYFLO CR manufactured by the new manufacturer is equivalent to ZYFLO CR manufactured by our current manufacturer. Any delays associated with the verification of a new manufacturer or conducting additional clinical bioequivalence trials could adversely affect our production schedule or increase our production costs.

We have not secured a long-term commercial supply arrangement for any of our product candidates other than the zileuton API. The manufacturing process for our product candidates is an element of the FDA approval process. We will need to contract with manufacturers who can meet the FDA requirements, including current Good Manufacturing Practices, on an ongoing basis. In addition, if we receive the necessary regulatory approval for our product candidates, we also expect to rely on third parties, including our collaborators, to produce materials required for commercial production. We may experience difficulty in obtaining adequate manufacturing capacity or timing for our needs. If we are unable to obtain or maintain contract manufacturing of these product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

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 the quarters ended December 31, 2007 and March 31, 2008, we recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that cannot be released into our commercial supply chain because they did not meet our product release specifications. In conjunction with our three third-party manufacturers for zileuton API, tablet cores and coating and release, we have initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. We have incurred

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and expect to continue to incur significant costs in connection with our investigation. In April 2008, pending the completion of the investigation, we placed 12 additional batches of the tablet cores of ZYFLO CR on a quality assurance hold. We are currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR, if any, that may be released for commercial supply. These supply chain difficulties could impact the level of commercial supply of ZYFLO CR available for sale and, if not corrected, prevent us from supplying any further product to our wholesale distributors. If the supply issues are not resolved in the near term, we expect that our existing inventory of ZYFLO CR should support our current level of sales to wholesale distributors through mid-July 2008.

If we do not have a sufficient commercial supply of ZYFLO CR available, we may decide to reinitiate the marketing and supply of ZYFLO to the market. In April 2008, we began to reinitiate manufacture of ZYFLO in order to be able to have a supply of ZYFLO available if we decide it is necessary to reinitiate marketing and supply of ZYFLO to the market. However, reintroducing ZYFLO to replace ZYFLO CR could be confusing for physicians and patients. As a result of potential physician and patient confusion relating to the reintroduction of ZYFLO to the market and ZYFLO s less convenient four times daily dosing regimen, our sales of ZYFLO would likely not meet either the level of sales of ZYFLO CR since its market launch in September 2007 or the historical level of sales of ZYFLO prior to the market launch of ZYFLO CR.

If our investigation regarding our supply chain requires changes to our manufacturing processes or materials in order to be able to supply sufficient levels of ZYFLO CR to satisfy our commercial needs, the costs to manufacture ZYFLO CR may be significantly higher than we had anticipated. As of March 31, 2008, we have expensed $1.2 million relating to the eight batches that recently failed to meet product release specifications and we expect to incur other significant costs in connection with our investigation. If we are not able to supply ZYFLO CR at a commercially acceptable cost and level, we could experience cash flow difficulties and additional financial losses. Depending on the outcome of the investigation, we may not be able to obtain reimbursement from any of our third-party manufacturers for existing or additional batches of ZYFLO CR that do not meet our product release specifications.

Under our merger agreement with Cornerstone, it is a condition to Cornerstone s obligation to consummate the merger that either ZYFLO CR or ZYFLO must be available and ready for purchase by third party wholesalers or retailers during the period prior to the closing of the merger, other than during any period not exceeding 30 consecutive days. If the proposed merger with Cornerstone is not consummated, we would be subject to all of the additional risks described above under Risks Related to Our Proposed Merger with Cornerstone .

Any failure to manage and maintain our distribution network could compromise sales of ZYFLO CR and harm our business.

We rely on third parties to distribute ZYFLO CR to pharmacies. We have contracted with ICS, a third-party logistics company, to warehouse and distribute ZYFLO CR to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. ICS is our exclusive supplier of commercial distribution logistics services. The wholesalers in turn distribute to chain and independent pharmacies. Sales to AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation collectively accounted for at least 95% of our annual billings for ZYFLO CR and ZYFLO during 2007. 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.

We rely on Phoenix Marketing Group LLC to distribute product samples to our sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. We rely on RxHope to administer our patient assistance program and to distribute samples of ZYFLO CR to physicians and other prescribers who are authorized under state law to receive and dispense samples.

This distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. Failure to maintain our contracts with ICS, the wholesalers, Phoenix and RxHope, or the inability or failure of any of them to adequately perform as agreed under their respective contracts with us,

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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 were unable to replace ICS, AmerisourceBergen, Cardinal, McKesson, Phoenix or RxHope in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting any of them, the distribution of ZYFLO CR could be delayed or interrupted, which would damage our results of operations and market position. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product sales and fulfill our regulatory obligations. If we are unable to effectively manage and maintain our distribution network, sales of ZYFLO CR could be severely compromised and our business could be harmed.

