

CRITICAL THERAPEUTICS INC

Form 10-Q

August 11, 2008

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**Form 10-Q**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For The Quarterly Period Ended June 30, 2008**
- or**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the Transition Period From        to**

**Commission File Number: 000-50767**

**Critical Therapeutics, Inc.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**04-3523569**

*(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  No

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

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(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  No

As of August 8, 2008, the registrant had 43,357,098 shares of Common Stock, \$0.001 par value per share, outstanding.

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**CRITICAL THERAPEUTICS, INC.**

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**Table of Contents****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 Critical Therapeutics, Inc.'s proposed merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone, including the expected timetable for completing the transaction; Critical Therapeutics' 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 Critical Therapeutics' drug development programs and related trials; the efficacy of Critical Therapeutics' drug candidates; and Critical Therapeutics' 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. Critical Therapeutics 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 Critical Therapeutics' critical accounting estimates and risks relating to: the ability to consummate the proposed merger with Cornerstone; Critical Therapeutics' ability to successfully market and sell ZYFLO CR, including the success of Critical Therapeutics' co-promotion arrangement with Dey, L.P., a wholly owned subsidiary of Mylan Inc., or DEY; Critical Therapeutics' ability to transition its management team effectively; Critical Therapeutics' ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO CR and ZYFLO® (zileuton tablets) immediate-release formulation of zileuton, or ZYFLO; 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; Critical Therapeutics' heavy dependence on the commercial success of ZYFLO CR; Critical Therapeutics' ability to maintain regulatory approvals to market ZYFLO CR; Critical Therapeutics' ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; Critical Therapeutics' ability to maintain compliance with NASDAQ listing standards; the results of preclinical studies and clinical trials with respect to Critical Therapeutics' products under development and whether such results will be indicative of results obtained in later clinical trials; Critical Therapeutics' ability to obtain the substantial additional funding required to conduct Critical Therapeutics' development and commercialization activities; Critical Therapeutics' dependence on its strategic collaboration with MedImmune, Inc., a wholly owned subsidiary of AstraZeneca PLC, or MedImmune; and Critical Therapeutics' ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO CR, Critical Therapeutics' 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, Critical Therapeutics' 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 Critical Therapeutics' views only as of the date of this quarterly report on Form 10-Q and should not be relied upon as representing Critical Therapeutics' views as of any subsequent date. Critical Therapeutics anticipates that subsequent events and developments will cause Critical Therapeutics' views to change. However, while Critical Therapeutics may elect to update these forward-looking statements publicly at some point in the future, Critical Therapeutics specifically disclaims any obligation to do so, except as may be required by law, whether as a result of new information, future events or otherwise. Critical Therapeutics' forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments it may make. In particular, unless otherwise stated or the context otherwise requires, Critical Therapeutics has prepared this quarterly report on Form 10-Q as if Critical Therapeutics were going to remain a standalone,

independent company. If Critical Therapeutics consummates the merger with Cornerstone, the descriptions of Critical Therapeutics 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.

**Table of Contents****Item 1. Financial Statements****CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>June 30, 2008</b>	<b>December 31, 2007</b>
	<b>(Unaudited)</b>	
	<b>In thousands</b>	
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 10,952	\$ 33,828
Accounts receivable, net	1,520	1,273
Amount due under collaboration agreements		31
Inventory, net	7,760	5,599
Prepaid expenses and other	2,490	2,174
Total current assets	22,722	42,905
Fixed assets, net	352	1,151
Other assets	284	868
Total assets	\$ 23,358	\$ 44,924
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Current portion of long-term debt	\$	\$ 370
Current portion of accrued license fees	1,796	1,838
Current portion of deferred co-promotion fees	1,880	1,880
Accounts payable	4,311	5,283
Accrued expenses	5,325	7,154
Total current liabilities	13,312	16,525
Long-term portion of accrued license fees, less current portion		1,754
Long-term portion of deferred co-promotion fees, less current portion	8,870	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 42,987,848 and 42,805,348 shares at June 30, 2008 and December 31, 2007, respectively	43	43
Additional paid-in capital	209,919	208,420

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Accumulated deficit	(208,770)	(191,372)
Accumulated other comprehensive loss	(16)	
Total stockholders' equity	1,176	17,091
Total liabilities and stockholders' equity	\$ 23,358	\$ 44,924

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

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>			
	<b>In thousands except share and per share data</b>			
Revenues:				
Net product sales	\$ 3,894	\$ 2,291	\$ 7,227	\$ 5,185
Revenue under collaboration and license agreements		1,136		1,737
Total revenues	3,894	3,427	7,227	6,922
Costs and expenses:				
Cost of products sold	2,832	680	4,657	1,421
Research and development	1,563	10,104	6,927	13,022
Sales and marketing	2,153	2,600	6,031	4,582
General and administrative	2,796	3,533	6,010	6,588
Restructuring charges	1,204		1,204	
Total costs and expenses	10,548	16,917	24,829	25,613
Operating loss	(6,654)	(13,490)	(17,602)	(18,691)
Other income (expense):				
Interest income	71	564	289	1,154
Interest expense	(36)	(30)	(85)	(69)
Total other income	35	534	204	1,085
Net loss	\$ (6,619)	\$ (12,956)	\$ (17,398)	\$ (17,606)
Net loss per share	\$ (0.15)	\$ (0.30)	\$ (0.41)	\$ (0.41)
Basic and diluted weighted-average common shares outstanding	42,910,348	42,571,420	42,857,558	42,513,852

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

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
	<b>In thousands</b>	
Cash flows from operating activities:		
Net loss	\$ (17,398)	\$ (17,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	235	335
Amortization of premiums on short-term investments and other	79	4
(Gain) loss on sale of fixed assets	(106)	18
Impairment charge on fixed asset	393	
Preferred stock received in license agreement, net		(400)
Stock-based compensation expense	1,499	2,038
Changes in assets and liabilities:		
Accounts receivable	(247)	(137)
Amount due under collaboration agreements	31	619
Inventory	(2,161)	(337)
Prepaid expenses and other assets	(148)	(1,211)
Accounts payable	(972)	342
Accrued expenses	(1,829)	(776)
Accrued license fees	(1,875)	3,495
Deferred collaboration revenue and fees		(675)
Deferred product revenue		(1,178)
Deferred co-promotion fees	(684)	6,943
Net cash used in operating activities	(23,183)	(8,526)
Cash flows from investing activities:		
Proceeds from sale of investment	400	
Proceeds from sale of fixed assets	278	212
Purchases of fixed assets	(1)	
Net cash provided by investing activities	677	212
Cash flows from financing activities:		
Proceeds from exercise of stock options and other		295
Repayments of long-term debt and capital lease obligations	(370)	(556)
Net cash used in financing activities	(370)	(261)

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Net decrease in cash and cash equivalents	(22,876)	(8,575)
Cash and cash equivalents at beginning of period	33,828	48,388
Cash and cash equivalents at end of period	\$ 10,952	\$ 39,813
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	\$ 10	\$ 74

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

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**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 subsidiaries (collectively, 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 amended, as filed with the Securities and Exchange Commission (the SEC).

Operating results for the three and six-month periods ended June 30, 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, accrued and prepaid expenses, short-term investments, stock-based compensation and income taxes.

***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). 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. 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 exact exchange ratio per share of

Cornerstone's common stock will be based in part 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.

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The consummation of the Merger is subject to a number of closing conditions, including the approval of the Company'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 the Company's 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.

On July 22, 2008, the Company, in connection with its proposed merger, filed a registration statement on Form S-4 with the SEC.

***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 \$17.4 million in the six months ended June 30, 2008 and \$17.6 million in the six months ended June 30, 2007. As of June 30, 2008, the Company had an accumulated deficit of approximately \$209 million. For the year ended December 31, 2007 and the six months ended June 30, 2008, the Company recorded \$11.0 million and \$7.2 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 SetPoint Medical Corporation (formerly known as Innovative Metabolics, Inc.) ( SetPoint ), payments from Dey, L.P., a wholly owned subsidiary of Mylan, Inc. ( DEY ), under its zileuton co-promotion agreement and revenue from sales of ZYFLO CR and ZYFLO.

For the six months ended June 30, 2008, the Company's net cash used in operating activities was \$23.2 million. Based on its current operating plans, the Company believes that its available cash and cash equivalents and anticipated cash received from product sales will not be sufficient to fund the Company's operations for the next twelve months. 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.

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 or made to other collaborators based on other applicable generally accepted accounting principles in the United States of America (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 the 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.

In May 2008, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP (the GAAP hierarchy). SFAS 162 makes the GAAP hierarchy explicitly and directly applicable to preparers of financial statements, a step that recognizes preparers' responsibilities for selecting the accounting principles for their financial statements, and sets the stage for making the framework of the FASB Concept Statements fully authoritative. The effective date for SFAS 162 is 60 days following the SEC's approval of the Public Company Accounting Oversight Board's related amendments to remove the GAAP hierarchy from auditing standards, where it has resided for some time. The Company does not expect the adoption of SFAS 162 to have a material impact on its financial statements and results of operations.

In April 2008, the FASB issued FASB Staff Position Financial Accounting Standard 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). In developing assumptions about renewal or

extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for the entity-specific factors in paragraph 11 of SFAS 142. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company does not expect the adoption of FSP FAS 142-3 to have a material impact on its financial statements and results of operations.

In December 2007, the FASB issued 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 it elected not 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.



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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(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 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 June 30, 2008 and 2007, the Company's allowances for ZYFLO CR and ZYFLO product returns were \$119,000 and \$153,000, 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 first quarter of 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 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.

*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,

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 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 SetPoint, the Company licensed to SetPoint patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. Under the agreement with SetPoint, the Company received an initial license fee of \$500,000 in cash and SetPoint junior preferred stock valued at \$500,000 in connection with SetPoint'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 SetPoint 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 SetPoint and included the payments of \$100,000 in cash and SetPoint 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, SetPoint 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 U.S. Food and Drug Administration (the FDA) or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by SetPoint and its affiliates.

On March 14, 2008, the Company sold the 400,000 shares of junior preferred stock issued to it by SetPoint in May 2007 in connection with SetPoint'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 SetPoint'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 SetPoint prior to February 1, 2009 at a price per share greater than the price they paid the Company.

At June 30, 2008, the Company's accounts receivable balance of \$1.5 million was net of allowances of \$34,000. 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 June 30, 2008, the Company held \$284,000 in an auction rate security with a AAA credit rating upon purchase. The Company has been informed that there is insufficient demand at auction for this 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 \$284,000 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.

Table of Contents**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 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 June 30, 2008 (in thousands):

	<b>Fair Value Measurements at June 30, 2008</b>			
	<b>Total Carrying Value at June 30, 2008</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Using Significant Other</b>	<b>Significant</b>
<b>Observable Inputs (Level 2)</b>			<b>Unobservable Inputs (Level 3)</b>	
Available for sale securities:				
U.S. government-backed securities	\$ 1,048	\$	\$ 1,048	\$
Auction rate security	284			284
Total assets measured at fair value	\$ 1,332	\$	\$ 1,048	\$ 284

The following table provides a rollforward of the Company's assets and liabilities whose fair value measurements were Level 3 (in thousands):

	<b>Auction Rate Security (Level 3)</b>
Total carrying value at January 1, 2008	\$ 300
Unrealized loss	(13)
Total carrying value at March 31, 2008	\$ 287
Unrealized loss	(3)

Total carrying value at June 30, 2008	\$	284
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U.S. government-backed securities 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 as of June 30, 2008 had original maturities of less than 90 days and therefore investments were classified as cash equivalents.

