CRITICAL THERAPEUTICS INC
Form 10-Q
May 10, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For The Quarterly Period Ended March 31, 2007
or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period _____ to_____
Commission File Number: 000-50767
Critical Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
60 Westview Street Lexington, Massachusetts	**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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer o Accelerated Filer þ Non-Accelerated Filer o

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

As of May 1, 2007, the registrant had 43,135,791 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. Financial Information

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the expected timing and outcome of the New Drug Application, or NDA, submission for the controlled-release formulation of zileuton, or zileuton CR, possible therapeutic benefits and market acceptance of ZYFLO® (zileuton tablets) and, if approved, zileuton CR, the progress and timing of our drug development programs and related trials, the efficacy of our drug candidates, our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, project, should, will, would or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates and risks relating to: the expected timing and outcome of the NDA for zileuton CR and related discussions with the U.S. Food and Drug Administration, or FDA; our ability to transition our management team effectively; our ability to rely on historical data in seeking marketing approval for zileuton CR, including the sufficiency and acceptability of the results of the pharmacokinetic studies of zileuton CR for FDA purposes; our ability to successfully market and sell ZYFLO and, if approved, zileuton CR, including the success of our co-promotion arrangement with Dey, L.P.; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO and, if approved, zileuton CR; patient, physician and third-party payor acceptance of ZYFLO and, if approved, zileuton CR, as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO and, if approved, zileuton CR; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; conducting clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our products under development and whether such results will be indicative of results obtained in later clinical trials; our heavy dependence on the commercial success of ZYFLO and, if approved, zileuton CR; our ability to obtain the substantial additional funding required to conduct our research, development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO, zileuton CR, our discoveries and drug candidates. These and other risks are described in greater detail below under the caption Risk Factors in Part II, Item 1A. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this quarterly report represent our views only as of the date of this quarterly report and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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Item 1. Financial Statements

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

in thousands	March 31, 2007	December 31, 2006
Assets:		
Current assets:		
Cash and cash equivalents	$ 45,330	$ 48,388
Accounts receivable, net	807	877
Amount due under collaboration agreements	31	650
Short-term investments	650	650
Inventory, net	4,622	4,048
Prepaid expenses and other	974	980
Total current assets	52,414	55,593
Fixed assets, net	2,237	2,421
Other assets	168	168
Total assets	$ 54,819	$ 58,182
Liabilities and Stockholders Equity:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	$ 926	$ 1,012
Accounts payable	1,123	1,049
Accrued expenses	2,954	3,941
Deferred collaboration revenue and fees	3,105	675
Deferred product revenue		1,178
Total current liabilities	8,108	7,855
Long-term debt and capital lease obligations, less current portion	229	421
Commitments and contingencies (Note 8)		
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 43,066,209 and 42,902,142 shares at March 31, 2007 and December 31, 2006, respectively	43	43
Additional paid-in capital	205,566	204,378
Deferred stock-based compensation	(64)	(99)
Accumulated deficit	(159,049)	(154,399)
Accumulated other comprehensive loss	(14)	(17)

Total stockholders equity	46,482	49,906
Total liabilities and stockholders equity	$ 54,819	$ 58,182

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

in thousands except share and per share data	Three Months Ended March 31, 2007	2006
Revenues:		
Net product sales	$ 2,894	$ 1,022
Revenue under collaboration agreements	601	1,251
Total revenues	3,495	2,273
Costs and expenses:		
Cost of products sold	741	504
Research and development	2,918	9,393
Sales and marketing	1,982	6,907
General and administrative	3,055	2,928
Total costs and expenses	8,696	19,732
Operating loss	(5,201)	(17,459)
Other income (expense):		
Interest income	590	772
Interest expense	(39)	(60)
Total other income	551	712
Net loss	$ (4,650)	$ (16,747)
Net loss per share	$ (0.11)	$ (0.49)
Basic and diluted weighted-average common shares outstanding	42,456,700	34,096,625

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

in thousands	Three Months Ended March 31, 2007	2006
Cash flows from operating activities:		
Net loss	$ (4,650)	$ (16,747)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	166	248
Amortization of premiums on short-term investments and other	3	30
Gain on sale of fixed assets	(8)	
Reserve for inventory		144
Stock-based compensation expense	1,042	1,423
Changes in assets and liabilities:		
Accounts receivable	70	535
Amount due under collaboration agreements	619	(250)
Inventory	(574)	15
Prepaid expenses and other	6	512
Accounts payable	74	(1,902)
Accrued expenses	(987)	(518)
Deferred collaboration revenue and fees	2,430	(1,001)
Deferred product revenue	(1,178)	(278)
Net cash used in operating activities	(2,987)	(17,789)
Cash flows from investing activities:		
Proceeds from sale of fixed assets	26	
Purchases of fixed assets		(206)
Proceeds from sales and maturities of short-term investments		20,126
Purchases of short-term investments		(2,317)
Net cash provided by investing activities	26	17,603
Cash flows from financing activities:		
Proceeds from exercise of stock options	181	41
Repayments of long-term debt and capital lease obligations	(278)	(293)
Net cash used in financing activities	(97)	(252)
Net decrease in cash and cash equivalents	(3,058)	(438)
Cash and cash equivalents at beginning of period	48,388	57,257
Cash and cash equivalents at end of period	$ 45,330	$ 56,819
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 42	$ 62

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

(1) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Critical Therapeutics, Inc. and its subsidiary (the Company), and have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The Company believes that all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation, have been included. The information included in this quarterly report on Form 10-Q should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and footnotes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2006 filed with the Securities and Exchange Commission, or SEC.

Operating results for the three-month periods ended March 31, 2007 and 2006 are not necessarily indicative of the results for the full year.

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

(2) Revenue Recognition

Revenue Recognition and Deferred Revenue

The Company recognizes revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB 101, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition,* or 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 only commercial product, ZYFLO, and its collaboration agreements. These collaboration 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.

The Company sells ZYFLO to wholesalers, distributors and pharmacies, which have the right to return purchased product. In accordance with Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists,* or SFAS No. 48, the Company deferred revenue on product shipments until the Company could reasonably estimate returns relating to these shipments. Because ZYFLO was a new product for the Company and this was its first commercial product launch, the Company did not have an objective measurement or history to allow it to estimate returns in 2005 and 2006. In the first quarter of 2007, based on the Company s return experience since it launched ZYFLO in October 2005, the Company began recording revenue upon shipment to third parties including wholesalers, distributors and pharmacies and provided a reserve for potential returns from these third parties based on its product returns experience. In connection with this change in estimate, the Company recorded an increase in net product sales in the three months ended March 31, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000.

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 statement 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

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performance period as set forth in the contracts based on proportional performance and adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by the Company s collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with the Company, the Company does not recognize revenues in excess of cumulative cash collections.

At March 31, 2007, the Company s account receivable balance of $807,000 was net of allowances of $17,000. At March 31, 2006, the Company s account receivable balance of $489,000 was net of allowances of $12,000.

(3) Cash Equivalents and Short-Term Investments

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

Short-term investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have a maturity date greater than 90 days that can be sold within one year. These securities are held until such time as the Company intends to use them to meet the ongoing liquidity needs to support its operations. These investments are recorded at fair value and accounted for as available-for-sale securities. The unrealized gain (loss) during the period is recorded as an adjustment to stockholders equity. The Company recorded unrealized gains on investments of $3,000 and $29,000 during the three months ended March 31, 2007 and 2006, respectively. The cost of the debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period. The Company has concluded that the unrealized gain (loss) on investments is temporary and therefore no impairment exists during the three-month period ended March 31, 2007.

(4) Inventory

Inventory is stated at the lower of cost or market, with cost determined under the first-in, first-out (FIFO) method. As of March 31, 2007, the Company held $4.6 million in inventory to be used for commercial sales related to its commercial product, 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. Inventory consisted of the following at March 31, 2007 and December 31, 2006, respectively (in thousands):

	March 31, 2007	December 31, 2006
Raw material	$ 4,634	$ 3,662
Work in process		83
Finished goods	107	422
Total inventory	4,741	4,167
Less: reserve	(119)	(119)
Inventory, net	$ 4,622	$ 4,048

The Company currently purchases the API for its commercial requirements for ZYFLO from a single source. In addition, the Company currently manufactures ZYFLO with a single third-party manufacturer. Pending approval of zileuton CR, the Company will continue to purchase its API for commercial requirements from a single source and will manufacture zileuton CR with a single third-party manufacturer. 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 the commercial product could have a material adverse effect on the Company s business, financial position and results of operations.

(5) 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-month periods ended March 31, 2007 and 2006, and comprehensive loss is the unrealized gain (loss) on short-term investments for the period. Total comprehensive loss was $4.6 million and $16.7 million for the three-month periods ended March 31, 2007 and 2006, respectively. The unrealized gain (loss) on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet.

(6) Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R), using the modified prospective application method, which allows the Company to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after the required effective date. Because the Company issued options prior to March 19, 2004, the date it filed its initial registration statement on Form S-1, or S-1, with the SEC, at values less than fair market value, the Company recorded deferred compensation. Options granted prior to the initial S-1 filing continue to be accounted for under

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APB No. 25.

All stock-based awards to non-employees are accounted for at their fair market value in accordance with SFAS 123(R) and Emerging Issues Task Force 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 No. 96-18.

Stock option activity for the three-month periods ended March 31, 2007 and 2006:

	2007		2006	
	Number of Shares	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
Outstanding January 1	5,714,770	$ 4.60	6,200,106	$ 5.03
Granted	201,000	2.05	741,000	6.97
Exercised	(173,567)	1.04	(89,204)	0.46
Cancelled	(595,804)	5.81	(62,594)	6.34
Outstanding March 31	5,146,399	$ 4.48	6,789,308	$ 5.29
Exercisable March 31	1,605,090	$ 5.15	1,948,758	$ 3.76

The weighted average remaining contractual term and the aggregate intrinsic value for options outstanding at March 31, 2007 were 8.5 years and $694,000, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options exercisable at March 31, 2007 were 7.7 years and $385,000, respectively. The weighted average exercise price and the number of options vested or expected to vest at March 31, 2007 were $4.56 and 4,058,703, respectively. The total intrinsic value of the options exercised during the three months ended March 31, 2007 was approximately $160,000.

