CRITICAL THERAPEUTICS INC
Form 10-Q
August 09, 2006

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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 June 30, 2006

or

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

For the Transition Period from _____ to _____

Commission File Number: 000-50767

Critical Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(781) 402-5700

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer 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 August 7, 2006, the registrant had 34,244,456 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, which we refer to as the Exchange Act. For this purpose, any statements contained herein regarding possible therapeutic benefits and market acceptance of ZYFLO® (zileuton tablets), 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, other than statements of historical facts, are forward-looking statements made 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, may, plan, project, should, will, would o 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 extent of market acceptance of ZYFLO; our ability to rely on historical data in seeking marketing approval for the controlled-release formulation of zileuton, including the sufficiency and acceptability of the results of the pharmacokinetic studies of the controlled-release formulation of zileuton for U.S. Food and Drug Administration, or FDA, purposes; the expected timing and outcome of the new drug application, or NDA, for the controlled-release formulation of zileuton and related discussions with the FDA; our ability to maintain regulatory approval to market and sell ZYFLO; our ability to transition our management team effectively; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO; patient, physician and third-party payor acceptance of ZYFLO as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO; 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; the timing and success of submission, acceptance and approval of regulatory filings, including the new drug application for the controlled-release formulation of zileuton; our heavy dependence on the commercial success of ZYFLO and, if approved, the controlled-release formulation of zileuton; 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, 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, except share data	June 30, 2006	December 31, 2005
Assets:		
Current assets:		
Cash and cash equivalents	$ 37,292	$ 57,257
Accounts receivable, net	957	1,024
Amount due under collaboration agreements	250	205
Short-term investments	14,869	25,554
Inventory, net	2,786	1,869
Prepaid expenses and other	1,563	2,179
Total current assets	57,717	88,088
Fixed assets, net	3,333	3,563
Other assets	168	168
Total assets	$ 61,218	$ 91,819
Liabilities and Stockholders Equity:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	$ 1,151	$ 1,179
Accounts payable	4,292	4,615
Accrued expenses	4,568	4,876
Revenue deferred under collaboration agreements	3,259	5,706
Deferred product revenue	1,272	1,707
Total current liabilities	14,542	18,083
Long-term debt and capital lease obligations, less current portion	930	1,489
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 34,237,790 and 34,126,977 shares at June 30, 2006 and December 31, 2005, respectively	34	34
Additional paid-in capital	182,806	181,718
Deferred stock-based compensation	(296)	(3,794)
Accumulated deficit	(136,767)	(105,617)
Accumulated other comprehensive loss	(31)	(94)
Total stockholders equity	45,746	72,247

Total liabilities and stockholders equity	$ 61,218	$ 91,819

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 June 30, 2006	Three Months Ended June 30, 2005	Six Months Ended June 30, 2006	Six Months Ended June 30, 2005
Revenues:				
Net product sales	$ 1,809	$	$ 2,831	$
Revenue under collaboration agreements	1,696	1,431	2,947	2,790
Total revenues	3,505	1,431	5,778	2,790
Costs and expenses:				
Cost of products sold	890		1,394	
Research and development	6,935	6,652	16,328	13,226
Sales and marketing	5,663	1,755	12,570	2,992
General and administrative	5,081	2,741	8,009	5,763
Total costs and expenses	18,569	11,148	38,301	21,981
Operating loss	(15,064)	(9,717)	(32,523)	(19,191)
Other income (expense):				
Interest income	716	428	1,488	825
Interest expense	(55)	(38)	(115)	(80)
Total other income	661	390	1,373	745
Net loss	($ 14,403)	($ 9,327)	($ 31,150)	($ 18,446)
Net loss per share	($ 0.42)	($ 0.37)	($ 0.91)	($ 0.75)
Basic and diluted weighted-average common shares outstanding	34,203,598	25,045,206	34,150,432	24,457,098

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	June 30, 2006	2005
Cash flows from operating activities:		
Net loss	($ 31,150)	($ 18,446)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	500	393
Amortization of premiums on short-term investments and other	(1)	585
Loss on disposal of fixed assets	51	
Reserve for inventory	702	
Stock-based compensation expense	4,523	952
Changes in assets and liabilities:		
Accounts receivable	67	
Amount due under collaboration agreements	(45)	(475)
Inventory	(1,619)	
Prepaid expenses and other	616	(882)
Accounts payable	(323)	(1,445)
Accrued expenses	(308)	114
Revenue deferred under collaboration agreements	(2,447)	(1,684)
Deferred product revenue	(435)	
Net cash used in operating activities	(29,869)	(20,888)
Cash flows from investing activities:		
Purchases of fixed assets	(321)	(827)
Proceeds from sales and maturities of short-term investments	22,551	42,190
Purchases of short-term investments	(11,802)	(27,708)
Net cash provided by investing activities	10,428	13,655
Cash flows from financing activities:		
Net proceeds from private placement of common stock		51,535
Proceeds from exercise of stock options	63	21
Proceeds from long-term debt		418
Repayments of long-term debt and capital lease obligations	(587)	(505)
Net cash provided by (used in) financing activities	(524)	51,469
Net increase (decrease) in cash and cash equivalents	(19,965)	44,236
Cash and cash equivalents at beginning of period	57,257	11,980
Cash and cash equivalents at end of period	$ 37,292	$ 56,216

Supplemental disclosures of cash flow information:

Cash paid during the period for:		
Interest	$ 117	$ 80
Non-cash investing and financing activities:		
Adjustment to deferred stock-based compensation for services to be performed	$ 716	$ 146
Unrealized gain on investments	$ 63	$ 101
Common stock offering expenses included in accrued expenses	$	$ 173

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, 2005 filed with the Securities and Exchange Commission, or SEC.

Operating results for the three and six-month periods ended June 30, 2006 and 2005 are not necessarily indicative of the results for the full year. Certain amounts in the condensed consolidated statement of operations for the six months ended June 30, 2005 have been reclassified to conform to current year presentation.

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, 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.

The Company sells ZYFLO, a tablet formulation of zileuton, to wholesalers, distributors and pharmacies, which have the right to return purchased product. In accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, the Company cannot recognize revenue on product shipments until it can reasonably estimate returns relating to these shipments. Under SFAS No. 48, the Company defers recognition of revenue on product shipments of ZYFLO to its customers until the product is dispensed through patient prescriptions. The Company estimates prescription units dispensed based on distribution channel data provided by external, independent sources. ZYFLO received by patients through prescription is not subject to return. During the second quarter of 2006, the Company obtained additional distribution channel data from mail-order pharmacies and non-retail facilities, such as clinics and hospitals, allowing it to better estimate total prescriptions filled. This resulted in the recognition of $173,000 of additional revenue in the second quarter of 2006. For the quarter ended June 30, 2006, product sales, net of discounts and rebates, was $1.8 million. Product shipments not recognized are included in deferred product revenue on the accompanying consolidated balance sheet. The Company will continue to recognize revenue upon prescription units dispensed until it can reasonably estimate

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product returns based on its product returns experience. At that time, the Company will record a one-time increase in net product sales related to the recognition of revenue previously deferred. In addition, the Company s product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

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 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. In June 2006, the Company revised its cost estimate to reflect lower than expected costs to be incurred over the remainder of the MedImmune contract. The change in estimate resulted in an increase in revenue recognized of approximately $479,000 in the second quarter of 2006.

At June 30, 2006, the Company s account receivable balance was net of allowances of $22,000.

(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 $34,000 and $63,000 during the three and six months ended June 30, 2006, respectively. The Company recorded unrealized gains on investments of $131,000 and $101,000 during the three and six months ended June 30, 2005, 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 and six months ended June 30, 2006.

(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 June 30, 2006, the Company held $2.8 million in inventory to be used for sales related to its commercial product, ZYFLO. The Company analyzes its inventory levels quarterly and writes-down 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 or inventory that does not meet certain Company specifications is disposed of and the related costs are written off. In the quarter ended June 30, 2006, approximately eight lots of ZYFLO tablets did not meet manufacturing specifications. The deviations were a result of the Company s contract manufacturer failing to meet the Company s manufacturing specifications. In the three months ended June 30, 2006, the Company recorded a reserve of approximately $464,000 related to ZYFLO s active pharmaceutical ingredient, or API, costs related to the product not meeting the Company s manufacturing specifications and $95,000 related to other inventory that is unlikely to be sold. In June 2006, the Company recorded a receivable, included in its other current assets, of $590,000 for reimbursement owed to it for $464,000 of costs related to API and $126,000 of costs related to samples and certain manufacturing costs related to these lots not meeting the manufacturing specifications. At June 30, 2006, the inventory related to these lots has not yet been disposed.

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Inventory consisted of the following at June 30, 2006 and December 31, 2005, respectively (in thousands):

	June 30, 2006	December 31, 2005
Raw material	$ 3,081	$ 1,425
Work in process		332
Finished goods	687	392
Total inventory	3,768	2,149
Less: reserve	(982)	(280)
Inventory, net	$ 2,786	$ 1,869

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. 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 and six months ended June 30, 2006 and 2005, and comprehensive loss is the unrealized gain (loss) on short-term investments for the period. Total comprehensive loss was $14.4 million and $31.1 million for the three and six months ended June 30, 2006, respectively, and was $9.2 million and $18.3 million for the three and six months ended June 30, 2005, 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

Prior to January 1, 2006, the Company accounted for stock-based awards to employees using the intrinsic-value method as prescribed by APB No. 25 and related interpretations. Accordingly, no compensation expense was recorded for options issued to employees in fixed amounts and with fixed exercise prices at least equal to the fair market value of the Company s common stock at the date of grant. Conversely, when the exercise price for accounting purposes was below fair value of the Company s common stock on the date of grant, a non-cash charge to compensation expense was recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. 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 deemed fair market value. This resulted in recording deferred 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. Options granted prior to the date of the initial S-1 filing continue to be accounted for under 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. The Company periodically remeasures the fair value of the unvested portion of stock-based awards to non-employees, resulting in charges or credits to operations in periods when such remeasurement results in differences between the fair value of the underlying common stock and the exercise price of the options that is greater than or less than the differences, if any, between the fair value of the underlying common stock and the exercise price of the options at their respective previous measurement dates. For the three and six months ended June 30, 2006 the Company reduced its previously

recorded deferred stock-based compensation by approximately $139,000 and $285,000, respectively.