The Company's auction rate security instrument is classified as an available-for-sale security and recorded at fair value. However, due to recent events in credit markets, auctions for this security failed during the first and second quarters 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 June 30, 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 the fair value of the Company's auction rate security, which the Company attributes to liquidity issues rather than credit issues, the Company has recorded an unrealized loss of \$16,000 to accumulated other comprehensive loss.

**Table of Contents****CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(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 ( Abbott ) and entered into an agreement with Jagotec AG, a subsidiary of SkyePharma PLC ( Jagotec ), to in-license the controlled-release technology relating to zileuton from Jagotec. 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 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's 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. The Company included the \$1.9 million that was due on the first anniversary in accounts payable at June 30, 2008 and paid the amount in July 2008. For the three and six months ended June 30, 2008, the Company recorded interest expense of \$36,000 and \$79,000, respectively, related to the accretion of the discount.

**(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 June 30, 2008, the Company held \$7.8 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 June 30, 2008, the Company had an inventory reserve of \$2.5 million. The inventory reserve relates to product that did not meet the Company's product release specifications for ZYFLO CR and to tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines.

Inventory consisted of the following at June 30, 2008 and December 31, 2007, respectively (in thousands):

	<b>June 30, 2008</b>	<b>December 31, 2007</b>
Raw material	\$ 6,172	\$ 2,587
Work in process	4,021	3,062
Finished goods	71	766
Total inventory	10,264	6,415
Less: reserve	(2,504)	(816)
Inventory, net	\$ 7,760	\$ 5,599

*Risk and uncertainties.* The Company currently purchases zileuton active pharmaceutical ingredient ( API ) for its commercial requirements for ZYFLO CR and ZYFLO from a single source. In addition, the Company currently contracts with single parties for the manufacture of tablet cores of ZYFLO CR and the coating and packaging of ZYFLO CR tablets and the manufacture of ZYFLO. 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

Table of Contents**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. In addition, as discussed in Note 9, the Company has agreed to purchase specified quantities of API in 2008 and 2009.

**(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 and six months ended June 30, 2008 and 2007, and comprehensive loss is the unrealized gain (loss) on investments for the period. Total comprehensive loss was \$6.6 million and \$13.0 million for the three months ended June 30, 2008 and 2007, respectively and \$17.4 million and \$17.6 million for the six months ended June 30, 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*.

Stock option activity for the six-month period ended June 30, 2008 was as follows:

		<b>2008</b>	
	<b>Number of</b>	<b>Weighted-Average</b>	
	<b>Shares</b>	<b>Exercise Price</b>	
		<b>per Share</b>	
Outstanding January 1	5,020,903	\$	4.20
Granted	12,000		0.90
Exercised			
Cancelled	(1,985,565)		4.06
Outstanding June 30	3,047,338	\$	4.28
Vested and Expected to Vest June 30	2,776,753	\$	4.34
Exercisable June 30	1,973,525	\$	4.77

The weighted-average remaining contractual term and the aggregate intrinsic value for options outstanding at June 30, 2008 were 6.3 years and zero, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options exercisable at June 30, 2008 were 5.3 years and zero, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options vested and expected to vest at June 30, 2008

were 6.2 years and zero, respectively. There were no options exercised during the six months ended June 30, 2008.

The total fair value of the shares vested and unexercised during the three and six months ended June 30, 2008 was \$90,000 and \$147,000, respectively. As of June 30, 2008, there was \$3.3 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 1.9 years.

The Company anticipates recording additional stock-based compensation expense of \$900,000 in the remaining two quarters of 2008, \$1.6 million in 2009 and \$742,000 thereafter relating to the amortization of unrecognized compensation expense as of June 30, 2008. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

**Table of Contents****CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Option valuation models require the input of highly subjective assumptions. The Company has computed the impact under the fair value method for options granted using the Black-Scholes option-pricing model for the six months ended June 30, 2008 and 2007. The Company did not grant options during the three months ended June 30, 2008. The Company increased its expected volatility assumption for the six months ended June 30, 2008 to 73% from 70% 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:

	<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
Risk free interest rate	2.8%	4.8%
Expected dividend yield	0%	0%
Expected forfeiture rate	10.6%	10.2%
Expected life	6.25 years	6.20 years
Expected volatility	73%	70%
Weighted-average fair value of options granted equal to fair value	\$ 0.60	\$ 1.52

**(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 10,638,645 and 12,835,478 as of June 30, 2008 and 2007, respectively. These anti-dilutive securities consist of outstanding stock options, warrants and unvested restricted common stock as of June 30, 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 \$26.0 million as of June 30, 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 June 30, 2008, the Company had \$93,000 and \$864,000 included in prepaid expenses and accrued expenses,

respectively, related to its research and development agreements. These research and development expenses are accounted for as such costs are incurred. In addition, as of June 30, 2008, the Company had \$1.9 million in license fees in accounts payable and \$1.8 million in accrued license fees representing the net present value of the Company's milestone obligations due on the first and second anniversary, respectively, of the FDA's approval of ZYFLO CR. In addition, during the quarter ended

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. At June 30, 2008, \$768,000 remains in accrued expenses related to these termination costs.

In addition, on August 20, 2007, the Company entered into an agreement with Jagotec 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 PLC 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.

In February 2005, the Company 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 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, in the amount of \$2.0 million and \$2.0 million, respectively, with approximately \$1.3 million in 2009 subject to the right of cancellation. 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 June 30, 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, 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 \$6.7 million as of June 30, 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

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 deferred the \$12 million in aggregate payments received 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. For the three and six months ended June 30, 2008, approximately \$483,000 and \$684,000, respectively, were 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 ( 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. On July 2, 2008, the Company provided notice to DEY that it had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

**(11) Restructuring Plans and Impairment of Asset**

In the second quarter of 2008, the Company recorded restructuring charges of \$1.2 million in its efforts to reduce its operating expenses in order to better align its operating cost structure with the current economic environment, the current business strategy and to improve operating margins. The business units affected included sales and marketing and research and development.

In connection with these restructuring charges, the Company terminated 21 employees, or approximately 28% of the Company's workforce in May and June 2008, resulting in severance benefits of \$1.2 million, which were accrued during the second quarter. As a result of terminating these employees, the Company recorded automobile lease termination fees, outplacement service fees and an impairment charge for software and lab equipment for which the future use was currently uncertain totaling \$41,000. At June 30, 2008, the Company had \$928,000 remaining in accrued expenses related to the restructuring, which it expects to pay in full by the end of the fourth quarter. The Company may 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.

During the second quarter of 2008, the Company concluded that the estimated undiscounted cash flows associated with a fixed asset would not recover the carrying amount. Accordingly, the Company adjusted this asset to its current fair market value estimated to be \$100,000. The Company recorded a \$393,000 impairment charge for the asset and included the impairment charge in research and development expenses.

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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 Critical Therapeutics' financial statements and accompanying notes included in this quarterly report and Critical Therapeutics' audited financial statements included in Critical Therapeutics' 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. Critical Therapeutics' 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 is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory diseases, as well as other inflammatory diseases linked to the body's inflammatory response. Critical Therapeutics' two marketed products are ZYFLO CR, an extended-release formulation of zileuton, which the U.S. Food and Drug Administration, or FDA, approved in May 2007, and ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. Critical Therapeutics licensed from Abbott Laboratories, or Abbott, exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions.

Critical Therapeutics began selling ZYFLO CR in the United States in September 2007 and began selling ZYFLO in the United States in October 2005. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. In March 2008, Critical Therapeutics began to experience supply chain issues with batches of ZYFLO CR that could not be released into the commercial supply chain because they did not meet its product release specifications. Critical Therapeutics expects to resume distribution of ZYFLO in September 2008 to help manage any potential impact to patients of supply chain issues for ZYFLO CR.

In addition, Critical Therapeutics is developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In June 2008, Critical Therapeutics announced results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

Critical Therapeutics is also developing other product candidates directed towards reducing the potent inflammatory response that it believes 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. Critical Therapeutics' 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.

Critical Therapeutics has been conducting preclinical work in its alpha-7 program. Critical Therapeutics believes the successful development of a small molecule product candidate targeting the 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, Critical Therapeutics selected lead and backup molecules for evaluation in good laboratory practices, or GLP, toxicology studies. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an investigational new drug application, or IND, could be filed in 2009. In addition, Critical Therapeutics plans to seek collaborations with other pharmaceutical companies for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist within this program prior to the initiation of human clinical trials. Critical Therapeutics licensed to SetPoint patent rights and know-how relating to the mechanical

and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Critical Therapeutics has been collaborating with MedImmune on the development of monoclonal antibodies directed toward a cytokine called high mobility group box protein 1, or HMGB1, which Critical Therapeutics believes may be an important target for the development of products to treat diseases mediated by the body's

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inflammatory response. In addition, Critical Therapeutics has been collaborating with Beckman Coulter, Inc., or Beckman Coulter, on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

Until the closing of the proposed merger with Cornerstone, Critical Therapeutics expects to continue its commercial and development activities in accordance with its existing business strategy with an increased focus on managing its cash position. Unless otherwise stated or the context otherwise requires, Critical Therapeutics has prepared this quarterly report on Form 10-Q as if it were going to remain a standalone, independent company, and has not reflected in this quarterly report any changes to Critical Therapeutics' business that may occur if it consummates the proposed merger with Cornerstone. For instance, the combined company's clinical and preclinical pipeline will include a number of product candidates. The combined company is expected to implement a strategic review of its product development pipeline. Following the strategic review, the combined company may seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions. If Critical Therapeutics consummates the merger with Cornerstone, many of the forward-looking statements in this quarterly report would no longer be applicable.

On April 21, 2008, Critical Therapeutics received notification that for the prior 30 consecutive business days the bid price of its 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).

On May 16, 2008, Critical Therapeutics received notification that its stockholders' equity of \$7,126,000, as reported in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 that it filed with the Securities and Exchange Commission, or SEC, does not comply with the minimum stockholders' equity requirement of \$10,000,000 for continued listing on The NASDAQ Global Market pursuant to NASDAQ Marketplace Rule 4450(a)(3).

On June 13, 2008, NASDAQ approved the transfer of the listing of Critical Therapeutics' common stock from The NASDAQ Global Market to The NASDAQ Capital Market effective at the opening of business on June 17, 2008. A condition to approval of the transfer of the listing was Critical Therapeutics' satisfaction of The NASDAQ Capital Market's continued listing requirements, other than the \$1.00 per share minimum bid price requirement. Separately, if Critical Therapeutics meets all of The NASDAQ Capital Market's initial listing requirements, other than the minimum bid price requirement, on October 20, 2008, which is the date that is 180 days following the date Critical Therapeutics received notification from NASDAQ that it failed to comply with the minimum bid price requirement, Critical Therapeutics will have the remainder of an additional 180 calendar day grace period while listed on The NASDAQ Capital Market to regain compliance with NASDAQ's minimum bid price requirement. There can be no assurance that on October 20, 2008 Critical Therapeutics will comply with The NASDAQ Capital Market's initial listing requirements, including The NASDAQ Capital Market's minimum stockholders' equity requirement. Critical Therapeutics' stockholders' equity of \$1.2 million, as reported in this quarterly report on Form 10-Q, does not comply with the minimum stockholders' equity requirement of \$2.5 million for continued listing on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 4310(c)(3). As a result, Critical Therapeutics anticipates that NASDAQ will notify Critical Therapeutics of this deficiency and request that Critical Therapeutics provide NASDAQ with a plan of compliance with respect to the continued listing requirements.

