CRITICAL THERAPEUTICS INC
Form 10-Q
October 20, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For The Quarterly Period Ended September 30, 2008

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period From to

Commission File Number: 000-50767

Critical Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
60 Westview Street Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	*(Zip Code)*

(781) 402-5700

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of October 17, 2008, the registrant had 43,332,598 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. FINANCIAL INFORMATION

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding 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 collaboration agreement 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, ZYFLO and 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.

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Item 1. ***Financial Statements***

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2008	December 31, 2007
	(Unaudited)	
	(In thousands)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 7,014	$ 33,828
Accounts receivable, net	3,643	1,273
Inventory, net	7,064	5,599
Prepaid expenses and other	1,817	2,205
Total current assets	19,538	42,905
Fixed assets, net	305	1,151
Other assets	277	868
Total assets	$ 20,120	$ 44,924
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Current portion of long-term debt	$	$ 370
Current portion of accrued license fees	1,817	1,838
Current portion of deferred co-promotion fees	1,880	1,880
Accounts payable	2,795	5,283
Accrued expenses	5,819	7,154
Total current liabilities	12,311	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	7,987	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 43,062,448 and 42,805,348 shares at September 30, 2008 and December 31, 2007, respectively	43	43
Additional paid-in capital	210,543	208,420
Accumulated deficit	(210,764)	(191,372)
Total stockholders (deficit) equity	(178)	17,091

Total liabilities and stockholders equity	$ 20,120	$ 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)			
	(In thousands, except share and per share data)			
Revenues:				
Net product sales	$ 5,993	$ 3,126	$ 13,220	$ 8,311
Revenue under collaboration and license agreements		93		1,830
Total revenues	5,993	3,219	13,220	10,141
Costs and expenses:				
Cost of products sold	2,307	1,232	6,964	2,653
Research and development	497	3,939	7,424	16,961
Sales and marketing	1,768	3,574	7,799	8,156
General and administrative	3,403	2,653	9,413	9,241
Restructuring charges			1,204	
Total costs and expenses	7,975	11,398	32,804	37,011
Operating loss	(1,982)	(8,179)	(19,584)	(26,870)
Other income (expense):				
Interest income	10	474	299	1,628
Interest expense	(22)	(81)	(107)	(150)
Total other income (expense)	(12)	393	192	1,478
Net loss	$ (1,994)	$ (7,786)	$ (19,392)	$ (25,392)
Net loss per share	$ (0.05)	$ (0.18)	$ (0.45)	$ (0.60)
Basic and diluted weighted-average common shares outstanding	43,025,652	42,615,318	42,913,928	42,548,001

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

	Nine Months Ended September 30,	
	2008	2007
	(Unaudited) (In thousands)	
Cash flows from operating activities:		
Net loss	($ 19,392)	($ 25,392)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	282	483
Amortization of premiums on short-term investments and other	123	72
(Gain) loss on sale of fixed assets	(106)	27
Impairment charge on fixed assets	393	
Lease abandonment charge		286
Preferred stock received in license agreement, net		(400)
Stock-based compensation expense	2,123	2,914
Changes in assets and liabilities:		
Accounts receivable	(2,370)	(1,309)
Inventory	(1,465)	(187)
Prepaid expenses and other assets	556	(52)
Accounts payable	(2,488)	703
Accrued expenses	(1,335)	(66)
Accrued license fees	(1,875)	3,495
Deferred collaboration revenue and fees		(675)
Deferred product revenue		(1,178)
Deferred co-promotion fees	(1,567)	6,615
Net cash used in operating activities	(27,121)	(14,664)
Cash flows from investing activities:		
Proceeds from sales and maturities of investments	400	300
Proceeds from sale of fixed assets and other	278	216
Purchases of fixed assets	(1)	(7)
Net cash provided by investing activities	677	509
Cash flows from financing activities:		
Proceeds from exercise of stock options and other		299
Repayments of long-term debt and capital lease obligations	(370)	(836)
Net cash used in financing activities	(370)	(537)
Net decrease in cash and cash equivalents	(26,814)	(14,692)
Cash and cash equivalents at beginning of period	33,828	48,388
Cash and cash equivalents at end of period	$ 7,014	$ 33,696

Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 10	$ 101

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 nine-month periods ended September 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.

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

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

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 October 3, 2008, the Company announced that the SEC had declared effective its Registration Statement on Form S-4 in connection with the Merger. The Company s stockholders of record on September 29, 2008 will vote on the issuance of the Company s shares pursuant to the Merger Agreement and the other proposals set forth in the proxy statement/prospectus included in the Registration Statement at a special meeting of stockholders to be held on Friday, October 31, 2008.

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 $19.4 million in the nine months ended September 30, 2008 and $25.4 million in the nine months ended September 30, 2007. As of September 30, 2008, the Company had an accumulated deficit of approximately $211 million. For the year ended December 31, 2007 and the nine months ended September 30, 2008, the Company recorded $11.0 million and $13.2 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 ZYFLO 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 nine months ended September 30, 2008, the Company s net cash used in operating activities was $27.1 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.

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.

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

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 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 shall be applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its financial statements and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* (SFAS 159). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159

on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company s financial statements and results of operations, as the Company 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.

(2) Revenue Recognition

Revenue Recognition

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

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 September 30, 2008 and 2007, the Company s allowances for ZYFLO CR and ZYFLO product returns were $370,000 and $286,000, 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.

Revenue under collaboration and license agreements. Under the Company s collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in the Company s statements of operations when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company s collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. The Company assesses proportional performance based on the progress of its research and development efforts, including employees salaries and benefits,

laboratory supplies and third-party research consulting fees, during the term of its agreements. The Company considers these to be the most reliable measure of progress. 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. All of the Company s research activities under the research plan with MedImmune were completed in 2007.

Under the Company s license agreement with SetPoint (formerly known as Innovative Metabolics, Inc.), 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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARIES
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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 September 30, 2008, the Company s accounts receivable balance of $3.6 million was net of allowances of $77,000. 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 highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. At September 30, 2008, the Company had an investment with a carrying amount of $277,000 in an auction rate security with a AAA credit rating upon purchase and $7.0 million in cash and cash equivalents, including investments in money market funds and U.S. Treasury securities. These cash equivalent securities would be subject to Level 2 valuation inputs as described below.

The Company has been informed that there is insufficient demand at auction for its auction rate security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Because this amount is currently not liquid and the Company does not intend to hold the security until recovery, the Company has recorded the decline in fair value of $23,000 in the Company s statement of operations. The Company has classified its auction rate security as a long-term investment and has included the amount in other assets on the Company s accompanying balance sheet.

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 September 30, 2008 (in thousands):

		Fair Value Measurements at September 30, 2008 Using		
	Total Carrying Value at	Quoted Prices	Other Observable	Significant Unobservable

	September 30, 2008	in Active Markets (Level 1)	Inputs (Level 2)	Inputs (Level 3)
Auction rate security measured at fair value	$ 277	$	$	$ 277

The following table provides a rollforward of the Company s assets and liabilities whose fair value measurements were Level 3 (The loss was recognized in the quarter ended September 30, 2008) (in thousands):

	Auction Rate Security (Level 3)
Total carrying value at January 1, 2008	$ 300
Recognized loss	(23)
Total carrying value at September 30, 2008	$ 277

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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 nine months 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 September 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.

(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 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 nine months ended September 30, 2008, the Company recorded interest expense of $21,000 and $100,000, respectively, related to the accretion of the discount. In addition, at September 30, 2008, $1.8 million related to milestone obligations due on the second anniversary of the FDA s approval was included in the Company s balance sheet as accrued license fees.

(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 September 30, 2008, the Company held $7.1 million in inventory to be used for commercial sales related to its commercial products, ZYFLO CR and ZYFLO. 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 September 30, 2008, the Company had an inventory reserve of $2.6 million. The inventory reserve primarily 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 September 30, 2008 and December 31, 2007, respectively (in thousands):

	September 30, 2008	December 31, 2007
Raw material	$ 5,639	$ 2,587
Work in process	3,454	3,062
Finished goods	599	766
Total inventory	9,692	6,415
Less: reserve	(2,628)	(816)
Inventory, net	$ 7,064	$ 5,599

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 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 nine months ended September 30, 2007, and comprehensive loss is the unrealized gain (loss) on investments for the period. There was no difference between net loss, as reported in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2008. Total comprehensive loss was $2.0 million and $7.8 million for the three months ended September 30, 2008 and 2007, respectively and $19.4 million and $25.4 million for the nine months ended September 30, 2008 and 2007, respectively.

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(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 nine-month period ended September 30, 2008 was as follows:

	2008	
	Number of Shares	Weighted-Average Exercise Price Per Share
Outstanding January 1	5,020,903	$ 4.20
Granted	12,000	0.90
Exercised		
Cancelled	(2,527,336)	4.38
Outstanding September 30	2,505,567	$ 4.00
Vested and Expected to Vest September 30	2,280,432	$ 4.05
Exercisable September 30	1,665,447	$ 4.34

The weighted-average remaining contractual term and the aggregate intrinsic value for options outstanding at September 30, 2008 were 7.0 years and zero, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options exercisable at September 30, 2008 were 6.4 years and zero, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options vested or expected to vest at September 30, 2008 were 6.9 years and zero, respectively. There were no options exercised during the nine months ended September 30, 2008.

The total grant date fair value of the shares vested and unexercised during the three and six months ended September 30, 2008 was $30,000 and $92,000, respectively. As of September 30, 2008, there was $2.5 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 $177,000 in the fourth quarter of 2008, $1.6 million in 2009 and $721,000 thereafter relating to the amortization of unrecognized compensation expense as of September 30, 2008. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

(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 9,984,424 and 12,740,445 as of September 30, 2008 and 2007, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of September 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.

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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 $22.0 million as of September 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 September 30, 2008, the Company had $275,000 included in accrued expenses related to its research and development agreements. These research and development expenses are accounted for as such costs are incurred. In addition, as of September 30, 2008, the Company had $1.8 million in accrued license fees representing the net present value of the Company s milestone obligations due on the second anniversary of the FDA s approval of ZYFLO CR. In addition, during the quarter ended 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 September 30, 2008, $212,000 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. The Company has committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 20, 2008. 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 September 30, 2008, no reserves have been recorded for potential losses on 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 $6.6 million as of September 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.

In connection with the proposed merger, the Company is obligated to make certain payments to executives and employees upon the change of control. If the merger is consummated the Company would be required to pay $387,000 to its executives and employees. These payments are not included in the Company s results of operations as of September 30, 2008.

(10) DEY Co-Promotion and Marketing Services Agreements

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

Under the co-promotion agreement, DEY paid the Company a non-refundable upfront payment of $3.0 million in March 2007, a milestone payment of $4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a

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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 nine months ended September 30, 2008, approximately $883,000 and $1.6 million, 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 was 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 September 30, 2008, the Company had $253,000 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 fair 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 during the second quarter of 2008.