For the three and six months ended June 30, 2005, had employee compensation expense been determined based on the fair value at the date of grant consistent with SFAS No. 123(R), the Company s pro forma net loss and pro forma net loss per share would have been as follows:

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	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
(in thousands, except loss per share data)		
Net loss as reported	$ (9,327)	$ (18,446)
Add: Stock-based compensation expense included in reported net loss	448	895
Deduct: Stock-based compensation expense determined under fair value method	(846)	(1,672)
Net loss pro forma	$ (9,725)	$ (19,223)
Net loss per share (basic and diluted):		
As reported	$ (0.37)	$ (0.75)
Pro forma	$ (0.39)	$ (0.79)

Stock option activity for the six months ended June 30, 2006 and June 30, 2005 was as follows:

	2006		2005	
	Number of Shares	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
Outstanding January 1	6,200,106	$ 5.03	4,500,270	$ 4.23
Granted	741,250	6.97	358,500	7.27
Exercised	(89,204)	0.46	(13,668)	1.50
Cancelled	(62,594)	6.34	(3,540)	5.28
Outstanding March 31	6,789,558	$ 5.29	4,841,562	$ 4.46
Granted	1,661,250	3.99	311,000	5.64
Exercised	(21,609)	1.04	(1,383)	5.86
Cancelled	(1,020,344)	5.85	(58,000)	6.50
Outstanding June 30	7,408,855	$ 4.93	5,093,179	$ 4.51
Exercisable June 30	2,595,458	$ 4.13	960,495	$ 1.83

The weighted average remaining contractual term and the aggregate intrinsic value for options outstanding at June 30, 2006 were 8.7 years and $3.4 million, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options exercisable at June 30, 2006 were 7.9 years and $2.8 million, respectively. The total intrinsic value of the options exercised during the three months ended June 30, 2006 was approximately $65,000.

As of June 30, 2006, $297,000 of deferred compensation has yet to be recognized. Such amounts will be recognized over the next 20 months. The Company expenses this deferred stock-based compensation to operations over the vesting period of the options and recorded stock-based compensation expense of $158,000 for the six months ended June 30, 2006 and $952,000 for the six months ended June 30, 2005.

The total fair value of the shares vested (other than pre S-1 shares vested) and expensed during the three months ended June 30, 2006 was $2.5 million. As of June 30, 2006 there was $17.1 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 1.6 years.

The Company anticipates recording additional stock-based compensation expense of $3.4 million in the second half of 2006, $6.4 million in 2007, $4.4 million in 2008 and $2.9 million thereafter relating to the amortization of unrecognized compensation expense as of June 30, 2006. 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

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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 quarter ended June 30, 2006 and has computed the pro forma disclosures required under the modified prospective method for the quarter ended June 30, 2005. The Company increased its assumption for the three and six months ended June 30, 2006 regarding expected volatility to 60% from 58% in the corresponding periods of 2005. The revised rate is based on the Company s actual historical volatility since its initial public offering. In addition, the Company increased its assumption for the three and six months ended June 30, 2006 regarding expected life to 6.25 years from 4 years in prior years. The expected life of options granted was estimated using the simplified method calculation as prescribed by SFAS No. 123(R). The assumptions used and weighted-average information are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Risk free interest rate	5.1%	3.9%	4.9%	3.7%
Expected dividend yield	0%	0%	0%	0%
Expected forfeiture rate	4.2%		4.2%	
Expected life	6.25 years	4 years	6.25 years	4 years
Expected volatility	60%	58%	60%	58%
Weighted-average fair value of options granted equal to fair value	$ 2.45	$ 3.01	$ 2.99	$ 2.69

The Company has had three stock option plans since its inception: the 2004 Stock Incentive Plan (the 2004 Stock Plan), the 2003 Stock Incentive Plan (the 2003 Stock Plan) and the 2000 Equity Incentive Plan (the 2000 Equity Plan). These plans permit the granting of stock awards to key employees, directors, consultants, and vendors of the Company and its affiliates. Awards under the 2004 Stock Plan, the 2003 Stock Plan and the 2000 Equity Plan may include incentive stock options, nonqualified stock options, and restricted common stock. Awards can only be made currently under the 2004 Stock Plan.

In April 2006, the stockholders of the Company approved the Company s 2006 Employee Stock Purchase Plan (the 2006 Stock Purchase Plan). The 2006 Stock Purchase Plan was adopted by the Company s board of directors in February 2006. The 2006 Stock Purchase Plan provides for the issuance of up to 400,000 shares of the Company s common stock to participating employees and is implemented by offering periods with a duration of six months. Offerings will begin each June 1 and December 1, or the first business day thereafter, commencing June 1, 2006.

On the first day of an offering period, the Company will grant to each eligible employee who has elected to participate in this plan a purchase right for shares of common stock. The employee may authorize up to 15% of his or her compensation to be deducted during the offering period. On the last business day of the offering period, the employee will be deemed to have exercised the purchase right, at the applicable purchase price per share, to the extent of accumulated payroll deductions. The purchase price per share under this plan will be 85% of the lesser of the closing price per share of the common stock on the Nasdaq Global Market on the first day of the offering period or the last business day of the offering period. The 2006 Stock Purchase Plan may be terminated at any time by the Company s board of directors.

In June 2006, both the Company s former President and Chief Executive Officer and Senior Vice President of Sales and Marketing resigned. Upon resignation, 50% of their remaining unvested stock-based compensation awards vested. In accordance with SFAS No. 123(R), the Company recorded stock-based compensation for all accelerated awards. In June 2006, the Company recorded $1.3 million of stock-based compensation expense in general and administrative expense and $525,000 of stock-based compensation expense in sales and marketing expense due to the acceleration of vesting on options held by the former President and Chief Executive Officer and Senior Vice President of Sales and Marketing, respectively.

(7) Restructuring

In May 2006, the Company recorded charges of $499,000 for a restructuring of its operations that is intended to better align costs with revenue and operating expectations. The restructuring charges, which include $95,000 in general and administrative expense, $231,000 in research and development expense and $173,000 in sales and marketing expense, pertain to employee severance benefits, outplacement services, automobile lease termination fees and impairment of assets.

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The restructuring charges were recorded in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

In connection with the restructuring plan, the Company terminated 27 employees or approximately 16% of the Company s workforce, resulting in a severance charge of $383,000, which was accrued in May 2006. None of these employees remained employed as of May 31, 2006. As a result of terminating these employees, the Company recorded an automobile lease termination fee of $54,000, an outplacement service fee of $39,000 and an impairment charge of $23,000 for computer equipment for which the future use is currently uncertain. In the second quarter of 2006 the Company paid $203,000 of severance and other related charges which include $35,000 in general and administrative expense, $111,000 in research and development expense and $57,000 in sales and marketing expense. At June 30, 2006, the Company had $296,000 remaining in accrued expense related to its May restructuring.

In addition, at June 30, 2006, the Company had $972,000 of accrued severance and bonus expense related to the resignation of its former President and Chief Executive Officer and its former Senior Vice President of Sales and Marketing, which is not included in the restructuring charges above. These amounts are expected to be paid in December 2006 in accordance with the contractual terms of the severance and release agreements signed by the individuals.

(8) Basic and Diluted Loss per Share

Basic and diluted net loss per common share is calculated by dividing the net loss by the weighted-average number of unrestricted common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, 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 10,917,110 and 8,680,590 as of June 30, 2006 and 2005, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of June 30, 2006 and 2005.

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 June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Weighted-average common shares outstanding	34,236,210	25,192,703	34,190,231	24,647,257
Less: weighted-average restricted common shares outstanding	(32,612)	(147,498)	(39,799)	(190,158)
Basic and diluted weighted-average common shares outstanding	34,203,598	25,045,206	34,150,432	24,457,098

(9) 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 $13.7 million as of June 30, 2006. 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 June 30, 2006, the Company has $130,000 and $912,000 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.

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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 Shasun Pharma Solutions Ltd. (formerly Rhodia Pharma Solutions), or Shasun, for commercial production of the API for ZYFLO, subject to specified limitations, through December 31, 2009. Under this agreement, the Company committed to purchase a minimum amount of API by December 31, 2006. The API purchased from Shasun currently has a shelf-life of 24 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. As of June 30, 2006, no reserves have been recorded for purchase commitments.

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.

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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, 2005 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

We are a biopharmaceutical company and have devoted substantially all of our efforts since inception to the commercialization of our product, ZYFLO, research and development and in-licensing of product candidates designed to treat respiratory, inflammatory and critical care diseases linked to the body s inflammatory response. ZYFLO is approved by the FDA for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. We were incorporated in July 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.

We began selling ZYFLO in the United States in October 2005. In addition, we believe that zileuton has potential therapeutic benefits in a range of other diseases and conditions, such as acute asthma exacerbations and chronic obstructive pulmonary disease, or COPD. We are currently incurring costs to expand the potential applications of zileuton through development of additional formulations, including controlled-release and intravenous formulations. In April 2006, the FDA accepted our proposal to submit a new drug application, or NDA, for our controlled-release formulation of zileuton with six months of primary and accelerated stability data and to provide additional stability data during the NDA review period, without impacting the action date by the FDA. We submitted the NDA to the FDA on July 31, 2006.

