CRITICAL THERAPEUTICS INC
Form 10-Q
November 09, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

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

For the Quarterly Period Ended September 30, 2007

or

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

For the Transition Period _____ to _____

Commission File Number: 000-50767

Critical Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(781) 402-5700

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

As of November 2, 2007, the registrant had 43,125,425 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. Financial Information

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding our commercial launch of ZYFLO CR (zileuton) extended-release tablets, or ZYFLO CR; possible therapeutic benefits and market acceptance of ZYFLO CR and ZYFLO® (zileuton tablets); the progress and timing of our drug development programs and related trials; the efficacy of our drug candidates; and our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, will, would or other words that convey 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: our ability to successfully market and sell ZYFLO CR and ZYFLO, including the success of our co-promotion arrangement with Dey, L.P., a wholly-owned subsidiary of Mylan Inc., or DEY; our current review of our business strategy and future operations, and the implementation of changes in our strategy and future operations, if any, approved by our board of directors; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO CR and ZYFLO; patient, physician and third-party payor acceptance of ZYFLO CR and ZYFLO as safe and effective therapeutic products; adverse side effects experienced by patients taking ZYFLO CR or ZYFLO; our heavy dependence on the commercial success of ZYFLO CR and ZYFLO; our ability to maintain regulatory approvals to market ZYFLO CR and ZYFLO; the success of our co-promotion agreement with DEY for PERFOROMIST (formoterol fumarate) Inhalation Solution, or PERFOROMIST; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; conducting clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our products under development and whether such results will be indicative of results obtained in later clinical trials; our ability to obtain the substantial additional funding required to conduct our research, development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc., a wholly-owned subsidiary of AstraZeneca PLC; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO CR, 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. In particular, as discussed elsewhere in this quarterly report on Form 10-Q, we are considering potential changes in our business strategy and future operations. If we determine to pursue an alternative strategy or engage in a strategic transaction, the descriptions of our strategy, future operations and financial position, future revenues, projected costs and prospects and the plans and objectives of management in this quarterly report on Form 10-Q may no longer be applicable. Because of the significant uncertainty regarding our future plans, the forward-looking statements contained herein do not reflect the potential impact of a potential change in our existing business strategy.

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Item 1. Financial Statements

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

in thousands	September 30, 2007	December 31, 2006
Assets:		
Current assets:		
Cash and cash equivalents	$ 33,696	$ 48,388
Accounts receivable, net	2,186	877
Amount due under collaboration agreements	31	650
Short-term investments	350	650
Inventory, net	4,235	4,048
Prepaid expenses and other	1,651	980
Total current assets	42,149	55,593
Fixed assets, net	1,702	2,421
Other assets	568	168
Total assets	$ 44,419	$ 58,182
Liabilities and Stockholders Equity:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	$ 548	$ 1,012
Current portion of accrued license fees	1,816	
Accounts payable	1,752	1,049
Accrued expenses	4,161	3,941
Deferred collaboration revenue		675
Deferred product revenue		1,178
Deferred co-promotion fees	6,615	
Total current liabilities	14,892	7,855
Long-term debt and capital lease obligations, less current portion	49	421
Long-term portion of accrued license fees, less current portion	1,734	
Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, par value $0.001; authorized 5,000,000 shares; no shares issued and outstanding		
Common stock, par value $0.001; authorized 90,000,000 shares; issued and outstanding 43,125,425 and 42,902,142 shares at September 30, 2007 and December 31, 2006, respectively	43	43
Additional paid-in capital	207,514	204,378
Deferred stock-based compensation	(22)	(99)
Accumulated deficit	(179,791)	(154,399)

Accumulated other comprehensive loss		(17)
Total stockholders equity	27,744	49,906
Total liabilities and stockholders equity	$ 44,419	$ 58,182