If we are unable to enter into additional collaboration agreements, we may not be able to continue development of our product candidates.

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. We may seek to enter into additional collaboration agreements with pharmaceutical or biotechnology companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, we have determined 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 face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. We may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to us. If we are not successful in efforts to enter into a collaboration arrangement with respect to a product candidate, we may not have sufficient funds to develop any of our product candidates internally. If we do not have sufficient funds to develop our product candidates, we will not be able to bring these product candidates to market and generate revenue. In addition, our inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on our financial condition and results of operations because:

- we may be required to expend our own funds to advance the product candidate to commercialization;
- revenue from product sales could be delayed; or
- we may elect not to develop or commercialize the product candidate.

We plan to rely significantly on third parties to market some product candidates, and these third parties may not successfully commercialize these product candidates.

For product candidates with large target physician markets, we plan to rely significantly on sales, marketing and distribution arrangements with third parties. For example, we plan to rely on MedImmune for the commercialization of any anti-HMGB1 products that we develop, and we plan to rely on 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.

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Risks Relating to Intellectual Property and Licenses

If we or our licensors are not able to obtain and enforce patent and other intellectual property protection for our discoveries or discoveries we have in-licensed, our ability to prevent third parties from using our inventions and proprietary information will be limited and we may not be able to operate our business profitably.

Our success depends, in part, on our ability to protect proprietary products, methods and technologies that we invent, develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. The composition of matter patent for zileuton in the United States will expire in December 2010. The patent for ZYFLO CR, which relates only to the controlled-release technology used to control the release of zileuton, will expire in June 2012. We are exploring strategies to extend and expand the patent protection for our zileuton products, but we may not be able to obtain additional patent protection.

Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date that will not be filed in foreign countries and for which a request for non-publication is filed, and because even patent applications for which no request for non-publication is made are not published until approximately 18 months after filing, third parties may have already filed patent applications for technology covered by our pending patent applications, and our patent applications may not have priority over any such patent applications of others. There may also be prior art that may prevent allowance of our patent applications or enforcement of our or our licensors issued patents.

Our patent strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely or successful manner. Moreover, the mere issuance of a patent does not guarantee that it is valid or enforceable. As a result, even if we obtain patents, they may not be valid or enforceable against third parties.

Our pending patent applications and those of our licensors may not result in issued patents. In addition, the patent positions of pharmaceutical or biotechnology companies, including ours, are generally uncertain and involve complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others with respect to our products in the future.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by a competitor, any competitive advantage that we may have had in the development or commercialization of our product candidates would be minimized or eliminated.

Our confidentiality agreements with our current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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Litigation regarding patents, patent applications and other proprietary rights is expensive and time consuming. If we are unsuccessful in litigation or other adversarial proceedings concerning patents or patent applications, we may not be able to protect our products from competition or we may be precluded from selling our products. If we are involved in such litigation, it could cause delays in, or prevent us from, bringing products to market and harm our ability to operate.

Our success will depend in part on our ability to uphold and enforce the patents or patent applications owned or co-owned by us or licensed to us that cover our products and product candidates. Litigation, interferences or other adversarial proceedings relating to our patents or patent applications could take place in the United States or foreign courts or in the United States or foreign patent offices or other administrative agencies. Proceedings involving our patents or patent applications could result in adverse decisions regarding:

- the patentability of our applications, including those relating to our products; or
- the enforceability, validity or scope of protection offered by our patents, including those relating to our products.

These proceedings are costly and time consuming. 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 time and attention of our management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on our business.

If it is determined that we do infringe a patent right of another, we may be required to seek a license, defend an infringement action or challenge the validity of the patent in court. In addition, if we are not successful in infringement litigation brought against us and we do not license or develop non-infringing technology, we may:

- incur substantial monetary damages, potentially including treble damages, if we are found to have willfully infringed on such parties patent rights;
- encounter significant delays in bringing our product candidates to market; or
- be precluded from participating in the manufacture, use or sale of our products or methods of treatment.

If any parties should successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages. In addition to any damages we might have to pay, a court could require us to stop the infringing activity. Moreover, any legal action against us or our collaborators claiming damages and seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any such required license may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us.

If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology or products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, our MedImmune collaboration 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.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

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We in-license a significant portion of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop and market our zileuton products, our HMGB1 products and some of our other product candidates.