As described above, the Company had previously recorded deferred compensation for options granted prior to the date of its initial S-1 filing at prices deemed to be below fair value. As of March 31, 2007, $64,000 of deferred compensation has yet to be recognized for these options. Such amounts will be recognized during 2007. The Company has expensed this deferred stock-based compensation to operations over the vesting period of the options and recorded $8,000 and $262,000 as stock-based compensation expense for the three months ended March 31, 2007 and March 31, 2006, respectively, related to these options.

The total fair value of the shares vested and unexercised (other than pre S-1 shares) and expensed during the three months ended March 31, 2007 was $682,000. As of March 31, 2007, there was $8.5 million of total unrecognized compensation expense (including the pre S-1 shares) 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 1.5 years.

The Company anticipates recording additional stock-based compensation expense of $3.2 million in the remaining three quarters of 2007, $2.9 million in 2008 and $2.4 million thereafter relating to the amortization of unrecognized compensation expense as of March 31, 2007. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

Option valuation models require the input of highly subjective assumptions. Because changes in subjective input assumptions can materially affect the fair value estimate, in management s opinion, the calculated fair value may not necessarily be indicative of the actual fair value of the stock options. The Company has computed the impact under SFAS No. 123(R) for options granted using the Black-Scholes option-pricing model for the quarters ended March 31, 2007 and 2006. The Company increased its expected volatility assumption for the three months ended March 31, 2007 to 66% from 59% in the corresponding period of 2006. The rate is based on the Company s actual historical volatility since its initial public offering. The expected life of options granted was estimated using the simplified method calculation as prescribed by SEC Staff Accounting Bulletin No. 107. The assumptions used and weighted-average

information are as follows:

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	Three Months Ended March 31,	
	2007	2006
Risk free interest rate	4.6%	4.5%
Expected dividend yield	0%	0%
Expected forfeiture rate	10.2%	4.2%
Expected life	6.25 years	6.25 years
Expected volatility	66%	59%
Weighted-average fair value of options granted equal to fair value	$ 1.35	$ 4.21

(7) 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, since the effects of potentially dilutive securities are anti-dilutive for all periods presented. Anti-dilutive securities that are not included in the diluted net loss per share calculation aggregated 12,908,520 and 10,312,480 as of March 31, 2007 and 2006, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of March 31, 2007 and 2006.

The following table reconciles the weighted-average common shares outstanding to the shares used in the computation of basic and diluted weighted-average common shares outstanding:

	Three Months Ended March 31,	
	2007	2006
Weighted-average common shares outstanding	43,012,227	34,143,741
Less: weighted-average restricted common shares outstanding	555,527	47,116
Basic and diluted weighted-average common shares outstanding	42,456,700	34,096,625

(8) Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on 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 U.S. Food and Drug Administration, or FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company s products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately $20.1 million as of March 31, 2007. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in and timing of the development of the Company s product candidates. As of March 31, 2007, the Company has $227,000 and $320,000 included in prepaid expenses and accrued expenses, respectively, related to these agreements on the accompanying condensed consolidated balance sheet. These agreements are accounted for under the percentage of completion method.

The Company is also party to a number of agreements that require it to make milestone payments, royalties on net sales of the Company s products and payments on sublicense income received by the Company. In addition, the Company entered into a manufacturing and supply agreement with Rhodia Pharma Solutions, which was assigned to Shasun Pharma Solutions Ltd. or Shasun, for commercial production of the active pharmaceutical ingredient (API) for ZYFLO, 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 2007 and in the first quarter of 2008. The API purchased from Shasun currently has a shelf-life of 36 months. The Company evaluates the need to

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provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. As of March 31, 2007, no reserves have been recorded for purchase commitments.

On May 9, 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 zileuton CR in tablet form. Under this agreement, the Company is responsible for supplying uncoated zileuton CR tablets to Patheon. The Company has agreed to purchase at least 50% of its requirements for such manufacturing services for zileuton CR for sale in the United States from Patheon each year for the term of the agreement.

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. For all periods presented, the Company is not a party to any pending material litigation or other material legal proceedings.

(9) DEY Co-promotion and Marketing Services Agreement

On March 13, 2007, the Company entered into an agreement with DEY, L.P, an affiliate of Merck KGaA (DEY), under which the Company and DEY agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and zileuton 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. In addition, DEY has agreed to pay the Company milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, the Company will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties, up to $1.95 million. The Company agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, after third-party royalties, in excess of $1.95 million. From the date DEY begins detailing ZYFLO through the commercial launch of zileuton CR, the Company has agreed to pay DEY 70% of quarterly net sales of ZYFLO, after third party royalties, in excess of $1.95 million. Following the commercial launch of zileuton CR through December 31, 2010, the Company has agreed to pay DEY 35% of quarterly net sales, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through December 31, 2013, the Company has agreed to pay DEY 20% of quarterly net sales, after third-party royalties, in excess of $1.95 million. The co-promotion agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties.

Under the co-promotion agreement, the Company has deferred the $3.0 million payment received upon signing. The Company expects to amortize the $3.0 million payment over the term of the agreement, along with any future milestone payments received from DEY. The Company expects to record all ZYFLO and, if approved, zileuton CR sales generated by the combined sales force.

(10) Income Tax

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. As of the date of adoption, the total amount of net unrecognized tax benefit is $0.2 million, which has been recorded with an offsetting adjustment to the Company s valuation allowance. Accordingly, there was no adjustment to retained earnings (accumulated deficit) at the date of adoption.

The Company did not recognize any accrued interest and penalties related to unrecognized tax benefits as no amounts would be due as a result of the Company s net tax loss carryforward. The Company s policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. Tax years for 2000 to 2006 remain subject to examination for federal and numerous state jurisdictions. The primary state jurisdiction is the Commonwealth of Massachusetts.

(11) Subsequent Events

IMI License Agreement

In January 2007, the Company entered into an exclusive license agreement (the License Agreement) with Innovative Metabolics, Inc. (IMI) under which the Company granted to IMI an exclusive worldwide license under

patent rights and know-how controlled by the Company relating to the stimulation of the vagus nerve to make, use and sell products and methods covered by the licensed patent rights and know-how in the licensed field. The licensed field includes mechanical and electrical stimulation of the vagus nerve and excludes pharmacological modulation of a cholinergic receptor (including the nicotinic alpha-7 cholinergic receptor).

In May 2007, in consideration for the license, IMI paid the Company an initial license fee of $400,000 in cash and IMI preferred stock valued at $400,000, after taking into account payments that the Company is obligated to make to The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute). Under the License Agreement, IMI also agreed to pay $800,000, after taking into account payments that the Company is obligated to make to The Feinstein Institute for Medical Research, upon the achievement of certain regulatory approvals and royalties based on net sales of licensed products and methods by IMI and its affiliates.

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

You should read the following discussion together with our financial statements and accompanying notes included in this quarterly report and our audited financial statements included in our annual report on Form 10-K for the year ended December 31, 2006 which is on file with the SEC. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under Risk Factors in Part II, Item 1A.

Financial Operations Overview

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body s inflammatory response. Our marketed product is ZYFLO, an immediate-release tablet formulation of zileuton, which the FDA approved in 1996 for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO and other formulations of zileuton for multiple diseases and conditions. We began selling ZYFLO in the United States in October 2005. In addition, we are developing a controlled-release formulation of zileuton, or zileuton CR, and an injectable formulation of zileuton, or zileuton injection. In connection with a restructuring that we announced in October 2006, we decided to focus our resources on these formulations.

Zileuton CR is a tablet designed to be taken twice daily, two tablets per dose. We have submitted a new drug application, or NDA, for zileuton CR that was accepted for filing by the FDA as of September 29, 2006. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If we receive regulatory approval on a timely basis, we expect to launch zileuton CR in the second half of 2007.

On March 13, 2007, we entered into an agreement with Dey, L.P., or Dey, an affiliate of Merck KGaA, under which we and DEY agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR. Under the co-promotion agreement, DEY paid us a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement. In addition, DEY has agreed to pay us milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, we will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties, up to $1.95 million. We have agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, after third-party royalties, in excess of $1.95 million.

We have deferred the $3.0 million payment received upon signing the DEY co-promotion agreement. We expect to amortize the $3.0 million payment over the term of the agreement, along with any future milestone payments received from DEY. We expect to record all ZYFLO sales generated by the combined sales force.

In addition, we are developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In August 2006, we announced results from our Phase I/II clinical trial designed to evaluate safety, tolerability and pharmacokinetics of zileuton injection in patients with asthma. We plan to initiate a Phase II clinical trial in the second half of 2007 with zileuton injection in asthma patients.

We are also developing other product candidates to regulate the excessive inflammatory response that can damage vital internal organs and, in the most severe cases, result in multiple organ failure and death. The inflammatory response occurs following stimuli such as infection or trauma. Our product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body s inflammatory response.

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

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agreement with MedImmune, the obligations of both companies remain unchanged as a result of MedImmune s recently announced sale to AstraZeneca PLC, and the two companies expect to continue to move forward with the HMGB1 program.

We are conducting preclinical work in our small molecule alpha-7 program through a small team of scientists. We believe the successful development of a product candidate targeting the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. We plan to seek a collaborator for our alpha-7 program and do not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement.

We were incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed our name to Critical Therapeutics, Inc. in March 2001. We completed an initial public offering of our common stock in June 2004, and our common stock is currently traded on the NASDAQ Global Market.

Since our inception, we have incurred significant losses each year. As of March 31, 2007, we had an accumulated deficit of $159.0 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue over the next several years as we fund our development programs, market and sell ZYFLO and prepare for the potential commercial launch of our product candidates. Since our inception, we have raised proceeds to fund our operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, and revenues from sales of ZYFLO.

Revenues. From our inception on July 14, 2000 through the third quarter of 2005, we derived all of our revenues from license fees, research and development payments and milestone payments that we have received from our collaboration agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, we began selling, and recognizing revenue, from our first commercial product, ZYFLO. In the first quarter of 2007, based on our return experience since our ZYFLO launch in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and provided an adequate reserve for potential returns from these third parties based on our product returns experience.