(12) Legal Proceedings

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against the Company and each of its directors in the Court of Chancery of The State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli and Jean George* (Case No. 4039, Court of Chancery, State of Delaware). The plaintiff, which claims to be a stockholder of the Company, brought the lawsuit on its own behalf, and is seeking certification of the lawsuit as a class action on behalf of all stockholders of the Company, except the defendants and their affiliates. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by

failing to provide the Company s stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed Merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed Merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed Merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties; (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties; (iv) in the event the proposed Merger is consummated, rescinding it and setting it aside or awarding rescissory damages; (v) awarding compensatory damages against defendants, jointly and severally; and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, the Company and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that the Company would make certain additional disclosures to its stockholders, which are contained in a supplement to the proxy statement/prospectus that has been mailed to the Company s stockholders. Subject to the completion of certain confirmatory discovery by counsel to the plaintiff, the memorandum of understanding contemplates that the parties will enter into a stipulation of settlement. The stipulation of settlement will be subject to customary conditions, including court approval. If the court approves the settlement, the settlement will resolve all of the claims that were or could have been brought in the action being settled, including all claims relating to the Merger, the Merger Agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the parties contemplate that plaintiff s counsel will petition the court for an award of attorneys fees and expenses to be paid by the Company, the amount of which will either be agreed to by the parties or awarded by the court. The Company is currently unable to determine the financial impact of this lawsuit and whether this matter will have a material adverse effect on its consolidated financial statements.

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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, 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 resumed 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 a collaboration agreement with MedImmune for 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 inflammatory response. In addition, Critical Therapeutics has a collaboration agreement with Beckman Coulter, Inc., or Beckman Coulter, for 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.

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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 SEC did 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 the proposed merger with Cornerstone is not completed and, in January 2009, Critical Therapeutics meets all of The NASDAQ Capital Market s initial listing requirements, other than 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 in such a scenario Critical Therapeutics would comply with The NASDAQ Capital Market s initial listing requirements, including The NASDAQ Capital Market s minimum stockholders equity requirement.

On August 13, 2008, Critical Therapeutics received notification that, based on its stockholders equity of $1.2 million, as reported in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and a market value of its common stock as of August 12, 2008 of $13.0 million, Critical Therapeutics does not comply with NASDAQ Marketplace Rule 4310(c)(3), which requires it to have, for continued listing on The NASDAQ Capital Market, a minimum of $2.5 million in stockholders equity or market value of listed securities of $35.0 million or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. As a result, the Listing Qualifications Staff is reviewing Critical Therapeutics eligibility for continued listing on The NASDAQ Capital Market. To facilitate the review, Critical Therapeutics has provided to the Listing Qualifications Staff a definitive plan, based on completing the proposed merger with Cornerstone, to achieve and sustain compliance with all NASDAQ Capital Market listing requirements. If after the conclusion of its review process the Listing Qualifications Staff determines that Critical Therapeutics plan does not adequately address the deficiencies noted, the Staff will provide written notice to Critical Therapeutics that its common stock will be delisted from The NASDAQ Capital Market. In such event, Critical Therapeutics may appeal the Staff s decision to a NASDAQ Listing Qualifications Panel.

On October 3, 2008, Critical Therapeutics announced that the SEC had declared effective its Registration Statement on Form S-4 in connection with the Merger. Critical Therapeutics stockholders of record on September 29, 2008 will vote on the issuance of Critical Therapeutics shares pursuant to the merger agreement and the other proposals set forth in the proxy statement/prospectus included in the Registration Statement at a special meeting of stockholders to be held on Friday, October 31, 2008.

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 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. After September 27, 2010, DEY may terminate the co-promotion agreement with six-months prior written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if ZYFLO CR cumulative net sales, as defined in the co-promotion agreement, for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. The ZYFLO CR cumulative net sales, as defined in the

co-promotion agreement, for the four consecutive calendar quarters ending September 30, 2008 were $12.9 million. At September 30, 2008, Critical Therapeutics had $7.1 million in inventory. Critical Therapeutics expects that its inventory levels 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

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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 August and September 2008, Critical Therapeutics released and made available for shipment to wholesale distributors an aggregate of six batches of finished ZYFLO CR tablets that met its product release specifications. 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 and the release of the six batches of ZYFLO CR in August and September 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 affected 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 affected 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.

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™ (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 was 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. The total $17.9 million in initial fees and research funding was recognized over the term of the research portion of the license and collaboration agreement using the proportional performance method. All of Critical Therapeutics research activities under the research plan with MedImmune were completed in 2007.

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.

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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 $19.4 million in the nine months ended September 30, 2008 and $25.4 million in the nine months ended September 30, 2007. As of September 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $211 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 it funds its development programs, markets and sells ZYFLO CR and ZYFLO and prepares for the potential commercial launch of its product candidates. Based on its current operating plan, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will not be sufficient to fund anticipated levels of operations for the next twelve months. Based on its current liquidity plans, Critical Therapeutics would be required to raise capital in the first quarter of 2009 to continue operations. 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 resumed 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.

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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 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 September 30, 2008, $212,000 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 September 30, 2008, $1.8 million related to milestone obligations due on the second anniversary of the FDA s approval was included in Critical Therapeutics balance sheet as accrued license fees.

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 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

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, as amended. 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.

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Revenue Recognition

Revenue from Product Sales. 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. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on sales or invoice data and historical experience.

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. As of September 30, 2008, the distribution channel for ZYFLO CR, net of the return reserve, was approximately 13-16 weeks of commercial inventory based upon a range of expected patient prescriptions.

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 as the products are substantially similar.

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 and ZYFLO was $370,000 as of September 30, 2008.

Prompt Payment Discounts. Critical Therapeutics offers wholesale distributors a 2% prompt payment discount as an incentive to remit payment within the first 30 days after the date of its invoice. Because its wholesale distributors typically take the prompt payment discount, Critical Therapeutics accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of its original sale to them, and Critical Therapeutics applies earned discounts at the time of payment. Critical Therapeutics adjusts the accrual quarterly to reflect actual experience. Historically, these adjustments have not been material. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

Medicaid Rebates. Critical Therapeutics participates in state Medicaid programs. Critical Therapeutics records an accrual for rebates to be provided through the Medicaid Drug Rebate Program as a reduction of sales when the product is sold. Critical Therapeutics rebates individual states for all eligible units purchased under the Medicaid

program based on a rebate per unit calculation, which is derived from its Average Manufacturer Price. By statute, states are required to report quarterly drug utilization data to labelers participating in the Medicare or Medicaid rebate program after each reporting period. Critical Therapeutics determines its estimate of the Medicaid rebates accrual primarily based on historical experience regarding Medicaid rebates, legal interpretations of the applicable laws related to the Medicaid program and any new information regarding changes in the Medicaid programs regulations and guidelines that would impact the amount of the rebates. Critical Therapeutics adjusts the accrual rate quarterly to reflect actual experience. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

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Chargebacks. Although Critical Therapeutics sells ZYFLO and ZYFLO CR primarily to wholesale distributors, as a result of participating in the Medicaid Drug Rebate Program, certain governmental entities, such as the Department of Veterans Affairs or Department of Defense, can purchase product from its wholesalers at a specified discounted price. Critical Therapeutics provides a credit to the wholesale distributor, or a chargeback, representing the difference between the wholesale distributor s acquisition list price and the discounted price. As a result, at the time Critical Therapeutics ships the product and records the related sale, Critical Therapeutics must estimate the likelihood that its products sold to wholesale distributors might ultimately be sold to federal government entities. Critical Therapeutics determines its estimates based on the historical chargeback data Critical Therapeutics receives from wholesalers, which detail historical buying patterns and the applicable chargeback rates. Critical Therapeutics adjusts the accrual rate quarterly to reflect actual experience. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

The following table provides a summary of activity with respect to Critical Therapeutics sales allowances.

	Sales Returns	Prompt Payment Discounts	Medicaid Discounts	Chargebacks
Balance at December 31, 2007	873	25	95	13
Current provision	379	270	141	95
Changes in prior year estimate	(440)		(18)	5
Payments and credits	(442)	(222)	(169)	(99)
Balance at September 30, 2008	$ 370	$ 73	$ 49	$ 14

Revenue under Collaboration and License Agreements. 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 under its collaboration agreements 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. Critical Therapeutics assesses proportional performance based on the progress of its research and development efforts, including employees salaries and benefits, laboratory supplies and third-party research consulting fees, during the term of its agreements. Critical Therapeutics considers these to be the most reliable measure of progress. 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. In estimating the progress of its research and development activities for the research portion of the MedImmune agreement, Critical Therapeutics utilized assumptions regarding the major drivers of the program, including the proposed duration of the research term, the estimated time to complete the research phase of the program and the expected costs of personnel, laboratory supplies and third-party consulting required to complete its obligations under the research plan. As a result of a change in estimate of the term during which services would be provided from 41 to 47 months covered by its research plan with MedImmune, Critical Therapeutics decreased revenue recognized of approximately $237,000 in 2005. In addition, in 2006, Critical Therapeutics revised its estimate of remaining total research and development costs to be incurred under the collaboration agreement with MedImmune as a result of lower than expected research and development costs incurred due to more rapid advancement of the program. This change in estimate resulted in an increase in revenue recognized of approximately $2.0 million in 2006. All of Critical Therapeutics research activities under the research plan with MedImmune were completed in 2007. Critical Therapeutics had no changes in estimates related to its agreement with Beckman Coulter.

Under its agreement with MedImmune, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. Critical Therapeutics has not recorded and will not record these future development and commercialization milestones until they are achieved.

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.

Inventory

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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 September 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 September 30, 2008, Critical Therapeutics had an inventory reserve of $2.6 million. The inventory reserve includes $571,000 recorded in the fourth quarter of 2007, $622,000 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 and $133,000 in the third 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 September 30, 2008, Critical Therapeutics had $7.1 million in inventory, net of the inventory reserve. Critical Therapeutics expects its inventory levels to increase 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 Therapeutics listed price for 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 have consisted 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.

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 September 30, 2008, Critical Therapeutics held $277,000 in an auction rate security and $7.0 million in cash and cash equivalents, including money market funds and U.S. Treasury securities. During the first nine months of 2008, Critical Therapeutics was informed that there was insufficient demand at auction for the auction rate 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

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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 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 September 30, 2008 and 2007

Revenues

Revenue from Product Sales. Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of $6.0 million in the three months ended September 30, 2008, compared to $3.1 million from product sales of ZYFLO and ZYFLO CR in the three months ended September 30, 2007, an increase of $2.9 million, or 92%. The increase in product revenue is primarily attributable to a 15% increase in prescription volume over the corresponding period in 2007 and a 5% increase in the wholesale acquisition price of products sold over the corresponding period in 2007 as well as the result of an increase in the amount of ZYFLO CR purchased by wholesalers to replenish their available supplies following the shortage of commercial product that occurred in the second quarter of 2008 due to the previously disclosed supply chain issues with ZYFLO CR.

Revenue under Collaboration and License Agreements. Critical Therapeutics did not recognize any collaboration revenue in the three months ended September 30, 2008, compared to $93,000 it recognized in collaboration revenue in the three months ended September 30, 2007. License revenue for the three months ended September 30, 2007 was primarily due to $61,000 in license

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revenue related to Critical Therapeutics license agreement with SetPoint. At September 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 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 September 30, 2008 was $2.3 million, compared to $1.2 million in the three months ended September 30, 2007, an increase of $1.1 million, or 87%. Gross margin was 61% for the three months ended September 30, 2008 and 61% for the three months ended September 30, 2007. Cost of products sold in the three months ended September 30, 2008 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO CR and ZYFLO, royalties to Abbott and Jagotec AG, a subsidiary of SkyePharma, PLC, or Jagotec, related to ZYFLO and ZYFLO CR and reserves established for excess of obsolete inventory. Cost of products sold in the three months ended September 30, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalty payments to Abbott and Jagotec under the license agreement for ZYFLO CR and ZYFLO and reserves established for excess or obsolete inventory.

Critical Therapeutics recorded inventory reserves of $133,000 the three months ended September 30, 2008 and $219,000 for the three months ended September 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 ZYFLO 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 September 30, 2008 were $497,000, compared to $3.9 million in the three months ended September 30, 2007, a decrease of approximately $3.4 million, or 87%. This decrease was primarily due to lower expenses associated with Critical Therapeutics Phase IV clinical trial for ZYFLO CR, its Phase II zileuton injection clinical trial and its alpha-7 preclinical program.