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

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

in thousands except share and per share data	Three Months Ended September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006
Revenues:				
Net product sales	$ 3,126	$ 1,879	$ 8,311	$ 4,710
Revenue under collaboration and license agreements	93	2,499	1,830	5,446
Total revenues	3,219	4,378	10,141	10,156
Costs and expenses:				
Cost of products sold	1,232	267	2,653	1,662
Research and development	3,939	6,736	16,961	23,063
Sales and marketing	3,574	3,906	8,156	16,476
General and administrative	2,653	2,907	9,241	10,916
Total costs and expenses	11,398	13,816	37,011	52,117
Operating loss	(8,179)	(9,438)	(26,870)	(41,961)
Other income (expense):				
Interest income	474	612	1,628	2,100
Interest expense	(81)	(54)	(150)	(169)
Total other income	393	558	1,478	1,931
Net loss	($7,786)	($8,880)	($25,392)	($40,030)
Net loss per share	($0.18)	($0.26)	($0.60)	($1.17)
Basic and diluted weighted-average common shares outstanding	42,615,318	34,251,656	42,548,001	34,184,551

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)

	Nine Months Ended September 30,	
in thousands	**2007**	**2006**
Cash flows from operating activities:		
Net loss	($25,392)	($40,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	483	745
Accretion (amortization) of premiums on short-term investments and other	72	(72)
Loss on disposal of fixed assets	27	51
Lease abandonment charge	286	
Change in reserve for inventory	476	757
Preferred stock received in license agreement, net	(400)	
Stock-based compensation expense	2,914	6,009
Changes in assets and liabilities:		
Accounts receivable	(1,309)	129
Amount due under collaboration agreements	619	(45)
Inventory	(663)	(1,751)
Prepaid expenses and other	(671)	1,093
Accounts payable	703	(3,107)
Accrued expenses	(66)	(237)
Accrued license fees	3,495	
Deferred collaboration revenue	(675)	(4,696)
Deferred product revenue	(1,178)	(445)
Deferred co-promotion fees	6,615	
Net cash used in operating activities	(14,664)	(41,599)
Cash flows from investing activities:		
Proceeds from sale of fixed assets	216	
Purchases of fixed assets	(7)	(376)
Proceeds from sales and maturities of short-term investments	300	32,855
Purchases of short-term investments		(11,802)
Net cash provided by investing activities	509	20,677
Cash flows from financing activities:		
Proceeds from exercise of stock options and other	299	121
Repayments of long-term debt and capital lease obligations	(836)	(899)
Net cash used in financing activities	(537)	(778)
Net decrease in cash and cash equivalents	(14,692)	(21,700)
Cash and cash equivalents at beginning of period	48,388	57,257
Cash and cash equivalents at end of period	$ 33,696	$ 35,557

Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 101	$ 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, 2006 filed with the Securities and Exchange Commission (the SEC).

Operating results for the three and nine-month periods ended September 30, 2007 and 2006 are not necessarily indicative of the results for the full year.

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

Since the Company s inception, it has incurred significant losses each year. As of September 30, 2007, the Company had an accumulated deficit of $179.8 million. The Company expects to incur significant losses for the foreseeable future and it may never achieve profitability. Although the size and timing of its future operating losses are subject to significant uncertainty, the Company expects its operating losses to continue over the next several years as it funds its development programs, markets and sells ZYFLO CR and ZYFLO and prepares for the potential commercial launch of its product candidates. Since the Company s inception, it has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from its collaborators MedImmune and Beckman Coulter, license fees from IMI, payments from DEY under its zileuton co-promotion agreement and revenues from sales of ZYFLO and ZYFLO CR.