On July 22, 2008, Critical Therapeutics filed its registration statement on Form S-4 in connection with its proposed merger with Cornerstone.

## **Financial Operations Overview**

On March 13, 2007, Critical Therapeutics entered into an agreement with Dey, L.P., a wholly owned subsidiary of Mylan, Inc., or DEY, under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion agreement, DEY paid Critical Therapeutics 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

new drug application, or NDA, for ZYFLO CR and a milestone payment of \$5.0 million following Critical Therapeutics' commercial launch of ZYFLO CR. Under the co-promotion agreement, Critical Therapeutics records all quarterly net sales of ZYFLO CR and ZYFLO, after

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third-party royalties, up to \$1.95 million and pays DEY a commission on quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of \$1.95 million.

At June 30, 2008, Critical Therapeutics had \$7.8 million in inventory. Critical Therapeutics expects that its inventory levels in the second half of 2008 will increase as a result of its API purchase commitments in the fourth quarter. Significant differences between Critical Therapeutics' current estimates and judgments and future estimated demand for its 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 its financial condition and results of operations during the period in which Critical Therapeutics recognizes charges for excess inventory. For example, in the quarter ended June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that were not released into Critical Therapeutics' commercial supply chain, consisting of one batch of ZYFLO CR that did not meet Critical Therapeutics' product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that did not complete manufacturing within the NDA-specified manufacturing timelines. In addition, in the quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded inventory reserves with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics' commercial supply chain because they did not meet Critical Therapeutics' product release specifications. These charges were included in cost of products sold in the statements of operations for these periods. In conjunction with Critical Therapeutics' three third-party manufacturers for zileuton active pharmaceutical ingredient, or API, tablet cores and coating and release, Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. Critical Therapeutics has incurred and expects to continue to incur significant costs in connection with its investigation. To date, the investigation has not identified a clear source of the issue. In early August 2008, Critical Therapeutics released and made available for shipment to wholesale distributors one batch of finished ZYFLO CR tablets that met its product release specifications. As of August 8, 2008, Critical Therapeutics has an additional four batches of finished ZYFLO CR tablets that it expects to be available for shipment to its wholesale distributors in August 2008. Critical Therapeutics is currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR, if any, that may be released for commercial supply. If not corrected, the ongoing supply chain difficulties could prevent Critical Therapeutics from supplying any further product to its wholesale distributors. Based on its current level of sales, the release of the one batch of ZYFLO CR in early August 2008 and assuming the release and availability for shipment to wholesale distributors of the four additional batches of ZYFLO CR in August 2008, Critical Therapeutics estimates that wholesale distributors and retail pharmacies will have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the fourth quarter of 2008.

Currently, Critical Therapeutics purchases its API for commercial requirements for ZYFLO CR and ZYFLO from a single source. In addition, Critical Therapeutics currently contracts with single third parties for the manufacture of uncoated ZYFLO CR tablets, for the entire manufacturing of ZYFLO tablets and the coating and packaging of ZYFLO CR 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 Critical Therapeutics' commercial products could have a material adverse effect on its business, financial position and results of operations.

As it moves forward with its proposed merger with Cornerstone, Critical Therapeutics is continuing to focus on conserving cash resources and has begun to take steps to reduce spending on development programs and personnel. On May 8, 2008, as part of this effort, Critical Therapeutics announced that it had eliminated six positions, or approximately 8% of its workforce. The headcount reductions primarily affect Critical Therapeutics' research and development group. In addition, on June 12, 2008, Critical Therapeutics announced that it eliminated an additional 15 positions, or approximately 23% of its remaining workforce during the month of June. The June 2008 headcount reductions primarily affect employees performing sales and development functions. Critical Therapeutics may consider further reductions in 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 Critical Therapeutics

business needs and financial resources.

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In connection with the implementation of the May 8, 2008 and June 12, 2008 reductions in its workforce, Critical Therapeutics recorded a charge of approximately \$1.2 million of severance benefits in the second quarter of 2008.

On June 25, 2007, Critical Therapeutics entered into a definitive agreement with DEY to jointly promote PERFOROMIST<sup>(tm)</sup> (formoterol fumarate) Inhalation Solution, or PERFOROMIST, DEY's product for the treatment of chronic obstructive pulmonary disease, or COPD. Under the agreement, DEY granted Critical Therapeutics a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. In October 2007, Critical Therapeutics announced that it had commercially launched PERFOROMIST with DEY. Under the agreement, DEY pays Critical Therapeutics a commission on retail sales of PERFOROMIST above a specified baseline. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

In July 2003, Critical Therapeutics 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 Critical Therapeutics initial fees of \$10.0 million in late 2003 and \$2.5 million in early 2004. In addition, MedImmune agreed to pay Critical Therapeutics \$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 Critical Therapeutics for the HMGB1 program.

In January 2007, Critical Therapeutics entered into an exclusive license agreement with SetPoint Medical Corporation (formerly known as Innovative Metabolics, Inc.), or SetPoint, under which Critical Therapeutics licensed to SetPoint patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. In May 2007, under the agreement with SetPoint, Critical Therapeutics received an initial license fee of \$500,000 in cash and SetPoint junior preferred stock valued at \$500,000 in connection with SetPoint's first financing. However, under Critical Therapeutics' license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute), or The Feinstein Institute, Critical Therapeutics was obligated to pay The Feinstein Institute \$100,000 of this cash payment and SetPoint junior preferred stock valued at \$100,000. Critical Therapeutics included in revenue under collaboration and license agreements in 2007 the \$1.0 million total license fee that it received from SetPoint and included in research and development expenses the payments of \$100,000 in cash and SetPoint junior preferred stock valued at \$100,000 that it made to The Feinstein Institute. These amounts were recorded in the second quarter of 2007. Under the license agreement, SetPoint also has agreed to pay Critical Therapeutics \$1.0 million, excluding a \$200,000 payment that Critical Therapeutics 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 SetPoint and its affiliates. In March 2008, Critical Therapeutics sold the remaining 400,000 shares of junior preferred stock to two investors, which had participated in SetPoint'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 SetPoint prior to February 1, 2009 at a price per share greater than they paid Critical Therapeutics.

## ***Going Concern Assumption***

Since its inception, Critical Therapeutics has incurred significant losses each year. Critical Therapeutics 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. Critical Therapeutics had net losses of \$17.4 million in the six months ended June 30, 2008 and \$17.6 million in the six months ended June 30, 2007. As of June 30, 2008, Critical Therapeutics had an accumulated deficit of approximately \$209 million. Critical Therapeutics expects to incur significant losses for the foreseeable future and may never achieve profitability. Although the size and timing of its future operating losses are subject to significant uncertainty, Critical Therapeutics expects its operating losses to continue over the next several years as its funds its

development programs, market and sell ZYFLO CR and prepare for the potential commercial launch of its product candidates. Based on its current operating plan,

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Critical Therapeutics believes that its available cash 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. Since its inception, Critical Therapeutics has raised proceeds to fund its operations through: public offerings of common stock, private placements of equity securities, revenues from sales of ZYFLO and ZYFLO CR, payments from DEY under its zileuton co-promotion agreement, debt financings, the receipt of interest income, payments from its collaborators, MedImmune and Beckman Coulter and license fees from SetPoint.

### ***Revenues***

From its inception on July 14, 2000 through the third quarter of 2005, Critical Therapeutics derived all of its revenues from license fees, research and development payments and milestone payments that it has received from its collaboration and license agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, Critical Therapeutics began selling, and recognizing revenue from, ZYFLO. In September 2007, Critical Therapeutics began selling, and recognizing revenue, from ZYFLO CR. In 2007, Critical Therapeutics also recorded license revenue from its license agreement with SetPoint. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. Critical Therapeutics expects to resume distribution of ZYFLO in September 2008.

### ***Cost of Products Sold***

Cost of products sold consists of manufacturing, distribution and other costs related to Critical Therapeutics 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 Critical Therapeutics 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 Critical Therapeutics 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 Critical Therapeutics approved NDA for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses have included the cost of Critical Therapeutics medical affairs and medical information functions, which educated physicians on the scientific aspects of Critical Therapeutics commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, Critical Therapeutics records manufacturing expenses associated with a product as cost of products sold rather than as research and development expenses. Critical Therapeutics expenses research and development costs and patent related costs as they are incurred. Because of Critical Therapeutics ability to utilize resources across several projects, many of its research and development costs are not tied to any particular project and are allocated among multiple projects. Critical Therapeutics records direct costs on a project-by-project basis. Critical Therapeutics records 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 Critical Therapeutics HMGB1 and alpha-7 programs due to the costs associated with conducting late stage clinical trials and large-scale manufacturing.

Critical Therapeutics expects that research and development expenses relating to its 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 its decisions based on these outcomes. Critical Therapeutics also expects manufacturing expenses for some programs included in research and development expenses to increase if it scales up production of

zileuton injection for later stages of clinical development. Critical Therapeutics 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, Critical Therapeutics

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discontinued the trial because patient enrollment was significantly slower than it had anticipated. In the first quarter of 2008, Critical Therapeutics 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. At June 30, 2008, \$768,000 remains in accrued expenses related to these termination costs.

As a result of the FDA's approval of the NDA for ZYFLO CR in May 2007, Critical Therapeutics 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 anniversaries of the FDA's approval. Critical Therapeutics included these milestone payments and accruals in research and development expenses in its 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. At June 30, 2008, \$1.9 million related to milestone obligations due on the first anniversary of the FDA's approval was included in Critical Therapeutics' accounts payable.

### ***Sales and Marketing Expenses***

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, managed care and sales operations functions, as well as other costs related to ZYFLO CR and ZYFLO. Critical Therapeutics also incurred marketing and other costs related to its launch of ZYFLO CR in September 2007. Other costs included in sales and marketing expenses include sales and marketing costs related to Critical Therapeutics co-promotion and marketing agreement, cost of product samples of ZYFLO CR and ZYFLO, promotional materials, market research and sales meetings. Critical Therapeutics expects to continue to incur sales and marketing costs associated with enhancing Critical Therapeutics' sales and marketing functions and maintaining Critical Therapeutics' increased sales force to support ZYFLO CR. In addition, under its co-promotion agreement with DEY, Critical Therapeutics has deferred the \$12.0 million in aggregate upfront and milestone payments that it received in 2007. Critical Therapeutics is 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. Critical Therapeutics records all ZYFLO CR and ZYFLO 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 in sales and marketing expenses.

### ***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 Critical Therapeutics' financial condition and results of operations are based on Critical Therapeutics' 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 Critical Therapeutics to make estimates and judgments that affect its 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, Critical Therapeutics' reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

Critical Therapeutics regards an accounting estimate or assumption underlying Critical Therapeutics' 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

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

Critical Therapeutics' significant accounting policies are more fully described in the notes to its consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2007. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. Critical Therapeutics has discussed its accounting policies with the audit committee of its board of directors, and believes that its estimates relating to revenue recognition, product returns, inventory, accrued and prepaid expenses, short-term investments, stock-based compensation and income taxes described below fit the definition of critical accounting estimates.