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

	Three Months Ended September 30,	
	2008	2007
	(In thousands)	
Zileuton (ZYFLO and ZYFLO CR)	$ (82)	$ 1,993
Zileuton injection	165	344
CTI-01		6
Alpha-7	96	812
HMGB1	15	85
General research and development expenses	144	475
Stock-based compensation expense	159	224
Total research and development expenses	$ 497	$ 3,939

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

Zileuton (ZYFLO and ZYFLO CR). During the three months ended September 30, 2008, Critical Therapeutics did not incur any costs related to its orally dosed zileuton programs, compared to $2.0 million during the three months ended September 30, 2007. This decrease was primarily due to the following:

$480,000 reduction in salaries and other personnel related costs as a result of Critical Therapeutics May and June 2008 restructurings and a reduction in associated facilities and overhead costs;

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$1.4 million decrease in clinical and manufacturing costs related to Critical Therapeutics Phase IV clinical trial for ZYFLO CR; and

$241,000 decrease in clinical, preclinical and manufacturing costs related to Critical Therapeutics R(+) isomer program for zileuton.

Zileuton Injection. During the three months ended September 30, 2008, Critical Therapeutics incurred $165,000 in expenses related to its zileuton injection program, compared to $344,000 during the three months ended September 30, 2007, a decrease of $179,000, or 52%. This decrease 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 September 30, 2008, Critical Therapeutics incurred $96,000 in expenses related to its alpha-7 program, compared to $812,000 during the three months ended September 30, 2007, a decrease of $716,000, or 88%. 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.

HMGB1. During the three months ended September 30, 2008, Critical Therapeutics incurred $15,000 in expenses related to its HMGB1 program, compared to $85,000 in expenses during the three months ended September 30, 2007. Since the end of the second quarter of 2007, Critical Therapeutics has not conducted, and currently does not anticipate conducting in the future, any research and development activities relating to the HMGB1 program. In addition, under the terms of the agreement with MedImmune, MedImmune is responsible for all of the research and development expenses of the HMGB1 program will be assumed by MedImmune as the program advances into later stages of preclinical development. The expenses for the HMGB1 program previously borne by Critical Therapeutics 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 previous 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 $144,000 in the three months ended September 30, 2008, compared to $475,000 in the three months ended September 30, 2007, a decrease of $331,000, or 70%. 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 decreased to $159,000 in the three months ended September 30, 2008, compared to $224,000 in the three months ended September 30, 2007.

Sales and Marketing. Sales and marketing expenses for the three months ended September 30, 2008 were $1.8 million, compared to $3.6 million for the three months ended September 30, 2007, a decrease of $1.8 million, or 51%. This decrease was primarily attributable to the following:

$583,000 decrease related to amortization of Critical Therapeutics deferred sales and marketing expense;

$768,000 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;

$632,000 decrease in employee travel and other employee related expenses following Critical Therapeutics personnel reductions in 2008;

$279,000 decrease in salary and other costs related to the second quarter of 2008 reductions in Critical Therapeutics specialty sales force and sales management; and

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$250,000 decrease in consulting and market data costs.

These decreases were offset, in part, by an increase of approximately $779,000 in co-promotion fees owed to DEY in accordance with the co-promotion agreement.

The number of employees performing sales and marketing functions decreased to 29 employees at September 30, 2008 from 53 employees at September 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 cost reductions of its May and June 2008 restructuring plans.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2008 were $3.4 million, compared to $2.7 million for the three months ended September 30, 2007, an increase of $750,000, or 28%. This increase was primarily attributable to an increase of $347,000 in legal fees and an increase of $527,000 in printing and other related costs to Critical Therapeutics proposed merger with Cornerstone. These costs were offset, in part, by a decrease of $192,000 in stock-based compensation. The number of employees performing general and administrative functions was 11 employees at September 30, 2008 and 14 employees at September 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.

Other Income. Interest income for the three months ended September 30, 2008 was $10,000, compared to $474,000 for the three months ended September 30, 2007, a decrease of $464,000, or 98%. This decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to $22,000 for the three months ended September 30, 2008 and $81,000 for the three months ended September 30, 2007. Interest expense primarily relates to the accretion of the discount on Critical Therapeutics accrued second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR.

Nine months Ended September 30, 2008 and 2007

Revenues

Revenue from Product Sales. Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of $13.2 million in the nine months ended September 30, 2008, compared to revenue from product sales of ZYFLO and ZYFLO CR of $8.3 million in the nine months ended September 30, 2007, an increase of $4.9 million, or 59%. The increase in product revenue is primarily attributable to a 46% increase in prescription volume over the corresponding period in 2007 and an 11% increase in the wholesale acquisition price of products sold from the corresponding period in 2007. In addition, in the nine months ended September 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 nine months ended September 30, 2008, compared to $1.8 million recognized in collaboration and license revenue in the nine months ended September 30, 2007. Collaboration revenue for the nine months ended September 30, 2007 was primarily due to $1.1 million in license revenue related to Critical Therapeutics license agreement with SetPoint and the recognition of $400,000 of 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 nine months ended September 30, 2007 also included approximately $368,000 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 September 30, 2007.

At September 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 $7.0 million in the nine months ended September 30, 2008, compared to $2.7 million in the nine months ended September 30, 2007, an increase of $4.3 million, or 162%. Gross margin was 47% for the nine months ended September 30, 2008 and 68% for the nine months ended September 30, 2007. Cost of products sold in the nine months ended September 30, 2008 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO CR and ZYFLO, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory.

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Cost of products sold in the nine months ended September 30, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalty payments to Abbott and Jagotec under the license agreement for ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory.

Critical Therapeutics recorded inventory reserves of $2.1 million for the nine months ended September 30, 2008. The write-offs in the nine months ended September 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 recorded inventory reserves of $219,000 during the nine months ended September 30, 2007.

Research and Development Expenses. Research and development expenses in the nine months ended September 30, 2008 were $7.4 million, compared to $17.0 million in the nine months ended September 30, 2007, a decrease of approximately $9.5 million, or 56%. 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 nine months ended September 30, 2008 and 2007:

	Nine months Ended September 30,	
	2008	2007
	(In thousands)	
Zileuton (ZYFLO and ZYFLO CR)	$ 3,458	$ 11,867
Zileuton injection	1,605	658
CTI-01		(78)
Alpha-7	1,142	2,659
HMGB1	18	294
General research and development expenses	552	799
Stock-based compensation expense	649	762
Total research and development expenses	$ 7,424	$ 16,961

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

Zileuton (ZYFLO and ZYFLO CR). During the nine months ended September 30, 2008, Critical Therapeutics incurred $3.5 million in expenses related to its orally dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $11.9 million during the nine months ended September 30, 2007, a decrease of $8.4 million, or 71%. 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;
- $1.5 million reduction in salaries and related costs as a result of Critical Therapeutics 2008 restructurings and a reduction in associated facilities and overhead costs;
- $667,000 decrease in clinical and manufacturing costs related to Critical Therapeutics R(+) isomer program for zileuton; and

$145,000 decrease in clinical and manufacturing costs related to Critical Therapeutics Phase IV clinical trial for ZYFLO CR, which was discontinued in March 2008.

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.

Zileuton Injection. During the nine months ended September 30, 2008, Critical Therapeutics incurred $1.6 million in expenses related to its zileuton injection program, compared to $658,000 during the nine months ended September 30, 2007, an increase of $947,000, or 144%. This increase was primarily due to clinical trial expenses related to the Phase II clinical trial, which concluded in the first half of 2008.

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CTI-01. During the nine months ended September 30, 2008, Critical Therapeutics did not incur any costs related to its CTI-01 program. During the nine months ended September 30, 2007, Critical Therapeutics received a net credit of $78,000 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 nine months ended September 30, 2008, Critical Therapeutics incurred $1.1 million of expenses related to its alpha-7 program, compared to $2.7 million during the nine months ended September 30, 2007, a decrease of $1.5 million, or 57%. 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 nine months ended September 30, 2008, Critical Therapeutics incurred $18,000 of expenses related to its HMGB1 program, compared to $294,000 during the nine months ended September 30, 2007, a decrease of $276,000, or 94%. 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 $552,000 in the nine months ended September 30, 2008, compared to $799,000 in the nine months ended September 30, 2007, a decrease of $247,000, or 31%. 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 $649,000 in the nine months ended September 30, 2008, compared to $762,000 in the nine months ended September 30, 2007, a decrease of $113,000, or 15%. 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 nine months ended September 30, 2008 were $7.8 million, compared to $8.2 million for the nine months ended September 30, 2007. The $357,000, or 4%, decrease was primarily attributable to the following:

$1.2 million decrease related to amortization of Critical Therapeutics deferred sales and marketing expense;

$858,000 decrease related to marketing expenses to be reimbursed by DEY associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement;

$317,000 decrease in sample costs; and

$270,000 decrease in consulting costs.

These decreases were partially offset by the following:

$1.4 million increase in co-promotion fees owed to DEY;

$702,000 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

$207,000 increase in salary and other employee related costs.

The number of employees performing sales and marketing functions decreased to 29 employees at September 30, 2008 from 53 employees at September 30, 2007.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2008 were $9.4 million, compared to $9.2 million for the nine months ended September 30, 2007, an increase of $172,000, or 2%. This increase was primarily due to an increase of $1.1 million in legal fees and an increase of $495,000 in printing and other related costs to Critical Therapeutics proposed merger with Cornerstone and a

$105,000 increase in salary and other employee related costs. These increases were offset, in part, by a decrease of $842,000 in consulting costs, a decrease of $603,000 in stock-based compensation expense and a decrease of $104,000 in depreciation expense. The number of employees performing general and administrative functions was 11 employees at September 30, 2008 and 14 employees at September 30, 2007.

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Restructuring Charges. Restructuring charges totaled $1.2 million in the first nine months of 2008 related to actions Critical Therapeutics took in the second quarter of 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 nine months ended September 30, 2008 was $299,000, compared to $1.6 million for the nine months ended September 30, 2007, a decrease of $1.3 million, or 82%. This decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to $107,000 for the nine months ended September 30, 2008 and $150,000 for the nine months ended September 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 September 30, 2008, Critical Therapeutics had $7.3 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 September 30, 2008 for milestone payments and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program. As of September 30, 2008, Critical Therapeutics had completed the research term of its agreement with MedImmune and will not conduct any future research or development activities under this agreement.

Under its agreement with MedImmune, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124.0 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. Critical Therapeutics has not recorded and will not record these future development and commercialization milestones until they are achieved.

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 $27.1 million for the nine months ended September 30, 2008, compared to $14.7 million for the nine months ended September 30, 2007, an increase of $12.5 million, or 85%. Net cash used in operations for the nine months ended September 30, 2008 consisted of a net loss of $19.4 million, depreciation and amortization expense, the amortization of premiums on short-term investments, the gain on the disposal of fixed assets and impairment charge on fixed assets of $692,000, stock-based compensation expense of $2.1 million and a $10.5 million decrease as a result of changes in the working capital accounts. This $10.5 million decrease was primarily due to a $1.5 million increase in inventory, a $2.4 million increase in accounts receivable, a $1.9 million decrease in accrued license fees and a $3.8 million reduction in its accounts payable and accrued

expenses.