The Company s board of directors is in the process of reviewing a range of strategic alternatives that could result in potential changes to the Company s current business strategy and future operations. As part of this process, the Company is considering alternatives to its current business strategy, and it has engaged an investment bank to advise it in considering its potential strategic alternatives. After concluding this review, it is possible that the Company could determine to pursue one or more of the strategic alternatives that it is considering or a variation of one of these alternatives. Pending any decision to change strategic direction, the Company is continuing its commercial and development activities in accordance with its existing business strategy with an increased focus on its cash position. As a result of this review, the extent of the Company s future capital requirements is difficult to assess. Based on its current operating plans, the Company believes that its available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under existing collaboration agreements will be sufficient to fund anticipated levels of operations into the fourth quarter of 2008. For the nine months ended September 30, 2007, the Company s net cash used in operating activities was $14.7 million. If the Company s existing resources are insufficient to satisfy its liquidity requirements, either under its current operating plan or any new operating plan it may adopt, it may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to the Company on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of the Company s stockholders. If the Company is unable to obtain funding on a timely basis, it may be required to significantly delay, limit or eliminate

one or more of its development or commercialization programs, which could harm its financial condition and operating results. The Company also could be required to seek funds through arrangements with collaborators or others that may require it to relinquish rights to some of its technologies, product candidates or products which it would otherwise pursue on its own.

Recent Accounting Pronouncements

In June 2007, the Financial Accounting Standards Board s (FASB) Emerging Issues Task Force (EITF) issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The Company is currently evaluating the impact of EITF 07-3 on its financial statements and results of operations.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* (FAS 159). FAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. FAS 159 requires companies to provide additional information that will help investors and other users of

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financial statements to more easily understand the effect of a company s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the effect FAS 159 will have on its consolidated financial position and results of operations, if any.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* (FAS 157). FAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of FAS 157 to significantly affect its financial condition or results of operations.

(2) Revenue Recognition

Revenue Recognition and Deferred Revenue

The Company recognizes revenue in accordance with the SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101) as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. The Company s revenue is currently derived from product sales of its commercially marketed products, ZYFLO® (zileuton) tablets (ZYFLO), and ZYFLO CR (zileuton) extended-release tablets (ZYFLO CR) and its collaboration and license agreements. The collaboration and license agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties. In addition, the Company s product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

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

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

The Company s estimates of product returns, rebates and chargebacks require management s subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, chargebacks and other discounts exceed the

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estimates the Company made at the time of sale, its financial position, results of operations and cash flows would be negatively impacted.

As of September 30, 2007, the Company s allowances for ZYFLO CR and ZYFLO product returns were $112,000 and $174,000, respectively. Prior to the first quarter of 2007, the Company deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as the Company was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, the Company began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties and sufficient history existed to make such estimates. In connection with this change in estimate, the Company recorded an increase in net product sales in the nine months ended September 30, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000 and was reported in our results for the first quarter of 2007. In September 2007, the Company launched ZYFLO CR and recorded $870,000 in net product sales of ZYFLO CR in the third quarter as a result of the launch. The Company anticipates that the rate of return for ZYFLO CR will be comparable to the rate of return used for ZYFLO. As a result, the Company recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns.

Revenue under collaboration and license agreements. Under the Company s collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in the Company s statements of operations when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company s collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by the Company s collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with the Company, the Company does not recognize revenues in excess of cumulative cash collections.

Under the Company s license agreement with Innovative Metabolics, Inc. (IMI), the Company licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. Under the agreement with IMI, the Company received an initial license fee of $500,000 in cash and IMI preferred stock valued at $500,000. However, under its license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute)(the Feinstein Institute), the Company was obligated to pay to the Feinstein Institute $100,000 of this cash payment and IMI preferred stock valued at $100,000. The Company included in revenue under collaboration and license agreements in the nine months ended September 30, 2007 the $1.0 million total initial license fee that the Company received from IMI and included the payments of $100,000 in cash and IMI preferred stock valued at $100,000 that the Company made to The Feinstein Institute in research and development expenses. These amounts were recorded in the second quarter of

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2007. Under the license agreement, IMI also has agreed to pay the Company $1.0 million, excluding a $200,000 payment that the Company would be obligated to pay to the Feinstein Institute, upon full regulatory approval of a licensed product by the U.S. Food and Drug Administration (FDA) or a foreign counterpart agency and royalties based on net sales of licensed products and methods by IMI and its affiliates.