***Revenue Recognition***

Critical Therapeutics sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return purchased product. Critical Therapeutics commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. Critical Therapeutics 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. Critical Therapeutics 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.

Prior to the first quarter of 2007, Critical Therapeutics deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as it 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, based on its product return experience since it launched ZYFLO in October 2005, Critical Therapeutics 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, Critical Therapeutics 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 Critical Therapeutics' results for the first quarter of 2007. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. As a result, Critical Therapeutics recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns from these third parties based on its product returns experience with ZYFLO and other factors.

Under its collaboration agreements with MedImmune and Beckman Coulter, Critical Therapeutics 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 Critical Therapeutics' statements of operations when earned. Critical Therapeutics must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by its collaborators. Critical Therapeutics 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 development of the product. Because MedImmune and Beckman Coulter can each cancel its agreement with it, Critical Therapeutics does not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of Critical Therapeutics' operations because, in each case, the adjustment is limited to the cash received.

Under its license agreement with SetPoint, Critical Therapeutics included in revenue from collaboration and license agreements in the second quarter of 2007 a \$1.0 million initial license fee that it received from SetPoint and included in research and development expenses a related \$100,000 cash payment and SetPoint preferred stock payment valued

at \$100,000 that it made to The Feinstein Institute.

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### ***Product Returns***

Consistent with industry practice, Critical Therapeutics offers 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 launch in October 2005, Critical Therapeutics began shipping ZYFLO with an expiration date of 12 months. Since its launch of ZYFLO, Critical Therapeutics has extended ZYFLO's expiration date from 12 months to 24 months. In September 2007, Critical Therapeutics launched ZYFLO CR, which currently has an expiration date of 18 months. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. Critical Therapeutics may adjust its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include Critical Therapeutics' estimate of inventory levels of its 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. Critical Therapeutics evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly. As a result of this ongoing evaluation, Critical Therapeutics' product return reserve for ZYFLO CR was \$119,000 as of June 30, 2008. Critical Therapeutics expects to resume supply of ZYFLO in September 2008. At that time, Critical Therapeutics will need to evaluate its estimate of product returns for the reintroduction of ZYFLO to the market.

### ***Inventory***

Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Critical Therapeutics' estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of Critical Therapeutics' inventories could vary significantly from its estimates and could have a material effect on Critical Therapeutics' financial condition and results of operations in any reporting period. Critical Therapeutics determines the estimated useful life of its inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of June 30, 2008, inventory consists of API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. On a quarterly basis, Critical Therapeutics analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of Critical Therapeutics' expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At June 30, 2008, Critical Therapeutics had an inventory reserve of \$2.5 million. The inventory reserve includes \$571,000 recorded in the fourth quarter of 2007, \$622,000 recorded in the first quarter of 2008 and \$160,000 in the second quarter of 2008 relating to nine batches that did not meet Critical Therapeutics' product release specifications for ZYFLO CR and \$1.1 million in the second quarter of 2008 relating to seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. As of June 30, 2008, Critical Therapeutics had \$7.8 million in inventory, net of the inventory reserve. Critical Therapeutics expects its inventory levels to increase in the second half of 2008 as a result of its API purchase commitments in the fourth quarter of 2008.

### ***Accrued Expenses***

As part of the process of preparing Critical Therapeutics' consolidated financial statements, Critical Therapeutics is required to estimate certain expenses. This process involves identifying services that have been performed on Critical Therapeutics' behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in Critical Therapeutics' consolidated financial statements. Examples of estimated expenses for which Critical Therapeutics accrues 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, Critical Therapeutics estimates are based on its estimated mix of sales to various third-party payors, which are either contractually or statutorily entitled to certain discounts off Critical

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Therapeutics' listed price of ZYFLO and ZYFLO CR. In the event that Critical Therapeutics' sales mix to certain third-party payors is different from its estimates, Critical Therapeutics may be required to pay higher or lower total rebates than it has estimated. In connection with service fees, Critical Therapeutics' estimates are most affected by its understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of Critical Therapeutics' service providers invoice it monthly in arrears for services performed; however, certain service providers invoice it based upon milestones in its agreements with them. In the event that it does not identify certain costs that it has begun to incur, or, under or over-estimates the level of services performed or the costs of such services, Critical Therapeutics' 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 subject to judgment. Critical Therapeutics makes these judgments based upon the facts and circumstances known to it 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. Critical Therapeutics records any unrealized gain (loss) during the year as an adjustment to stockholders' equity unless it determines that the unrealized gain (loss) is not temporary. Critical Therapeutics adjusts the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because Critical Therapeutics has determined that the unrealized gain (loss) on its investments has been temporary, it has not recorded any impairment losses since inception.

It is Critical Therapeutics' intent to hold its investments until such time as it intends to use them to meet the ongoing liquidity needs of its operations. However, if the circumstances regarding an investment, such as a change in an investment's external credit rating, or its liquidity needs were to change, Critical Therapeutics would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses. At June 30, 2008, Critical Therapeutics held \$284,000 in an auction rate security. In the first and second quarters of 2008, Critical Therapeutics was informed that there was insufficient demand at auction for this security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Critical Therapeutics has classified its investment in an auction rate security as a long-term investment and has included the amount in other assets on its balance sheet.

## ***Stock-Based Compensation***

Critical Therapeutics applies 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 it 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.

Critical Therapeutics accounts 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). Critical Therapeutics uses 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 Critical Therapeutics under SFAS 123(R) and 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 Critical Therapeutics estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or

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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, Critical Therapeutics uses 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, Critical Therapeutics estimates the fair value of the equity instruments based upon the consideration of factors that it deems to be relevant at the time using cost, market or income approaches to such valuations.

## ***Income Taxes***

As part of the process of preparing its consolidated financial statements, Critical Therapeutics is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves estimating Critical Therapeutics' 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. At December 31, 2007, Critical Therapeutics had federal tax net operating loss carryforwards of approximately \$163 million, which expire beginning in 2021 and had state tax net operating loss carryforwards of approximately \$154 million which expire beginning in 2008. Critical Therapeutics also has research and experimentation credit carryforwards of approximately \$1.9 million as of December 31, 2007, which expire beginning in 2021. Critical Therapeutics has recorded a full valuation allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that Critical Therapeutics determines in the future that it will be able to realize all or a portion of a net deferred tax benefit, an adjustment to the 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 therein.

Critical Therapeutics did not recognize any accrued interest and penalties related to unrecognized tax benefits, as no amounts would be due as a result of its net tax loss carryforward. Critical Therapeutics' 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 Critical Therapeutics is subject is the Commonwealth of Massachusetts.

## **Results of Operations**

### ***Three Months Ended June 30, 2008 and 2007***

#### **Revenues**

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of \$3.9 million in the three months ended June 30, 2008, compared to \$2.3 million from product sales of ZYFLO in the three months ended June 30, 2007. The increase in product revenue is primarily attributable to an 83% increase in prescription volume over the corresponding period in 2007, an 11% increase in the wholesale acquisition price of products sold over the corresponding period in 2007 and a \$144,000 reduction in Critical Therapeutics' product return expense over the corresponding period in 2007.

*Revenue under Collaboration and License Agreements.* Critical Therapeutics did not recognize any collaboration revenue in the three months ended June 30, 2008 compared to \$1.1 million it recognized in collaboration revenue in the three months ended June 30, 2007. License revenue for the three months ended June 30, 2007 was primarily due to the recognition of \$1.0 million in license revenue related to Critical Therapeutics' license agreement with SetPoint. At

June 30, 2008, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of its agreement with MedImmune. Critical Therapeutics' revenue recognized from existing collaborations for the remainder of 2008 is likely to decline substantially compared to corresponding periods in 2007 because Critical Therapeutics has now recognized all of the revenue that it previously deferred. Going forward, Critical Therapeutics' revenue from collaboration

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agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under its existing agreements, or will be dependent upon entering into new collaboration agreements.

**Costs and Expenses**

*Cost of Products Sold.* Cost of products sold in the three months ended June 30, 2008 was \$2.8 million, compared to \$680,000 in the three months ended June 30, 2007, an increase of \$2.2 million, or 316%. Gross margin was 27% for the three months ended June 30, 2008 and 70% for the three months ended June 30, 2007. Cost of products sold in the three months ended June 30, 2008 consisted primarily of the expenses associated with manufacturing ZYFLO CR and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec AG, a subsidiary of SkyePharma, PLC, or Jagotec, related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. Cost of products sold in the three months ended June 30, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO.

Critical Therapeutics recorded inventory reserves of \$1.3 million for the three months ended June 30, 2008. The reserve in the three months ended June 30, 2008 resulted from one batch of ZYFLO CR that did not meet Critical Therapeutics product release specifications and seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. Critical Therapeutics did not record any inventory reserves during the three months ended June 30, 2007.

As a result of the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics gross margins, excluding write-offs, will likely decrease further 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 Jagotec for utilization of its controlled-release technology. This likely decrease could be offset, in part, by an increase in Critical Therapeutics wholesale acquisition price of ZYFLO CR and Critical Therapeutics ability to spread some of its fixed costs associated with managing its supply chain over a larger revenue base in 2008.

*Research and Development Expenses.* Research and development expenses in the three months ended June 30, 2008 were \$1.6 million, compared to \$10.1 million in the three months ended June 30, 2007, a decrease of approximately \$8.5 million, or 85%. This decrease was primarily due to lower expenses associated with Critical Therapeutics ZYFLO CR milestone fees paid and accrued for, its Phase IV clinical trial for ZYFLO CR and its alpha-7 and HMGB1 preclinical programs. These lower expenses were offset, in part, by an increase in expenses related to Critical Therapeutics zileuton injection Phase II clinical trial costs and an impairment loss on a fixed asset used as part of Critical Therapeutics second supplier program for ZYFLO CR.

The following table summarizes the primary components of Critical Therapeutics research and development expenses for the three months ended June 30, 2008 and 2007:

	<b>Three Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Zileuton (ZYFLO and ZYFLO CR)	\$ 285	\$ 8,537
Zileuton injection	395	159
CTI-01		(96)
Alpha-7	453	1,014

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HMGB1		91
General research and development expenses	179	100
Stock-based compensation expense	251	299
Total research and development expenses	\$ 1,563	\$ 10,104

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The following summarizes the expenses associated with Critical Therapeutics' primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During the three months ended June 30, 2008, Critical Therapeutics incurred \$285,000 in expenses related to its orally dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to \$8.5 million during the three months ended June 30, 2007, a 97% decrease. This decrease was primarily due to the following:

\$3.1 million in milestone fees paid to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007;

\$3.5 million in accrued milestone payments to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007, which are due on the first and second anniversaries of the FDA's approval;

\$630,000 reduction in salaries and other personnel related costs as a result of Critical Therapeutics' December 2006 and May 2007 restructurings and a reduction in associated facilities and overhead costs;

\$896,000 decrease in clinical and manufacturing costs related to Critical Therapeutics' Phase IV clinical trial for ZYFLO CR; and

\$382,000 decrease in manufacturing costs related to Critical Therapeutics' R(+) isomer program for zileuton.