We are a party to a number of licenses that give us rights to third-party intellectual property that is necessary for our business. In fact, we acquired the rights to each of our product candidates under licenses with third parties. These licenses impose various development, commercialization, funding, royalty, diligence and other obligations on us. If we breach these obligations, our licensors may have the right to terminate the licenses or render the licenses non-exclusive, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology, or at least to do so on an exclusive basis.

Risks Relating to Our Financial Results and Need for Additional Financing

We have incurred losses since inception and we anticipate that we will continue to incur losses for the foreseeable future. If we do not generate significant revenues, we will not be able to achieve profitability.

We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. We had net losses of $10.8 million in the three months ended March 31, 2008 and $4.7 million in the three months ended March 31, 2007. As of March 31, 2008, we had an accumulated deficit of approximately $202 million. We recorded revenue from the sale of ZYFLO and ZYFLO CR of $11.0 million for the year ended December 31, 2007 and $3.3 million for the three months ended March 31, 2008 and have not recorded revenue from any other product. We expect that we will continue to incur substantial losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts. We expect that the losses that we incur will fluctuate from quarter to quarter and that these fluctuations may be substantial. We will need to generate significant revenues to achieve profitability. Until we are able to generate such revenues, we will not be profitable and will need to raise substantial additional capital to fund our operations.

We will require substantial additional capital to fund our operations. If additional capital is not available, we may need to delay, limit or eliminate our development and commercialization processes.

We expect to devote substantial resources to support ongoing sales and marketing efforts for ZYFLO CR and to fund the development of our other product candidates. Our funding requirements will depend on numerous factors, including:

- the ongoing costs of marketing ZYFLO CR;
- the scope, costs and results of our clinical trials on ZYFLO CR and zileuton injection;
- the amount and timing of sales and returns of ZYFLO CR and ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO CR;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, IMI or future collaborators or licensees;

the timing, receipt and amount of sales and royalties, if any, from our product candidates;

continued progress in our research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under our license agreements;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

the cost of obtaining and maintaining licenses to use patented technologies;

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potential acquisition or in-licensing of other products or technologies;

our ability to establish and maintain additional collaborative or co-promotion arrangements; and

the ongoing time and costs involved in corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act of 2002.

Other than payments that we may receive from our collaborations with DEY and MedImmune, sales of ZYFLO CR represent our only sources of cash flow and revenue. We believe that our ability to access external funds will depend upon market acceptance of ZYFLO CR, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to successfully commercialize ZYFLO CR. Based on our current operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the first quarter of 2009.

Our net cash used for operating activities was $14.4 million for the year ended December 31, 2007 and $13.9 million for the three months ended March 31, 2008, and we had minimal capital expenditures. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional products or product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Under our merger agreement with Cornerstone, any financing transaction would require Cornerstone s consent. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products, which we would otherwise pursue on our own.

As a result of our recurring losses from operations, accumulated deficit and our expectation that we will incur substantial additional operating costs for the foreseeable future, as discussed in Note 1 to our consolidated financial statements, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. We have prepared our financial statements on the assumption that we will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about our ability to continue as a going concern may 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 the estimates we make, or the assumptions on which we rely, in preparing our financial statements prove inaccurate, our 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 these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, 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, our reserve for potential

returns for ZYFLO CR and ZYFLO is based on our historical experience of product returns for ZYFLO and other factors that could significantly impact expected returns. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct. If our estimates are inaccurate, this could adversely affect our stock price.

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Risks Relating to Our 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.

If we fail to continue to meet all applicable continued listing requirements of The NASDAQ Global 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 listed on The NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements. On April 21, 2008, we received notification from the NASDAQ Listings Qualifications Department that for the prior 30 consecutive business days the bid price of our common stock on The NASDAQ Global Market had closed below the minimum $1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5), or the Minimum Bid Price Rule. In accordance with NASDAQ Marketplace Rule 4450(e)(2), we have 180 calendar days, or until October 20, 2008, or the Required Date, to regain compliance with the Minimum Bid Price Rule. In the event that we do not regain compliance with the Minimum Bid Price Rule by the Required Date, NASDAQ will provide written notification that our securities will be delisted from The NASDAQ Global Market. At that time, we may appeal NASDAQ s determination to delist our securities to a NASDAQ Listing Qualifications Panel. Alternatively, we could apply to transfer our listing to The NASDAQ Capital Market, a trading market for smaller companies, provided that we meet all applicable requirements for initial listing on The NASDAQ Capital Market other than the Minimum Bid Price Rule. If such an application were approved and we otherwise maintain the listing requirements for The NASDAQ Capital Market, other than with respect to the Minimum Bid Price Rule, we would be afforded the remainder of an additional 180 calendar day grace period while listed on The NASDAQ Capital Market to regain compliance with the Minimum Bid Price Rule. We will consider available options if our common stock does not trade at a level likely to result in us regaining compliance with the Minimum Bid Price Rule. In addition, to retain our listing on The NASDAQ Global Market we must maintain either minimum stockholders equity of $10.0 million or an aggregate market value of our common stock of $50.0 million. We may not continue to meet the minimum bid price requirement under NASDAQ rules or the other applicable continued listing requirements for The NASDAQ Global Market.