Investing Activities. Investing activities provided $677,000 of net cash in the nine months ended September 30, 2008, compared to $509,000 in the nine months ended September 30, 2007, an increase of $168,000, or 33%. During the nine months ended September 30, 2008, Critical Therapeutics made minimal capital expenditures. Net cash provided by investing activities for the nine months ended September 30, 2008 primarily related to proceeds from Critical Therapeutics sale of assets of $278,000 and its sale of its SetPoint junior preferred 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 nine months ended September 30, 2008, Critical Therapeutics used $370,000 of net cash in financing activities, compared to $537,000 in the nine months ended September 30, 2007. Net cash used in financing activities for the nine months ended September 30, 2008 primarily related to the repayment of long-term debt.

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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. 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 $19.4 million in the nine months ended September 30, 2008 and $25.4 million in the nine months ended September 30, 2007. As of September 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $211 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. Based on its current operating plan, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will not be sufficient to fund anticipated levels of operations for the next twelve months. Based on its current liquidity plans, Critical Therapeutics would be required to raise capital in the first quarter of 2009 to continue operations. 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 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 collaboration agreements with MedImmune and Beckman Coulter, sales of ZYFLO CR and ZYFLO represent Critical Therapeutics only sources of cash flows and revenue. In addition to

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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 nine months ended September 30, 2008, Critical Therapeutics net cash used for operating activities was $27.1 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 stockholders. For example, if Critical Therapeutics raises additional funds by issuing equity securities, further dilution to Critical Therapeutics then-existing stockholders will result. Such equity securities may have rights and preferences superior to those of the holders of Critical Therapeutics common stock. If Critical Therapeutics is unable to obtain funding on a timely basis, Critical Therapeutics may be required to significantly delay, limit or eliminate one or more of its development or commercialization programs, which could harm its financial condition and operating results. Critical Therapeutics also could be required to seek funds through arrangements with collaborators or others that may require Critical Therapeutics to relinquish rights to some of its technologies, product candidates or products, which Critical Therapeutics would otherwise pursue on its own.

Contractual Obligations

Critical Therapeutics has summarized in the table below its fixed contractual obligations as of September 30, 2008:

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than One Year**	**One to Three Years**	**Three to Five Years**	**More Than Five Years**
			(In thousands)		
Manufacturing and clinical trial agreements	$ 14,332	$ 7,933	$ 6,391	$ 8	$
Research and license agreements	7,665	2,050	885	920	3,810
Marketing costs	6,601	2,851	3,750		
Severance agreements	346	346			
Lease obligations	169	169			
Total contractual cash obligations	$ 29,113	$ 13,349	$ 11,026	$ 928	$ 3,810

The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. On August 20, 2007, Critical Therapeutics entered into an agreement with Jagotec, under which Jagotec agreed to manufacture and supply bulk ZYFLO CR tablet cores for commercial sale. Critical Therapeutics has agreed to purchase minimum quantities of ZYFLO CR tablet cores during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. Critical Therapeutics has committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 20, 2008. For the term of the contract, Critical Therapeutics 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 Critical Therapeutics provides Jagotec with 24-months prior written notice of termination or Jagotec provides Critical Therapeutics with 36-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents it from importing, exporting or selling ZYFLO CR. Critical Therapeutics also may terminate the agreement upon six-months advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and it determines to permanently cease commercialization of ZYFLO CR. Likewise, Critical Therapeutics may terminate the agreement upon 12-months advance notice if it intends to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, Critical Therapeutics has agreed to purchase 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

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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. 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 September 30, 2008, Critical Therapeutics has made aggregate milestone payments of $9.3 million to Abbott under its license agreements related to ZYFLO and ZYFLO CR and, as of September 30, 2008, has included $1.5 million in accrued license fees related to the achievement of the second 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 September 30, 2008, Critical Therapeutics has made aggregate milestone payments of $3.4 million to Jagotec under its agreement and, as of September 30, 2008, has included $363,000 in accrued license fees related to the achievement of the second 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 second anniversary milestone payments related to the FDA s approval of ZYFLO CR due to Abbott and Jagotec totaling $1.9 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 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 September 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. 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

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In November 2007, the FASB, Emerging Issues Task Force, or EITF, issued EITF Issue No. 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 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. 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. Critical Therapeutics 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 No. 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 requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. Critical Therapeutics 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 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 shall be 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

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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 and has included the now expanded disclosures in Note 3. 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 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 September 30, 2008, Critical Therapeutics estimates that the fair value of its investment portfolio would not change by a material amount. 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. At September 30, 2008, Critical Therapeutics had an investment with a carrying value of $277,000 in an auction rate security with a AAA credit rating upon purchase and $7.0 million in cash and cash equivalents, including money market funds and U.S. Treasury securities. 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 September 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 September 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 September 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.***

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its directors in the Court of Chancery of The State of Delaware. The action is *captioned Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George* (Case No. 4039, Court of Chancery, State of Delaware). The plaintiff, which claims to be a stockholder of Critical Therapeutics, brought the lawsuit on

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its own behalf, and is seeking certification of the lawsuit as a class action on behalf of all stockholders of Critical Therapeutics, except the defendants and their affiliates. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties, (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties, (iv) in the event the proposed merger is consummated, rescinding it and setting it aside or awarding rescissory damages, (v) awarding compensatory damages against defendants, jointly and severally, and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, Critical Therapeutics and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that Critical Therapeutics would make certain additional disclosures to its stockholders, which are contained in a supplement to the proxy statement/prospectus that has been mailed to Critical Therapeutics s stockholders. Subject to the completion of certain confirmatory discovery by counsel to the plaintiff, the memorandum of understanding contemplates that the parties will enter into a stipulation of settlement. The stipulation of settlement will be subject to customary conditions, including court approval. If the court approves the settlement, the settlement will resolve all of the claims that were or could have been brought in the action being settled, including all claims relating to the merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the parties contemplate that plaintiff s counsel will petition the court for an award of attorneys fees and expenses to be paid by Critical Therapeutics, the amount of which will either be agreed to by the parties or awarded by the court.

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.

Risks Relating to the Proposed Merger with Cornerstone

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

On May 1, 2008, Critical Therapeutics entered into a merger agreement with Cornerstone. If the merger is completed, at the effective time of the merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of 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 proposed merger with Cornerstone is subject to a number of closing conditions, including the approval by 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.

If the proposed merger is not consummated, Critical Therapeutics may be subject to the following risks:

Critical Therapeutics has incurred and expects to continue to incur significant expenses related to the proposed merger with Cornerstone. As of September 30, 2008, Critical Therapeutics had approximately $2.3 million of fees and expenses billed and accrued in connection with the proposed merger for legal, financial advisory, accounting and other services. These fees and expenses are payable by Critical Therapeutics even if the merger is not consummated.

If the merger agreement is terminated, 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 would not be obligated to pay Cornerstone the $1.0 million termination fee if Critical Therapeutics stockholders fail to approve the proposals presented at the special meeting unless at or prior to the time of such failure an acquisition proposal relating to Critical Therapeutics was announced and was not abandoned or withdrawn.

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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.

The market price of Critical Therapeutics common stock may decline further 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.

If the Delaware Court of Chancery enjoins Critical Therapeutics from proceeding with the merger, Critical Therapeutics will have a limited ability to continue its current operations if a third party is unwilling to provide equivalent or more attractive consideration than proposed in connection with the proposed merger with Cornerstone.

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its directors in the Court of Chancery of The State of Delaware. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties; (iii) ordering defendants to explore alternatives and to negotiate in good faith with all *bona fide* interested parties; (iv) in the event the proposed merger is consummated, rescinding it and setting it aside or awarding rescissory damages; (v) awarding compensatory damages against defendants, jointly and severally; and (vi) awarding the plaintiff and the purported class their costs and fees.

If the Court of Chancery enjoins Critical Therapeutics from proceeding with the merger and the merger is not consummated, Critical Therapeutics may be subject to each of the risks described in the immediately preceding risk factor. In particular, if the proposed merger with Cornerstone is not consummated, Critical Therapeutics will have a limited ability to continue its current operations without obtaining additional financing. If 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 addition, defending against the lawsuit will be costly and time consuming for Critical Therapeutics and may distract Critical Therapeutics management from day to day operations. If the lawsuit is successful, Critical Therapeutics could be required to pay monetary damages and the plaintiffs costs and fees.

On October 17, 2008, Critical Therapeutics and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that Critical Therapeutics would make certain additional disclosures to its stockholders, which are contained in a supplement to the proxy statement/prospectus that has been mailed to Critical Therapeutics s stockholders. Subject to the completion of certain confirmatory discovery by counsel to the plaintiff, the memorandum of understanding contemplates that the parties will enter into a stipulation of settlement. The stipulation of settlement will be subject to customary conditions, including court approval. If the court approves the settlement, the settlement will resolve all of the claims that were or could have been brought in the action being settled, including all claims relating to the merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the parties contemplate that plaintiff s counsel will petition the court for an award of attorneys fees and expenses to be paid by Critical Therapeutics, the amount of which will either be agreed to by the parties or awarded by the court.

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. While the merger agreement is in effect and subject to limited exceptions, Critical Therapeutics 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 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, a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to Critical Therapeutics stockholders.

Negative perceptions regarding the pending merger may harm Critical Therapeutics business and employee relationships.

During the pendency of the merger, uncertainty or negative perceptions regarding the merger or the combined company s business and prospects could harm relationships that Critical Therapeutics has established as an independent, standalone company. For example:

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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 the ability of Critical Therapeutics to retain its key employees, who may seek other employment opportunities.

In addition, during the pendency of the merger, the management team of Critical Therapeutics may be distracted from day to day operations as a result of the proposed merger.

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 resumed the supply of ZYFLO in September 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. In the nine months ended September 30, 2008, Critical Therapeutics experienced supply chain issues in manufacturing ZYFLO CR and recorded an inventory reserve for an aggregate of 12 batches of ZYFLO CR that could not be released into Critical Therapeutics supply chain. If Critical Therapeutics is unable to manufacture or release ZYFLO CR on a timely and consistent basis, some physicians may prescribe ZYFLO to ensure that their patients with asthma continue to have access to zileuton as a treatment option. ZYFLO, which is dosed four times per day, contains the same zileuton active pharmaceutical ingredient, or API, as ZYFLO CR, which is dosed two tablets twice daily. When prescribed as indicated in their respective labels, both ZYFLO CR and ZYFLO provide a patient with 2,400 mg of zileuton per day. Both ZYFLO CR and ZYFLO are approved by the FDA for the same indication.

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.

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 $875,000 for the nine months ended September 30, 2008. Critical Therapeutics recorded revenue from the sale of ZYFLO CR of $2.3 million for the

year ended December 31, 2007 and $12.3 million for the nine months ended September 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 tablet four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two tablets twice daily, or if patients do not comply with the dosing schedule and take less than

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the prescribed number of tablets, Critical Therapeutics sales of ZYFLO CR will be limited and Critical Therapeutics revenues will be adversely affected.

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 most instances, ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR.

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.

Concerns regarding the safety profile of ZYFLO CR may limit market acceptance of ZYFLO CR, and, if significant adverse events related to ZYFLO CR occur, Critical Therapeutics may be exposed to product liability claims.

Market perceptions about the safety of ZYFLO also may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of 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 Therapeutics revise the labeling of ZYFLO and ZYFLO CR to include statements regarding the potential for suicidal thoughts or other behavior-related changes 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.