We are also developing 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.

HMGB1. We believe that a cytokine called HMGB1, or high mobility group box protein 1, may be an important target for the development of products to treat inflammation-mediated diseases because of the timing and the duration of its release from cells into the bloodstream. We are currently collaborating with MedImmune, Inc. on preclinical development of monoclonal antibodies directed towards HMGB1 in a number of animal models. We believe these antibodies could act to neutralize circulating HMGB1 and be used to target diseases such as sepsis or rheumatoid arthritis. In addition, we are currently collaborating with Beckman Coulter, Inc. on development of a diagnostic directed towards measuring HMGB1 in the bloodstream.

Alpha-7. We are developing small molecules designed to inhibit the body s inflammatory response by acting on the nicotinic alpha-7 cholinergic target, which is a cell receptor associated with the production of the cytokines that play a fundamental role in the inflammatory response. We believe that successful development of a product candidate targeting the nicotinic alpha-7 cholinergic target could lead to an oral anti-cytokine therapy for acute and chronic inflammatory diseases

CTI-01. In March 2006, we announced that we had discontinued a Phase II clinical trial of 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. We discontinued the trial after routine testing revealed some swelling in the butyl rubber stoppers used to seal

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the vials that stored the drug. We are analyzing the safety and efficacy data from the 102 patients who received medication before we discontinued the trial. We expect to complete our analysis of the trial data in the third quarter of 2006. Decisions on the future development of CTI-01 will depend upon the outcome of the analysis of the data.

Since our inception, we have incurred significant losses each year. As of June 30, 2006, we had an accumulated deficit of $136.8 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability at all. 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.

In May 2006, we announced a comprehensive review of our cost structure to reduce expenses for 2006 and 2007. These reductions are intended to reduce our operating expenses to allow us to better support our operations leading up to our anticipated 2007 launch of the controlled-release formulation of zileuton. After a preliminary review of our operating budget, we identified approximately $15 million to $20 million in potential cost reductions for 2006. Prior to June 30, 2006, we finalized and implemented the steps that we anticipate will be necessary to realize these cost reductions. We anticipate these cost reductions to come primarily from lower spending on early stage discovery and research programs, reduced headcount and a deferral of some manufacturing initiatives. In addition, based on an evaluation of all our sales territories for performance and market potential, we identified territories for consolidation or elimination and have reduced our sales force to approximately 60 representatives from 80 representatives.

In June 2006, we announced that Paul D. Rubin, M.D. had stepped down from his position as our President and Chief Executive Officer and resigned from our board of directors and that Frederick Finnegan had resigned from his position as our Senior Vice President of Sales and Marketing. In connection with these departures, we are obligated to make aggregate lump sum cash severance payments of approximately $947,000 to these former executives.

Since inception, we have raised proceeds to fund our operations through our initial public offering of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, and, beginning in the fourth quarter of 2005, revenues from sales of ZYFLO.

In July 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1. Under this collaboration, MedImmune paid us initial fees of $12.5 million in 2003 and an additional $500,000 in the first half of 2006, $2.75 million in 2005 and $1.5 million in 2004 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program.

In January 2005, we entered into a license agreement with Beckman Coulter relating to the development of diagnostics for measuring HMGB1. In consideration for the license, Beckman Coulter paid us a product evaluation license fee of $250,000 in February 2005.

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 shipping our first commercial product, ZYFLO. We recorded $1.0 million and $1.8 million in net product sales for the quarters ended March 31, 2006 and June 30, 2006, respectively.

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 write-offs to reserve for excess or obsolete inventory. Most of our

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manufacturing and distribution costs are paid to third party manufacturers. However, there are some internal costs reflected in cost of products sold, including salaries and expenses related to managing our supply chain and for quality assurance and release testing.

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 the controlled-release formulation of zileuton, 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 research and development expenses. We expense research and development costs and patent related costs as 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 later stage programs such as the intravenous 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 development portfolio will fluctuate depending primarily on the timing of clinical trials, milestone payments to third parties, and manufacturing initiatives. We expect to incur increased expenses over the next several years for clinical trials of our product development candidates, including the controlled-release and intravenous formulations of zileuton and alpha-7. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we complete registration activities relating to the manufacturing of the controlled-release formulation of zileuton and scale up production of the intravenous formulation of zileuton for late phase clinical trials. We also expect to initiate a post-marketing, Phase IIIb program for ZYFLO to examine its potential clinical benefits in certain populations of asthma patients, which, if conducted, would be included in research and development expenses.

Sales and Marketing. Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales and marketing functions as well as other costs related to ZYFLO. Other costs reflected in sales and marketing include the cost of product samples of ZYFLO, promotional materials, market research and sales meetings. We expect to continue to incur significant sales and marketing costs associated with our sales force and the continued enhancement of the sales and marketing infrastructure to support ZYFLO. If any of our other product candidates are approved for marketing, we expect to incur additional expenses related to enhancing our sales and marketing functions and adding additional sales representatives.

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 reflected in general and administrative expenses include certain facility costs as well as professional fees for legal and accounting services.

Deferred Stock-Based Compensation Expense. As discussed more fully in Note 6 to our condensed consolidated financial statements included herein and in Notes 7 and 8 to our consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2005, in lieu of cash payments, we granted options to purchase 120,000 shares of common stock to non-employees during the six months ended June 30, 2005. We recorded these grants at fair value when granted. We periodically remeasure the fair value of the unvested portion of these grants, resulting in charges or credits to operations in periods when such remeasurement results in differences between the fair value of the underlying common stock and the exercise price of the options that is greater than or less than the differences, if any, between

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the fair value of the underlying common stock and the exercise price of the options at their respective previous measurement dates. During the six months ended June 30, 2006, we granted no options to purchase shares of our common stock to non-employees. For the six months ended June 30, 2006 we reduced our previously recorded deferred stock-based compensation by approximately $285,000. During the six months ended June 30, 2006 and June 30, 2005, we granted options to purchase 86,250 and 75,000 shares of common stock, respectively, to members of our board of directors.

As discussed more fully in Note 6 to our condensed consolidated financial statements included herein and Notes 7 and 8 to our consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2005, we granted options to purchase 2,316,250 and 474,500 shares of our common stock to employees during the six months ended June 30, 2006 and June 30, 2005, respectively. In addition, certain of the employee options granted during 2004 and prior years were deemed for accounting purposes to have been granted with exercise prices below their then-current market value. We recorded the value of these differences as deferred stock-based compensation and amortized the deferred amounts as charges to operations over the vesting periods of the grants, resulting in stock-based compensation expense. We recorded stock-based compensation expense of $35,000 and $448,000 for the three months ended June 30, 2006 and June 30, 2005, respectively, and $443,000 and $895,000 for the six months ended June 30, 2006 and June 30, 2005, respectively, related to stock options granted to employees at exercise prices below their current market value on the date of grant.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations is based on our unaudited 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 Consolidated Financial Statements and Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies in our annual report on Form 10-K for the year ended December 31, 2005. 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, accrued expenses, stock-based compensation and income taxes described under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies in our annual report on Form 10-K for the year ended December 31, 2005, fit the definition of critical accounting estimates.

Revenue Recognition. In the fourth quarter of 2005, we launched our first commercial product, ZYFLO. 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 defer revenue on product shipments until we can reasonably estimate returns relating to these shipments. Because ZYFLO is a new product for us and this is our first commercial product launch, we do not currently have an objective measurement or history to allow us to estimate returns. Accordingly, we are deferring the recognition of revenue on product shipments of ZYFLO to our customers until the product is 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. We currently estimate prescription units dispensed based on distribution channel data provided by external sources. We will

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continue to recognize revenue based upon prescriptions dispensed until we can reasonably estimate product returns based on our product returns experience. When a reasonable estimate can be determined, we will likely record a one-time increase in net product sales related to the recognition of revenue previously deferred, net of an estimate for remaining product returns. In order to match the cost of products shipped to customers with the underlying revenue, we have deferred the recognition of costs related to shipments that have not been recognized as revenue.

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 amount of cash received would be a limiting factor in determining the adjustment.

Inventory. Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In June 2006, ZYFLO s twelve-month shelf life was extended to a fifteen-month shelf life. As of June 30, 2006, inventory consists of zileuton API, which is raw material in powder form and finished ZYFLO 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 to cost of product revenues. During the quarter ended June 30, 2006, we recorded a reserve to cost of products sold of $95,000, excluding amounts to be reimbursed, for inventory that was unlikely to be sold.

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

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Short-term investments. 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 to support 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. We review the appropriateness of all investment classifications at each reporting date.

Stock-Based Compensation. Prior to January 1, 2006, we elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation Accounting Principles Board Opinion,* or SFAS 123. Accordingly, we did not record stock-based compensation expense for stock options issued to employees in fixed amounts with exercise prices at least equal to the fair value of the underlying common stock on the date of grant. Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), using the modified prospective application method, which requires the Company to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after the required effective date. In the notes to our consolidated financial statements included herein, we have provided pro forma disclosures for the three and six months ended June 30, 2005 in accordance with SFAS 123(R).

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) and Emerging Issues Task Force Issue No. 96-18, or EITF 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

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 or sold by us under SFAS 123(R) and EITF 96-18 requires fair value estimates of the equity instrument granted or sold. 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 us 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 June 30, 2006, we had federal and state tax net operating loss carryforwards of approximately $115.3 million, which expire beginning in 2021 and 2006, respectively. We also have research and experimentation credit carryforwards of approximately $1.5 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 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.