At September 30, 2007, the Company s accounts receivable balance of $2.2 million was net of allowances of $41,000. At September 30, 2006, the Company s accounts receivable balance of $913,000 was net of allowances of $18,000.

(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 has unrealized gains on investments of $17,000 and $65,000 as of September 30, 2007 and 2006, respectively. The cost of the debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period.

(4) Research and License Agreements

In December 2003, the Company entered into an agreement to in-license the controlled-release formulation and the injectable formulation of zileuton from Abbott Laboratories and entered into an agreement with a subsidiary of SkyePharma PLC (SkyePharma), to in-license the controlled-release technology relating to zileuton from SkyePharma. Under these agreements, the Company is required to make milestone payments for successful completion of the technology transfer, filing and approval of the product in the United States and commercialization of the product. In May 2007, the Company received approval by the FDA of the new drug application (NDA) for ZYFLO CR. As a result of the FDA approval, the Company paid $3.1 million under these agreements in June 2007, which is included in the results for the nine months ended September 30, 2007, and accrued an additional $1.8 million and $1.7 million that will be due on the first and second anniversary, respectively, of the FDA s approval of ZYFLO CR. The amounts due on the first and second anniversary of the FDA s approval were accrued at the present value of the total $3.8 million owed, and the accretion of the discount is included in interest expense. The $3.1 million paid as a result of the FDA approval of ZYFLO CR and the accrued $1.8 million and $1.7 million that will be due on the first and second anniversary, respectively, of the FDA s approval of ZYFLO CR were included in the Company s research and development expenses in the second quarter of 2007. For the three and nine months ended September 30, 2007, the Company recorded interest expense of $42,000 and $55,000, respectively, related to the accretion of the discount.

(5) Inventory

Inventory is stated at the lower of cost or market, with cost determined under the first-in, first-out or FIFO method. As of September 30, 2007, the Company held $4.2 million in inventory to be used for

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sales related to its commercial products, ZYFLO and ZYFLO CR. The Company analyzes its inventory levels quarterly and records reserves for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. At September 30, 2007, the Company had an inventory reserve of $596,000. The inventory reserve includes $398,000, recorded in work in process, relating to certain batches of ZYFLO CR tablets that did not meet certain Company specifications and $193,000, recorded in the third quarter of 2007, relating to excess ZYFLO finished tablets that the Company believes may not be sold as a result of the Company s recent launch of ZYFLO CR. In addition, in the third quarter of 2007, the Company received a credit for $398,000 related to the batches of ZYFLO CR that were reserved for in the second quarter of 2007. At September 30, 2007, the inventory related to these lots has not yet been disposed of. Inventory consisted of the following at September 30, 2007 and December 31, 2006, respectively (in thousands):

	September 30, 2007	December 31, 2006
Raw material	$ 3,048	$ 3,662
Work in process	1,423	83
Finished goods	360	422
Total inventory	4,831	4,167
Less: reserve	(596)	(119)
Inventory, net	$ 4,235	$ 4,048

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

(6) Comprehensive Loss

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2007 and 2006, and comprehensive loss is the unrealized gain (loss) on short-term investments for the period. Total comprehensive loss was $7.8 million and $25.4 million for the three and nine months ended September 30, 2007, respectively, and $8.9 million and $40.0 million for the three and nine months ended September 30, 2006, respectively. The unrealized gain (loss) on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet.

(7) Stock-Based Compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS No. 123(R)) using the modified prospective application method, which allows the Company to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after the required effective date. Because the Company issued options prior to March 19, 2004, the date it filed its initial registration statement on Form S-1 with the SEC, at values less than fair market value, the Company continues to amortize deferred compensation related to those awards under Accounting Principles Board No. 25 (APB No. 25).