If the use of ZYFLO CR or ZYFLO harms people, Critical Therapeutics may be subject to costly and damaging product liability claims. Critical Therapeutics currently has products liability insurance coverage for the policy year starting October 29, 2007 with a $20.0 million annual aggregate limit and a $20.0 million individual claim limit, which is subject to a per claim deductible and a policy aggregate deductible. This product liability insurance covers both product liability claims for ZYFLO CR and ZYFLO and clinical trial liability claims for Critical Therapeutics product candidates. The annual cost of this products liability insurance was approximately $400,000 for the policy year starting October 29, 2007. This insurance policy may not provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, Critical Therapeutics may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that Critical Therapeutics has not anticipated in its

business plans. Any product liability claim against Critical Therapeutics, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention and harm Critical Therapeutics reputation.

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. As of September 30, 2008, Critical Therapeutics s sales force is approximately 26 sales representatives. Building Critical Therapeutics

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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, L.P., a wholly owned subsidiary of Mylan Inc., or 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™ (formoterol fumarate) Inhalation Solution, or PERFOROMIST, for the long-term, twice-daily maintenance treatment of bronchoconstriction for emphysema and chronic bronchitis, which is also known as chronic obstructive pulmonary disease, or COPD. Under the PERFOROMIST co-promotion agreement, DEY agreed to pay 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.

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 nine months ended September 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. Critical Therapeutics has committed to purchase a minimum amount of zileuton API from Shasun of $2.0 million in 2008 and $2.0 million in 2009, although Critical Therapeutics has the right to reduce by $1.3 million the amount of zileuton API it must purchase in 2009 by providing written notice to Shasun no later than December 31, 2008. The API purchased from Shasun currently has a shelf-life of 36 months. In addition, Critical Therapeutics has committed

to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 30, 2008. 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 September 30, 2008, Critical Therapeutics had $7.1 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 nine months ended September 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

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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 manufacturing timelines specified pursuant to the new drug application, or NDA, for ZYFLO CR. 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.

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 Ingleheim GmbH and Pfizer. Other novel approaches are also in development.

Critical Therapeutics is also developing 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

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

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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.

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

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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. This material weakness related to the operation of controls over accounting for non-routine transactions, specifically the accrual of milestone obligations due under certain of Critical Therapeutics contractual arrangements in accordance with GAAP. As a result of this material weakness, a material adjustment was recorded to Critical Therapeutics draft interim financial statements after the financial close of the second quarter of 2007. While Critical Therapeutics internal disclosure controls and procedures detected the need to accrue for the milestone obligations, Critical Therapeutics did not initially reach the appropriate conclusion relative to the timing of the accrual recognition. 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 September 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.

Risks Relating to Critical Therapeutics Dependence on Third Parties

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

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

Critical Therapeutics has contracted with Shasun Pharma Solutions Ltd., or Shasun, for commercial production of the zileuton API, subject to specified limitations, through December 31, 2010. Zileuton API is used in Critical Therapeutics FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in Critical Therapeutics zileuton injection product candidate. Critical Therapeutics only source of supply for zileuton API is Shasun, which

manufactures the zileuton API in the United Kingdom. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture API for Critical Therapeutics.

Critical Therapeutics has contracted with Jagotec AG, or Jagotec, a subsidiary of SkyePharma PLC, or SkyePharma, for the manufacture of core tablets for ZYFLO CR for commercial sale. Critical Therapeutics only source of supply for the core tablets

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of ZYFLO CR is Jagotec, which manufactures them in France. The manufacture of the core tablets for ZYFLO CR could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

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

Critical Therapeutics has contracted with Patheon to manufacture ZYFLO tablets for commercial sale. Patheon is currently Critical Therapeutics only source of finished ZYFLO tablets. The manufacture of the finished ZYFLO tablets could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

Critical Therapeutics is dependent upon Shasun, Patheon and Jagotec as sole providers, and will be dependent on any other third parties who manufacture Critical Therapeutics product candidates, to perform their obligations in a timely manner and in accordance with applicable government regulations. If third-party manufacturers with whom Critical Therapeutics contracts fail to perform their obligations, Critical Therapeutics may be adversely affected in a number of ways, including the following:

- Critical Therapeutics may not be able to meet commercial demands for ZYFLO CR and ZYFLO;
- Critical Therapeutics may be required to cease distribution or issue recalls;
- Critical Therapeutics may not be able to initiate or continue clinical trials of its product candidates that are under development; and
- Critical Therapeutics may be delayed in submitting applications for regulatory approvals for its product candidates.

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

The zileuton API is manufactured in the United Kingdom by Shasun, and Critical Therapeutics either stores the zileuton API at a Shasun warehouse or ships the zileuton API either directly to a contract manufacturer or to a third-party warehouse. For the manufacture of ZYFLO CR, Critical Therapeutics ships zileuton API to France for manufacturing of core tablets by Jagotec and Critical Therapeutics ships core tablets from France to the United States to be coated, packaged and labeled at Patheon. For the manufacture of ZYFLO, Critical Therapeutics ships zileuton API to the United States to be manufactured, packaged and labeled at Patheon. While in transit, Critical Therapeutics zileuton API and ZYFLO CR core tablets, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment from Shasun, Critical Therapeutics zileuton API, which is stored in France at Jagotec or in the United States at Patheon or at third-party warehouse, or Critical Therapeutics ZYFLO CR core tablets, which are stored at Patheon prior to coating and packaging, and Critical Therapeutics finished ZYFLO CR and ZYFLO products, which are stored at Critical Therapeutics third-party logistics provider, Integrated Commercialization Solutions, Inc., or ICS, could be lost or suffer damage, which would render them unusable. Critical Therapeutics has attempted to take appropriate risk mitigation steps and to obtain transit insurance. However, depending on when in the process the zileuton API, ZYFLO CR core tablets or finished product is lost or damaged, Critical Therapeutics may have limited recourse for recovery against its manufacturers or insurers. As a result, Critical Therapeutics financial performance could be impacted by any such loss or damage to its zileuton API, ZYFLO CR

core tablets or finished products.

Critical Therapeutics may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If Critical Therapeutics were required to change manufacturers for the zileuton API, ZYFLO CR tablet cores, ZYFLO or ZYFLO CR or coating, Critical Therapeutics would be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, Critical Therapeutics would be required to conduct additional clinical bioequivalence trials to demonstrate that the finished product manufactured by the new manufacturer is equivalent to the finished product manufactured by Critical Therapeutics current manufacturer. Any delays associated with the verification of a new manufacturer or conducting additional clinical bioequivalence trials could adversely affect Critical Therapeutics production schedule or increase Critical Therapeutics production costs.

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

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

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 could not be 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 could not complete manufacturing within the NDA-specified manufacturing timelines. 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. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton 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 August and September 2008, Critical Therapeutics released and made available for shipment to wholesale distributors an aggregate of six batches of finished ZYFLO CR tablets that met its product release specifications. 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 and the release of six batches of ZYFLO CR in August and September 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.

If Critical Therapeutics investigation regarding its supply chain requires changes to its manufacturing processes or materials in order to be able to supply sufficient levels of ZYFLO CR to satisfy its commercial needs, the costs to manufacture ZYFLO CR may be significantly higher than Critical Therapeutics had anticipated. As of September 30, 2008, Critical Therapeutics has expensed $2.6 million relating to the aggregate of nine batches of ZYFLO CR that failed to meet product release specifications and the seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA- specified manufacturing timelines. In addition, Critical Therapeutics expects to incur other significant costs in connection with its investigation. If Critical Therapeutics is not able to supply ZYFLO CR at a commercially acceptable cost and level, Critical Therapeutics could experience cash flow difficulties and additional financial losses. Depending on the outcome of the investigation, Critical Therapeutics may not be able to obtain reimbursement from any of its third-party manufacturers for existing or additional batches of ZYFLO CR that do not meet Critical Therapeutics product release specifications.

In April 2008, Critical Therapeutics began to reinitiate manufacture of ZYFLO in order to have a supply of ZYFLO available to reinitiate marketing and supply of ZYFLO to the market given the supply chain issues being experienced for ZYFLO CR. In September 2008, Critical Therapeutics resumed distribution of ZYFLO to help manage the potential impact to patients of supply chain issues for ZYFLO CR. However, reintroducing ZYFLO could be confusing for physicians and patients, and possibly third party wholesalers and retailers. As a result of this potential confusion relating to the reintroduction of ZYFLO to the market and ZYFLO s less convenient four times daily dosing regimen, Critical Therapeutics sales of ZYFLO will likely not meet either the level of sales of ZYFLO CR since its

market launch in September 2007 or the historical level of sales of ZYFLO prior to the market launch of ZYFLO CR. Under the merger agreement, it is a condition to Cornerstone s obligation to consummate the merger that either ZYFLO CR or ZYFLO must be available and ready for purchase by third-party wholesalers or retailers during the period prior to the closing of the merger, other than during any period not exceeding 30 consecutive days. If the proposed merger with Cornerstone is not consummated, Critical Therapeutics would be subject to all of the additional risks described above under Risks Related to the Merger .

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

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Critical Therapeutics relies on third parties to distribute ZYFLO CR and ZYFLO to pharmacies. Critical Therapeutics has contracted with ICS, a third-party logistics company, to warehouse and distribute ZYFLO CR and ZYFLO to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. ICS is Critical Therapeutics exclusive supplier of commercial distribution logistics services. The wholesalers in turn distribute to chain and independent pharmacies. Sales to AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation collectively accounted for at least 95% of Critical Therapeutics annual billings for ZYFLO CR and ZYFLO during 2007. The loss of any of these wholesaler customers accounts or a material reduction in their purchases could harm Critical Therapeutics business, financial condition and results of operations.

Critical Therapeutics distribution network requires significant coordination with Critical Therapeutics supply chain, sales and marketing and finance organizations. Failure to maintain Critical Therapeutics contracts with ICS, the wholesalers, or the inability or failure of any of them to adequately perform as agreed under their respective contracts with Critical Therapeutics, could negatively impact Critical Therapeutics. Critical Therapeutics does not have its own warehouse or distribution capabilities, Critical Therapeutics lacks the resources and experience to establish any of these functions and Critical Therapeutics does not intend to establish these functions in the foreseeable future. If Critical Therapeutics was unable to replace ICS, AmerisourceBergen, Cardinal Health or McKesson Corporation in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting any of them, the distribution of ZYFLO CR and ZYFLO could be delayed or interrupted, which would damage Critical Therapeutics results of operations and market position. Failure to coordinate financial systems could also negatively impact Critical Therapeutics ability to accurately report and forecast product sales and fulfill Critical Therapeutics regulatory obligations. If Critical Therapeutics is unable to effectively manage and maintain its distribution network, sales of ZYFLO CR and ZYFLO could be severely compromised and Critical Therapeutics business could be harmed.

Critical Therapeutics depends on DEY to jointly promote and market ZYFLO CR. This co-promotion arrangement may not be successful.

Critical Therapeutics is relying on DEY to jointly promote and market ZYFLO CR. ZYFLO CR and ZYFLO are Critical Therapeutics only commercially marketed products. Critical Therapeutics ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of Critical Therapeutics co-promotion arrangement with DEY. DEY initiated promotional detailing activities for ZYFLO CR in September 2007 after initiating promotional detailing for ZYFLO in April 2007.

After September 27, 2010, DEY may terminate the co-promotion agreement with six-months prior written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if ZYFLO CR cumulative net sales, as defined in the co-promotion agreement, for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. The ZYFLO CR cumulative net sales, as defined in the co-promotion agreement, for the four consecutive calendar quarters ended September 30, 2008 were $12.9 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party. Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In particular, both Critical Therapeutics and DEY have agreed to provide a minimum number of details per month for ZYFLO CR.