Results of Operations

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Three Months Ended June 30, 2006 and 2005

Revenue from Product Sales. We recognized revenue from product sales, net of discounts and rebates, of $1.8 million in the three months ended June 30, 2006 related to sales of ZYFLO. Under SFAS No. 48, we cannot recognize revenue from product shipments until the right to return the product has lapsed or until we can reasonably estimate returns relating to the shipments to third parties. In accordance with SFAS No. 48, we are currently deferring recognition of revenue on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product is dispensed through patient prescriptions. Shipments of ZYFLO to third parties not recognized as revenue are included in deferred product revenue on our balance sheet. This deferred revenue, which amounted to $1.3 million at June 30, 2006, will be recognized as revenue as prescriptions are filled in future periods, or will be reversed if the product is returned in future periods. The deferred cost of product sold related to the ZYFLO deferred revenue totaled $96,000 at June 30, 2006 and is included in prepaid expenses and other current assets on our balance sheet. During the second quarter of 2006, we obtained additional distribution channel data from mail-order pharmacies and non-retail facilities, such as clinics and hospitals, allowing us to better estimate total prescriptions filled. This resulted in the recognition of $173,000 of additional revenue in the second quarter of 2006 from prescriptions that relate to the period from launch in October 2005 to the end of the first quarter of 2006.

Revenue under Collaboration Agreements. We recognized collaboration revenues of $1.7 million for the three months ended June 30, 2006 compared to $1.4 million in the three months ended June 30, 2005. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid us that we recognized in each period, and a portion of the $500,000, $2.75 million and $1.5 million billed to MedImmune for milestone payments and development support in the first half of 2006, in 2005 and in 2004, respectively. Since we entered into the agreement with MedImmune in 2003, we have billed a total of $17.3 million to MedImmune, consisting of the $12.5 million up-front payment, a $1.25 million milestone payment and $3.5 million of development support. We have recognized $14.0 million of these amounts as collaboration revenue to date. We have reported the balance of the payments, totaling $3.3 million, 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 2006 and 2007. As of June 30, 2006, we had a total of $3.3 million in deferred collaboration revenue remaining to be recognized under our collaboration agreements with MedImmune and Beckman Coulter. In June 2006, we revised our cost estimate to reflect lower than expected costs to be incurred over the remainder of the contract. The change in estimate resulted in an increase in revenue recognized of approximately $479,000 in the second quarter of 2006.

Cost of products sold. Cost of products sold in the three months ended June 30, 2006 was $890,000. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO, a royalty payment to Abbott from the license agreement for ZYFLO and a charge of $187,000 to write-down excess finished goods inventory that we do not currently expect to be sold in the future. The write-down resulted from excess inventory on-hand at June 30, 2006 with an expiration date on or before October 2006 as well as API we believe will not be sold.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2006 were $6.9 million compared to $6.7 million for the three months ended June 30, 2005. The increase of approximately $283,000 was primarily due to an increase in expenses related to our research and development activities which are discussed in more detail below. With the commercial launch of ZYFLO in October 2005, the costs of manufacturing ZYFLO are now included in cost of products sold.

The following table summarizes the primary components of our direct research and development expenses for the three months ended June 30, 2006 and 2005:

	Three Months Ended June 30,	
	2006	2005
	(in thousands)	

Zileuton	$ 3,718	$ 3,406
CTI-01	831	536
HMGB1	519	481

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	Three Months Ended June 30,	
	2006	2005
	(in thousands)	
Alpha-7	985	587
General research and development expenses	635	1,326
Stock-based compensation expense	247	316
Total research and development expenses	$ 6,935	$ 6,652

We anticipate that our research and development expenses will continue to increase as we further advance our research and development projects. The following summarizes the expenses associated with our primary research and development programs:

Zileuton. During the three months ended June 30, 2006, we incurred $3.7 million of expenses related to our zileuton program compared to $3.4 million during the three months ended June 30, 2005. This increase was primarily due to clinical costs associated with our intravenous and controlled-release formulations of zileuton, our continued work related to the manufacturing of our NDA registration batches for our controlled-release formulation of zileuton and expenses incurred by our medical affairs and medical information functions related to scientific support of ZYFLO, our only product approved for marketing in the United States. This increase was offset in part by a decrease in costs related to our Phase II clinical trial of ZYFLO in patients with moderate to severe inflammatory acne, which we completed in 2005. In the second half of 2006, we expect to continue our research and development expenses for zileuton related to the controlled-release formulation of zileuton and the anticipated clinical trials of the controlled-release and intravenous formulations of zileuton. We expect to pay a total of $1.9 million to third parties upon the filing of our NDA for the controlled-release formulation of zileuton. These milestone payments will be expensed in the third quarter of 2006 based upon our filing date of July 31, 2006. We also expect to incur expenses related to additional clinical studies of zileuton in certain patient populations and continued operation of our medical affairs function. The actual costs and timing for the development and commercialization of our zileuton product candidates are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. As a result, we are unable to estimate the costs or the timing of advancing our zileuton product candidates through clinical development and commercialization.

CTI-01. During the three months ended June 30, 2006 expenses for CTI-01 increased compared to the three months ended June 30, 2005. This increase was primarily due to higher clinical trial costs, offset by lower preclinical and manufacturing costs. In addition, in March 2006 we announced our decision to discontinue the Phase II clinical trial of CTI-01 due to an issue related to the durability of the stoppers used to seal the containers that potentially could have affected the integrity of clinical supplies of the product candidate at the trial sites. We expect to incur additional costs for this program for the remainder of 2006 to collect and analyze the safety and efficacy data from the patients who received medication in the trial. Decisions on the future development of CTI-01 will depend upon the outcome of the analysis of the data. As a result, we are unable to estimate any additional costs that may be required to advance this program.

HMGB1. Expenses for HMGB1 remained consistent in the three months ended June 30, 2006 compared to the three months ended June 30, 2005. Expenses related to HMGB1 are related to laboratory supplies for our continued testing obligations under our collaboration agreement with MedImmune. Our expenses for this program may vary from period to period depending on the resources required for activities being performed by us and those performed by MedImmune. We currently anticipate that most research and development costs relating to HMGB1 in 2006 will be covered by funding from MedImmune under our collaboration agreement. However, we expect to undertake some internal research and preclinical testing of HMGB1, and we cannot be certain that the research payments received from MedImmune will fully cover the costs associated with these activities. Because our 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. As a result, we are not able to estimate the costs or the timing of advancing any HMGB1-inhibiting product candidate or candidates through clinical development. A significant amount of these clinical costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the

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accompanying statement of operations as part of research and development expenses, while the funding received from MedImmune to fund our research efforts is included in revenue under collaboration agreements.

Alpha-7. During the three months ended June 30, 2006, we incurred $985,000 of expenses related to our alpha-7 program as compared to $587,000 during the three months ended June 30, 2005. This increase was primarily due to personnel costs, laboratory supplies and contract research associated with our efforts to discover and develop small molecule product candidates. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development, and we expect to incur additional expenses to discover additional molecules under this program. 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 and the development strategy adopted. 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.

Our general research and development expenses, which are not allocated to any specific program, decreased by $691,000 in the three months ended June 30, 2006 as compared to the three months ended June 30, 2005 primarily due to improved cost allocation methods for our research and development personnel and the related laboratory and general expenses for our existing research and development programs. Unallocated facility and related costs for the three months ended June 30, 2006 were $117,000 as compared to $470,000 for the three months ended June 30, 2005.

Our stock-based compensation expense decreased by $69,000 in the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. This decrease was primarily due to the effects of the change in the market price of our common stock on unvested non-employee options offset, in part, by the impact of adopting SFAS 123(R). 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 the three months ended June 30, 2006, which resulted in an adjustment to our stock-based compensation expense to non-employees of $139,000, while the fair value of our common stock increased slightly during the three months ended June 30, 2005, which resulted in $186,000 of stock-based compensation expense.

Sales and Marketing. Sales and marketing expenses for the three months ended June 30, 2006 were $5.7 million compared to $1.8 million for the three months ended June 30, 2005. The $3.9 million increase in the three months ended June 30, 2006 was primarily attributable to the hiring of additional sales management and our specialty sales force in late 2005 as well as an increase in marketing and other costs associated with our commercial product, ZYFLO. In addition, in the three months ended June 30, 2006, we incurred approximately $302,000 of severance and $525,000 of additional stock-based compensation expense, related to the resignation of our former Senior Vice President of Sales and Marketing. The number of employees performing sales and marketing functions increased from 31 employees at June 30, 2005 to 77 employees at June 30, 2006.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2006 were $5.1 million compared to $2.7 million for the three months ended June 30, 2005. The $2.4 million increase in the three months ended June 30, 2006 was primarily attributable to $749,000 of severance expense, of which $670,000 related to the departure of our former President and Chief Executive Officer, and an increase of $1.8 million in stock-based compensation expense related to our adoption of SFAS 123(R), which included $1.3 million in stock-based compensation expense related to the accelerated vesting of certain stock options upon the departure of our former President and Chief Executive Officer. These increases were offset, in part, by lower personnel related costs as a result of our cost reduction program that we announced in May 2006. The number of employees performing general and administrative functions decreased from 24 employees at June 30, 2005 to 22 employees at June 30, 2006.

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Other Income. Interest income for the three months ended June 30, 2006 was $716,000 compared to $428,000 for the three months ended June 30, 2005. The increase in the three months ended June 30, 2006 was primarily attributable to higher interest rates and a higher average cash and investment balance primarily due to our June 2005 private placement. Interest expense amounted to $55,000 and $38,000 for the three months ended June 30, 2006 and June 30, 2005, respectively. The interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Six Months Ended June 30, 2006 and 2005

Revenue from Product Sales. We recognized revenue from product sales, net of discounts and rebates, of $2.8 million in the six months ended June 30, 2006 related to sales of ZYFLO following our product launch in October 2005.