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

Research and Development Expenses. Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, milestone payments to third parties, costs related to the development of our NDA for zileuton CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, manufacturing expenses associated with a product will be recorded as cost of products sold rather than as research and development expenses. We expense research and development costs and patent related costs as they are incurred. Because of our ability to utilize resources across several projects, many of our research and development costs are not tied to any particular project and are allocated among multiple projects. We record direct costs on a project-by-project basis. We record indirect costs in the aggregate in support of all research and development. Development costs for clinical development stage programs such as the injectable formulation of zileuton tend to be higher than earlier stage programs such as our HMGB1 and alpha-7 programs, due to the costs associated with conducting clinical trials and large-scale manufacturing.

We expect that research and development expenses relating to our portfolio will fluctuate depending primarily on the timing of clinical trials, milestone payments to third parties, and manufacturing initiatives. We expect to incur

additional expenses over the next several years for clinical trials of our product development candidates, including the controlled-release and injectable formulations of zileuton. As a result of our October 2006 restructuring, we anticipate that our research and development expenses will decrease in 2007 compared to 2006. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we scale up production of zileuton injection for later stages of clinical development. We also expect to initiate clinical trials related to zileuton CR to examine its potential clinical benefits in particular populations of asthma patients, which, if conducted,

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would be included in research and development expenses. If the NDA for zileuton CR is approved by the FDA in 2007, we will be obligated to make milestone payments totaling $3.1 million to third parties in the period when the approval is obtained. These milestone payments will be included in research and development expenses in the applicable period.

Sales and Marketing. Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, sales operations and our managed care functions as well as other costs related to ZYFLO. We will also be incurring marketing and other costs in preparation for the anticipated launch of zileuton CR in the second half of 2007. Other costs included in sales and marketing expenses include sales and marketing cost related to our co-promotion and marketing agreement, cost of product samples of ZYFLO, promotional materials, market research and sales meetings. We expect to continue to incur sales and marketing costs associated with our sales force to support ZYFLO. If zileuton CR is approved for marketing, we expect to incur additional expenses related to enhancing our sales and marketing functions and adding sales representatives. In addition, under our co-promotion agreement, we have deferred the $3.0 million payment received upon signing. We expect to amortize the $3.0 million payment over the term of the agreement, along with any future milestone payments received from DEY.

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 and accounting services.

Critical Accounting Policies

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

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

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

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

Revenue Recognition. We sell ZYFLO to wholesalers, distributors and pharmacies, which have the right to return purchased product. In accordance with Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists,* or SFAS No. 48, we deferred revenue on product shipments until we could reasonably estimate returns relating to these shipments. Because ZYFLO was a new product for us and this was our first commercial product launch, we did not have an objective measurement or history to allow us to estimate returns in 2005 and 2006. Accordingly, in 2005 and 2006, we deferred the recognition of revenue on product shipments of ZYFLO to our customers until the product was dispensed through patient prescriptions. Since product dispensed to patients through prescription is not subject to return, there is no remaining contingency that would prohibit revenue recognition once delivered through prescription. In the first quarter of 2007, based on our product return experience since we launched ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including

wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties. In connection with this change, we recorded an increase in net product sales in the three months ended March 31, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000.

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

Product Returns. Consistent with industry practice, we offer customers the ability to return products during the six months prior to, and the twelve months after, the product expires. At the time of commercial launch in October 2005, we began shipping our products with an expiration date of 12 months. Since our launch of ZYFLO, we have extended ZYFLO s expiration date from 12 months to 21 months as of March 31, 2007. In April 2007, ZYFLO's expiration date extended to 24 months. We may adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. As a result of this ongoing evaluation, our product return reserve was $138,000 at March 31, 2007. We evaluate this reserve on a quarterly basis, assessing each of the factors described above, and adjust the reserve accordingly.

Inventory. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. We determine the estimated useful life of our inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of March 31, 2007, inventory consists of zileuton active pharmaceutical ingredient, or API, which is raw material in powder form, and finished tablets to be used for commercial sale. On a quarterly basis, we analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of our expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of March 31, 2007, we had a reserve against our inventory of approximately $119,000 for product that is not expected to be sold.

Accrued Expenses. As part of the process of preparing our condensed consolidated financial statements, we are required to estimate certain expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our condensed consolidated financial statements. Examples of estimated expenses for which we accrue include professional service fees, such as fees paid to lawyers and accountants, rebates to third parties, including government programs such as Medicaid or private insurers, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical materials and restructuring charges.

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

services commence, the level of services performed on or before a given date and the cost of such services are often subject to judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Short-term Investments. Short-term investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. We record any unrealized gain (loss) during the year as an adjustment to stockholders equity unless we determine that the

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unrealized gain (loss) is not temporary. We adjust the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because we have determined that the unrealized gain (loss) on our investments have been temporary, we have not recorded any impairment losses since inception.

It is our intent to hold our short-term investments until such time as we intend to use them to meet the ongoing liquidity needs of our operations. However, if the circumstances regarding an investment or our liquidity needs were to change, such as a change in an investment s external credit rating, we would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses.

Stock-Based Compensation. Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the modified prospective application method, which requires us to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after January 1, 2006 if such awards were granted after becoming a public company.

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

The two factors which most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted by us under SFAS 123(R) and EITF 96-18 requires fair value estimates of the equity instrument granted. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, we use the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees or non-employees, we estimate the fair value of the equity instruments based upon the consideration of factors which we deem to be relevant at the time using cost, market or income approaches to such valuations.

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of March 31, 2007, we had federal and state tax net operating loss carryforwards of approximately $136 million, which expire beginning in 2021 and 2007, respectively. We also have research and experimentation credit carryforwards of approximately $2.3 million, which expire beginning in 2021. We have 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 we determine in the future that we will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. As of the date of adoption, the total amount of net unrecognized tax benefit is $0.2 million, which has been recorded with an offsetting adjustment to our valuation allowance. Accordingly, there was no adjustment to retained earnings (accumulated deficit) at the date of adoption.

We did not recognize any accrued interest and penalties related to unrecognized tax benefits as no amounts would be due as a result of our net tax loss carryforward. Our policy is to record interest and penalties related to

unrecognized tax benefits in income tax expense. Tax years for 2000 to 2006 remain subject to examination for federal and numerous state jurisdictions. The primary state jurisdiction is the Commonwealth of Massachusetts.

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Results of Operations

Three Months Ended March 31, 2007 and 2006

Revenues

Revenue from Product Sales. We recognized revenue from product sales of ZYFLO of $2.9 million in the three months ended March 31, 2007 compared to $1.0 million in three months ended March 31, 2006. The increase in product revenue is primarily attributable to a 56% increase in prescription volume over the corresponding period in 2006. In addition, we recorded a $953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. On January 1, 2007, based on our product return experience since our launch of ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as we are now able to estimate product returns.

Prior to this change in the three months ended March 31, 2007, we recognized revenue from product shipments when we have determined the right to return the product has lapsed or when we can reasonably estimate returns relating to the shipments to third parties under SFAS No. 48. For example, during the first quarter of 2006, we deferred recognition of revenue on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product is dispensed through patient prescriptions. We deferred the cost of product shipped to third parties that has not been recognized as revenue in accordance with our revenue recognition policy until the product was dispensed through patient prescriptions. This deferred cost of product sold totaled $215,000 as of March 31, 2006, and was included in prepaid expenses and other current assets.

Revenue under Collaboration Agreements. We recognized collaboration revenues of $601,000 in the three months ended March 31, 2007 compared to $1.3 million in the three months ended March 31, 2006. Collaboration revenue for the three months ended March 31, 2007 was primarily due to the recognition of $400,000 of deferred revenue recognized under our collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with our HMGB1 program. Collaboration revenue also included approximately $201,000 related to a portion of the $12.5 million of initial fees MedImmune paid to us that we recognized over the duration of the contract, and the $5.3 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through March 31, 2007. Collaboration revenue for the three months ended March 31, 2006 was primarily comprised of the portion of the initial fees MedImmune paid us that we recognized in each period, and a portion of milestone payments and development support billed to MedImmune in the first quarter of 2006, in 2005 and in 2004.

Since we entered into the agreement with MedImmune in 2003, we have billed a total of $17.8 million to MedImmune, consisting of the $12.5 million initial payment, a $1.3 million milestone payment and $4.0 million of development support. We have recognized $17.7 million of these amounts as collaboration revenue to date. We have reported the balance of the payments, totaling $105,000, as deferred collaboration revenue and will recognize such amount over the remaining estimated research term of our agreement with MedImmune based on the proportion of cumulative costs incurred as a percentage of the total costs estimated for the performance period. We currently estimate that the balance in deferred revenue will be recognized during the second quarter of 2007. Our revenue recognized from existing collaborations in 2007 may decline substantially since we have already recognized most of the revenue that we previously deferred. Going forward, our revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under our existing agreements, or will be dependent upon us entering into new collaboration agreements.

Costs and Expenses

Cost of Products Sold. Cost of products sold in the three months ended March 31, 2007 was $741,000, compared to $504,000 in the three months ended March 31, 2006. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. As a result of our change in estimate we recorded $166,000 in cost of product sold in the three months ended March 31, 2007. We recorded $144,000 of inventory write-offs in the three months ended March 31, 2006. We did not record any inventory write-offs during the three months ended March 31, 2007. The write-offs in the first quarter of 2006 resulted from excess or obsolete inventory that could no longer be used for commercial sale.

Excluding the impact of write-offs, our gross margins from product sales was 74% in the three months ended March 31, 2007, compared to 65% in the three months ended March 31, 2006. This increase in gross margins resulted from our ability to spread some of our fixed costs associated with managing the supply chain over a larger revenue base in 2007. If we are able to commercially launch zileuton CR, our gross margins could be negatively impacted by an additional royalty obligation to SkyePharma for utilization of their controlled-release technology.