If we fail to continue to meet all applicable continued listing requirements of The NASDAQ Global Market in the future and NASDAQ determines to delist our common stock or transfer our listing from The NASDAQ Global Market to The NASDAQ Capital Market, 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.

Immediately prior to the effective time of our proposed merger with Cornerstone, we have agreed to effect a reverse stock split of our common stock based on a ratio to be mutually agreed upon by us and Cornerstone. The reverse stock split is necessary so that as of the effective time of the merger we will satisfy the minimum bid price requirement pursuant to NASDAQ s initial listing standards.

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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:

- our proposed merger with Cornerstone and related developments, including the timing thereof;
- the amount and timing of sales of ZYFLO CR;
- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;
- the availability and timely delivery of a sufficient supply of ZYFLO CR;
- the amount of rebates, discounts and chargebacks to wholesalers, Medicaid and managed care organizations related to ZYFLO CR;
- the amount and timing of product returns for ZYFLO CR and ZYFLO;
- achievement of, or the failure to achieve, milestones under our development agreement with MedImmune, our license agreements with Beckman Coulter and IMI and, to the extent applicable, other licensing and collaboration agreement;
- 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:

- developments with respect to our proposed merger with Cornerstone;
- our operating results, including the amount and timing of sales of ZYFLO CR;
- 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 over us 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 April 30, 2008, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 22.9% 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 management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

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 to which we are subject include provisions in our by-laws providing that stockholders meetings may be called only by our president or the majority of our board of directors and a provision in our certificate of incorporation providing that our stockholders may not take action by written consent.

Additionally, our 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 our stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that we issue. As a result, our issuance of preferred stock could cause the market value of our 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 may use this provision to prevent changes in our management. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds.***

Not applicable.

Item 3. ***Defaults Upon Senior Securities.***

Not applicable.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

Not applicable.

Item 5. ***Other Information.***

As we move forward with our proposed merger with Cornerstone, we are continuing to focus on conserving cash resources and have begun to take steps to reduce spending on development programs and personnel. On May 8, 2008, as part of this effort, we announced that we had eliminated six positions, or approximately 8% of our workforce. The headcount reductions primarily affect our research and development group. We expect to consider further reductions in headcount in additional areas of our business in the future

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in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on our business needs and financial resources.

In connection with the implementation of the May 8, 2008 reduction in our workforce, we expect to record a charge of approximately $540,000 in the second quarter of 2008 primarily relating to cash severance payments. We will record the restructuring charges in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.*

Item 6. ***Exhibits.***

The exhibits listed in the accompanying exhibit index are filed as part of this Quarterly Report on Form 10-Q.

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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.

CRITICAL THERAPEUTICS, INC.

Date: May 12, 2008

/s/ Trevor Phillips
Trevor Phillips, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2008

/s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer and Senior Vice President of Finance and Corporate Development
(Principal Financial Officer)

Date: May 12, 2008

/s/ Jeffrey E. Young
Jeffrey E. Young
Vice President of Finance, Chief Accounting Officer and Treasurer
(Principal Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1	Agreement for Termination of Lease and Voluntary Surrender of Premises by and between ARE 60 Westview, LLC and the Registrant, dated January 16, 2008 (Incorporated by reference to Exhibit 99.2 to the Registrant s Current Report on Form 8-K dated January 16, 2008, as filed with the SEC on January 18, 2008 (SEC File No. 000-50767)).
10.2	Amendment No. 1 dated as of March 31, 2008 to Agreement for Termination of Lease and Voluntary Surrender of Premises by and between ARE 60 Westview, LLC and the Registrant.
10.3	Sublease by and between Microbia Precision Engineering, Inc. and the Registrant, dated January 16, 2008 (Incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated January 16, 2008, as filed with the SEC on January 18, 2008 (SEC File No. 000-50767)).
31.1	Certification of the 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 the 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 the 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 the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.