Revenue from Collaboration Agreements. We recognized collaboration revenues of $2.9 million for the six months ended June 30, 2006 compared to $2.8 million for the six months ended June 30, 2005. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid us that we recognized in each period and a portion of the $500,000, $2.75 million and $1.5 million billed to MedImmune in the first half of 2006, in 2005 and in 2004, respectively, for milestone payments and development support. We have reported the balance of the payments as deferred revenue and will recognize such amount over the estimated 47-month 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. As of June 30, 2006, we had $3.3 million in deferred revenue remaining to be recognized under our collaboration agreements with MedImmune and Beckman Coulter.

Cost of products sold. Cost of products sold in the six months ended June 30, 2006 were $1.4 million. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO, a royalty payment to Abbott from the license agreement for ZYFLO and a charge of $702,000 to write-down excess finished goods inventory that we do not currently expect to be sold in the future. The write-down resulted from excess inventory on-hand at June 30, 2006 with an expiration date on or before December 2006 as well as API we believe will not be sold.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2006 were $16.3 million compared to $13.2 million for the six months ended June 30, 2005. This increase of approximately $3.1 million was primarily due to an increase in expenses related to our research and development activities which are discussed in more detail below.

The following table summarizes the primary components of our direct research and development expenses for the six months ended June 30, 2006 and 2005:

	Six Months Ended June 30,	
	2006	**2005**
	(in thousands)	
Zileuton	$ 8,718	$ 6,810
CTI-01	2,373	1,231
HMGB1	1,025	988
Alpha-7	2,132	1,074
General research and development expenses	1,480	2,806
Stock-based compensation expense	600	317
Total research and development expenses	$ 16,328	$ 13,226

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We anticipate that our research and development expenses will continue to increase as we further advance our research and development projects. The following summarizes the expenses associated with our primary research and development programs:

Zileuton. During the six months ended June 30, 2006, we incurred $8.7 million of expenses related to our zileuton program compared to $6.8 million during the six months ended June 30, 2005. This increase was primarily due to increased clinical costs related to our intravenous and controlled-release formulations of zileuton, our continued work related to the manufacturing of our NDA registration batches for our controlled-release formulation of zileuton and expenses incurred by our medical affairs and medical information functions related to scientific support of ZYFLO. This increase was offset, in part, by a decrease in costs related to our Phase II clinical trial of ZYFLO in patients with moderate to severe inflammatory acne, which we completed in 2005.

CTI-01. Expenses for CTI-01 increased by $1.2 million in the six months ended June 30, 2006 compared to the six months ended June 30, 2005. This increase was primarily due to higher clinical trial costs related to our Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine offset by lower preclinical and manufacturing costs. In March 2006, we announced our decision to discontinue the Phase II clinical trial of CTI-01 due to an issue related to the durability of the stoppers used to seal the containers that potentially could have affected the integrity of clinical supplies of the product candidate at the trial sites.

HMGB1. Expenses for HMGB1 remained consistent in the six months ended June 30, 2006 compared to the six months ended June 30, 2005. Expenses related to HMGB1 are related to our continued testing under our collaboration agreement with MedImmune.

Alpha-7. During the six months ended June 30, 2006, we incurred $2.1 million of expenses in connection with our alpha-7 program compared to $1.1 million during the six months ended June 30, 2005. This increase was primarily due to personnel costs, laboratory supplies and contract research associated with our efforts to discover and develop small molecule product candidates.

Our general research and development expenses, which are not allocated to any specific program, decreased by $1.3 million in the six months ended June 30, 2006 as compared to the six months ended June 30, 2005 primarily due to improved cost allocation methods for our research and development personnel and the related laboratory and general expenses for our existing research and development programs. Unallocated facility and related costs for the six months ended June 30, 2006 were $252,000 as compared to $1.2 million for the six months ended June 30, 2005.

Our stock-based compensation expense increased $283,000 in the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. This increase was primarily due to the effects of our implementation of SFAS 123(R) and the change in the market price of our common stock on unvested non-employee options.

Sales and Marketing. Sales and marketing expenses for the six months ended June 30, 2006 were $12.6 million compared to $3.0 million for the six months ended June 30, 2005. The $9.6 million increase in the six months ended June 30, 2006 was primarily attributable to the hiring of our sales management, the hiring and training of our specialty sales force in August 2005 as well as an increase in marketing and other costs associated with ZYFLO. In addition, in the six months ended June 30, 2006, we incurred approximately $302,000 of severance and $525,000 of additional stock-based compensation expense, related to the resignation of our Senior Vice President of Sales and Marketing. The number of employees performing sales and marketing functions increased from 31 employees at June 30, 2005 to 77 employees at June 30, 2006.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2006 were $8.0 million compared to $5.8 million for the six months ended June 30, 2005. The $2.2 million increase in the

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six months ended June 30, 2006 was primarily attributable to $749,000 of severance expense, of which $670,000 related to the resignation of our former President and Chief Executive Officer, and an increase of $2.2 million in stock-based compensation expense related to our adoption of SFAS 123(R), which included the accelerated vesting of certain stock options upon the departure of our former President and Chief Executive Officer. These increases were offset, in part, by expenses related to our June 2005 private placement which were not recurring and by lower personnel related costs as a result of our cost reduction program that we announced in May 2006. The number of employees performing general and administrative functions decreased from 24 employees at June 30, 2005 to 22 employees at June 30, 2006.

Other Income. Interest income for the six months ended June 30, 2006 was $1.5 million compared to $825,000 for the six months ended June 30, 2005. The increase in the six months ended June 30, 2006 was primarily attributable to higher interest rates and higher average cash and investment balances related to our June 2005 financing. Interest expense amounted to $115,000 and $80,000 for the six months ended June 30, 2006 and June 30, 2005, respectively.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have financed our operations through the sale of common and preferred stock, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter and, beginning in the fourth quarter of 2005, revenue generated from sales of ZYFLO. As of June 30, 2006, we had $52.2 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 July 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 $4.5 million through June 30, 2006 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program.

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 for Medical Research, formerly the North Shore-Long Island Jewish Research Institute, on milestone payments we receive from MedImmune. We do not anticipate receiving any additional milestone payments from MedImmune in the second half of 2006.

Credit Agreement with Silicon Valley Bank. We finance the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment and software licenses and the completion of leasehold improvements through advances under our credit agreement with Silicon Valley Bank which was most recently modified as of January 6, 2006. 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 June 30, 2006, we had $2.0 million in debt outstanding under this credit agreement related to equipment advances.

The equipment advances made prior to the modification of our credit agreement on June 30, 2004 accrue 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

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advance amount up to 8.5% of the original principal. As of June 30, 2006, we had $231,000 in outstanding equipment advances made prior to June 30, 2004.

Advances made under the modified credit agreement accrue interest at a rate equal to the prime rate plus 2% per year. As of June 30, 2006, outstanding equipment advances under the modified credit agreement had a weighted-average effective interest rate of approximately 10.0% 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. As of June 30, 2006 we had no borrowing capacity available under the modified credit agreement. As of June 30, 2006, we had $1.8 million in outstanding advances under the modified credit agreement.

Cash Flows

Operating Activities. Net cash used in operating activities was $29.9 million for the six months ended June 30, 2006, compared to $20.9 million for the six months ended June 30, 2005. Net cash used in operations for the six months ended June 30, 2006 consisted of a net loss of $31.2 million, depreciation and amortization expense and the amortization of premiums on short-term investments of $500,000, a loss on the disposal of fixed assets of $51,000, stock-based compensation expense of $4.5 million, reserve for inventory expense of $702,000 and a decrease in working capital accounts of $4.5 million. Our cash used in operations decreased from $17.8 million in the first quarter of 2006 to $12.1 million in the second quarter of 2006 primarily as a result of our restructuring plan announced in May 2006.

Investing Activities. Investing activities provided $10.4 million of cash in the six months ended June 30, 2006, compared to $13.7 million of cash provided by investing activities in the six months ended June 30, 2005. In the six months ended June 30, 2006, we made capital expenditures of $321,000, mainly for laboratory equipment associated with our research and development activities and software, and we sold $22.6 million of our short-term investments which was offset by purchases of $11.8 million of short-term investments.

Financing Activities. In the six months ended June 30, 2006, we used $524,000 of net cash in financing activities, compared to $51.5 million of net cash provided by financing activities in the six months ended June 30, 2005. Net cash used in financing activities for the six months ended June 30, 2006 principally related to our repayment of our long-term debt offset, in part, by proceeds from stock option exercises. The net cash provided by financing activities for the six months ended June 30, 2005 related to our private placement of common stock and warrants in June 2005 to certain institutional and other accredited investors.