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

Stock option activity for the nine-month periods ended September 30, 2007 and 2006 was as follows:

	2007		2006	
	Number of Shares	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
Outstanding January 1	5,714,770	$ 4.60	6,200,106	$ 5.03
Granted	201,000	2.05	741,250	6.97
Exercised	(173,567)	1.04	(89,204)	0.46
Cancelled	(595,804)	5.81	(62,594)	6.34
Outstanding March 31	5,146,399	4.48	6,789,558	5.29
Granted	210,500	2.41	1,661,250	3.99
Exercised	(71,241)	1.04	(21,609)	1.04
Cancelled	(207,501)	3.97	(1,020,344)	5.85
Outstanding June 30	5,078,157	4.46	7,408,855	4.93
Granted	391,300	2.16	93,000	3.52
Exercised	(2,578)	1.24	(58,076)	0.89
Cancelled	(442,041)	3.96	(396,392)	6.12
Outstanding September 30	5,024,838	$ 4.33	7,047,387	$ 4.88
Exercisable September 30	2,052,645	$ 5.13	2,700,177	$ 4.29

The weighted-average remaining contractual term and the aggregate intrinsic value for options outstanding at September 30, 2007 were 8.1 years and $278,000, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options exercisable at September 30, 2007 were 7.4 years and $227,000, respectively. The weighted-average exercise price and the number of options vested or expected to vest at September 30, 2007 were $4.49 and 4,306,307, respectively. The total intrinsic value of the options exercised during the three months and nine months ended September 30, 2007 was approximately $2,000 and $61,000, respectively.

As described above, the Company had previously recorded deferred compensation for options granted prior to the date of its initial S-1 filing at prices deemed to be below fair value. As of September 30, 2007, $22,000 of deferred compensation has yet to be recognized for these options. Such amounts will be recognized during the fourth quarter of 2007. The Company has expensed this stock-based compensation to operations over the vesting period of the options and recorded $41,000 and $105,000 as stock-based compensation expense for the nine months ended September 30, 2007 and 2006, respectively. For the three months ended September 30, 2007 and 2006, the Company recorded $4,000 of stock-based compensation and a $52,000 adjustment to stock-based compensation, respectively.

The total fair value of the shares vested and unexercised (other than pre-S-1 shares) and expensed during the three and nine months ended September 30, 2007 was approximately $380,000 and $1.6 million, respectively. As of September 30, 2007, there was $6.3 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 1.3 years.

The Company anticipates recording additional stock-based compensation expense of $896,000 in the fourth quarter of 2007, $2.8 million in 2008 and $2.6 million thereafter relating to the amortization of unrecognized compensation expense as of September 30, 2007. These anticipated compensation expenses do not include any adjustment for future options to purchase common stock granted to employees.

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Option valuation models require the input of highly subjective assumptions. The Company has computed the impact under SFAS No. 123(R) for options granted using the Black-Scholes option-pricing model for the three months ended September 30, 2007 and 2006. The Company increased its expected volatility assumption for the three and nine months ended September 30, 2007 to 73% and 72%, respectively, from 61% and 60% in the corresponding periods of 2006. The rate is based on the Company s actual historical volatility since its initial public offering. The expected life of options granted was estimated using the simplified method calculation as prescribed by SEC Staff Accounting Bulletin No. 107. The assumptions used and weighted-average information are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Risk-free interest rate	4.5%	4.7%	4.7%	4.9%
Expected dividend yield	0%	0%	0%	0%
Expected forfeiture rate	10.2%	4.2%	10.2%	4.2%
Expected life	6.25 years	6.25 years	6.22 years	6.25 years
Expected volatility	73%	61%	72%	60%
Weighted-average fair value of options	$1.48	$2.17	$1.50	$2.96

(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 12,740,445 and 10,541,881 as of September 30, 2007 and 2006, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of September 30, 2007 and 2006.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Weighted-average common shares outstanding	43,150,692	34,268,407	43,095,789	34,216,576
Less: weighted-average unvested restricted common shares outstanding	(535,374)	(16,751)	(547,788)	(32,025)
Basic and diluted weighted-average common shares outstanding	42,615,318	34,251,656	42,548,001	34,184,551

(9) Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with research and development activities relating to its existing product candidates as well as discovery efforts relating to potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company s fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on