The decreases in the costs described above were partially offset by a \$393,000 asset impairment charge related to Critical Therapeutics' second supplier program for ZYFLO CR. Critical Therapeutics does not expect to continue to incur substantial research and development expenses for the remainder of 2008 in support of ZYFLO CR.

*Zileuton Injection.* During the three months ended June 30, 2008, Critical Therapeutics incurred \$395,000 in expenses related to its zileuton injection program, compared to \$159,000 during the three months ended June 30, 2007, an increase of \$236,000, or 148%. This increase was primarily due to costs related to Critical Therapeutics' Phase II clinical trial for zileuton injection, which began in October 2007. As Critical Therapeutics has completed the analysis of the data and reported the results of the Phase II clinical trial, it does not expect to incur additional costs associated with the development of zileuton injection during the remainder of 2008. Critical Therapeutics currently expects to seek a collaborator to develop and commercialize its zileuton injection product candidate.

*Alpha-7.* During the three months ended June 30, 2008, Critical Therapeutics incurred \$453,000 in expenses related to its alpha-7 program, compared to \$1.0 million during the three months ended June 30, 2007, a decrease of \$561,000, or 55%. 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. Critical Therapeutics anticipates that the research and development expenses for its alpha-7 program will not grow substantially for the remainder of 2008, as it expects increased costs related to preclinical studies conducted by third parties to advance the lead molecule to be offset by a reduced number of employees working on this program. Critical Therapeutics anticipates that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. Critical Therapeutics currently expects to seek a collaborator for its alpha-7 program to develop and commercialize possible product candidates. However, because this project is at a very early stage of development, 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 Critical Therapeutics chooses to develop, the clinical indications

developed, the development strategy adopted, and the terms of a collaboration, if it is able to enter into one. As a result, Critical Therapeutics is unable to estimate the costs or the timing of advancing a small molecule from its alpha-7 program through clinical development.

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*HMGB1.* During the three months ended June 30, 2008, Critical Therapeutics did not incur any expenses related to its HMGB1 program, compared to \$91,000 in expenses during the three months ended June 30, 2007. Critical Therapeutics has not conducted, and currently does not anticipate conducting, significant research and development activities relating to the HMGB1 program in 2008. In addition, a larger portion of the expenses of the 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 the HMGB1 program 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 Critical Therapeutics' research efforts is included in revenue under collaboration agreements.

Critical Therapeutics' general research and development expenses, which are not allocated to any specific program, were \$179,000 in the three months ended June 30, 2008, compared to \$100,000 in the three months ended June 30, 2007, an increase of \$79,000. Critical Therapeutics' general research and development expenses, which are incurred in support of all of its 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, Critical Therapeutics' stock-based compensation expense remained consistent in the three months ended June 30, 2008, compared to the three months ended June 30, 2007.

*Sales and Marketing.* Sales and marketing expenses for the three months ended June 30, 2008 were \$2.2 million, compared to \$2.6 million for the three months ended June 30, 2007. The \$447,000 decrease was primarily attributable to the following:

\$424,000 decrease related to amortization of Critical Therapeutics' deferred sales and marketing expense;

\$468,000 decrease related to promotional materials, advertising, other costs and expenses to be reimbursed by DEY associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement; and

\$230,000 decrease in sample costs.

These decreases were offset, in part, by an increase of approximately \$425,000 in co-promotion fees owed to DEY in accordance with the co-promotion agreement and an increase of \$358,000 in salary and other personnel-related costs as a result of Critical Therapeutics' increased headcount of employees performing sales and marketing functions.

The number of employees performing sales and marketing functions increased to 34 employees at June 30, 2008 from 26 employees at June 30, 2007. Critical Therapeutics expects that its sales and marketing costs will decrease during the remainder of 2008 as it focuses on conserving cash resources and realizes the anticipated benefits of its May and June 2008 restructuring plans.

*General and Administrative Expenses.* General and administrative expenses for the three months ended June 30, 2008 were \$2.8 million, compared to \$3.5 million for the three months ended June 30, 2007, a decrease of \$737,000, or 21%. This decrease was primarily attributable to a decrease of \$673,000 in advisory fees paid in connection with the signing of Critical Therapeutics' agreement with DEY and the subsequent milestone payments in 2007, a decrease of \$221,000 in stock-based compensation and a decrease of \$111,000 in salary and other personnel related costs offset, in part, by an increase of \$399,000 in legal fees primarily related to Critical Therapeutics' proposed merger with

Cornerstone. The number of employees performing general and administrative functions was 12 employees at June 30, 2008 and 14 employees at June 30, 2007. Critical Therapeutics expects that its general and administrative expenses will increase during the remainder of 2008 compared to corresponding periods in 2007 as it incurs additional professional fees relating to the proposed merger with Cornerstone.

*Restructuring Charges.* Restructuring charges totaled \$1.2 million in the second quarter of 2008 related to actions Critical Therapeutics took in May and June 2008. In May 2008, Critical Therapeutics announced that

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it had eliminated six positions, or approximately 8% of its workforce. The headcount reduction primarily affected the research and development group. In addition, in June 2008, Critical Therapeutics announced that it had eliminated an additional 15 positions, or approximately 23% of its remaining workforce. The June 2008 headcount reductions primarily affected employees performing sales and development functions. Critical Therapeutics 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 Critical Therapeutics' business needs and financial resources. The restructuring charges for 2008 were comprised of \$1.2 million in severance, benefit and other related payments, and \$41,000 in vehicle lease termination charges, asset impairment charges and outplacement services.

*Other Income.* Interest income for the three months ended June 30, 2008 was \$71,000, compared to \$564,000 for the three months ended June 30, 2007, a decrease of \$493,000, or 88%. This decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to \$36,000 for the three months ended June 30, 2008 and \$30,000 for the three months ended June 30, 2007. Interest expense primarily relates to the accretion of the discount on Critical Therapeutics' accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR.

***Six Months Ended June 30, 2008 and 2007*****Revenues**

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of \$7.2 million in the six months ended June 30, 2008, compared to revenue from product sales of ZYFLO of \$5.2 million in the six months ended June 30, 2007. The increase in product revenue is primarily attributable to a 66% increase in prescription volume over the corresponding period in 2007, an 11% increase in the wholesale acquisition price of products sold from the corresponding period in 2007 and a \$884,000 reduction in Critical Therapeutics' product return expense for ZYFLO CR and ZYFLO from the corresponding period in 2007. In addition, in the six months ended June 30, 2007, Critical Therapeutics 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 Critical Therapeutics' product return experience since the launch of ZYFLO in October 2005, Critical Therapeutics 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 Critical Therapeutics was now able to estimate product returns.

*Revenue under Collaboration and License Agreements.* Critical Therapeutics did not recognize any collaboration or license revenue in the six months ended June 30, 2008, compared to \$1.7 million recognized in collaboration and license revenue in the six months ended June 30, 2007. Collaboration revenue for the six months ended June 30, 2007 was primarily due to \$737,000 in collaboration revenue from Critical Therapeutics' collaboration with MedImmune and \$1.0 million in license revenue related to Critical Therapeutics' license agreement with SetPoint. Collaboration revenue of \$737,000 related to the collaboration with MedImmune and Beckman Coulter in the six months ended June 30, 2007 was primarily attributable to the recognition of \$400,000 of deferred revenue recognized under Critical Therapeutics' collaboration agreement with Beckman Coulter for a license fee paid to develop a diagnostic assay in connection with Critical Therapeutics' HMGB1 program. Collaboration revenue in the six months ended June 30, 2007 also included approximately \$337,000 related to a portion of the \$12.5 million of initial fees MedImmune paid to Critical Therapeutics that it 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 June 30, 2008, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of its agreement with MedImmune.

Costs and Expenses

*Cost of Products Sold.* Cost of products sold was \$4.7 million in the six months ended June 30, 2008, compared to \$1.4 million in the six months ended June 30, 2007, an increase of \$3.2 million, or 228%. Gross margin was 36% for the six months ended June 30, 2008 and 73% for the three months ended June 30, 2007.

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Cost of products sold in the six months ended June 30, 2008 consisted primarily of the expenses associated with manufacturing ZYFLO CR and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. Cost of products sold in the six months ended June 30, 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 Critical Therapeutics change in estimates relating to recognition of ZYFLO sales, Critical Therapeutics recorded an additional \$166,000 in cost of products sold in the six months ended June 30, 2007.

Critical Therapeutics recorded inventory reserves of \$1.9 million for the six months ended June 30, 2008. The write-offs in the six months ended June 30, 2008 resulted from five batches of ZYFLO CR that did not meet Critical Therapeutics product release specifications and seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that did not complete manufacturing within the NDA-specified manufacturing timelines. Critical Therapeutics did not record any inventory reserves during the six months ended June 30, 2007.

*Research and Development Expenses.* Research and development expenses in the six months ended June 30, 2008 were \$6.9 million, compared to \$13.0 million in the six months ended June 30, 2007, a decrease of approximately \$6.1 million, or 47%. This decrease was primarily due to lower expenses associated with Critical Therapeutics ZYFLO CR milestone fees paid and accrued for, its Phase IV clinical trial and its alpha-7 and HMGB1 preclinical programs. These lower expenses were offset, in part, by an increase in expenses related to Critical Therapeutics zileuton injection Phase II clinical trial costs.

The following table summarizes the primary components of Critical Therapeutics research and development expenses for the six months ended June 30, 2008 and 2007:

	<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Zileuton (ZYFLO and ZYFLO CR)	\$ 3,539	\$ 9,872
Zileuton injection	1,441	315
CTI-01		(83)
Alpha-7	1,046	1,847
HMGB1	3	210
General research and development expenses	408	322
Stock-based compensation expense	490	539
<b>Total research and development expenses</b>	<b>\$ 6,927</b>	<b>\$ 13,022</b>

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

*Zileuton (ZYFLO and ZYFLO CR).* During the six months ended June 30, 2008, Critical Therapeutics incurred \$3.5 million in expenses related to its orally dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to \$9.9 million during the six months ended June 30, 2007, a decrease of \$6.3 million, or 64%. This decrease was primarily due to the following:

\$3.1 million in milestone fees paid to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007;

\$3.5 million in accrued milestone payments to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007, which are due on the first and second anniversaries of the FDA's approval;

\$902,000 reduction in salaries and other personnel related costs as a result of Critical Therapeutics December 2006 and May 2007 restructurings and a reduction in associated facilities and overhead costs;

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\$426,000 decrease in manufacturing costs related to Critical Therapeutics R(+) isomer program for zileuton; and

\$102,000 reduction in clinical and manufacturing costs for ZYFLO.

The decreases in the costs described above were partially offset by a \$1.3 million increase in clinical and manufacturing costs for related to Critical Therapeutics Phase IV clinical trial for ZYFLO CR, which was discontinued in March 2008, and a \$393,000 asset impairment charge related to Critical Therapeutics second supplier program for ZYFLO CR.

*Zileuton Injection.* During the six months ended June 30, 2008, Critical Therapeutics incurred \$1.4 million in expenses related to its zileuton injection program, compared to \$315,000 during the six months ended June 30, 2007, an increase of \$1.1 million, or 357%. This increase was primarily due to clinical trial expenses related to the Phase II clinical trial, which concluded in the first half of 2008.