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 June 30, 2006. If not utilized, federal and state net operating loss carryforwards will begin to expire in 2021 and 2006, respectively. 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, support our sales and marketing efforts, achieve regulatory approvals, commercialize ZYFLO and, subject to regulatory approval, commercially launch the controlled-release formulation of zileuton and any future product candidates. We also expect to spend approximately $200,000 in capital expenditures in the remainder of 2006 for the purchase of software, computer equipment, manufacturing equipment and equipment for our laboratories. Our funding requirements will depend on numerous factors, including:

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the costs of ongoing sales and marketing for ZYFLO;

the timing, receipt and amount of sales from ZYFLO;

the costs and timing of the development, regulatory submission and approval and the commercial launch of the controlled-release formulation of zileuton, if and when it is approved by regulatory authorities;

the amount and timing of the cost reductions that we announced in May 2006;

the scope and results of our clinical trials;

advancements of other product candidates into development;

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

the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals;

the timing, receipt and amount of milestone and other payments, if any, from 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 cost of manufacturing, marketing and sales activities;

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

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

our ability to establish and maintain additional collaborative 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 MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only source of revenue until we commercially launch the controlled-release formulation of zileuton, if it is approved. In addition to the foregoing factors, we believe that our ability to access external funds will depend upon the market acceptance of ZYFLO, and the controlled-release formulation, if approved, 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 sell ZYFLO and obtain regulatory approval for and successfully commercialize the controlled-release formulation of zileuton. 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 the third quarter of 2007. Our operating plans assume the effective implementation of the cost reductions that we announced in May 2006. After a preliminary review of our operating budget, we identified approximately $15 million to $20 million in potential cost reductions for 2006. Prior to June 30,

2006, we finalized and implemented the steps that we anticipate will be necessary to realize these cost reductions.

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For the six months ended June 30, 2006, our net cash used for operating activities was $29.9 million and we had capital expenditures of $321,000. 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.

Contractual Obligations

We have summarized in the table below our fixed contractual obligations as of June 30, 2006.

		Payments Due by Period			
Contractual Obligation	**Total**	**Less than One year**	**One to Three years**	**Three to Five years**	**After five Years**
(in thousands)					
Short and long term debt	$ 1,997	$ 1,100	$ 897	$	$
Research and license agreements	7,035	74	141	354	6,466
Consulting agreements	187	187			
Manufacturing and clinical trial agreements	6,483	3,191	3,292		
Lease obligations	4,860	1,991	2,869		
Total contractual cash obligations	$ 20,562	$ 6,543	$ 7,199	$ 354	$ 6,466

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 June 30, 2006, we have paid an aggregate of $4.25 million to Abbott under our license agreements related to the immediate and controlled-release formulations of zileuton. In addition, under our manufacturing agreement with SkyePharma, through its subsidiary Jagotec, for the controlled-release version of zileuton, we agreed to make aggregate milestone payments of up to $6.6 million upon the achievement of various development and commercialization milestones. Through June 30, 2006, we have paid and accrued an aggregate of $2.0 million to SkyePharma under our agreement. In the third quarter, we will pay Abbott and SkyePharma approximately $1.5 million and $375,000, respectively, related to filing of our NDA with the FDA for our controlled-release formulation of zileuton.

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

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MedImmune. Our license agreements are described more fully in Note 11 of the Notes to Consolidated Financial Statements in our annual report on Form 10-K for the year ended December 31, 2005.

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 Note 8 to our condensed consolidated financial statements included herein, we entered into a manufacturing and supply agreement with Rhodia Pharma Solutions for commercial production of the zileuton API, subject to specified limitations, through December 31, 2009. On June 30, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions Ltd., or Shasun. Under this agreement, we committed to purchase a minimum amount of API by December 31, 2006. The API purchased from Shasun currently has a shelf-life of 24 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 2006, 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 June 30, 2006.

Significant differences between our current estimates and judgments and future estimated demand for our product and the useful life of our inventory may result in significant charges for excess inventory or unnecessary 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, in the second quarter of 2006 we recorded a charge of $95,000, excluding amounts to be reimbursed, to reserve for excess inventory that was unlikely to be sold. The charge was included in cost of products sold in the accompanying statement of operations.

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 June 30, 2006, we estimate that the fair value of our investment portfolio would decline by approximately $10,000. 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.

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Item 4. Controls and Procedures

Our management, with the participation of Frank E. Thomas, in his capacities as our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2006. 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 June 30, 2006, Mr. Thomas, our principal executive officer and principal financial officer, concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2006 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, 2005.

Risks Relating to Our Business

If the market is not receptive to ZYFLO or, if approved for sale, the controlled-release formulation of zileuton, we will be unable to generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

The FDA approved our supplemental new drug application, or sNDA, to manufacture and market ZYFLO for commercial sale on September 28, 2005. In late October 2005, we commercially launched ZYFLO. The commercial success of ZYFLO and, if approved for sale, the controlled-release formulation of zileuton will depend upon their acceptance by the medical community, third-party payors and patients. Physicians will prescribe ZYFLO and the controlled-release formulation of zileuton only if they determine, based on experience, clinical data, side effect profiles or other factors, that these products either alone or in combination with other products are appropriate for managing their patient s asthma.

Despite being approved by the FDA since 1996, ZYFLO has not achieved broad market acceptance. In the 12-month period ending September 2003, only 1,700 physicians prescribed the product. During the period between our commercial launch in October 2005 through the week ending June 30, 2006, prescription data for ZYFLO indicates that approximately 2,400 physicians prescribed the product. For the six months ended June 30, 2006 we recorded revenue from the sale of ZYFLO of only $2.8 million. We may have difficulty expanding the prescriber and patient base for ZYFLO if physicians view the product as less effective than other products on the market or view its clinical data as outdated. In addition, ZYFLO requires dosing four times per day, which some physicians and patients may find inconvenient compared to other available asthma therapies that require dosing only once or twice daily.

Moreover, perceptions about the safety of ZYFLO could limit the market acceptance of ZYFLO and the controlled-release formulation of zileuton. In the placebo-controlled clinical trials that formed the basis for FDA approval of the NDA for ZYFLO, 1.9% of patients taking ZYFLO experienced increased levels of a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream, compared to 0.2% of patients receiving placebo. In addition, prior to FDA approval, a long-term trial was conducted in 2,947 patients to evaluate the safety of ZYFLO, particularly in relation to liver enzyme effects. In this safety trial, 4.6% of the patients taking ZYFLO experienced increased levels of ALT of over three times the levels normally seen in the bloodstream, compared to 1.1% of patients receiving placebo. The overall percentage of patients that experienced increases in ALT of over three times the levels normally seen in the bloodstream was 3.2% in approximately 5,000 asthma patients who received ZYFLO in the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin, a protein. Furthermore, because ZYFLO can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO and may be advisable for patients taking our other zileuton product candidates. 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. As a result, many physicians may have negative perceptions about the safety of ZYFLO and other zileuton product candidates, which could limit their commercial acceptance. The absence of ZYFLO from the market prior to our commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues.

The position of ZYFLO in managed care formularies, which are lists of approved products developed by managed care organizations, may also make 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.

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If we are unable to expand the use of ZYFLO or if any existing negative perceptions about ZYFLO persist, we will have difficulty achieving market acceptance for our other oral zileuton product candidates, such as the controlled-release formulation of zileuton, if approved. If we are unable to achieve market acceptance of ZYFLO or the controlled-release formulation of zileuton, we will not generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

Our business will depend heavily on the commercial success of ZYFLO and, if approved for sale, the controlled-release formulation of zileuton.

ZYFLO is our only commercial product. Other than the controlled-release formulation of zileuton, our product candidates are in early clinical, preclinical and research stages of development and are a number of years away from commercialization. As a result, ZYFLO and, if approved for sale, the controlled-release formulation of zileuton, will account for almost all of our revenues for the foreseeable future. Research and development of product candidates is a lengthy and expensive process. Our early-stage product candidates in particular will require substantial funding for us to complete preclinical testing and clinical trials, initiate manufacturing and, if approved for sale, initiate commercialization. If ZYFLO and the controlled-release formulation of zileuton are not commercially successful, we may be forced to find additional sources of funding earlier than we anticipated. If we are not successful in obtaining additional funding on acceptable terms, we may be forced to significantly delay, limit or eliminate one or more of our research, development or commercialization programs. In addition, we may be forced to dismantle or redeploy the sales force that we built in connection with the launch of ZYFLO and the anticipated launch of other product candidates.

If we do not successfully build and maintain an effective internal sales force and an adequate marketing and sales infrastructure, our ability to independently launch and market our product candidates, including ZYFLO, will be impaired.

We are independently selling and marketing ZYFLO. If approved for sale, we intend to independently launch and market the controlled-release formulation of zileuton and other product candidates. We reduced the size of our sales force as part of the cost reduction program that we announced in May 2006. In addition, our Senior Vice President of Sales and Marketing resigned in June 2006 and our Vice President of Sales resigned in July 2006. As of July 31, 2006, we had a sales force of approximately 58 sales representatives.

For the six months ended June 30, 2006, we had incurred sales and marketing costs of approximately $5.7 million. We expect to incur additional sales and marketing costs prior to the launch of the controlled-release formulation of zileuton. We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build and maintain a significant or effective sales force. Our difficulty in achieving market acceptance of ZYFLO since its commercial launch in October 2005, the reduction in the size of our sales force in the second quarter of 2006 and the resignations of our Senior Vice President of Sales and Marketing and Vice President of Sales could make it difficult for us to hire and retain qualified sales and marketing personnel and develop and maintain an effective sales force. If we are not successful in our efforts to develop and maintain an effective internal sales force or sales management team, our ability to independently launch and market our product candidates, including ZYFLO and the controlled-release formulation of zileuton, if approved, will be impaired.

We are investing significant amounts of money and management resources to develop internal sales and marketing capabilities. We are using a third party for distribution of ZYFLO. If we are unable to successfully commercialize ZYFLO, we will have incurred significant unrecoverable expenses. Likewise, if we expand our sales force in anticipation of approval of the controlled-release formulation of zileuton or our other product candidates, we will incur significant costs.

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

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We purchased quantities of raw materials and supplies of ZYFLO tablets in connection with the commercial launch of ZYFLO. In addition, we could be required to buy excess inventory to meet our minimum purchase obligations under our supply agreements with our third-party manufacturers. If we fail to successfully commercialize ZYFLO, our inventories could be materially impaired and their value diminished, and we will have incurred significant unrecoverable expenses.