If DEY were to terminate or breach the co-promotion agreement, and Critical Therapeutics was unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promoting and marketing ZYFLO CR, Critical Therapeutics sales of ZYFLO CR would be limited and Critical Therapeutics would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. DEY is a subsidiary of Mylan. Mylan acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic business, of which DEY was a part. Critical Therapeutics cannot predict what impact Mylan s acquisition of DEY may have on Critical Therapeutics co-promotion arrangement with DEY. For example, in February 2008, Mylan announced that it is pursuing strategic alternatives for DEY, including the potential sale of the business. Any decision by DEY or Mylan

not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit Critical Therapeutics ability to generate significant revenues from product sales. Furthermore, if DEY does not have sufficient sales capabilities, as a result of difficulty retaining or hiring sales representatives following Mylan s announcement that it is pursuing strategic alternatives for DEY or otherwise, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

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

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Critical Therapeutics is relying on MedImmune, Inc., a wholly owned subsidiary of AstraZeneca PLC, or MedImmune, to fund the development of and to commercialize product candidates in Critical Therapeutics HMGB1 program. Critical Therapeutics is relying on Beckman Coulter, Inc., or Beckman Coulter, to fund the development and to commercialize diagnostics in Critical Therapeutics HMGB1 program. All of Critical Therapeutics revenues prior to October 2005, when Critical Therapeutics commercially launched ZYFLO, were derived from Critical Therapeutics collaboration agreements with MedImmune and Beckman Coulter. Additional payments due to Critical Therapeutics under the collaboration agreements with MedImmune and Beckman Coulter are generally based on the achievement of specific development and commercialization milestones that may not be met. In addition, the collaboration agreements entitle Critical Therapeutics to royalty payments that are based on the sales of products developed and marketed through the collaborations. These future royalty payments may not materialize or may be less than expected if the related products are not successfully developed or marketed or if Critical Therapeutics is forced to license intellectual property to continue to generate revenues for Critical Therapeutics.

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

Critical Therapeutics license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party. If Beckman Coulter were to terminate or breach Critical Therapeutics arrangement, and Critical Therapeutics was unable to enter into a similar agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on its own, the development and commercialization of a diagnostic based on the detection of HMGB1 likely would be delayed, curtailed or terminated.

In addition, Critical Therapeutics collaborations with MedImmune and Beckman Coulter and any future collaborative arrangements that Critical Therapeutics enters into with third parties may not be scientifically or commercially successful. Factors that may affect the success of Critical Therapeutics collaborations include the following:

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

- reductions in marketing or sales efforts or a discontinuation of marketing or sales of Critical Therapeutics products by Critical Therapeutics collaborators would reduce Critical Therapeutics revenues, which Critical Therapeutics expects will be based on a percentage of net sales by collaborators;

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

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

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

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

Critical Therapeutics may seek to enter into collaboration agreements with other parties in the future that relate to Critical Therapeutics other product candidates, and Critical Therapeutics is likely to have similar risks with regard to any such future collaborations.

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

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

If Critical Therapeutics is unable to enter into additional collaboration agreements, Critical Therapeutics may not be able to continue development of its product candidates.

Critical Therapeutics drug development programs and potential commercialization of Critical Therapeutics product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. Critical Therapeutics may seek to enter into additional collaboration agreements with pharmaceutical or biotechnology companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, Critical Therapeutics has determined as a strategic matter to seek to enter into collaboration arrangements with respect to the development of its alpha-7 product candidates and its zileuton injection product candidate. Critical Therapeutics is not currently actively engaged in negotiations with respect to and has no current understandings, agreements or commitments for any such collaboration arrangements. Critical Therapeutics faces, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. Critical Therapeutics may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to Critical Therapeutics. If Critical Therapeutics is not successful in its efforts to enter into a collaboration arrangement with respect to a product candidate, Critical Therapeutics may not have sufficient funds to develop any of its product candidates internally. If Critical Therapeutics does not have sufficient funds to develop its product candidates, Critical Therapeutics will not be able to bring these product candidates to market and generate revenue. In addition, Critical Therapeutics inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on Critical Therapeutics financial condition and results of operations because:

Critical Therapeutics may be required to expend its own funds to advance the product candidate to commercialization;

revenue from product sales could be delayed; or

Critical Therapeutics may elect not to develop or commercialize the product candidate.

Critical Therapeutics plans to rely significantly on third parties to market some product candidates, and these third parties may not successfully commercialize these product candidates.

For product candidates with large target physician markets, Critical Therapeutics plans to rely significantly on sales, marketing and distribution arrangements with third parties. For example, Critical Therapeutics relies on MedImmune for the commercialization of any anti-HMGB1 products that are developed under the exclusive license and collaboration agreement between the parties, and Critical Therapeutics plans to rely on Beckman Coulter for the commercialization of any diagnostic assay for HMGB1. Critical Therapeutics may not be successful in entering into additional marketing arrangements in the future and, even if successful, Critical Therapeutics may not be able to enter into these arrangements on terms that are favorable to Critical Therapeutics. In addition, Critical Therapeutics may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, Critical Therapeutics future revenues may suffer.

Risks Relating to Critical Therapeutics Financial Results and Need for Additional Financing

Critical Therapeutics has incurred losses since inception and Critical Therapeutics anticipates that it will continue to incur losses for the foreseeable future. If Critical Therapeutics does not generate significant revenues, Critical Therapeutics will not be able to achieve profitability.

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 $19.4 million in the nine months ended September 30, 2008 and $25.4 million in the nine months ended September 30, 2007. As of September 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $211 million. Critical Therapeutics recorded revenue from the sale of ZYFLO and ZYFLO CR of $11.0 million for the year ended December 31, 2007 and $13.2 million for the nine months ended September 30, 2008. Critical Therapeutics has not

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recorded revenue from any products other than ZYFLO CR and ZYFLO. 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. Critical Therapeutics expects that the losses that it incurs will fluctuate from quarter to quarter and that these fluctuations may be substantial. Critical Therapeutics will need to generate significant revenues to achieve profitability. Until Critical Therapeutics is able to generate such revenues, it will not be profitable and will need to raise substantial additional capital to fund its operations.

Critical Therapeutics will require substantial additional capital to fund its operations. If additional capital is not available, Critical Therapeutics may need to delay, limit or eliminate its development and commercialization efforts.

Critical Therapeutics expects to devote substantial resources to support ongoing sales and marketing efforts for ZYFLO CR and to fund the development of its other product candidates. 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.

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 flow and revenue. Critical Therapeutics believes that its ability to access external funds will depend upon market acceptance of ZYFLO CR, the success of Critical Therapeutics other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, Critical Therapeutics 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 Critical Therapeutics ability to successfully commercialize ZYFLO CR. Based on Critical Therapeutics current 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.

Critical Therapeutics net cash used for operating activities was $14.4 million for the year ended December 31, 2007 and $27.1 million for the nine months ended September 30, 2008. Critical Therapeutics had minimal capital expenditures for the nine months ended September 30, 2008. If Critical Therapeutics existing resources are insufficient to satisfy its liquidity requirements or if Critical Therapeutics acquires or licenses rights to additional products or product candidates, Critical Therapeutics may need to raise additional external funds through collaborative arrangements and public or private financings. Under Critical Therapeutics merger agreement with Cornerstone, any financing transaction would require Cornerstone s consent. Additional financing may not be available to Critical Therapeutics on acceptable terms or at all. If Critical Therapeutics is unable to obtain

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funding on a timely basis, Critical Therapeutics may be required to significantly delay, limit or eliminate one or more of its research, development or commercialization programs, which could harm its financial condition and operating results.

Even if Critical Therapeutics is able to obtain additional capital to fund its operations, the terms may not be favorable to Critical Therapeutics or its stockholders.

If Critical Therapeutics future capital requirements require it to raise additional external funds, collaborative arrangements or public or private financings may only be available on unfavorable terms. For example, arrangements with collaborators or others may require Critical Therapeutics to relinquish valuable rights to its technologies, product candidates or products, which Critical Therapeutics would otherwise pursue on its own. In addition, debt financing, if available, may involve agreements that include covenants limiting or restricting Critical Therapeutics ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Critical Therapeutics raises additional funds by issuing equity securities, stockholders will experience dilution. Furthermore, any debt financing or additional equity that Critical Therapeutics raises may contain terms, such as liquidation and other preferences, that are not favorable to Critical Therapeutics or its stockholders.

The audit report issued by Critical Therapeutics independent registered public accounting firm stating that there is substantial doubt about Critical Therapeutics ability to continue as a going concern could make it more difficult for Critical Therapeutics to obtain additional financing.

As a result of Critical Therapeutics recurring losses from operations, accumulated deficit and Critical Therapeutics expectation that it will incur substantial additional operating costs for the foreseeable future, as discussed in Note 1 to Critical Therapeutics consolidated financial statements included in Critical Therapeutics Annual Report on Form 10-K for the year ended December 31, 2007, as amended, 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 Critical Therapeutics 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 its ability to continue as a going concern may make it more difficult for Critical Therapeutics to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, suppliers and employees.

If the estimates Critical Therapeutics makes, or the assumptions on which Critical Therapeutics relies, in preparing its financial statements prove inaccurate, Critical Therapeutics actual results may vary from those reflected in its projections.

Critical Therapeutics financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires Critical Therapeutics to make estimates and judgments that affect the reported amounts of Critical Therapeutics assets, liabilities, revenues and expenses, the amounts of charges accrued by Critical Therapeutics and related disclosure of contingent assets and liabilities. Critical Therapeutics bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. For example, Critical Therapeutics reserve for potential returns for ZYFLO CR and ZYFLO is based on its historical experience of product returns for ZYFLO and other factors that could significantly impact expected returns. Critical Therapeutics cannot assure you, however, that its estimates, or the assumptions underlying them, will be correct. If Critical Therapeutics estimates are inaccurate, this could adversely affect its stock price.

Risks Relating to Intellectual Property and Licenses

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

Critical Therapeutics success depends, in part, on its ability to protect proprietary products, methods and technologies that Critical Therapeutics invents, develops or licenses under the patent and other intellectual property laws of the United States and other countries, so that Critical Therapeutics can prevent others from using its inventions and proprietary information. The composition of matter patent for zileuton in the United States will expire in December 2010. The patent for ZYFLO CR, which relates only to the controlled-release technology used to control

the release of zileuton, will expire in June 2012. Critical Therapeutics is exploring strategies to extend and expand the patent protection for its zileuton products, but Critical Therapeutics may not be able to obtain additional patent protection.

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

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patent applications of others. There may also be prior art that may prevent allowance of Critical Therapeutics patent applications or enforcement of Critical Therapeutics or Critical Therapeutics licensors issued patents.

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

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

Critical Therapeutics also relies on trade secrets, know-how and technology, which are not protected by patents, to maintain its competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, any competitive advantage that Critical Therapeutics may have had in the development or commercialization of its product candidates would be minimized or eliminated. Critical Therapeutics confidentiality agreements with its current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors may not effectively prevent disclosure of Critical Therapeutics confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of Critical Therapeutics proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect Critical Therapeutics competitive business position.

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

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

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

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

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

incur substantial monetary damages, potentially including treble damages, if Critical Therapeutics is found to have willfully infringed on such parties patent rights;

encounter significant delays in bringing Critical Therapeutics product candidates to market; or

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be precluded from participating in the manufacture, use or sale of Critical Therapeutics products or methods of treatment.

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

If Critical Therapeutics fails to obtain a required license or is unable to design around a patent, Critical Therapeutics may be unable to effectively market some of its technology or products, which could limit Critical Therapeutics ability to generate revenues or achieve profitability and possibly prevent Critical Therapeutics from generating revenue sufficient to sustain its operations. In addition, Critical Therapeutics MedImmune collaboration agreement provides that a portion of the royalties payable to Critical Therapeutics by MedImmune for licenses to Critical Therapeutics intellectual property may be offset by amounts paid by MedImmune to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in Critical Therapeutics revenues.