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the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company s products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately $47.7 million as of September 30, 2007. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in the Company s clinical trials and timing of the development of the Company s product candidates. As of September 30, 2007, the Company had $411,000 and $402,000 included in prepaid expenses and accrued expenses, respectively, related to its research and development agreements on the accompanying condensed consolidated balance sheet. These research and development expenses are accounted as such costs are incurred. In addition, as of September 30, 2007, the Company had $3.6 million in accrued license fees representing the net present value of the Company s milestone obligations due on the first and second anniversary of the FDA s approval of ZYFLO CR. These accrued license fees are reflected in the Company s results for the nine months ended September 30, 2007 and are included as accrued license fees on the accompanying condensed consolidated balance sheet.

In addition, on August 20, 2007, the Company entered into an agreement with Jagotec AG, a subsidiary of SkyePharma PLC, under which Jagotec agreed to manufacture and supply bulk uncoated tablets of ZYFLO CR to the Company for commercial sale. The Company previously had contracted with Jagotec for the manufacture of ZYFLO CR for clinical trials and regulatory review. Under the terms of the prior agreement, the Company and Jagotec had agreed to negotiate a commercial manufacturing agreement for ZYFLO CR. SkyePharma has guaranteed the performance by Jagotec of all obligations under the commercial manufacturing agreement. The Company has agreed to purchase minimum quantities of ZYFLO CR during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, the Company has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless the Company provides Jagotec with 24-months prior written notice of termination or Jagotec provides the Company with 36-months prior written notice of termination. The Company also entered into a manufacturing and supply agreement with Rhodia Pharma Solutions, which was assigned to Shasun Pharma Solutions Ltd. (Shasun), for commercial production of the API for ZYFLO and ZYFLO CR, subject to specified limitations, through December 31, 2009. Under this agreement, the Company committed to purchase minimum amounts of API in the first quarter of 2008. The API purchased from Shasun currently has a shelf-life of 36 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. As of September 30, 2007, no reserves have been recorded for purchase commitments.

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

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

(10) DEY Co-Promotion and Marketing Services Agreements

On March 13, 2007, the Company entered into an agreement with Dey, L.P. (DEY), a subsidiary of Mylan, Inc., under which the Company and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and ZYFLO CR in the United States, together with the Company.

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

The Company has deferred the $7.0 million in aggregate payments received to date and is amortizing these payments over the term of the agreement, and expects to defer the future $5.0 million milestone payment the Company expects to become payable from DEY in the fourth quarter of 2007. The amortization of the upfront and milestone payments will be offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. The Company records all ZYFLO and ZYFLO CR sales generated by the combined sales force and records any co-promotion fees paid to DEY and the amortization of the upfront and milestone

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payments as sales and marketing expenses. For the three and nine months ended September 30, 2007, approximately $328,000 and $385,000, respectively, was amortized from the deferred co-promotion fees representing the amount earned by DEY during the periods.

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

(11) Income Tax

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. As of the date of adoption, the total amount of net unrecognized tax benefit was $202,000, which has been recorded as a reduction to the deferred tax asset with an offsetting adjustment to the Company s valuation allowance. Accordingly, there was no adjustment to accumulated deficit at the date of adoption. The Company did not recognize any accrued interest and penalties related to unrecognized tax benefits as no amounts would be due as a result of the Company s net tax loss carryforward. The Company s policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. 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. Tax years for 2000 to 2006 remain subject to examination for federal and numerous state jurisdictions. The primary state jurisdiction to which the Company is subject to tax is Massachusetts.

(12) Lease Abandonment

In the third quarter of 2007, the Company decided to cease its in-house research activities to focus on the clinical development and commercialization aspects of its business. Under SFAS No. 146, *Costs Associated with an Exit or Disposal Activity*, the Company recorded a liability of $360,000 in the quarter ended September 30, 2007 related to a portion of the remaining obligations under an operating lease that expires in March 2009 at its facility in Lexington, Massachusetts that the Company ceased to use. The liability recorded was reduced by an estimated sublease rental income that the Company estimates could be reasonably obtained for the unused portion of the facility. During the three months ended September 30, 2007, the Company adjusted its liability by $74,000 to reflect payments made during the third quarter of 2007 related to its deferred rental liability. The Company recorded the abandonment charge in research and development. As of September 30, 2007, the Company s remaining obligation under the operating lease related to the abandonment charge was $289,000, which is included in accrued expenses.