We have limited experience managing commercial supplies of ZYFLO since the launch in October 2005. Our current forecasting of inventory levels is based on our estimate of expected customer orders in combination with limited historical information regarding actual sales. In the quarter ended June 30, 2006, approximately eight lots of ZYFLO tablets did not meet our manufacturing specifications. The deviations were a result of our contract manufacturer failing to meet our manufacturing specifications. In June 2006, we recorded a receivable, included in our other current assets, of $590,000 for reimbursement owed to us for $464,000 of API costs and $126,000 of sample costs and certain manufacturing costs related to these lots not meeting the manufacturing specifications. In the quarter ended June 30, 2006, we also reserved for inventory of approximately $464,000 related to API costs related to the product not meeting the Company s manufacturing specifications and $95,000 related to other inventory that is unlikely to be sold. 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 unnecessary 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. If we are unable to manufacture or release ZYFLO, if we fail to maintain an adequate inventory, or if our inventory were to be destroyed or damaged or reached its expiration date, patients might not have access to ZYFLO, our reputation and our brand could be harmed and physicians may be less likely to prescribe ZYFLO in the future. Conversely, if we are unable to sell our inventory in a timely manner, we could experience cash flow difficulties and additional financial losses.

If the market is not receptive to our other 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;
- 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.

A key element of our strategy is to develop and commercialize product candidates that address large unmet medical needs in the critical care market. We seek to do so through:

- internal research programs;

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

in-licensing or acquisition of product candidates or approved products for the critical care market; 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 the cost reduction program that we announced in May 2006; 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.

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 in the critical care market. 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.

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

The development and commercialization of new drugs is highly competitive. We will face competition with respect to the development of product candidates and for ZYFLO 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, if approved for sale, the controlled-release formulation of zileuton. Many established therapies currently command large market shares in the mild to moderate asthma market,

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including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products. We will also face competition from other pharmaceutical companies seeking to develop drugs for the severe asthma market. The severe asthma market is currently served by the therapies developed for mild to moderate asthma and 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 $320.6 million in 2005.

Zileuton will also face intense competition if we are able to develop it as a treatment for 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.

Our therapeutic programs directed toward the body s inflammatory response 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, 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.

If we fail to effectively manage our growth, our business and our operating results could be adversely affected.

We may need to expand our administrative and operational infrastructure to support the potential growth in our business. As we advance our product candidates through clinical trials, we will need to continue to expand our development, regulatory and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers and other third parties. Our need to manage our operations and growth will require us to continue to improve our operational, financial and management controls, our reporting systems and our procedures in the United States and the other countries in which we operate. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner, or we may discover deficiencies in

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existing systems and controls that could expose us to an increased risk of incurring financial or accounting irregularities or fraud.

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

We depend on the principal members of our scientific and management staff, including Frank E. Thomas, our President, Walter Newman, Ph.D., our Chief Scientific Officer and Senior Vice President of Research and Development, 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, we announced that Paul D. Rubin, M.D. had stepped down from his position as our President and Chief Executive Officer and resigned from our board of directors and that Frederick Finnegan had resigned from his position as our Senior Vice President of Sales and Marketing. In July 2006, we announced that Anne M. Fields had resigned from her position of Vice President of Sales. We have not yet determined the impact that the departure of these executives may have on our ability to achieve our research, development and commercialization objectives. We put in place a new management structure and have promoted individuals already employed by us to assume the responsibilities of these executives. In addition, our board of directors appointed Robert H. Zeiger, a member of our board of directors and previously our lead independent director, to the position of Executive Chairman, a newly-created position during our transition to this new management structure. If we are unable to successfully transition our management staff to compensate for the loss of these executives, our achievement of our research, development and commercialization objectives could be significantly delayed or prevented. 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 and management personnel. We expect that our potential 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. We expect these demands will 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. As we transition to our new management structure, we may have difficulty attracting and retaining 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;

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;

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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.

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

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

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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, and 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 is in accordance 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 and our 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, with 136 employees as of June 30, 2006, the majority of whom joined us in 2005. 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 been adopted or are subject to change. For example, we are incurring additional expenses and devoting significant management time and attention to evaluating our internal control systems in order to allow our management to report on, and our registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that we implement do not comply with all of the relevant rules and regulations of the Securities and Exchange Commission and the Nasdaq Global Market, we may be subject to sanctions or investigation by regulatory authorities, including the Securities and Exchange Commission or the Nasdaq Global Market. This type of action could adversely affect our financial results or investors confidence in our company and our ability to access the capital markets. If we fail to develop and

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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 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. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. We cannot predict the full impact of the MMA and its regulatory requirements on our business. However, 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 ZYFLO or our product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time.

The MMA also establishes a prescription drug benefit beginning in 2006 for all Medicare beneficiaries. We cannot be certain that our products 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 the controlled-release formulation of zileuton 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 the controlled-release formulation of zileuton 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.

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If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

If our Medicaid rebate program practices are investigated or if the Medicaid portion of our ZYFLO sales grows, the costs could be substantial and our operating results could be adversely affected.

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.

In addition, because ZYFLO was previously marketed by Abbott prior to our licensing it, the rebate that we are required to pay to Medicaid for prescriptions filled by patients covered under a Medicaid program could be substantial. The calculation of the Medicaid rebate is based on the initial pricing set by Abbott with adjustments for inflation each year. Since the price set by Abbott for ZYFLO is below the price we are currently charging, we are subject to a Medicaid rebate of greater than 75% of our selling price. Based on historical prescribing patterns since our launch in October 2005, our Medicaid business has represented less than 5% of total ZYFLO prescriptions. However, if the Medicaid portion of our ZYFLO sales were to increase such that Medicaid represented a larger than expected percentage of the mix of sales for ZYFLO, the increased level of rebates could have a material adverse effect on our financial condition and results of operations.

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

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

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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.

While we have a property insurance policy that covers bio-contamination up to a $25,000 per-occurrence limit and covers 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 the controlled-release formulation of zileuton or our other 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 our only commercial product and can only be marketed in the United States.

We submitted an NDA to the FDA for the controlled-release formulation of zileuton on July 31, 2006. Abbott conducted the pivotal clinical trials on the controlled-release formulation of zileuton 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 data at 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. We conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of the controlled-release formulation of zileuton in volunteers under both fed and fasted 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. If the FDA disagrees with our conclusions regarding the sufficiency of the results from the bioavailability studies, then we could be required to conduct additional clinical trials to support our NDA, which could lead to unanticipated costs and delays.

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 the controlled-release formulation of zileuton 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

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candidates, we and our collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. We may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, we, one of our collaborators, institutional review boards, or regulatory agencies may hold, suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, in March 2006, we announced that we had discontinued a Phase II clinical trial of 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. We discontinued the trial after routine testing revealed some swelling in the butyl rubber stoppers used to seal the vials that stored the drug. We determined that the durability of the stopper could have affected the integrity of clinical supplies of the product candidate at the trial sites. We are analyzing the safety and efficacy data from the patients who received medication before we discontinued the trial. We expect to complete our analysis of the trial data in the second half of 2006. Decisions on the future development of CTI-01 will depend upon the outcome of the analysis of the data.

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 may not become commercially viable.

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

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

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients and volunteers into clinical trials;

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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 prelinical studies; or

the placement of a clinical hold on a trial.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the 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.

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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 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 affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to less market acceptance of our product candidates. These enforcement actions include:

product seizures;

voluntary or mandatory recalls;

suspension of review or refusal to approve pending applications;

voluntary or mandatory patient or physician notification;

withdrawal of product approvals;

restrictions on, or prohibitions against, marketing our product candidates;

restrictions on applying for or obtaining government bids;

fines;

restrictions on importation of our product candidates;

injunctions; and

civil and criminal penalties.

Risks Relating to Our Dependence on Third Parties

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 for the years ended December 31, 2003 and 2004 were derived from fees paid to us by MedImmune. Our revenues for the year ended December 31, 2005 and the six months ended June 30, 2006 were derived from fees paid to us by MedImmune and Beckman Coulter under our collaboration agreements with them and revenue from the sale of ZYFLO beginning in the fourth quarter of 2005; however, a significant portion of our revenues for the year ended December 31, 2005 and the six months ended June 30, 2006 continued to be 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

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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 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 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 relating to diagnostic assays for HMGB1 will terminate if Beckman Coulter does not exercise its option to continue the license by a future date. In addition, Beckman Coulter has the right to terminate the license agreement 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.

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

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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 active pharmaceutical ingredient, or API, and controlled-release formulation of zileuton tablets and commercial supplies of ZYFLO and the production of our product candidates for preclinical and clinical testing purposes. We expect to continue to rely on third parties for these purposes for the foreseeable future.

We have contracted with Shasun Pharma Solutions Ltd. for commercial production of the zileuton API, subject to specified limitations, through December 31, 2009. On March 31, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites were damaged, or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production.

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 the controlled-release formulation of zileuton 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 the controlled-release formulation of zileuton for clinical trials, regulatory review and, subject to negotiation of a commercial manufacturing agreement, commercial supplies. SkyePharma announced that it was the target of an unsolicited acquisition bid in November 2005. SkyePharma subsequently announced that it had retained an investment bank to consider strategic options, including the sale of the company. In February 2006, SkyePharma announced a new senior management team and the conclusion of its strategic review, deciding to concentrate on oral and pulmonary products and divest its injectable business. The sale of SkyePharma as a whole or in parts may impact our ability to produce the controlled-release formulation of zileuton.

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 the controlled-release formulation of zileuton, 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 successfully develop and commercialize our product candidates.