*CTI-01.* During the six months ended June 30, 2008, Critical Therapeutics did not incur any costs related to its CTI-01 program. During the six months ended June 30, 2007, Critical Therapeutics received a net credit of \$83,000 related to its CTI-01 program clinical trial costs. Effective February 2007, Critical Therapeutics terminated its license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals Inc. related to the development of CTI-01. Critical Therapeutics does not plan to pursue further development of CTI-01 or to incur additional costs related to CTI-01.

*Alpha-7.* During the six months ended June 30, 2008, Critical Therapeutics incurred \$1.0 million of expenses related to its alpha-7 program, compared to \$1.8 million during the six months ended June 30, 2007, a 43% 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.

*HMGB1.* During the six months ended June 30, 2008, Critical Therapeutics incurred \$3,000 of expenses related to its HMGB1 program, compared to \$210,000 during the six months ended June 30, 2007, a decrease of \$207,000, or 99%. Critical Therapeutics has not conducted, and currently does not anticipate conducting, significant research and development activities relating to its HMGB1 program in 2008.

Critical Therapeutics general research and development expenses, which were not allocated to any specific program, were \$408,000 in the six months ended June 30, 2008, compared to \$322,000 in the six months ended June 30, 2007, an increase of \$86,000, or 27%. Critical Therapeutics general research and development expenses, which were incurred in support of all of its 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, Critical Therapeutics stock-based compensation expense was \$490,000 in the six months ended June 30, 2008, compared to \$539,000 in the six months ended June 30, 2007, a decrease of \$49,000, or 9%. This decrease was primarily due to a continued reduction in stock-based compensation expense related to the reduction in the number of consultants and employees performing research and development functions.

*Sales and Marketing.* Sales and marketing expenses for the six months ended June 30, 2008 were \$6.0 million, compared to \$4.6 million for the six months ended June 30, 2007. The \$1.4 million increase was primarily attributable to the following:

\$990,000 increase in salary and other costs of employees performing sales and marketing functions;

\$1.5 million increase related to promotional materials, advertising and other costs associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement with DEY; and

\$626,000 increase in co-promotion fees owed to DEY.

These increases were partially offset by the following:

\$626,000 decrease related to amortization of Critical Therapeutics deferred sales and marketing expense;

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\$830,000 decrease related to expenses to be reimbursed by DEY associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement; and

\$257,000 decrease in sample costs.

The number of employees performing sales and marketing functions increased to 34 employees at June 30, 2008 from 26 employees at June 30, 2007.

*General and Administrative Expenses.* General and administrative expenses for the six months ended June 30, 2008 were \$6.0 million, compared to \$6.6 million for the six months ended June 30, 2007, a decrease of \$578,000, or 9%. This decrease was primarily due to a decrease of \$905,000 in advisory fees paid in connection with the signing of Critical Therapeutics' agreement with DEY in the first quarter of 2007 and a decrease of \$411,000 in stock-based compensation expense. These decreases were offset, in part, by an increase of \$724,000 in legal fees primarily related to Critical Therapeutics' proposed merger with Cornerstone. The number of employees performing general and administrative functions was 12 employees at June 30, 2008 and 14 employees at June 30, 2007.

*Restructuring Charges.* Restructuring charges totaled \$1.2 million in the second quarter of 2008 related to actions Critical Therapeutics took in May and June 2008. In May 2008, Critical Therapeutics announced that it had eliminated six positions, or approximately 8% of its workforce. The headcount reduction primarily affected the research and development group. In addition, in June 2008, Critical Therapeutics announced that it had eliminated an additional 15 positions, or approximately 23% of its remaining workforce. The June 2008 headcount reductions primarily affected employees performing sales and development functions. The restructuring charges for 2008 were comprised of \$1.2 million in severance, benefit and other related payments, and \$41,000 in vehicle lease termination charges, asset impairment charges and outplacement services.

*Other Income.* Interest income for the six months ended June 30, 2008 was \$289,000, compared to \$1.2 million for the six months ended June 30, 2007, a decrease of \$865,000, or 75%. This decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to \$85,000 for the six months ended June 30, 2008 and \$69,000 for the six months ended June 30, 2007. Interest expense primarily relates to the accretion of the discount on Critical Therapeutics' accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR and borrowings under Critical Therapeutics' loan with Silicon Valley Bank for capital expenditures.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since its inception on July 14, 2000, Critical Therapeutics has raised proceeds to fund its operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from its collaboration, license and co-promotion agreements, the exercise of stock options and revenues from sales of ZYFLO and ZYFLO CR. As of June 30, 2008, Critical Therapeutics had \$11.2 million in cash, cash equivalents and investments. Critical Therapeutics has invested its cash and cash equivalents primarily in highly liquid, interest-bearing, investment grade securities in accordance with its established corporate investment policy.

In July 2003, Critical Therapeutics 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 Critical Therapeutics initial fees of \$12.5 million and an additional \$5.4 million through June 30, 2008 for milestone payments

and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program. As of June 30, 2008, Critical Therapeutics had completed the research term of its agreement with MedImmune.

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Under Critical Therapeutics' collaboration with MedImmune, Critical Therapeutics 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 Critical Therapeutics is obligated to make to The Feinstein Institute on milestone payments it receives from MedImmune.

Under its co-promotion agreement with DEY, Critical Therapeutics 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 the commercial launch of ZYFLO CR.

### ***Cash Flow***

*Operating Activities.* Net cash used in operating activities was \$23.2 million for the six months ended June 30, 2008, compared to \$8.5 million for the six months ended June 30, 2007, an increase of \$14.7 million, or 172%. Net cash used in operations for the six months ended June 30, 2008 consisted of a net loss of \$17.4 million, depreciation and amortization expense, the amortization of premiums on short-term investments, the loss on the disposal of fixed assets and impairment charge on fixed assets of \$601,000, stock-based compensation expense of \$1.5 million and a \$7.9 million decrease as a result of changes in the working capital accounts. This \$7.9 million decrease was primarily due to a \$2.2 million increase in inventory, a \$1.9 million decrease in accrued license fees and a \$2.8 million reduction in its accounts payable and accrued expenses.

*Investing Activities.* Investing activities provided \$677,000 of net cash in the six months ended June 30, 2008, compared to \$212,000 in the six months ended June 30, 2007. During the six months ended June 30, 2008, Critical Therapeutics made minimal capital expenditures. Net cash provided by investing activities for the six months ended June 30, 2008 primarily related to proceeds from Critical Therapeutics' sale of assets of \$278,000 and its sale of its SetPoint stock for \$400,000. In addition, as interest rates have gradually decreased, Critical Therapeutics has maintained more of its investments as cash equivalents rather than short-term investments.

*Financing Activities.* In the six months ended June 30, 2008, Critical Therapeutics used \$370,000 of net cash in financing activities, compared to \$261,000 in the six months ended June 30, 2007. Net cash used in financing activities for the six months ended June 30, 2008 primarily related to the repayment of long-term debt.

### ***Income Taxes***

Critical Therapeutics has accumulated net operating losses and tax credits available to offset future taxable income for federal and state income tax purposes as of June 30, 2008. If not utilized, federal net operating loss carryforwards will begin to expire in 2021. State net operating loss carryforwards began to expire in 2006. The federal tax credits expire beginning in 2021. To date, Critical Therapeutics has not recognized the potential tax benefit of its net operating loss carryforwards or credits on its balance sheet or statements of operations. The future utilization of Critical Therapeutics net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code.

### ***Funding Requirements and Going Concern***

Critical Therapeutics has experienced significant operating losses in each year since its inception in 2000. Critical Therapeutics 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. Critical Therapeutics had net losses of \$17.4 million in the six months ended June 30, 2008 and \$17.6 million in the six months ended June 30, 2007. As of June 30, 2008, Critical Therapeutics had an accumulated deficit of approximately \$209 million. Critical Therapeutics expects that it will continue to incur substantial losses for

the foreseeable future as it spends significant amounts to fund its development and commercialization efforts. As a result, there is substantial doubt about Critical Therapeutics' ability to continue as a going concern. Critical Therapeutics' ability to continue as a going concern will require it to obtain additional financing to fund its operations. Critical Therapeutics has prepared its financial statements on the assumption that it will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about Critical Therapeutics' ability

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to continue as a going concern may make it more difficult to obtain financing for the continuation of operations and could result in the loss of confidence by investors, creditors, suppliers and employees.

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

the ongoing costs of sales and marketing of ZYFLO CR;

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

the costs of ongoing manufacturing activities for ZYFLO CR and ZYFLO;

the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for Critical Therapeutics' product candidates;

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

the timing, receipt and amount of sales and royalties, if any, from Critical Therapeutics' product candidates;

continued progress in Critical Therapeutics' research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under Critical Therapeutics' 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;

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

The extent of Critical Therapeutics' future capital requirements is difficult to assess and will depend largely on its ability to successfully manufacture and commercialize ZYFLO CR. Based on its operating plans, Critical Therapeutics believes that its available cash 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 six months ended June 30, 2008, Critical Therapeutics' net cash used for operating activities was \$23.2 million and Critical Therapeutics had minimal capital expenditures. If Critical Therapeutics' existing resources are insufficient to satisfy its liquidity requirements or if Critical Therapeutics acquires or licenses rights to additional product candidates, it may need to raise additional external funds through collaborative arrangements and public or private financings. Under Critical Therapeutics' Agreement and Plan of Merger with Cornerstone, or the Merger Agreement, any financing transaction would require Cornerstone's consent. Additional financing may not be available to Critical Therapeutics on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of Critical Therapeutics.



quantities of ZYFLO CR tablets that are subject to binding forecasts.

In addition, Critical Therapeutics entered into a manufacturing and supply agreement with Shasun Pharma Solutions Ltd., or Shasun, for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. Under this agreement, Critical Therapeutics has agreed to purchase specified quantities of API in 2008 and 2009 with a portion subject to the right of cancellation. The API purchased from Shasun currently has a minimum shelf-life of 36 months.

The amounts listed for research and license agreements represent Critical Therapeutics' fixed obligations payable to sponsor research and minimum royalty payments and milestone payments for licensed patents.

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These amounts do not include any additional amounts that Critical Therapeutics 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 IND to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of Critical Therapeutics' products in various countries.

Critical Therapeutics is party to a number of agreements that require it to make milestone payments. In particular, under Critical Therapeutics' license agreement with Abbott for zileuton, it 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 Critical Therapeutics, filing and approval of a product in the United States and specified minimum net sales of licensed products. Through June 30, 2008, Critical Therapeutics has made aggregate milestone payments of \$7.8 million to Abbott under its license agreements related to ZYFLO and ZYFLO CR and, as of June 30, 2008, has included \$1.5 million in accounts payable related to the achievement of the first anniversary milestone. In addition, under its license agreement with Jagotec for ZYFLO CR, Critical Therapeutics agreed to make aggregate milestone payments of up to \$6.6 million upon the achievement of various development and commercialization milestones. Through June 30, 2008, Critical Therapeutics has made aggregate milestone payments of \$3.0 million to Jagotec under its agreement and, as of June 30, 2008, has included \$375,000 in accounts payable related to the achievement of the first anniversary milestone. In May 2007, Critical Therapeutics 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 related to the FDA's approval of ZYFLO CR due to Abbott and Jagotec totaling \$3.8 million.