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

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

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

Risk Relating to Regulatory and Legal Compliance

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 health care 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 health care 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;

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

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

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

state and foreign law equivalents of the foregoing;

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

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

On January 1, 2006, Critical Therapeutics became a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the Medicaid rebate program, Critical Therapeutics pays a rebate for each unit of Critical Therapeutics product reimbursed by Medicaid. The amount of the rebate for each product is set by law. Critical Therapeutics is also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. Both the federal government and state governments have initiated investigations into the rebate practices of many pharmaceutical companies to ensure compliance with these rebate programs. Any investigation of Critical Therapeutics rebate practices could be costly, could divert the attention of Critical Therapeutics management and could damage Critical Therapeutics reputation.

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

If Critical Therapeutics promotional activities fail to comply with the FDA s regulations or guidelines, Critical Therapeutics may be subject to enforcement action by the FDA. For example, Critical Therapeutics received a warning letter from the FDA in November 2005 relating to certain promotional material that included an illustration of the mechanism of action for ZYFLO. The FDA asserted that the promotional material incorporating the illustration was false or misleading because it presented efficacy claims for ZYFLO, but failed to contain fair balance by not communicating the risks associated with its use and failing to present the approved indication for ZYFLO. In response to the warning letter, and as requested by the FDA, Critical Therapeutics stopped disseminating the promotional material containing the mechanism of action and Critical Therapeutics provided a written response to the FDA. As part of Critical Therapeutics response, Critical Therapeutics provided a description of its plan to disseminate

corrective messages about the promotional material to those who received this material. Critical Therapeutics revised the promotional material containing the mechanism of action to address the FDA s concerns regarding fair balance. If Critical Therapeutics promotional activities fail to comply with the FDA s regulations or guidelines, Critical Therapeutics could be subject to additional regulatory actions by the FDA, including product seizure, injunctions, and other penalties and Critical Therapeutics reputation and the reputation of ZYFLO CR in the market could be harmed. Any action against Critical Therapeutics for violation of these laws, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention from operating Critical Therapeutics business and damage Critical Therapeutics reputation or Critical Therapeutics brands. If there is a change in law, regulation or administrative or judicial interpretations, Critical Therapeutics may have to change or discontinue its business practices or its existing business practices could be challenged as unlawful, which could materially harm its business, financial condition and results of operations.

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

In recent years, several states, including California, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs and file periodic reports with the state on sales, marketing, pricing, reporting pricing and other activities. For example, a California statute effective July 1, 2005 requires pharmaceutical companies to adopt and post on their public web site a comprehensive compliance program that complies with the Pharmaceutical Research and Manufacturers of America *Code on Interactions with Healthcare Professionals* and the Office of Inspector General of the Department of Health and Human Services *Compliance Program Guidance for Pharmaceutical Manufacturers.* In addition, such compliance program must establish a specific annual dollar limit on gifts or other items given to individual health care professionals in California.

Maine, Minnesota, New Mexico, Nevada, Vermont, West Virginia and the District of Columbia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to health care practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and uncertain, and available guidance is limited. Critical Therapeutics is in the process of identifying the universe of state laws applicable to pharmaceutical companies and is taking steps to ensure that Critical Therapeutics comes into compliance with all such laws. Unless and until Critical Therapeutics is in full compliance with these laws, Critical Therapeutics could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm Critical Therapeutics business.

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

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

Critical Therapeutics corporate compliance and corporate governance programs cannot guarantee that Critical Therapeutics is in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, marketing, sales and reimbursement of ZYFLO CR and ZYFLO and Critical Therapeutics product candidates, together with Critical Therapeutics general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. Critical Therapeutics is a relatively small company and had approximately 42 employees as of September 30, 2008. Critical Therapeutics relies heavily on third parties to conduct many important functions. While Critical Therapeutics has developed and instituted a corporate compliance program based on what Critical Therapeutics believes are the current best practices and continues to update the program in response to newly implemented and changing regulatory requirements, it is possible that Critical Therapeutics may not be in compliance with all potentially applicable regulations. If Critical Therapeutics fails to comply with any of these regulations, Critical Therapeutics could be subject to a range of regulatory actions, including significant fines, litigation or other sanctions. Any action against Critical Therapeutics for a violation of these regulations, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention and harm Critical Therapeutics reputation.

As a publicly traded company, Critical Therapeutics is subject to significant legal and regulatory requirements, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and related regulations, some of which have

either only recently become applicable to Critical Therapeutics or are subject to change. For example, Critical Therapeutics is incurring additional expenses and devoting significant management time and attention to evaluating its internal control systems to allow Critical Therapeutics management to report on, and Critical Therapeutics independent registered public accounting firm to attest to, Critical Therapeutics internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that Critical Therapeutics has implemented do not comply with all of the relevant rules and regulations of the SEC and NASDAQ, Critical Therapeutics may be subject to sanctions or investigation by regulatory authorities, including the SEC or NASDAQ. This type of action could adversely affect Critical Therapeutics financial results or investors confidence in Critical Therapeutics and Critical Therapeutics ability to access the capital markets and could result in the delisting of Critical Therapeutics common stock from NASDAQ. If Critical Therapeutics fails to develop and maintain adequate controls and

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procedures, Critical Therapeutics may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in Critical Therapeutics stock price.

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

Critical Therapeutics sales of ZYFLO CR and ZYFLO are, and any future sales of Critical Therapeutics product candidates will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and Critical Therapeutics expects there will continue to be, state and federal legislative and administrative proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for Critical Therapeutics products could adversely impact Critical Therapeutics business. In addition, Critical Therapeutics believes that private insurers, such as MCOs, may adopt their own reimbursement reductions in response to legislation. Any reduction in reimbursement for Critical Therapeutics products could materially harm Critical Therapeutics results of operations. In addition, Critical Therapeutics believes that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of Critical Therapeutics products, which may adversely impact Critical Therapeutics product sales. Furthermore, when a new drug product is approved, governmental and private reimbursement for that product, and the amount for which that product will be reimbursed, are uncertain. Critical Therapeutics cannot predict the availability or amount of reimbursement for Critical Therapeutics product candidates and current reimbursement policies for marketed products may change at any time.

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

If Critical Therapeutics succeeds in bringing products in addition to ZYFLO CR and ZYFLO to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow Critical Therapeutics to sell its product candidates on a competitive basis to a sufficient patient population. Because Critical Therapeutics product candidates are in the development stage, Critical Therapeutics is unable at this time to determine the cost-effectiveness of these product candidates. Critical Therapeutics may need to conduct expensive pharmacoeconomic trials in order to demonstrate their cost-effectiveness. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the prices charged for medical products. Because Critical Therapeutics product candidates are in the development stage, Critical Therapeutics does not know the level of reimbursement, if any, it will receive for those product candidates if they are successfully developed. If the reimbursement Critical Therapeutics receives for any of its product candidates is inadequate in light of Critical Therapeutics development and other costs, Critical Therapeutics ability to realize profits from the affected product candidate would be limited. If reimbursement for Critical Therapeutics marketed products changes adversely or if Critical Therapeutics fails to obtain adequate reimbursement for its other current or

future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of Critical Therapeutics products or cause Critical Therapeutics to reduce the price of its products.

Risks Relating to Development, Clinical Testing and Regulatory Approval of Critical Therapeutics 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;

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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.

If Critical Therapeutics does not obtain the regulatory approvals or clearances required to market and sell Critical Therapeutics product candidates under development, Critical Therapeutics business may be unsuccessful.

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

The regulatory process to obtain marketing approval or clearance for a new drug or biologic takes many years, requires expenditures of substantial resources, is uncertain and is subject to unanticipated delays. Adverse side effects of a product candidate in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve or clear a particular product candidate for any or all indications for use.

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

Critical Therapeutics limited experience in obtaining regulatory approvals could delay, limit or prevent such approvals for its product candidates.

Critical Therapeutics has only limited experience in preparing applications and obtaining regulatory approvals and clearances for its product candidates. Since inception, Critical Therapeutics has received approval to market only two drugs in the United States, ZYFLO CR and ZYFLO. Critical Therapeutics limited experience in this regard could

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

If clinical trials for Critical Therapeutics product candidates are not successful, Critical Therapeutics may not be able to develop, obtain regulatory approval for and commercialize these product candidates successfully.

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Critical Therapeutics product candidates, such as zileuton injection and product candidates directed toward the body s inflammatory response, including in its alpha-7 and HMGB1 preclinical programs, are still in development and remain subject to clinical testing and regulatory approval or clearance. In order to obtain regulatory approvals or clearances for the commercial sale of Critical Therapeutics product candidates, Critical Therapeutics and its collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of Critical Therapeutics product candidates. Critical Therapeutics may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these clinical trials. If permitted, such clinical testing may not prove that Critical Therapeutics product candidates are safe and effective to the extent necessary to permit Critical Therapeutics to obtain marketing approvals or clearances from regulatory authorities. One or more of Critical Therapeutics product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, Critical Therapeutics, one of its collaborators, institutional review boards or regulatory agencies may hold, suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, in March 2006, Critical Therapeutics announced that it had discontinued a Phase II clinical trial of ethyl pyruvate, which Critical Therapeutics refers to as CTI-01, a small molecule product candidate that Critical Therapeutics had been developing for prevention of complications that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery. After reviewing the final data from the trial, Critical Therapeutics decided to discontinue further development of CTI-01. Critical Therapeutics subsequently terminated, effective in February 2007, the license agreements between Critical Therapeutics and the University of Pittsburgh and Xanthus Pharmaceuticals, Inc., formerly Phenome Sciences, Inc., or Xanthus Pharmaceuticals, related to patent rights related to CTI-01 controlled by University of Pittsburgh and Xanthus Pharmaceuticals.

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

Adverse or inconclusive clinical trial results concerning any of Critical Therapeutics product candidates could require Critical Therapeutics to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in a submission or approval for a narrower indication. If clinical trials fail, Critical Therapeutics product candidates would not become commercially viable.

If clinical trials for Critical Therapeutics product candidates are delayed, Critical Therapeutics would be unable to commercialize its product candidates on a timely basis, which would require Critical Therapeutics to incur additional costs and delay the receipt of any revenues from product sales.

Critical Therapeutics cannot predict whether it will encounter problems with any of its completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards, one of its collaborators or Critical Therapeutics to delay or suspend those clinical trials, or delay the analysis of data from Critical Therapeutics ongoing clinical trials.

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

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

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

delays in enrolling patients and volunteers into clinical trials;

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

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

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

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

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

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

the placement of a clinical hold on a trial.

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

For example, in March 2008, Critical Therapeutics discontinued its Phase IV clinical trial for ZYFLO CR designed to generate data in the current patient treatment setting because of patient enrollment that was significantly slower than Critical Therapeutics had anticipated. Critical Therapeutics initiated the trial in July 2007 and had enrolled only approximately 25% of the patients prior to discontinuing the trial. Critical Therapeutics had planned to use data from this trial to support ZYFLO CR s market position, and Critical Therapeutics may have increased difficulty promoting ZYFLO CR to physicians without this data.

Critical Therapeutics expects to rely on academic institutions and contract research organizations to supervise or monitor some or all aspects of the clinical trials for the product candidates Critical Therapeutics advances into clinical testing. Accordingly, Critical Therapeutics has less control over the timing and other aspects of these clinical trials than if Critical Therapeutics conducted them entirely on its own.