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Research and Development Expenses. Research and development expenses in the three months ended March 31, 2007 were $2.9 million, compared to $9.4 million in the three months ended March 31, 2006, a decrease of approximately $6.5 million, or 69%. This decrease was primarily due to lower expenses associated with the clinical trials, as well as the reduction in the number of employees performing research and development functions following our May and October 2006 restructurings.

The following table summarizes the primary components of our research and development expenses for the three months ended March 31, 2007 and 2006:

	Three Months Ended March 31,	
	2007	2006
	(in thousands)	
Zileuton (ZYFLO and zileuton CR)	$ 1,335	$ 3,863
Zileuton injection	156	1,137
CTI-01	13	1,542
Alpha-7	833	1,147
HMGB1	119	506
General research and development expenses	222	845
Stock-based compensation expense	240	353
Total research and development expenses	$ 2,918	$ 9,393

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

Zileuton (ZYFLO and zileuton CR). During the three months ended March 31, 2007, we incurred $1.3 million in expenses related to our orally-dosed zileuton programs, including ZYFLO and zileuton CR, compared to $3.9 million during the three months ended March 31, 2006, a 65% decrease. This decrease was primarily due to the following:

- $1.1 million reduction in clinical and manufacturing costs for our NDA registration batches related to our controlled-release formulation of zileuton;
- $487,000 reduction in consulting and scientific advisor fees related to the controlled-release NDA registration batches and ZYFLO product launch;
- $529,000 reduction in salaries and other personnel costs related to our 2006 restructurings; and

The decreases in the costs described above were partially offset by higher costs associated with the continued development of our life cycle extension program for zileuton.

We anticipate that our research and development expenses of our orally-dosed zileuton programs in future periods will consist primarily of costs related to conducting Phase IIIb or Phase IV clinical trials. We expect that these clinical trials will be designed to examine the utility of zileuton in particular groups of asthma patients. In addition, we expect to continue to incur research and development expenses to maintain and operate our medical affairs, medical information and pharmacovigilance functions in support of ZYFLO and zileuton CR.

Zileuton Injection. During the three months ended March 31, 2007, we incurred $156,000 in expenses related to our zileuton injection program, compared to $1.1 million during the three months ended March 31, 2006, an 86% decrease. This decrease was primarily due to reduction in clinical trial expense related to our Phase I/II clinical trial, which concluded in the first half of 2006. We expect that our costs associated with the development of zileuton injection will increase during 2007 as we initiate a Phase II clinical trial, progress into later stages of clinical development and continue the formulation development to be used in future clinical trials.

CTI-01. During the three months ended March 31, 2007, we incurred minimal expense related to our CTI-01 program, as compared to expenses of $1.5 million in the three months ended March 31, 2006. Effective February 2007, we terminated our license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals

related to the development of CTI-01. We do not plan to pursue further development or incur additional costs related to CTI-01.

Alpha-7. During the three months ended March 31, 2007, we incurred $833,000 of expenses in connection with research and development of our alpha-7 program, compared to $1.1 million during the three months ended March 31, 2006, a 27% decrease.

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This decrease was primarily due to a reduction in the number of employees working on the program following our October 2006 restructuring. We anticipate that our research and development expenses for our alpha-7 program will not grow substantially in 2007, as we expect increased costs related to preclinical studies conducted by third parties to advance our lead molecule to be offset by the reduced headcount of employees working on this program. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. We plan to seek a collaborator for our alpha-7 program and do not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the project we choose to develop, the clinical indication developed, the development strategy adopted, and the terms of a collaboration, if we are able to enter into one. As a result, we are unable to estimate the costs or the timing of advancing a small molecule from our alpha-7 program through clinical development.

HMGB1. During the three months ended March 31, 2007, we incurred $119,000 of expenses for our HMGB1 program, compared to $506,000 during the three months ended March 31, 2006, a 77% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for our continued testing under our collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. We anticipate that research and development costs relating to HMGB1 for the remainder 2007 will be lower as a result of our October 2006 restructuring. In addition, a larger portion of the expenses in our HMGB1 program will be assumed by MedImmune as the program advances into later stages of preclinical development. We also anticipate that some of our expenses in the HMGB1 program will be covered by funding and potential milestone payments from MedImmune under our collaboration agreement. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while the funding received from MedImmune and Beckman Coulter to fund our research efforts is included in revenue under collaboration agreements.

Our general research and development expenses, which are not allocated to any specific program, decreased by $623,000 in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006. This decrease was primarily attributable to reduction in salaries and wages and other employee related costs as a result of our May 2006 and October 2006 restructurings and improved cost allocation methods for our existing research and development personnel and the related laboratory and general expenses for our current research and development programs.

In addition, our stock-based compensation expense decreased $113,000 in the three months ended March 31, 2007, compared to the three months ended March 31, 2006. This decrease was primarily due to a $248,000 reduction in stock-based compensation expense related to the reduction in the number of employees performing research and development functions following our May 2006 and October 2006 restructurings offset, in part, by the effects of the change in the market price of our common stock on unvested non-employee options. The adjustment to stock-based compensation expense is calculated based on the change in fair value of our common stock during the period. The fair value of our common stock decreased during both the three months ended March 31, 2007 and the three months ended March 31, 2006, which resulted in an adjustment to our stock-based compensation expense to non-employees of $9,000 and $143,000 during each of those periods, respectively.

Sales and Marketing. Sales and marketing expenses for the three months ended March 31, 2007 were $2.0 million, compared to $6.9 million for the three months ended March 31, 2006. The $4.9 million decrease was primarily attributable to a decrease in the number of employees performing sales and marketing functions, as well as the absence of certain costs associated with the commercial launch of ZYFLO, including market research performed in the three months ended March 31, 2006. The number of employees performing sales and marketing functions decreased to 26 employees at March 31, 2007 from 99 employees at March 31, 2006. We expect that our sales and marketing costs will increase during 2007 as a result of our co-promotion and marketing agreement with DEY and the

anticipated launch of zileuton CR in the second half of 2007.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2007 were $3.1 million, compared to $2.9 million for the three months ended March 31, 2006. The increase in the three months ended March 31, 2007 was primarily due to increased legal, consulting and advisory fees associated with our recently signed co-promotion and marketing agreement with DEY, offset, in part, by a reduction in salaries and wages and other personnel costs as a result of our 2006 restructurings. The number of employees performing general and administrative functions was 14 employees at March 31, 2007 and 26 employees at March 31, 2006.

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Other Income. Interest income for the three months ended March 31, 2007 was $590,000, compared to $772,000 for the three months ended March 31, 2006. The decrease in the three months ended March 31, 2007 was primarily attributable to lower average cash and investment balances, offset, in part, by higher interest rates. Interest expense amounted to $39,000 and $60,000 for the three months ended March 31, 2007 and March 31, 2006, respectively. The interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have raised proceeds to fund our operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from our collaboration and co-promotion agreements, exercise of stock options, and, beginning in the fourth quarter of 2005, revenues from sales of ZYFLO. As of March 31, 2007, we had $46.0 million in cash, cash equivalents and short-term investments. We have invested our remaining cash balance in highly liquid, interest-bearing, investment grade securities in accordance with our established corporate investment policy.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid us initial fees of $12.5 million and an additional $5.3 million through March 31, 2007 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program. We invoiced MedImmune for an additional $31,000 for work performed in the three months ended March 31, 2007.

Under our collaboration with MedImmune, we may receive additional payments upon the achievement of research, development and commercialization milestones up to a maximum of $124.0 million, after taking into account payments we are obligated to make to The Feinstein Institute on milestone payments we receive from MedImmune. We anticipate that by the end of 2007, in addition to payments already received, we will receive $1.0 million in aggregate milestone payments from MedImmune, after taking into account payments we are obligated to make to The Feinstein Institute.

Under our co-promotion agreement with DEY we received a non-refundable upfront payment of $3.0 million on March 14, 2007. In addition, DEY has agreed to pay us milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing 60 days prior written notice. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million if DEY has paid us the $4.0 million milestone related to approval of the NDA for zileuton CR.

Credit Agreement with Silicon Valley Bank. We have financed the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment, software licenses and the completion of leasehold improvements through advances under a credit agreement with Silicon Valley Bank, which was most recently modified as of January 6, 2006. As of March 31, 2007, we had no borrowing capacity available under the modified credit agreement or any other credit agreement. We are currently considering financing alternatives to fund capital expenditures in the future.

We have granted Silicon Valley Bank a first priority security interest in substantially all of our assets, excluding intellectual property, to secure our obligations under the credit agreement. As of March 31, 2007, we had $1.1 million in debt outstanding under this credit agreement related to equipment advances. As a result of our October 2006 restructuring, we incurred restructuring charges for the impairment of some of our assets. As a result of these charges, we may be required to pay to Silicon Valley Bank the proceeds received from these impaired assets.

The equipment advances made prior to a modification of our credit agreement on June 30, 2004 accrued interest at a weighted-average effective interest rate of approximately 8.7% per year. We are required to make equal monthly payments of principal and interest with respect to each advance made prior to June 30, 2004. The total repayment term for equipment advances made prior to June 30, 2004 is 48 months. Upon the maturity of any advance made prior to June 30, 2004, we are required to make a final payment in addition to the repayment of principal and interest. The final payment will be in an amount equal to a specified percentage of the original advance amount up to 8.5% of the

original principal and is expected to be paid by the third quarter of 2007. As of March 31, 2007, we had an outstanding equipment advance made prior to June 30, 2004 of $50,000, accruing interest at 8.6% per year.

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Advances made under the modified credit agreement after June 30, 2004 accrue interest at a rate equal to the prime rate plus 2% per year. As of March 31, 2007, outstanding equipment advances under the modified credit agreement had a weighted-average effective interest rate of approximately 10.25% per year. Advances made under the modified credit agreement are required to be repaid in equal monthly installments of principal plus interest accrued through the repayment term, which range from 36 to 42 months. Repayment begins the first day of the month following the advance. No advances were made in the three months ended March 31, 2007 under the modified credit agreement.