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

The amounts listed for lease obligations represent the amounts Critical Therapeutics owes under its facility, computer and vehicle lease agreements under both operating and capital leases.

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

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

The amounts listed for research and license agreements, consulting agreements and manufacturing and clinical trial agreements include amounts that Critical Therapeutics owes under agreements that are subject to cancellation or termination by it 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 Critical Therapeutics could be obligated to pay to Cornerstone in specified circumstances in connection with the termination of the merger agreement with Cornerstone.

Critical Therapeutics 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, Critical Therapeutics is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its products. While Critical Therapeutics' purchase commitment for API from Shasun exceeds its current forecasted demand in 2008, Critical Therapeutics expects that any excess API purchased in 2008 and 2009 under its agreement with Shasun will 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 June 30, 2008.

**Effects of Inflation**

A substantial portion of Critical Therapeutics' assets are monetary, consisting primarily of cash, cash equivalents and investments. Because of their liquidity, these assets are not significantly affected by inflation.

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Critical Therapeutics also believes that it has intangible assets in the value of its technology. In accordance with generally accepted accounting principles, or GAAP, Critical Therapeutics has not capitalized the value of this intellectual property on its consolidated balance sheet. Because Critical Therapeutics intends to retain and continue to use its equipment, furniture and fixtures and leasehold improvements, it believes that the incremental inflation related to the replacement costs of such items will not materially affect its operations. However, the rate of inflation affects its expenses, such as those for employee compensation and contract services, which could increase Critical Therapeutics level of expenses and the rate at which it uses its 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. Critical Therapeutics 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*, 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 the 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 Critical Therapeutics financial statements and results of operations.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP, or the GAAP hierarchy. SFAS 162 makes the GAAP hierarchy explicitly and directly applicable to preparers of financial statements, a step that recognizes preparers' responsibilities for selecting the accounting principles for their financial statements, and sets the stage for making the framework of the FASB Concept Statements fully authoritative. The effective date for SFAS 162 is 60 days following the SEC's approval of the Public Company Accounting Oversight Board's related amendments to remove the GAAP hierarchy from auditing standards, where it has resided for some time. The Company does not expect the adoption of SFAS 162 to have a material impact on its financial statements and results of operations.

In April 2008, the FASB issued FASB Staff Position Financial Accounting Standard 142-3, *Determination of the Useful Life of Intangible Assets*, or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. In developing assumptions about renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for the entity-specific factors in paragraph 11 of SFAS 142. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after

December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure

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requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company does not expect the adoption of FSP FAS 142-3 to have a material impact on its 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 Critical Therapeutics if it is 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. Critical Therapeutics 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*, 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. Critical Therapeutics was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on Critical Therapeutics financial statements and results of operations, as it 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. Critical Therapeutics was required to adopt the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. Critical Therapeutics is currently evaluating the effect FSP 157-2 will have on its financial statements and results of operations.

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

Critical Therapeutics is exposed to market risk related to changes in interest rates. Critical Therapeutics' 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. Critical Therapeutics cash is deposited in and invested through highly rated financial institutions in North America. Critical Therapeutics 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 June 30, 2008, Critical Therapeutics estimates that the fair value of its investment portfolio would not change by a material amount.

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Critical Therapeutics could be exposed to losses related to these securities should one of its counterparties default. Critical Therapeutics attempts to mitigate this risk through credit monitoring procedures. Critical Therapeutics has the ability to hold its fixed income investments until maturity, and therefore Critical Therapeutics would not expect its operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on its investments. At June 30, 2008, Critical Therapeutics held approximately \$284,000 in an auction rate security with a AAA credit rating upon purchase. In February 2008, Critical Therapeutics was informed that there was insufficient demand at auction for this security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Critical Therapeutics has classified its investment in the auction rate security as a long-term investment and included the investment in other assets on its balance sheet.

**Item 4. *Controls and Procedures***

Critical Therapeutics management, with the participation of its chief executive officer and chief financial officer, evaluated the effectiveness of its disclosure controls and procedures as of June 30, 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. Critical Therapeutics 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 Critical Therapeutics disclosure controls and procedures as of June 30, 2008, its chief executive officer and chief financial officer concluded that, as of such date, its disclosure controls and procedures were effective at the reasonable assurance level.

No change in Critical Therapeutics 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 June 30, 2008 that has materially affected, or is reasonably likely to materially affect, its 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 Critical Therapeutics files with the Securities and Exchange Commission, in evaluating Critical Therapeutics and its business. If any of the following risks occur, Critical Therapeutics 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 Critical Therapeutics annual report on Form 10-K for the year ended December 31, 2007.

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**Risks Related to the Proposed Merger with Cornerstone**

*If the proposed merger with Cornerstone is not consummated, Critical Therapeutics' business could suffer materially and its stock price could decline.*

On May 1, 2008, Critical Therapeutics 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 Critical Therapeutics' common stock and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone's common stock will be assumed by Critical Therapeutics and become options and warrants to purchase Critical Therapeutics' common stock. The merger agreement provides that in the merger Critical Therapeutics will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of Critical Therapeutics' common stock, subject to adjustment as a result of a contemplated reverse stock split of Critical Therapeutics' 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 Critical Therapeutics' current stockholders will own approximately 30 percent, of Critical Therapeutics' 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 Critical Therapeutics' outstanding options and warrants. The exact exchange ratio per share of Cornerstone's common stock will be based in part 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 Critical Therapeutics' stockholders, approval by NASDAQ of Critical Therapeutics' application for re-listing of Critical Therapeutics' common stock in connection with the merger, the continued availability of Critical Therapeutics' products and other customary closing conditions. Critical Therapeutics is targeting a closing of the transaction in the fourth quarter of 2008.

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

Critical Therapeutics has incurred and expects to continue to incur significant expenses related to the proposed merger with Cornerstone even if the merger is not consummated.

The merger agreement contains covenants relating to Critical Therapeutics' solicitation of competing acquisition proposals and the conduct of Critical Therapeutics' 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, Critical Therapeutics may be unable to pursue business opportunities that would otherwise be in its best interest as a standalone company. If the merger agreement is terminated after Critical Therapeutics has invested significant time and resources in the transaction process, Critical Therapeutics will have a limited ability to continue its current operations without obtaining additional financing to fund its operations.

Critical Therapeutics 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.

Critical Therapeutics' 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 its business or prospects.

Some of Critical Therapeutics' suppliers, distributors and other business partners may seek to change or terminate their relationships with Critical Therapeutics 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 Critical Therapeutics' ability to retain its key employees, who may seek other employment opportunities.

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Critical Therapeutics' management team may be distracted from day to day operations as a result of the proposed merger.

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

In addition, if the merger agreement is terminated and Critical Therapeutics' board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the merger. In such circumstances, Critical Therapeutics' board of directors may elect to, among other things, divest all or a portion of Critical Therapeutics' business, or take the steps necessary to liquidate all of Critical Therapeutics' business and assets, and in either such case, the consideration that Critical Therapeutics receives may be less attractive than the consideration to be received by Critical Therapeutics pursuant to the merger agreement.

***During the pendency of the merger, Critical Therapeutics may not be able to enter into a business combination with another party because of restrictions in the merger agreement.***

Covenants in the merger agreement impede the ability of Critical Therapeutics to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the merger agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to such party entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of Critical Therapeutics' common stock, a tender offer for Critical Therapeutics' common stock or a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to such party's stockholders.

## **Risks Relating to Critical Therapeutics' Business**

***Critical Therapeutics' business depends heavily on the commercial success of ZYFLO CR.***

ZYFLO CR and ZYFLO are currently Critical Therapeutics' only commercially marketed products. Critical Therapeutics commercially launched ZYFLO CR on September 27, 2007. In February 2008, Critical Therapeutics discontinued the production and supply of ZYFLO, which Critical Therapeutics had commercially launched in October 2005, but Critical Therapeutics expects to resume the supply of ZYFLO in September 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. ZYFLO has not achieved broad market acceptance. If Critical Therapeutics is able to successfully commercialize ZYFLO CR, Critical Therapeutics expects it will account for a significant portion of Critical Therapeutics' revenues for the foreseeable future. However, Critical Therapeutics cannot assure you that ZYFLO CR will not suffer the same lack of broad market acceptance that has affected ZYFLO.

Critical Therapeutics' 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. Critical Therapeutics' early-stage product candidates in particular will require substantial funding for Critical Therapeutics to complete preclinical testing and clinical trials, initiate manufacturing and, if approved for sale, initiate commercialization. If ZYFLO CR is not commercially successful, Critical Therapeutics may be forced to find additional sources of funding earlier than Critical Therapeutics anticipated. If Critical Therapeutics is not successful in obtaining additional funding on acceptable terms, Critical Therapeutics may be forced to significantly delay, limit or

eliminate one or more of Critical Therapeutics' development or commercialization programs.

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***If ZYFLO CR does not achieve market acceptance, Critical Therapeutics may not be able to generate significant revenues unless Critical Therapeutics is 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 asthma. Critical Therapeutics believes 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 Critical Therapeutics may experience the same lack of market acceptance with ZYFLO CR that Critical Therapeutics has experienced with ZYFLO.

Despite being approved by the FDA since 1996, ZYFLO did not achieve broad market acceptance. During the period between Critical Therapeutics' commercial launch of ZYFLO in October 2005 through May 2008, prescription data for ZYFLO indicates that approximately 5,900 physicians prescribed the product. Critical Therapeutics recorded revenue from the sale of ZYFLO of \$8.7 million for the year ended December 31, 2007 and \$748,000 for the six months ended June 30, 2008. Critical Therapeutics recorded revenue from the sale of ZYFLO CR of \$2.3 million for the year ended December 31, 2007 and \$6.5 million for the six months ended June 30, 2008. Critical Therapeutics experienced difficulty expanding the prescriber and patient bases for ZYFLO, in part, Critical Therapeutics believes, 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, Critical Therapeutics' sales of ZYFLO CR will be limited and Critical Therapeutics' 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.

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 Critical Therapeutics successfully develops and commercializes. 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 Critical Therapeutics' 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.

In March 2008, the FDA issued an early communication regarding an ongoing safety review of the leukotriene montelukast relating to suicide and other behavior related adverse events. In that communication, the FDA stated that it was also reviewing the safety of other leukotriene medications. On May 27, 2008, Critical Therapeutics received a request from the FDA that Critical Therapeutics gather and provide to the FDA data from its clinical trial database to evaluate behavior-related adverse events for ZYFLO and ZYFLO CR. Depending on the results of such analyses and

the FDA's review, the FDA could request that Critical

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Therapeutics revise the labeling of ZYFLO and ZYFLO CR to include statements regarding the potential for suicidal thoughts or other behavior-related change associated with the use of zileuton. If the FDA requests that Critical Therapeutics add these statements or similar statements to its package inserts, sales of these products could suffer.

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 has been positioned on 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, Critical Therapeutics will have difficulty achieving market acceptance for ZYFLO CR. If Critical Therapeutics is unable to achieve market acceptance of ZYFLO CR, Critical Therapeutics will not generate significant revenues unless Critical Therapeutics is able to successfully develop and commercialize other product candidates.