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

If clinical trials are delayed, the commercial viability of Critical Therapeutics product candidates may be reduced. If Critical Therapeutics incurs costs and delays in its programs, or if Critical Therapeutics does not successfully develop and commercialize its products, Critical Therapeutics future operating and financial results will be materially affected.

Even if Critical Therapeutics obtains regulatory approvals or clearances, Critical Therapeutics products and product candidates will be subject to ongoing regulatory requirements and review. If Critical Therapeutics fails to comply with continuing U.S. and applicable foreign regulations, Critical Therapeutics could lose permission to manufacture, distribute and sell its products and, if approved, its product candidates.

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

As part of the approval of the NDA for ZYFLO CR in May 2007, the FDA required Critical Therapeutics to conduct a pediatric clinical trial of ZYFLO CR as a post-approval commitment and report the results to the FDA by June 2010. If Critical Therapeutics does not successfully begin and complete this clinical trial in the time required by the FDA, Critical Therapeutics ability to market and sell ZYFLO CR may be hindered, and Critical Therapeutics business may be harmed as a result.

Numerous proposals have been made in recent months and years to impose new requirements on drug approvals, expand post-approval requirements and restrict sales and promotional activities. For example, an NDA requires that an applicant submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, and federal legislation has been proposed that would require all new drug applicants to submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances and establish new requirements for disclosing the results of clinical trials. Additional measures have also been proposed to address perceived shortcomings in the FDA s handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices that some see as excessive or improper. If these or other legal or regulatory changes are enacted, it may become more difficult or burdensome for

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Critical Therapeutics to obtain extended or new product approvals, and Critical Therapeutics current approvals may be restricted or subject to onerous post-approval requirements. Such changes may increase Critical Therapeutics costs and adversely affect Critical Therapeutics operations. The ability of Critical Therapeutics or its partners to commercialize approved products successfully may be hindered, and Critical Therapeutics business may be harmed as a result.

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

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

- product seizures;
- voluntary or mandatory recalls;
- suspension of review or refusal to approve pending applications;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- restrictions on, or prohibitions against, marketing Critical Therapeutics product candidates;
- restrictions on applying for or obtaining government bids;
- fines;
- restrictions on importation of Critical Therapeutics product candidates;
- injunctions; and
- civil and criminal penalties.

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;
- 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.

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Risks Relating to Critical Therapeutics Common Stock

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

The market price of Critical Therapeutics common stock may fluctuate significantly in response to factors that are beyond Critical Therapeutics control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of Critical Therapeutics common stock, which could cause a decline in the value of Critical Therapeutics common stock. For example, between September 1, 2007 and October 16, 2008, the last practicable date prior to the filing of this Quarterly Report on Form 10-Q, the trading price of Critical Therapeutics common stock as reported on NASDAQ ranged from a high of $2.70 per share to a low of $0.12 per share. On April 30, 2008, the last full trading day prior to the public announcement of the proposed merger with Cornerstone, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Global Market was $0.62. On October 16, 2008, the last practicable date before the filing of this Quarterly Report on Form 10-Q, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Capital Market was $0.21 which represents a 66% decrease from the closing price on April 30, 2008.

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

Critical Therapeutics common stock is currently listed on The NASDAQ Capital Market. In order to maintain that listing, Critical Therapeutics must satisfy minimum financial and other listing requirements.

On April 21, 2008, Critical Therapeutics received notification from the NASDAQ Listings Qualification Department 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 from the NASDAQ Listings Qualification Department 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 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 the proposed merger with Cornerstone is not completed and, in January 2009, Critical Therapeutics meets all of The NASDAQ Capital Market s initial listing requirements, other than 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 in such a scenario Critical Therapeutics would comply with The NASDAQ Capital Market s initial listing requirements, including The NASDAQ Capital Market s minimum stockholders equity requirement. On August 13, 2008, Critical Therapeutics received notification from the NASDAQ Listing Qualification Department that, based on its stockholders equity of $1.2 million, as reported in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and a market value of its common stock as of August 12, 2008 of $13.0 million, Critical Therapeutics does not comply with NASDAQ Marketplace Rule 4310(c)(3), which requires it to have, for continued listing on The NASDAQ Capital Market, a minimum of $2.5 million in stockholders equity or market value of listed securities of $35.0 million or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. As a result, the Listing Qualifications Staff is reviewing Critical Therapeutics eligibility for continued listing on The NASDAQ Capital Market. To facilitate the review, Critical Therapeutics has provided to the Listing Qualifications Staff a definitive plan, based on completing the proposed

merger with Cornerstone, to achieve and sustain compliance with all NASDAQ Capital Market listing requirements. If after the conclusion of its review process the Listing Qualifications Staff determines that Critical Therapeutics plan does not adequately address the deficiencies noted, the Staff will provide written notice to Critical Therapeutics that its common stock will be delisted from The NASDAQ Capital Market. In such event, Critical Therapeutics may appeal the Staff s decision to a NASDAQ Listing Qualifications Panel. If Critical Therapeutics fails to continue to meet all applicable listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist its common stock, an active trading market for Critical Therapeutics common stock may not be sustained and the market price of Critical Therapeutics common stock could decline. If an active trading market for Critical Therapeutics common stock is not sustained, it will be difficult for Critical Therapeutics stockholders to sell shares of Critical Therapeutics common stock without further depressing the market price of Critical Therapeutics common stock or at all. A delisting of Critical Therapeutics common stock also could

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make it more difficult for Critical Therapeutics to obtain financing for the continuation of Critical Therapeutics operations and could result in the loss of confidence by investors, suppliers and employees.

Immediately prior to the effective time of the merger, Critical Therapeutics has agreed to effect a reverse stock split of Critical Therapeutics common stock such that outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, to be mutually agreed upon by Critical Therapeutics and Cornerstone, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split and publicly announced by Critical Therapeutics. The reverse stock split is necessary so that as of the effective time of the merger Critical Therapeutics will satisfy the minimum bid price requirement pursuant to NASDAQ s initial listing standards.

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

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

- Critical Therapeutics proposed merger with Cornerstone and related developments, including the timing thereof;
- the amount and timing of sales of ZYFLO CR and ZYFLO;
- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;
- the availability and timely delivery of a sufficient supply of ZYFLO CR and ZYFLO;
- the amount of rebates, discounts and chargebacks to wholesalers, Medicaid and MCOs related to ZYFLO CR and ZYFLO;
- the amount and timing of product returns for ZYFLO CR and ZYFLO;
- achievement of, or the failure to achieve, milestones under Critical Therapeutics development agreement with MedImmune, Critical Therapeutics license agreements with Beckman Coulter and SetPoint and, to the extent applicable, other licensing and collaboration agreement;
- the results of ongoing and planned clinical trials of Critical Therapeutics product candidates;
- production problems occurring at Critical Therapeutics third-party manufacturers;
- the results of regulatory reviews relating to the development or approval of Critical Therapeutics product candidates; and
- general and industry-specific economic conditions that may affect Critical Therapeutics research and development expenditures.

Due to the possibility of significant fluctuations, Critical Therapeutics does not believe that quarterly comparisons of Critical Therapeutics operating results will necessarily be indicative of Critical Therapeutics future operating performance. If Critical Therapeutics quarterly operating results fail to meet the expectations of stock market analysts

and investors, the price of Critical Therapeutics common stock may decline.

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

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

- developments with respect to Critical Therapeutics proposed merger with Cornerstone;

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Critical Therapeutics operating results, including the amount and timing of sales of ZYFLO CR and ZYFLO;

the availability and timely delivery of a sufficient supply of ZYFLO CR and ZYFLO;

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

the results of discovery, preclinical studies and clinical trials by Critical Therapeutics or Critical Therapeutics competitors;

the acquisition of technologies, product candidates or products by Critical Therapeutics or Critical Therapeutics competitors;

the development of new technologies, product candidates or products by Critical Therapeutics or Critical Therapeutics competitors;

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

significant acquisitions, strategic partnerships, joint ventures or capital commitments by Critical Therapeutics or Critical Therapeutics competitors.

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

As of September 30, 2008, Critical Therapeutics directors, executive officers and 10% or greater stockholders, together with their affiliates, to Critical Therapeutics knowledge, beneficially owned, in the aggregate, approximately 23.2% of Critical Therapeutics outstanding common stock. As a result, Critical Therapeutics directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to Critical Therapeutics stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of Critical Therapeutics assets. In addition, these persons, acting together, may have the ability to control the management and affairs of Critical Therapeutics. Accordingly, this concentration of ownership may harm the market price of Critical Therapeutics common stock by:

delaying, deferring or preventing a change in control of Critical Therapeutics;

impeding a merger, consolidation, takeover or other business combination involving Critical Therapeutics; or

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

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

Critical Therapeutics is incorporated in Delaware. Anti-takeover provisions of Delaware law and Critical Therapeutics charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, anti-takeover provisions to which Critical Therapeutics is subject include provisions in Critical Therapeutics bylaws and certificate of incorporation providing that, except as otherwise required by law, special meetings of the stockholders may be called only by Critical Therapeutics chairman of the board of directors, the chief executive officer, the president (if the president is different than the chief executive officer) or the board of directors and that stockholders may not take action by written consent and provisions in Critical Therapeutics bylaws providing

for the classification of Critical Therapeutics board of directors.

Additionally, Critical Therapeutics board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by Critical Therapeutics stockholders. The rights of holders of Critical Therapeutics common stock are subject to the rights of the holders of any preferred stock that Critical Therapeutics issues. As a result, Critical Therapeutics issuance of preferred stock could cause the market value of Critical Therapeutics common stock to decline and could make it more difficult for a third party to acquire a majority of Critical Therapeutics outstanding voting stock.

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

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

Item 6. ***Exhibits.***

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report on Form 10-Q, and such exhibit index is incorporated by reference herein.

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SIGNATURES

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

CRITICAL THERAPEUTICS, INC.

Date: October 20, 2008

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

Date: October 20, 2008

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

Date: October 20, 2008

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

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EXHIBIT INDEX

Exhibit Number	Description
2.1	Amendment No. 1, dated as of August 7, 2008, to Agreement and Plan of Merger, dated as of May 1, 2008, among Critical Therapeutics, Inc., Neptune Acquisition Corp., Cornerstone BioPharma Holdings, Inc. and Cornerstone BioPharma, Inc. (Incorporated by reference to Exhibit 2.2 to Critical Therapeutics Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (SEC File No. 000-50767)).
2.2	Amendment No. 1, dated as of August 7, 2008, to Merger Partner Noteholder Agreement, dated as of May 1, 2008, among Critical Therapeutics, Inc., Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals Ltd. (Incorporated by reference to Exhibit 2.5 to Critical Therapeutics Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (SEC File No. 000-50767)).
10.1	Form of Letter Agreement for Critical Therapeutics, Inc. Change of Control Cash Bonus Program, dated as of July 17, 2008, including a Schedule of Material Terms (Incorporated by reference to Exhibit 10.54 to Critical Therapeutics Registration Statement on Form S-4 filed with the SEC (SEC File No. 333-152442)).
10.2	First Amendment to Amended and Restated Employment Agreement, dated as of September 16, 2008, by and between Critical Therapeutics, Inc. and Scott B. Townsend (Incorporated by reference to Exhibit 10.55 to Critical Therapeutics Registration Statement on Form S-4 filed with the SEC (SEC File No. 333-152442)).
10.3	Restricted Stock Agreement, dated as of September 16, 2008, between Critical Therapeutics, Inc. and Scott B. Townsend (Incorporated by reference to Exhibit 10.56 to Critical Therapeutics Registration Statement on Form S-4 filed with the SEC (SEC File No. 333-152442)).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.