Cash Flows

Operating Activities. Net cash used in operating activities was $3.0 million for the three months ended March 31, 2007, as compared to $17.8 million for the three months ended March 31, 2006. Net cash used in operations for the three months ended March 31, 2007 consisted of a net loss of $4.7 million, depreciation and amortization expense, the amortization of premiums on short-term investments and the gain on the sales of fixed assets of $161,000, stock-based compensation expense of $1.0 million and a increase in working capital accounts of $460,000. The increase in working capital accounts was primarily due to a $3.0 million upfront payment that we received from DEY upon the signing of the co-promotion agreement, offset, in part, by a $1.2 million reduction in deferred product revenue and a $1.0 million reduction in accrued expenses.

Investing Activities. Investing activities provided $26,000 of cash in the three months ended March 31, 2007, compared to $17.6 million of cash in the three months ended March 31, 2006. During the three months ended March 31, 2007, we made no capital expenditures. In addition, as interest rates have gradually increased, we have maintained more of our proceeds from recent financings as cash equivalents rather than short-term investments.

Financing Activities. In the three months ended March 31, 2007, we used $97,000 of net cash in financing activities, compared to $252,000 in the three months ended March 31, 2006. Net cash used in financing activities for the three months ended March 31, 2007 principally related to our repayment of our long-term debt offset in part by proceeds from stock option exercises.

Income Taxes

We have accumulated net operating losses and tax credits available to offset future taxable income for federal and state income tax purposes as of March 31, 2007. 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, we have not recognized the potential tax benefit of our net operating loss carryforwards or credits on our balance sheet or statements of operations. The future utilization of our net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code.

Funding Requirements

We expect to devote substantial resources to continue our research and development efforts, including preclinical testing and clinical trials, enhance our sales and marketing infrastructure, achieve regulatory approvals, and, subject to regulatory approval, commercially launch zileuton CR and any future product candidates. We also expect to spend approximately $400,000 in capital expenditures in the remainder of 2007 for the purchase of software and computer equipment. We expect to fund our capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Our funding requirements will depend on numerous factors, including:

- the timing and costs of the regulatory approval and the commercial launch of zileuton CR, if and when it is approved by regulatory authorities;
- the scope, costs and results of our clinical trials on zileuton CR and zileuton injection;
- if approved, the amount and timing of sales and returns of zileuton CR;
- the timing and amount of sales and returns from ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO and, if approved, zileuton CR;

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

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

the timing, receipt and amount of sales and royalties, if any, from our potential products;

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

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

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

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

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

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

Other than payments that we receive from our collaborations with DEY, MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only sources of cash flows and revenue until we commercially launch zileuton CR, if it is approved. In addition to the foregoing factors, we believe that our ability to access external funds will depend upon the regulatory status of zileuton CR, market acceptance of zileuton CR, if approved, market acceptance of ZYFLO, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to obtain regulatory approval for, and successfully commercialize, zileuton CR. Based on our operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under existing collaboration agreements will be sufficient to fund anticipated levels of operations into 2009, assuming we receive FDA approval for and commercially launch zileuton CR in 2007. If zileuton CR is not approved and commercially launched in 2007, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the third quarter of 2008.

For the three months ended March 31, 2007, our net cash used for operating activities was $3.0 million, and we had no capital expenditures. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

Contractual Obligations

We have summarized in the table below our fixed contractual obligations as of March 31, 2007:

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	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)		
Short- and long-term debt	$ 1,222	$ 985	$ 237	$	$
Research and license agreements	6,594	170	526	644	5,254
Consulting agreements	243	243			
Severance agreements	18	18			
Manufacturing and clinical trial agreements	13,284	8,769	4,515		
Lease obligations	2,834	1,551	1,283		
Total contractual cash obligations	$ 24,195	$ 11,736	$ 6,561	$ 644	$ 5,254

The amounts listed for short- and long-term debt represent the principal and interest amounts we owe under our credit agreement with Silicon Valley Bank.

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

We are party to a number of agreements that require us to make milestone payments. In particular, under our license agreement with Abbott Laboratories for zileuton, we agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones relating to zileuton, including the completion of the technology transfer from Abbott to us, filing and approval of a product in the United States and specified minimum net sales of licensed products. Through March 31, 2007, we have made aggregate milestone payments of $5.3 million to Abbott under our license agreements related to ZYFLO and zileuton CR.

In addition, under our manufacturing agreement with SkyePharma, through its subsidiary Jagotec, for zileuton CR, we agreed to make aggregate milestone payments of up to $6.6 million upon the achievement of various development and commercialization milestones. Through March 31, 2007, we have made aggregate milestone payments of $2.4 million to SkyePharma under our agreement.

The amounts shown in the table do not include royalties on net sales of our products and payments on sublicense income that we may owe as a result of receiving payments under our collaboration agreement with MedImmune. Our license agreements are described in our annual report on Form 10-K for the year ended December 31, 2006.

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

The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. As discussed in our annual report on Form 10-K for the year ended December 31, 2006, we entered into a manufacturing and supply agreement with Rhodia Pharma Solutions Ltd. for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. On June 30, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions Ltd., sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhoda SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions Ltd., or Shasun. Under this agreement, we committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and in the first quarter of 2008. The API purchased from Shasun currently has a minimum shelf-life of

36 months. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While our purchase commitment for API from Shasun exceeds our current forecasted demand in 2007, we expect that any excess API purchased in 2006 under our agreement with Shasun will be used in commercial production batches in 2007 and 2008 and sold before it requires retesting. Therefore, no reserve for this purchase commitment has been recorded as of March 31, 2007.

Significant differences between our current estimates and judgments and future estimated demand for our product and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory. For example, we recorded charges of $299,000 in 2006 and $280,000 in 2005, respectively, to reserve for excess or obsolete inventory that had an expiration date such that the product was unlikely to be sold. The charge was included in cost of products sold in the accompanying statements of operations.

Currently we purchase our API for commercial requirements for ZYFLO from a single source. In addition, we currently manufacture ZYFLO with a single third-party manufacturer. Pending approval of zileuton CR, we will continue to purchase our API for commercial requirements from a single source and will manufacture zileuton CR with a single third-party manufacturer. 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 the commercial product could have a material adverse effect on our business, financial position and results of operations.

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of U.S. money market and corporate notes, directly or through managed funds, with maturities of two years or less. Our cash is deposited in and invested through highly-rated financial institutions in North America. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2007, we estimate that the fair value of our investment portfolio would decline by approximately $6,000. In addition, we could be exposed to losses related to these securities should one of our counterparties default. We attempt to mitigate this risk through credit monitoring procedures. Although we consider our investments to be available-for-sale securities in order to fund operations, if necessary, we have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Our management, with the participation of our president and chief executive officer, who functions as both our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2007, our chief executive officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Not applicable.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q and the other reports that we file with the Securities and Exchange Commission, in evaluating Critical Therapeutics and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors include any material changes to and supersede the risk factors previously disclosed in our annual report on Form 10-K for the year ended December 31, 2006.

Risks Relating to Our Business

Our business depends heavily on obtaining approval for and the commercial success of zileuton CR.

ZYFLO is our only commercial product and it has not achieved broad market acceptance. Other than zileuton CR, our product candidates are in early clinical, preclinical and research stages of development and are a number of years away from commercialization. Our NDA for zileuton CR was accepted for filing by the FDA as of September 29, 2006. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If zileuton CR is not approved on a timely basis or at all, it would have a material adverse effect on our business, financial condition and results of operations. If approved for sale, we expect zileuton CR would account for a significant portion of our revenues for the foreseeable future, and that sales of ZYFLO would decline as patients convert to zileuton CR.

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

If we do not obtain the regulatory approvals or clearances required to market and sell zileuton CR, our business may be unsuccessful.

We may not market zileuton CR in the United States, Europe or any other country without marketing approval from the FDA or the equivalent foreign regulatory agency. We have submitted an NDA to the FDA for zileuton CR, which was accepted for filing as of September 29, 2006. Abbott Laboratories conducted the pivotal clinical trials on zileuton CR before we in-licensed the product candidate. We are relying on the results of these prior pivotal clinical trials to support our NDA. If the pivotal trial data are not considered sufficient by the FDA or if the clinical sites do not pass FDA audits, we could be required to repeat some or all of the clinical trials, which would lead to unanticipated costs and delays. To be able to rely on the results of Abbott s pivotal clinical trials, we conducted two comparative bioavailability studies intended to show that the pharmacokinetic profile of the controlled-release zileuton tablets that we have manufactured is similar to the pharmacokinetic profile of the controlled-release zileuton tablets previously manufactured by Abbott and used in Abbott s clinical trials. We conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of zileuton CR in volunteers under both fed and fasting conditions. We believe that the results of the bioavailability studies are sufficient to allow us to bridge to the results of Abbott s prior clinical trials to support our NDA filing. The FDA has confirmed that this is a significant review issue. If the FDA disagrees with our conclusions regarding the sufficiency of the results from the bioavailability studies, we could be required to conduct additional clinical trials to support our NDA, which could lead to unanticipated costs and delays or to the termination of our program for zileuton CR. If we do not receive required regulatory approval or clearance to market zileuton CR, our ability to generate product revenues and achieve profitability, our reputation and our ability to raise additional capital will be materially impaired.

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If zileuton CR is not approved for sale or the market is not receptive to it, we may not be able to generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

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

Despite being approved by the FDA since 1996, ZYFLO, our first marketed zileuton product, has not achieved broad market acceptance. During the period between our commercial launch of ZYFLO in October 2005 through the week ending February 28, 2007, prescription data for ZYFLO indicates that approximately 3,981 physicians prescribed the product. For the year ended December 31, 2006, we recorded revenue from the sale of ZYFLO of only $6.6 million. For the quarter ended March 31, 2007, we recorded revenue from the sale of ZYFLO of $2.9 million. We have had difficulty expanding the prescriber and patient base for ZYFLO, in part, we believe, because some physicians view ZYFLO as less effective than other products on the market or view its clinical data as outdated and because it requires dosing of one pill four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. In addition, if physicians do not prescribe zileuton CR for the recommended dosing regimen of two pills twice daily or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, our sales of zileuton CR would be limited and our revenues would be adversely affected.