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. 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;

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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 the controlled-release formulation of zileuton, 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. Any delays associated with the verification of a new manufacturer could adversely affect our production schedule or increase our production costs.

We rely on a single source supplier for one of the starting materials for zileuton, and the loss of that supplier could prevent us from selling ZYFLO.

Sumitomo is currently the only qualified supplier of a chemical known as 2-ABT, one of the starting materials for the zileuton API. Shasun Pharma Solutions, which supplies us with the zileuton API, has an agreement with Sumitomo for the supply of 2-ABT to meet our current orders of zileuton API. If Sumitomo stops manufacturing or is unable to manufacture 2-ABT, or if Shasun is unable to procure 2-ABT from Sumitomo on commercially reasonable terms, we may be unable to continue to sell ZYFLO on commercially viable terms, if at all. In addition, Shasun s inability to procure 2-ABT could also impact our ability to commercialize the controlled-release formulation of zileuton, if it is approved by the FDA. Furthermore, because Sumitomo is currently the sole supplier of 2-ABT, Sumitomo has unilateral control over the price of 2-ABT. Any increase in the price for 2-ABT may reduce our gross margins.

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

We rely on third parties to distribute ZYFLO 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. The wholesalers in turn distribute it to chain and independent pharmacies. ICS is our exclusive supplier of commercial distribution logistics services. We rely on Phoenix Marketing Group LLC to distribute ZYFLO samples to our sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. We 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, and moreover we lack the resources and experience to establish any of these functions and do not intend to do so in the foreseeable future. We would be 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, and the distribution of ZYFLO could be delayed or interrupted, damaging 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 could be severely compromised and our business could be harmed.

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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. 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.

Risks Relating to Intellectual Property and Licenses

If we are not able to obtain and enforce patent and other intellectual property protection for our discoveries, 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 and develop 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. 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, 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 patent applications of others. There may also be prior art that may prevent allowance of our patent applications.

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.

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Our pending patent applications 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 which 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.

Litigation regarding patents, patent applications and other proprietary rights is expensive and time consuming. If we are unsuccessful in litigation concerning patents or patent applications owned or co-owned by us or licensed to us, 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 applications could take place in the United States in a federal court or in the U.S. Patent and Trademark Office or other administrative agencies. These proceedings could also take place in a foreign country, in either the court or the patent office of that country. Proceedings involving our patents or patent applications could result in adverse decisions regarding:

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

These proceedings are costly and time consuming. We may not have sufficient resources to bring these actions 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.

Our success will also depend in part on our ability to avoid infringement of the patent rights of others. For example, we are aware of third-party patents and patent applications that relate to a class of chemicals known as pyruvates, of which CTI-01, one of our product candidates, is a member. We believe that our anticipated uses of CTI-01 do not infringe any valid third-party patents. If any use of CTI-01 that we pursue for a particular indication were found to infringe a valid third-party patent, we could be precluded from selling CTI-01 for that indication and be forced to pay damages.

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

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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 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.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, it is our general practice to enter into confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information and, in such cases, we could not assert any trade secret rights against such parties. 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.

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.

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We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $31.2 million in the six months ended June 30, 2006 and $47.1 million in the year ended December 31, 2005. As of June 30, 2006, we had an accumulated deficit of approximately $136.8 million. For the six months ended June 30, 2006, we recorded $2.8 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 losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts and to enhance our core technologies. 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 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 continue our research and development efforts, including preclinical testing and clinical trials, support our sales and marketing infrastructure, achieve regulatory approvals, commercialize ZYFLO and, subject to regulatory approval, commercially launch the controlled-release formulation of zileuton and any future product candidates. Our funding requirements will depend on numerous factors, including:

- the costs of ongoing sales and marketing for ZYFLO;
- the timing, receipt and amount of sales from ZYFLO;
- the costs and timing of the development, regulatory submission and approval and the commercial launch of the controlled-release formulation of zileuton, if and when it is approved by regulatory authorities;
- the amount and timing of the cost reductions that we announced in May 2006;
- the scope and results of our clinical trials;
- advancements of other product candidates into development;
- potential acquisition or in-licensing of other products or technologies;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals;
- the timing, receipt and amount of milestone and other payments, if any, from 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 cost of manufacturing, marketing and sales activities;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the cost of obtaining and maintaining licenses to use patented technologies;
- our ability to establish and maintain additional collaborative 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.

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Other than payments that we receive from our collaborations with MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only source of revenue until we commercially launch the controlled-release formulation of zileuton if it is approved. In addition to the foregoing factors, we believe that our ability to access external funds will depend upon the 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 sell ZYFLO and obtain regulatory approval for and successfully commercialize the controlled-release formulation of zileuton. 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 the third quarter of 2007. Our operating plans assume the effective implementation of the cost reductions that we announced in May 2006.

For the six months ended June 30, 2006, our net cash used for operating activities was $29.9 million and we had capital expenditures of $321,000. 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 these 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. 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.

Changes in or interpretations of accounting rules and regulations, such as expensing of employee stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for business and market practices of biopharmaceutical companies are subject to review, interpretation and guidance from relevant accounting authorities, including the Securities and Exchange Commission, or the SEC. For example, a new accounting rule, which became effective for us on January 1, 2006, requires us to record stock-based compensation expense for the fair value of stock options granted to employees. We rely heavily on stock options to compensate existing employees and attract new employees. Adoption of the new accounting rule on stock-based compensation expense is expected to increase net losses or reduce net income in future periods. Because we will be required to expense stock options, we may reduce our reliance on stock options as a compensation tool. If we reduce our reliance on stock options, it may be more difficult for us to attract and retain qualified employees. If we do not reduce our reliance on stock options, our reported losses would increase. Although we believe that our accounting practices are consistent with current

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accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

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 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;
- the amount of rebates, discounts and chargebacks to be wholesalers, Medicaid and managed care organizations related to ZYFLO;
- the amount and timing of product returns for ZYFLO;
- achievement of, or the failure to achieve, milestones under our development agreement with MedImmune, our license agreement with Beckman Coulter and, to the extent applicable, other licensing and collaboration agreements;
- the results of ongoing and planned clinical trials of our product candidates;
- production problems occurring at our third party manufacturers;
- the results of regulatory reviews relating to the development or approval of our product candidates; and
- general and industry-specific economic conditions that may affect our research and development expenditures.

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

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

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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:

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 July 31, 2006, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 50.2% 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 determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

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

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

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

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

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, our anti-takeover provisions include provisions in our by-laws providing that stockholders meetings may be called only by the president or the majority of the 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

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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.

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds from Registered Securities

In June 2004, we sold 6,110,000 shares of our common stock in our initial public offering, including 110,000 shares upon the exercise of an over-allotment option by the underwriters, pursuant to a registration statement on Form S-1 (File No. 333-113727), which was declared effective by the SEC on May 26, 2004. Our net proceeds from the offering equaled approximately $37.8 million. Through June 30, 2006, we have used all of the net proceeds as follows: approximately $18.5 million of the net proceeds to establish sales and marketing capabilities and manufacturing and distribution arrangements to launch ZYFLO and approximately $19.3 million of the net proceeds to fund preclinical and clinical development of our product candidates.

We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any of our directors or officers, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours.

Item 3. Defaults Upon Senior Securities.

Not applicable.

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

The following matters were submitted to a vote of our stockholders at our 2006 Annual Meeting of Stockholders held on April 25, 2006 and approved by the requisite vote of our stockholders as follows:

1. To elect Richard W. Dugan, Christopher Mirabelli, Ph.D., and James B. Tananbaum, M.D. to our board of directors to serve as Class II directors, each for a term of three years.

	Number of Shares	
Nominee	**For**	**Withheld**
Richard W. Dugan	29,624,651	20,629
Christopher Mirabelli, Ph.D.	29,601,463	43,817
James B. Tananbaum, M.D.	29,265,801	379,479

2. To adopt the Critical Therapeutics, Inc. 2006 Employee Stock Purchase Plan, under which 400,000 shares of our common stock will be authorized for issuance.

Number of Shares			
For	**Against**	**Abstain**	**Broker Non-Vote**
26,111,852	241,339	1,300	3,290,789

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3. To ratify our board of directors selection of Deloitte & Touche LLP as our registered public accounting firm for the fiscal year ending December 31, 2006.

Number of Shares		
For	**Against**	**Abstain**
29,642,925	1,355	1,000

The number of shares of our common stock eligible to vote as of the record date of March 24, 2006 was 34,216,181 shares.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

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

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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: August 9, 2006

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

Date: August 9, 2006

/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	2006 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated April 27, 2006 (SEC File No. 000-50767)).
10.2	Employment Agreement, dated April 26, 2006 by and between the Registrant and Dana Hilt, M.D. (Incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated May 1, 2006 (SEC File No. 000-50767)).
10.3	Letter Agreement between the Registrant and Robert H. Zeiger, effective as of June 26, 2006 (Incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated June 27, 2006 (SEC File No. 000-50767)).
10.4	Employment Agreement dated June 26, 2006 by and between the Registrant and Jeffrey E. Young (Incorporated by reference to Exhibit 99.2 to the Registrant s Current Report on Form 8-K dated June 27, 2006 (SEC File No. 000-50767)).
10.5	Severance Agreement between the Registrant and Paul D. Rubin, M.D. dated July 10, 2006 (Incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated July 14, 2006 (SEC File No. 000-50767)).
10.6	Separation Agreement between the Registrant and Frederick Finnegan dated July 13, 2006 (Incorporated by reference to Exhibit 99.2 to the Registrant s Current Report on Form 8-K dated July 14, 2006 (SEC File No. 000-50767)).
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.