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

After increasing the size of Critical Therapeutics sales force in connection with the commercial launch of ZYFLO CR to approximately 42 sales representatives in October 2007, Critical Therapeutics decreased the size of its sales force to approximately 29 sales representatives as of June 30, 2008. Building Critical Therapeutics sales force involved significant time and expense. If Critical Therapeutics is not successful in its efforts to retain an adequate sales force, its ability to market and sell ZYFLO CR will be impaired.

In March 2007, Critical Therapeutics entered into a co-promotion agreement with DEY for the co-promotion of ZYFLO CR and ZYFLO. Critical Therapeutics 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, Critical Therapeutics agreed to provide a minimum number of promotional details per month by Critical Therapeutics sales representatives to a specified group of office-based physicians and other health care professionals for ZYFLO CR. If Critical Therapeutics is not successful in its 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 Critical Therapeutics experiences greater than expected turnover of sales representatives, Critical Therapeutics may have difficulty satisfying its minimum detailing obligations. In February 2008, Mylan Inc., or Mylan, 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 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 reductions in efforts under the co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit Critical Therapeutics ability to generate significant revenues from product sales.

On June 25, 2007, as contemplated by the terms of the zileuton co-promotion agreement, Critical Therapeutics and DEY entered into a separate definitive co-promotion agreement providing for Critical Therapeutics to co-promote DEY's product PERFOROMIST for the long-term, twice-daily maintenance treatment of COPD. Under the PERFOROMIST co-promotion agreement, DEY agreed to pay Critical Therapeutics a co-promotion fee based on retail sales of PERFOROMIST and Critical Therapeutics agreed to provide a minimum number of promotional details per month by Critical Therapeutics sales representatives to a specified group of office-based physicians and other health care professionals. Promoting both ZYFLO CR and PERFOROMIST may be challenging for Critical

Therapeutics sales representatives and may reduce their efficiency, which could negatively impact Critical  
Therapeutics revenues.

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The amount of any co-promotion fee that DEY pays to Critical Therapeutics 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 six months ended June 30, 2008, Critical Therapeutics 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. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

***A failure to maintain appropriate inventory levels could harm Critical Therapeutics' reputation and subject Critical Therapeutics to financial losses.***

Critical Therapeutics is subject to minimum purchase obligations under its supply agreements with its third-party manufacturers, which require Critical Therapeutics to buy inventory of the zileuton API and tablet cores for ZYFLO CR. If ZYFLO CR does not achieve the level of demand Critical Therapeutics anticipates, Critical Therapeutics may not be able to use the inventory it is required to purchase. As of June 30, 2008, Critical Therapeutics had \$7.8 million in inventory, consisting primarily of tablet cores and API. Based on Critical Therapeutics' current expectations regarding demand for ZYFLO CR, Critical Therapeutics expects that its inventory levels could increase substantially in the future as a result of its minimum purchase obligations under its supply agreements with third-party manufacturers and orders it has submitted to date. Significant differences between Critical Therapeutics' current estimates and judgments and future estimated demand for its products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If Critical Therapeutics is required to recognize charges for excess inventories, it could have a material adverse effect on Critical Therapeutics' financial condition and results of operations in the period in which Critical Therapeutics recognizes charges for excess inventory.

In the six months ended June 30, 2008, Critical Therapeutics recorded an inventory reserve for an aggregate of 12 batches of ZYFLO CR that could not be released into Critical Therapeutics' commercial supply chain, consisting of five batches that did not meet Critical Therapeutics' product release specifications and seven additional batches that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. Critical Therapeutics cannot assure you that it will not have similar manufacturing issues in producing ZYFLO CR in the future. If Critical Therapeutics is unable to manufacture or release ZYFLO CR on a timely and consistent basis, if Critical Therapeutics fails to maintain an adequate inventory of zileuton API or ZYFLO CR core tablets, if Critical Therapeutics' inventory were to be destroyed or damaged, or if Critical Therapeutics' inventory were to reach its expiration date, patients might not have access to ZYFLO CR, Critical Therapeutics' reputation and its brand could be harmed and physicians may be less likely to prescribe ZYFLO CR in the future. Conversely, if Critical Therapeutics is unable to sell Critical Therapeutics' inventory in a timely manner, Critical Therapeutics could experience cash flow difficulties and additional financial losses.

***If the market is not receptive to Critical Therapeutics' product candidates, Critical Therapeutics will be unable to generate revenues from sales of these products.***

The probability of commercial success of each of Critical Therapeutics' product candidates is subject to significant uncertainty. Factors that Critical Therapeutics believes will materially affect market acceptance of Critical Therapeutics' product candidates under development include:

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

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the safety, efficacy and ease of administration;

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 MCOs; and

the extent and success of Critical Therapeutics' sales and marketing efforts.

The failure of Critical Therapeutics' product candidates to achieve market acceptance would prevent Critical Therapeutics from ever generating meaningful revenues from sales of these product candidates.

***Critical Therapeutics may not be successful in its efforts to advance and expand its portfolio of product candidates.***

An element of Critical Therapeutics' strategy is to develop and commercialize product candidates that address large unmet medical needs. Critical Therapeutics seeks 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, Critical Therapeutics may seek to in-license or acquire product candidates or approved products. However, Critical Therapeutics 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 Critical Therapeutics due to their size, cash resources or greater clinical development and commercialization capabilities. Other factors that may prevent Critical Therapeutics from licensing or otherwise acquiring suitable product candidates or approved products include the following:

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

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

Critical Therapeutics may be unable to identify suitable products or product candidates within Critical Therapeutics' areas of expertise; and

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

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### ***Critical Therapeutics faces substantial competition. If Critical Therapeutics is unable to compete effectively, ZYFLO CR, ZYFLO and Critical Therapeutics product candidates may be rendered noncompetitive or obsolete.***

The development and commercialization of new drugs is highly competitive. Critical Therapeutics will face competition with respect to the development of product candidates and for ZYFLO CR, ZYFLO and any other products that Critical Therapeutics commercializes in the future from pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, companies selling low-cost generic substitutes, academic institutions, government agencies and research institutions.

A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO CR and ZYFLO. 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, Critical Therapeutics may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in June 2007, AstraZeneca PLC 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, zileuton, if Critical Therapeutics is 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 Ingelheim GmbH and Pfizer. Other novel approaches are also in development.

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

If Critical Therapeutics' 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. Critical Therapeutics does 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 Critical Therapeutics' products are approved.

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

significantly greater financial, technical and human resources than Critical Therapeutics has and may be better equipped to discover, develop, manufacture and commercialize products;

more extensive experience than Critical Therapeutics has 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

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collaborative arrangements in Critical Therapeutics target markets with leading companies and research institutions.

Critical Therapeutics will face competition based on the safety and effectiveness of Critical Therapeutics 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. Critical Therapeutics competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than Critical Therapeutics is able to. Accordingly, Critical Therapeutics competitors may commercialize products more rapidly or effectively than Critical Therapeutics is able to, which would adversely affect Critical Therapeutics competitive position, the likelihood that its product candidates will achieve initial market acceptance and its ability to generate meaningful revenues from its product candidates. Even if Critical Therapeutics product candidates achieve initial market acceptance, competitive products may render its products obsolete or noncompetitive. If Critical Therapeutics product candidates are rendered obsolete, it may not be able to recover the expenses of developing and commercializing those product candidates.

***If Critical Therapeutics is unable to retain key personnel and hire additional qualified personnel, Critical Therapeutics may not be able to achieve its goals.***

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

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

Recruiting and retaining qualified commercial personnel, in addition to Critical Therapeutics executive management team, will also be critical to Critical Therapeutics 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 Critical Therapeutics management, operational and financial resources. These demands

may require Critical Therapeutics to hire additional personnel and will require Critical Therapeutics' existing management personnel to develop additional expertise. Critical Therapeutics faces 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 Critical Therapeutics' product candidates.

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Critical Therapeutics has experienced turnover in its sales and marketing team. For example, Critical Therapeutics has experienced an increase in the number of voluntary resignations of its sales and marketing personnel after it publicly announced in November 2007 that it was in the process of reviewing a range of strategic alternatives that could result in potential changes to its current business strategy and future operations. The pendency of Critical Therapeutics proposed merger with Cornerstone could have a similar effect. In June 2008, Critical Therapeutics reduced the size of its sales force by eight sales representatives and three sales managers. If Critical Therapeutics is not successful in its efforts to retain its remaining qualified sales and marketing personnel, Critical Therapeutics' ability to market and sell ZYFLO CR and Critical Therapeutics' ability to deliver Critical Therapeutics' required level of promotional detailing under Critical Therapeutics' co-promotion agreements with DEY would be impaired.

Critical Therapeutics has also experienced turnover on its board of directors. For example, Critical Therapeutics has had eight directors leave its board and three directors join its board since June 1, 2006. Critical Therapeutics currently has four directors serving on its board. If Critical Therapeutics' board were to fail to satisfy the requirements of relevant rules and regulations of the SEC and NASDAQ relating to director independence or membership on board committees, this could result in the delisting of Critical Therapeutics' common stock from NASDAQ or could adversely affect investors' confidence in Critical Therapeutics and Critical Therapeutics' ability to access the capital markets. If Critical Therapeutics is unable to attract and retain qualified directors, the achievement of Critical Therapeutics' corporate objectives could be significantly delayed or may not occur.

***Critical Therapeutics identified a material weakness in its internal control over financial reporting for the second quarter and third quarter of 2007. If Critical Therapeutics fails to achieve and maintain effective internal control over financial reporting, Critical Therapeutics could face difficulties in preparing timely and accurate financial reports, which could result in a loss of investor confidence in Critical Therapeutics' reported results and a decline in Critical Therapeutics' stock price.***

In connection with the preparation of Critical Therapeutics' financial statements for the second quarter of 2007, Critical Therapeutics identified a material weakness in its internal control over financial reporting. As a result of this material weakness, Critical Therapeutics' management concluded that Critical Therapeutics' disclosure controls and procedures were not effective as of either June 30, 2007 or September 30, 2007. Critical Therapeutics implemented steps to remedy the material weakness, and Critical Therapeutics' management provided an unqualified assessment of Critical Therapeutics' internal control over financial reporting as of December 31, 2007. There were no material changes in Critical Therapeutics' internal control over financial reporting for the quarter ended June 30, 2008. Any failure or difficulties in maintaining these procedures and controls could cause Critical Therapeutics to fail to meet its periodic reporting obligations or result in its inability to prevent or detect material misstatements in its financial statements. It is possible that Critical Therapeutics' management may not be able to provide an unqualified assessment of Critical Therapeutics' internal control over financial reporting or disclosure controls and procedures in the future, or be able to provide quarterly certifications that Critical Therapeutics' disclosure controls and procedures are effective. It is also possible that Critical Therapeutics may identify additional significant deficiencies or material weaknesses in Critical Therapeutics' 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 Critical Therapeutics' financial statements, which in turn could harm Critical Therapeutics' business, lead to a decline in Critical Therapeutics' stock price and restrict Critical Therapeutics' ability to raise additional funds needed for the growth of its business.

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***Critical Therapeutics will spend considerable time and money complying with federal and state laws and regulations, and, if Critical Therapeutics is unable to fully comply with such laws and regulations, Critical Therapeutics could face substantial penalties.***

Critical Therapeutics is subject to extensive regulation by federal and state governments. The laws that directly or indirectly affect Critical Therapeutics' 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 Critical Therapeutics' 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 Critical Therapeutics 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 sta