Market perceptions about the safety of ZYFLO may limit the market acceptance of zileuton 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 zileuton CR, 1.94% of the patients taking zileuton CR in a three-month efficacy trial and 2.6% of the patients taking zileuton 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 can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO. Given the results of the zileuton CR clinical trials, these periodic liver function tests also are likely to be advisable for patients taking zileuton CR. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO and other zileuton product candidates, including zileuton CR. As a result, many physicians may have negative perceptions about the safety of ZYFLO and other zileuton product candidates, including zileuton CR, which could limit their commercial acceptance. The absence of ZYFLO from the market prior to our commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues. These negative perceptions could carry over to zileuton CR.

The position of ZYFLO in managed care formularies, which are lists of approved products developed by managed care organizations, has also made it more difficult to expand the current market share for this product. As a result of a lack of a sustained sales and marketing effort prior to our commercial launch in October 2005, in many instances ZYFLO had been relegated to a third-tier status, which typically requires the highest co-pay for patients. Similarly, we expect zileuton CR to have third-tier status in many instances as well. In some cases, managed care organizations, or MCOs, may require additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO or, if approved, zileuton CR.

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

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

We reduced the size of our sales force as part of the cost reduction program that we announced in May 2006 and then further reduced the size of our sales force in the fourth quarter of 2006 in connection with our October 2006 restructuring. As of March 31, 2007, we had 18 sales representatives. In addition, our Senior Vice President of Sales and Marketing resigned in June 2006, and our

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Vice President of Sales resigned in July 2006. Due to our difficulty in achieving market acceptance of ZYFLO since its commercial launch in October 2005, the reduction in the size of our sales force, and the resignations of our Senior Vice President of Sales and Marketing and Vice President of Sales, it may be difficult for us to hire and retain qualified sales and marketing personnel and maintain an effective sales force.

On March 13. 2007, we entered into a co-promotion agreement with Dey, L.P., or DEY, and we cannot predict whether the co-promotion arrangement will lead to increased sales for ZYFLO or, if approved by the FDA, zileuton CR. On April 30, 2007, DEY initiated promotional detailing activities for ZYFLO. Given the recent start of DEY s efforts, the potential success of the co-promotion arrangement is uncertain.

In connection with the anticipated launch of zileuton CR, we expect to increase the size of our sales force to approximately 40 sales representatives, which would involve significant time and expense. In addition, we may not be able to attract, hire, train and retain qualified sales and marketing personnel to rebuild the sales force. If we are not successful in our efforts to rebuild this sales force, our ability to launch and market zileuton CR independently would be impaired.

On March 13, 2007, as contemplated by the terms of the zileuton co-promotion agreement, we and DEY entered into a separate binding letter agreement providing for us to co-promote DEY s product candidate for chronic obstructive pulmonary disease, or COPD, if approved by the FDA. We cannot predict whether this COPD co-promotion arrangement will be successful.

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

We purchased quantities of raw materials and supplies of ZYFLO tablets in connection with the commercial launch of ZYFLO. These purchases were made consistent with our forecasts of inventory levels of ZYFLO that we based on our estimate of expected customer orders in combination with limited historical information regarding actual sales. Because product demand for ZYFLO has been less than we anticipated, our inventory levels of the API for ZYFLO have been higher than anticipated. In addition, we are subject to minimum purchase obligations under our supply agreements with our third-party manufacturers, which could require us to buy additional inventory. We plan to use a portion of the API manufactured for ZYFLO to manufacture zileuton CR. If ZYFLO demand does not increase or the approval and commercial launch of zileuton CR is delayed, we may not be able to reduce these inventories or use the additional inventory we are required to purchase. Significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If we are required to recognize charges for excess inventories, it could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory.

If we fail to maintain an adequate inventory of ZYFLO, API, or zileuton CR, if it is approved, or if our inventory were to be destroyed or damaged or reach its expiration date, patients may not have access to our products, our reputation and our brand could be harmed and physicians may be less likely to prescribe our products in the future.

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

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

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

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

the extent and success of our sales and marketing efforts.

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

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

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

internal research programs;

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.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new product candidates, whether conducted by us or by academic or other research institutions under sponsored research agreements, require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a variety of reasons, including:

the research methodology used may not be successful in identifying potential product candidates;

the time, money and other resources that we devote to our research programs may not be adequate, including as a result of our May 2006 and October 2006 cost reduction programs; or

potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be effective products.

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

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

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

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

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

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

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

The development and commercialization of new drugs is highly competitive. We will face competition with respect to the development of product candidates and for ZYFLO, zileuton CR, if approved, and any other products that we commercialize in the future from pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, companies selling low-cost generic substitutes, academic institutions, government agencies or research institutions. A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO and will compete with, if approved for sale, zileuton CR. Many established therapies currently command large market shares in the mild to moderate asthma market, including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products. We will also face competition in the severe asthma market. The severe asthma market is currently served by the therapies developed for mild to moderate asthma, as these therapies (Singulair®, Advair® and inhaled corticosteroids) are used in combination or add-on therapies in severe asthma, along with oral and injectable steroid treatments. One product, Xolair®, developed jointly by Novartis AG, Genentech, Inc. and Tanox, Inc., was approved in 2004 for severe allergic asthma and had U.S. sales of $320 million in 2005 and $427 million in 2006. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in July 2006, AstraZeneca announced the approval of Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a beta2-agonist, that is expected to compete in the moderate and severe asthma markets. AstraZeneca has stated that it expects to launch Symbicort® in 2007.

Zileuton will also face intense competition if we are able to develop it as a treatment for chronic obstructive pulmonary disease, or COPD. COPD is currently treated predominantly with drugs that are indicated for use in asthma only or asthma and COPD, anti-cholinergic drugs and lung reduction surgery. Spiriva®, a once daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer, has been approved in Europe and the United States. Other novel approaches are also in the development process.

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

If our therapeutic programs directed toward the body s inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc. s Enbrel®, Johnson & Johnson s Remicade®, and Abbott Laboratories Humira®, and diseases such as sepsis, like Eli Lilly and Company s Xigris®.

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

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

We will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate

meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products obsolete or noncompetitive. If our product candidates are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those product candidates.

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Our operating results may be harmed if our restructuring and cost reduction measures do not achieve the anticipated results or cause undesirable consequences.

In 2006, we implemented cost reduction measures, which have included, among other things, significant workforce reductions. Because of the nature and extent of the restructuring actions we have taken, we may have difficulty marketing and promoting ZYFLO or, if approved, zileuton CR. If we fail to achieve the desired results of our cost reduction measures, we may suffer material harm to our business.

Our cost reduction initiatives may result in unintended consequences, such as attrition beyond our planned reduction in workforce, reduced employee morale and reduced support from physicians. As a result of these factors, our employees may seek alternate employment. Attrition beyond our planned reduction in workforce could have a material adverse effect on our financial performance. In addition, as a result of these cost reduction programs and the reduction in our workforce, we face an increased risk of employment litigation.

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

We depend on the principal members of our management and scientific staff, including Frank E. Thomas, our President and Chief Executive Officer, Dana Hilt, M.D., our Chief Medical Officer and Senior Vice President of Clinical Development, and Trevor Phillips, Ph.D., our Chief Operating Officer and Senior Vice President of Operations. The loss of any of these individuals services would diminish the knowledge and experience that we, as an organization, possess and might significantly delay or prevent the achievement of our research, development or commercialization objectives and could cause us to incur additional costs to recruit replacement executive personnel. We do not maintain key person life insurance on any of these individuals or any of our other scientific and management staff.

In June 2006, Paul D. Rubin, M.D. stepped down from his position as our President and Chief Executive Officer and resigned from our board of directors, and Frederick Finnegan resigned from his position as our Senior Vice President of Sales and Marketing. In July 2006, Anne M. Fields resigned from her position of Vice President of Sales. In October 2006, Walter Newman, Ph.D. resigned from his position as our Senior Vice President of Research and Development and Chief Scientific Officer. We put in place a new management structure, with a smaller management team that does not include a chief scientific officer, and have promoted individuals already employed by us to assume additional responsibilities. If we are unsuccessful in transitioning our management staff to compensate for the loss of these executives, the achievement of our research, development and commercialization objectives could be significantly delayed or may not occur. In addition, our focus on transitioning to our new management structure could divert our management s attention from other business concerns. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs.

Our success depends in large part on our ability to attract and retain qualified scientific, commercial and management personnel. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, will place additional requirements on our management, operational and financial resources. These demands may require us to hire additional management and scientific personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the research, development, regulatory approval and commercialization of our product candidates.

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

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

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

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

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

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

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

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

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 sale, distribution, use, administration and prescribing of prescription drugs; and

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

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

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

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

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provided a written response to the FDA. As part of our response, we provided a description of our plan to disseminate corrective messages about the promotional material to those who received this material. We revised the promotional material containing the mechanism of action to address the FDA s concerns regarding fair balance. If our promotional activities fail to comply with the FDA s regulations or guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions, and other penalties and our reputation and the reputation of ZYFLO in the market could be harmed.

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

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

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

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

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

The development, manufacturing, pricing, marketing, sales and reimbursement of ZYFLO, zileuton CR and our other product candidates, together with our general operations, are subject to extensive regulation by Federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company and had approximately 59 employees as of March 31, 2007. We rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented and changing regulatory requirements, it is possible that we may not be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

As a publicly traded company, we are subject to significant legal and regulatory requirements, including the Sarbanes-Oxley Act of 2002 and related regulations, some of which have either only recently become applicable to us or are subject to change. For example, we continue to incur substantial expenses and are devoting significant management time and attention to evaluating our internal control systems in order to allow our management to report on, and our registered public accounting firm to attest to, our internal controls over financial reporting, as required by

Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that we have implemented do not comply with all of the relevant rules and regulations of the Securities and Exchange Commission, or SEC, and The NASDAQ Global Market, we may be subject to sanctions or investigation by regulatory authorities, including the SEC or The NASDAQ Global Market. This type of action could adversely affect our financial results or investors confidence in our company and

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our ability to access the capital markets. If we fail to maintain adequate controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in our stock price.