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

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

Financial Operations Overview

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body s inflammatory response. Our marketed products are ZYFLO CR, a controlled-release formulation of zileuton, which the U.S. Food and Drug Administration, or FDA, approved in May 2007, and ZYFLO, an immediate-release tablet formulation of zileuton, which the FDA approved in 1996. Both products are for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. We began selling ZYFLO in the United States in October 2005 and began selling ZYFLO CR in September 2007. In addition, we are developing an injectable formulation of zileuton, or zileuton injection.

We are in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. As part of this process, we are considering alternatives to our current business strategy designed to maximize the value of our commercial organization and product development programs, and we have engaged an investment bank to advise us in considering our potential strategic alternatives. After concluding this review, it is possible that we could determine to pursue one or more of the strategic alternatives that we are considering or a variation of one of these alternatives. For example, we could determine to:

engage in one or more potential transactions, such as the sale or divestiture of certain of our assets, the merger or sale of our company, or other strategic transactions; or

continue to operate our business in accordance with our existing business strategy.

Pending any decision to change strategic direction, we are continuing our commercial and development activities in accordance with our existing business strategy with an increased focus on our cash position. There can be no assurance that our evaluation of strategic alternatives will lead to a change in our current business strategy or future operations, or result in one or more transactions. If we decide to pursue an alternative strategy or engage in a strategic transaction, the descriptions of our strategy, future operations and financial position, future revenues, projected costs and prospects and the plans and objectives of management in this Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this quarterly report on Form 10-Q may no longer be applicable. Because of the significant uncertainty regarding our future plans, the forward-looking statements contained herein do not reflect the potential impact of a potential change in our existing business strategy.

On March 13, 2007, we entered into an agreement with Dey, L.P., or DEY, a subsidiary of Mylan, Inc., under which we and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion agreement, DEY paid us a non-refundable upfront payment of $3.0 million upon signing the co-

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promotion agreement and a milestone payment of $4.0 million following approval by the FDA of the NDA for ZYFLO CR. In addition, DEY has agreed to pay us $5.0 million following commercial launch of ZYFLO CR, which we expect to become payable in the fourth quarter of 2007. Under the co-promotion agreement, we will record all quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, up to $1.95 million and will pay DEY a commission on quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million.

Under the co-promotion agreement, we have deferred the $7.0 million in aggregate payments that we received from DEY to date and we are amortizing these payments over the term of the agreement. In addition, we will amortize the future $5.0 million milestone payment we expect to become payable from DEY in the fourth quarter of 2007. The amortization of the upfront and milestone payments will offset some or all of the co-promotion fees paid to DEY for promoting ZYFLO CR and ZYFLO in future periods under the agreement. We expect to record all ZYFLO CR and ZYFLO sales generated by the combined sales force and record any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses.

On June 25, 2007, we entered into a definitive agreement with DEY to jointly promote DEY s product PERFOROMIST (formoterol fumarate) Inhalation Solution, or PERFOROMIST, for the treatment of chronic obstructive pulmonary disease, or COPD. Under the agreement, DEY granted us a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. Under the agreement, after we begin detailing PERFOROMIST, DEY agreed to pay us a commission on retail sales of PERFOROMIST above a specified baseline. In October 2007, after expanding our sales force to over 40 representatives, we announced that we commercially launched PERFOROMIST with DEY. The agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties. The Company has the right to terminate the agreement after June 30, 2008 with 90-days advance written notice to DEY.