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

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

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

If we succeed in bringing products in addition to ZYFLO to the market, these products may not be considered cost effective and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates other than zileuton CR are in the development stage, we are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate their cost-effectiveness. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the prices charged for medical products. Because our product candidates other than zileuton CR are in the development stage, we do not know the level of reimbursement, if any, we will receive for those product candidates if they are successfully developed. If the reimbursement we receive for any of our product candidates is inadequate in light of our development and other costs, our ability to realize profits from the affected product candidate would be limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing and sale of drugs. If the use of ZYFLO, zileuton CR or one or more of our other product candidates harms people, we may be subject to costly and damaging product liability claims. We currently have a $20.0 million annual aggregate limit for insurance covering both product liability claims for ZYFLO and clinical trial liability claims for our product candidates. We may seek additional product liability insurance prior to marketing zileuton CR or any of our other product candidates. However, our insurance may not

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provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that we have not anticipated in our business plans. Any product liability claim against us, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

We handle hazardous materials and must comply with laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

Our research and development work involves, and any future manufacturing processes that we conduct may involve, the use of hazardous, controlled and radioactive materials. We are subject to Federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite precautionary procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

In addition, we may be required to incur significant costs to comply with laws and regulations in the future, or we may be materially and adversely affected by current or future laws or regulations related to hazardous materials or wastes.

While we have a property insurance policy that covers bio-contamination up to a $25,000 per-occurrence limit and radioactive contamination up to a $25,000 per-occurrence limit, this policy may not provide adequate coverage against potential losses, damages, penalties or costs relating to accidental contamination or injury as a result of hazardous, controlled or radioactive materials.

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

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

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

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

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

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

Our product candidates are still in development and remain subject to clinical testing and regulatory approval or clearance. In order to obtain regulatory approvals or clearances for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. We may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, we, one of our collaborators, institutional review boards, or regulatory agencies may hold,

suspend or terminate clinical

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trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, in March 2006, we announced that we had discontinued a Phase II clinical trial of ethyl pyruvate, which we refer to as CTI-01, a small molecule product candidate that we had been developing for prevention of complications that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery. After reviewing the final data from the trial, we decided to discontinue further development of CTI-01. Effective February 6, 2007, we terminated the license agreements between us and the University of Pittsburgh and Xanthus Pharmaceuticals, Inc., formerly Phenome Sciences, Inc., related to certain patent rights related to CTI-01 controlled by University of Pittsburgh and Xanthus.

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

Adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in a submission or approval for a narrower indication. If clinical trials fail, our product candidates would not become commercially viable. In particular, if our planned Phase IIIb clinical trial for zileuton CR fails or produces results that are adverse or inconclusive, our ability to commercialize zileuton CR successfully and our financial results could be materially and adversely affected.

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

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards or us to delay or suspend those clinical trials, or delay the analysis of data from our ongoing clinical trials.

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients and volunteers into clinical trials;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

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

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

the placement of a clinical hold on a trial.

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

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

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

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

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

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

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

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

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

fines;

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restrictions on importation of our product candidates;

injunctions; and

civil and criminal penalties.

Risks Relating to Our Dependence on Third Parties

We will depend on DEY to jointly promote and market ZYFLO and, if approved by the FDA, zileuton CR. This co-promotion arrangement may not be successful.

We are relying on DEY to jointly promote and market ZYFLO and, if approved by the FDA, zileuton CR. ZYFLO is our only commercial product, and it has not achieved broad market acceptance. Our sales force has not been successful to date in significantly expanding the market for ZYFLO. As a result, our ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of our co-promotion arrangement with DEY. DEY initiated promotional detailing activities for ZYFLO on April 30, 2007.

Beginning three years after the commercial launch of zileuton CR, DEY may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by us. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party. Both we and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In particular, both we and DEY have agreed to provide a minimum number of details per month for ZYFLO and zileuton CR. If DEY were to terminate or breach the co-promotion agreement, and we were unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promoting and marketing ZYFLO or zileuton CR, our sales of ZYFLO and zileuton CR would be limited and we would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO or zileuton CR beyond the minimum required by the terms of the co-promotion agreement. Any decision not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement would limit our ability to generate significant revenues from product sales.

DEY is a subsidiary of Merck KGaA. Merck KGaA has publicly announced that it is evaluating the possible sale of its generic business, of which DEY is a part. We cannot predict what impact Merck KGaA s consummation of a possible sale of its generic business may have on our co-promotion arrangement with DEY.

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

We are relying on MedImmune to fund the development of and to commercialize product candidates in our HMGB1 program. We are relying on Beckman Coulter to fund the development and to commercialize diagnostics in our HMGB1 program. All of our revenues prior to October 2005, when we commercially launched ZYFLO, were derived from our collaboration agreements with MedImmune and Beckman Coulter. Additional payments due to us under the collaboration agreements with MedImmune and Beckman Coulter are generally based on our achievement of specific development and commercialization milestones that we may not meet. In addition, the collaboration agreements entitle us to royalty payments that are based on the sales of products developed and marketed through the collaborations. These future royalty payments may not materialize or may be less than expected if the related products are not successfully developed or marketed or if we are forced to license intellectual property from third parties. Accordingly, we cannot predict if our collaborations with MedImmune and Beckman Coulter will continue to generate revenues for us.

Our collaboration agreement with MedImmune generally is terminable by MedImmune at any time upon six months notice or upon our material uncured breach of the agreement. Under the collaboration agreement, we are obligated to use commercially

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reasonable, good faith efforts to conduct the collaboration in accordance with rolling three-year research plans that describe and allocate between MedImmune and us responsibility for, among other things, the proposed research, preclinical studies, toxicology formulation activities and clinical studies for that time period. In addition, we and MedImmune agreed to work exclusively in the development and commercialization of HMGB1-inhibiting products for a period of four years, and, after such time, we have agreed to work exclusively with MedImmune in the development of HMGB1-inhibiting products for the remaining term of the agreement. If MedImmune were to terminate or breach our arrangement, and we were unable to enter into a similar collaboration agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on our own, the development and commercialization of our HMGB1 program likely would be delayed, curtailed or terminated. The delay, curtailment or termination of our HMGB1 program could significantly harm our future prospects. We intend to enter into collaboration agreements with other parties in the future that relate to other product candidates, and we are likely to have similar risks with regard to any such future collaborations.

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

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

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

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

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

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

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

On April 22, 2007, MedImmune publicly announced that it had entered into an agreement and plan of merger with AstraZeneca PLC and, pending consummation of the transaction, MedImmune would become an indirect wholly-owned subsidiary of AstraZeneca. We cannot predict what impact MedImmune s consummation of this transaction may have on our HMGB1 collaboration with MedImmune.

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

We have no manufacturing facilities and limited manufacturing experience. In order to continue to develop product candidates, apply for regulatory approvals and commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. We currently rely on third parties for production of the zileuton API and zileuton CR, commercial supplies of ZYFLO and preclinical and clinical supplies of our product candidates.

These third parties are currently our sole source suppliers, and we expect to continue to rely on them for these purposes for the foreseeable future.

We have a contract with Shasun Pharma Solutions Ltd. for commercial production of the zileuton API, subject to specified limitations, through December 31, 2009. The manufacturing process for the zileuton API involves an exothermic reaction that

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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 ZYFLO and zileuton CR.

We have contracted with Patheon Pharmaceuticals Inc. for the manufacture of commercial supplies of ZYFLO tablets. We have contracted with Patheon for a technology transfer program to enable Patheon to coat and package the core tablets of zileuton CR for clinical trials and regulatory review, and, subject to negotiation of a commercial manufacturing agreement, commercial supplies.

We have contracted with SkyePharma PLC, through its subsidiary Jagotec AG, for the manufacture of tablets of zileuton CR for clinical trials, regulatory review and commercial sale. In January 2007, following a decision to concentrate on oral and pulmonary products, SkyePharma announced that it had reached an agreement for the sale of its injectable business. If SkyePharma sells all or a part of its remaining business, our ability to produce zileuton CR may be impaired.

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

We are dependent upon Shasun Pharma Solutions, Patheon and SkyePharma as sole providers, and will be dependent on any other third parties who manufacture our product candidates, to perform their obligations in a timely manner and in accordance with applicable government regulations. For example, during the quarter ended June 30, 2006, one of our contract manufacturers failed to meet our manufacturing specifications relating to certain manufacturing batches of ZYFLO. If third-party manufacturers with whom we contract fail to perform their obligations, we may be adversely affected in a number of ways, including the following:

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

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

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

We rely on third parties to distribute ZYFLO and, if approved, zileuton CR, to pharmacies. We have contracted with Integrated Commercialization Services, Inc., or ICS, a third-party logistics company, to warehouse ZYFLO and distribute it to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. ICS is our exclusive supplier of commercial distribution logistics services. If zileuton CR is approved for sale by the FDA, we expect to contract with ICS to warehouse and distribute zileuton CR. The wholesalers in turn distribute it to chain and independent

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pharmacies. Sales to AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation collectively accounted for at least 75% of our annual billings for ZYFLO during 2006. The loss of any of these wholesaler customers accounts or a material reduction in their purchases could harm our business, financial condition and results of operations.

We rely on Phoenix Marketing Group LLC to distribute samples of ZYFLO and, if approved, zileuton CR, to our sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. We have contracted with RxHope, Inc. to implement a patient assistance program for ZYFLO. We rely on RxHope to administer our patient assistance program and to distribute ZYFLO to physicians and other prescribers who are authorized under state law to receive and dispense samples.

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

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

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. We may seek to enter into additional collaboration agreements with pharmaceutical companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, we have determined to seek to enter into a collaboration arrangement with respect to the development of our alpha-7 product candidate. We do not plan to proceed with clinical development of our alpha-7 product candidate without entering into such an arrangement. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. We may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to us. If we are not successful in efforts to enter into a collaboration arrangement with respect to a product candidate, we may not have sufficient funds to develop any of our product candidates internally. If we do not have sufficient funds to develop our product candidates, we will not be able to bring these product candidates to market and generate revenue. In addition, our inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on our financial condition and results of operations because:

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

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

For product candidates with large target physician markets, we plan to rely significantly on sales, marketing and distribution arrangements with third parties. For example, we plan to rely on MedImmune for the commercialization of any anti-HMGB1 products that we develop and we plan to rely on Beckman Coulter for the commercialization of any diagnostic assay for HMGB1. We may not be successful in entering into additional marketing arrangements in the

future and, even if successful, we may not be able to enter into these arrangements on terms that are favorable to us. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, our future revenues may suffer.

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Risks Relating to Intellectual Property and Licenses

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

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

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

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

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

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

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

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

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

the patentability of our applications, including those relating to our products; or

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

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

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

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

encounter significant delays in bringing our product candidates to market; or

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

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

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

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

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

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

Risks Relating to Our Financial Results and Need for Additional Financing

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

We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $4.7 million in the quarter ended March 31, 2007 and net losses of $48.8 million in the year ended December 31, 2006. As of March 31, 2007, we had an accumulated deficit of approximately $159.0 million. For the quarter ended March 31, 2007, we recorded $2.9 million of revenue from the sale of ZYFLO and have not recorded revenue from any other product. We expect that we will continue to incur substantial

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losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts. We expect that the losses that we incur will fluctuate from quarter to quarter and that these fluctuations may be substantial. We will need to generate significant revenues to achieve profitability. Until we are able to generate such revenues, we will not be profitable and will need to raise substantial additional capital to fund our operations.

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

We expect to devote substantial resources to support the anticipated commercial launch of zileuton CR, to fund addition clinical trials and pilot studies on zileuton CR and to fund the development of our other product candidates. Our funding requirements will depend on numerous factors, including:

- the timing and costs of the regulatory approval and the commercial launch of zileuton CR, if and when it is approved by regulatory authorities;
- the scope, costs and results of our clinical trials on zileuton CR and zileuton injection;
- if approved, the amount and timing of sales and returns of zileuton CR;
- the timing and amount of sales and returns from ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO and, if approved, zileuton CR;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter or future collaborators;
- the timing, receipt and amount of sales and royalties, if any, from our potential products;
- continued progress in our research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under our license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the cost of obtaining and maintaining licenses to use patented technologies;
- potential acquisition or in-licensing of other products or technologies;
- our ability to establish and maintain additional collaborative or co-promotion arrangements; and
- the ongoing time and costs involved in certain corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act of 2002.

Other than payments that we receive from our collaborations with DEY, MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only source of revenue until we commercially launch zileuton CR, if it is approved for sale by the FDA. We believe that our ability to access external funds will depend upon the regulatory status of zileuton CR, market acceptance of zileuton CR, if approved, market acceptance of ZYFLO, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to obtain regulatory approval for and successfully commercialize zileuton CR and to sell ZYFLO. Based on our operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into 2009, assuming we receive FDA approval for

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and commercially launch zileuton CR in 2007. If zileuton CR is not approved and commercially launched in 2007, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the third quarter of 2008.

For the quarter ended March 31, 2007, our net cash used for operating activities was $3.0 million, and we had no capital expenditures . For the year ended December 31, 2006, our net cash used for operating activities was $51.4 million, and we had capital expenditures of approximately $370,000. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, our reserve for potential returns for ZYFLO is based on our historical experience of product returns for ZYFLO and other factors that could significantly impact expected returns. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct. If our estimates are inaccurate, this could adversely affect our stock price.

Risks Relating to Our Common Stock

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

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

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

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

- the regulatory status of zileuton CR;
- if approved, the amount and timing of sales of zileuton CR;
- the amount and timing of sales of 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 or, if approved, zileuton CR;

the amount of rebates, discounts and chargebacks to wholesalers, Medicaid and managed care organizations related to ZYFLO or, if approved, zileuton CR;

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the amount and timing of product returns for ZYFLO or, if approved, zileuton CR;

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

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

production problems occurring at our third party manufacturers;

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

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

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

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

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

the regulatory status of zileuton CR;

if approved, the amount and timing of sales of zileuton CR;

our operating results, including the amount and timing of sales of ZYFLO;

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

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

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

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

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

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

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

As of April 30, 2007, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 37.9% of our outstanding common stock. As a result, our directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

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

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

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

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

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, anti-takeover provisions to which we are subject include provisions in our by-laws providing that stockholders meetings may be called only by our president or the majority of our board of directors and a provision in our certificate of incorporation providing that our stockholders may not take action by written consent.

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

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

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

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

Not applicable.

Item 5. Other Information.

Resignation of Christopher Walsh, Ph.D. as Class I Director

On May 9, 2007, Christopher Walsh, Ph.D., a class I director, notified us that he will resign from the Company s board of directors effective May 10, 2007.

Manufacturing Services Agreement with Patheon Pharmaceuticals Inc.

On May 9, 2007, we entered into a 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 the controlled-release formulation of zileuton (zileuton CR) in tablet form (the Patheon Agreement). Under the Patheon Agreement, we are responsible for supplying uncoated zileuton CR tablets to Patheon. We have agreed to purchase at least 50% of our requirements for such manufacturing services for zileuton CR for sale in the United States from Patheon each year during the term of the Patheon Agreement.

The Patheon Agreement has an initial term of three years beginning May 9, 2007, and will automatically continue for successive one-year periods thereafter, unless we provide Patheon with 12-months prior written notice of termination or Patheon provides us with 18-months prior written notice of termination. In addition, we have the right to terminate the Patheon Agreement upon 30-days prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling zileuton CR. We also have the right to terminate the Patheon Agreement upon 90-days prior written notice if an AB-rated generic product to zileuton CR is introduced in the United States. If we provide six-months advance notice that we intend to discontinue commercializing zileuton CR, we will not be required to purchase any additional quantities of zileuton CR finished tablets from Patheon, provided that we pay Patheon for a portion of specified fees and expenses associated with orders we previously placed. Patheon has the right to terminate the Patheon Agreement if we assign any of our rights under the agreement to an assignee other than a purchaser or merger partner that, in Patheon s reasonable opinion, is not a credit worthy substitute for us, is a competitor of Patheon or is an entity with whom Patheon has had prior unsatisfactory business relations. Furthermore, each party has the right to terminate the Patheon

Agreement upon the occurrence of a material uncured breach by the other party. If the Patheon Agreement expires or is terminated for any reason, we have agreed to take delivery of and pay for undelivered quantities of zileuton CR that we previously ordered, purchase, at cost, Patheon s inventory of zileuton CR maintained in contemplation of filling orders previously placed by us and pay the purchase price for components of the zileuton CR tablets ordered by Patheon from suppliers in reliance on orders we previously placed.

The Patheon Agreement is filed as Exhibit 10.5 to this Quarterly Report on Form 10-Q, and we refer you to such exhibit for the complete terms of the Patheon Agreement, which are incorporated herein by reference.

Amendment No. 1 to Agreement for Manufacturing and Supply of Zileuton with Shasun Pharma Solutions (as successor to Rhodia Pharma Solutions)

On May 9, 2007, we and Shasun Pharma Solutions Limited (Shasun) entered into Amendment No. 1 (the Amendment) to the Agreement for Manufacturing and Supply of Zileuton (the Original Agreement), dated February 8, 2005, by and between Shasun (as successor to Rhodia Pharma Solutions Limited by Deed of Novation dated March 14, 2007) and us. The Amendment amends the Original Agreement in the following material respects:

The Original Agreement had an initial term extending through December 31, 2009 and automatically extended for successive one-year periods thereafter, unless Shasun provided us with 18-months prior written notice of cancellation. Pursuant to the Amendment, this initial term extends through the earlier of (i) the date on which we have purchased a specified amount of the active product ingredient (API) for zileuton and (ii) December 31, 2010, subject to extension for successive one-year periods in the same manner as the Original Agreement.

Under the Original Agreement, we agreed to purchase a minimum amount of the API by December 31, 2006. As a result of the Amendment, this date has been extended to March 31, 2008.

Under the Original Agreement, Shasun has a right of first refusal to supply us with an additional amount of our API requirements beginning in calendar year 2007. As a result of the Amendment, this right of first refusal becomes effective on the earlier of (i) the date on which we have purchased a specified amount of the API and (ii) December 31, 2010.

Under the Original Agreement, we had the right to terminate the agreement upon 12-months prior written notice for any reason, provided that we could not terminate prior to January 1, 2008 for the purpose of retaining any other company to act as our exclusive supplier of the API. As a result of the Amendment, we cannot exercise this termination right before the earlier of (i) the date on which we have purchased a specified amount of the API and (ii) December 31, 2010. In addition, the Amendment provides that we will have the right to terminate the Original Agreement in the event that any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, or selling our zileuton products or the API. If we exercise our right to terminate the agreement prior to its scheduled expiration, we are obligated to reimburse Shasun for specified raw material and out-of-pocket costs.

The Amendment is filed as is filed as Exhibit 10.4 to this Quarterly Report on Form 10-Q, and we refer you to such exhibit for the complete terms of the Amendment, which are incorporated herein by reference. The Original Agreement was filed as Exhibit 10.25 to our Annual Report on Form 10-K for the year ended December 31, 2004. Certain portions of the Original Agreement as so filed were omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment, which was subsequently granted.

Item 6. Exhibits.

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

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SIGNATURES

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

CRITICAL THERAPEUTICS, INC.

Date: May 10, 2007

/s/ Frank E. Thomas
Frank E. Thomas
President and Chief Executive Officer
(*Principal Executive Officer and Principal Financial Officer*)

Date: May 10, 2007

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

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EXHIBIT INDEX

Exhibit Number	Description
10.1 +	Exclusive License Agreement, dated as of January 29, 2007, between the Registrant and Innovative Metabolics, Inc. (Incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K, dated January 29, 2007, as filed with the Securities and Exchange Commission on January 30, 2007).
10.2 +	Co-Promotion and Marketing Services Agreement by and between the Registrant and Dey, L.P. dated March 13, 2007.
10.3 +	Binding Letter Agreement relating to COPD Co-Promotion by and between the Registrant and Dey, L.P. dated March 13, 2007.
10.4 +	Amendment No. 1, dated May 9, 2007, to Agreement for Manufacturing and Supply of Zileuton effective February 8, 2005 by and between Shasun Pharma Solutions Limited and the Registrant.
10.5 +	Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant dated May 9, 2007.
31	Certification of the Principal Executive Officer and 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	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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