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

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

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

We are conducting preclinical work in our small molecule alpha-7 program. We believe the successful development of a product candidate targeting the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, we have selected a lead compound that is currently in development

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and which we are continuing to move toward an investigational new drug application, or IND, submission. In addition, we continue to seek collaborations with other pharmaceutical companies for our alpha-7 program. We have licensed to Innovative Metabolics, Inc., or IMI, patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Since our inception, we have incurred significant losses each year. As of September 30, 2007, we had an accumulated deficit of $179.8 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue over the next several years as we fund our development programs, market and sell ZYFLO CR and ZYFLO and prepare for the potential commercial launch of our product candidates. Since our inception, we have raised proceeds to fund our operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, license fees from IMI, payments from DEY under our zileuton co-promotion agreement and revenues from sales of ZYFLO and ZYFLO CR.

Revenues. From our inception on July 14, 2000 through the third quarter of 2005, we derived all of our revenues from license fees, research and development payments and milestone payments that we have received from our collaboration and license agreements with MedImmune, Beckman Coulter and IMI. In the fourth quarter of 2005, we began selling, and recognizing revenue, from ZYFLO. In September 2007, we began selling, and recognizing revenue, from ZYFLO CR. In the first quarter of 2007, we began recording revenue upon product shipment to third parties, including wholesalers, distributors and pharmacies, and provided an adequate reserve for potential returns from these third parties based on our product returns experience with ZYFLO and other factors. We anticipate that the rate of return for ZYFLO CR will be comparable to the rate of return for ZYFLO. As a result, we also expect to recognize revenue for sales of ZYFLO CR upon shipment to third parties and record a reserve for potential returns for these third parties based on our product returns experience with ZYFLO and other factors.

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

Research and Development Expenses. Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, such as a Phase IV clinical trial of ZYFLO CR that we initiated in July 2007, milestone payments to third parties, costs related to the development of our recently approved new drug application, or NDA, for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, we record manufacturing expenses associated with a product as cost of products sold rather than as research and development expenses. We expense research and development costs and patent related costs as they are incurred. Because of our ability to utilize resources across several projects, many of our research and development costs are not tied to any particular project and are allocated among multiple projects. We record direct costs on a project-by-project basis. We record indirect costs in the aggregate in support of all research and development. Development costs for clinical development stage

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programs such as zileuton injection tend to be higher than earlier stage programs such as our HMGB1 and alpha-7 programs, due to the costs associated with conducting clinical trials and large-scale manufacturing.

We expect that research and development expenses relating to our portfolio will fluctuate depending primarily on the timing of clinical trials, related manufacturing initiatives and milestone payments to third parties. We expect to incur additional expenses over the next several years for clinical trials of ZYFLO CR and our product development candidates, including zileuton injection. As a result of our October 2006 restructuring, we anticipate that our research and development expenses will decrease in 2007 compared to 2006. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we scale up production of zileuton injection for later stages of clinical development. We have initiated a Phase IV clinical trial related to ZYFLO CR to examine its potential clinical benefits in a particular population of asthma patients, which will be included in research and development expenses. As a result of the FDA s approval of the NDA for ZYFLO CR in May 2007, we made milestone payments totaling $3.1 million and accrued at present value an additional $3.5 million related to milestone obligations due on the first and second anniversary of the FDA s approval. We included these milestone payments and accruals in research and development expenses in our results for the second quarter of 2007 and included the accretion of the discount related to the present value of the milestone obligations in interest expense.

Sales and Marketing Expenses. Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing and our sales operations functions as well as other costs related to ZYFLO CR and ZYFLO. We also incurred marketing and other costs related to our launch of ZYFLO CR in September 2007. Other costs included in sales and marketing expenses include sales and marketing cost related to our co-promotion and marketing agreement, cost of product samples of ZYFLO CR and ZYFLO, promotional materials, market research and sales meetings. We expect to continue to incur sales and marketing costs associated with enhancing our sales and marketing functions and maintaining our increased sales force to support ZYFLO CR and ZYFLO. We expect to incur additional expenses related to our recent commercial launch of ZYFLO CR. In addition, under our co-promotion agreement with DEY, we have deferred the $7.0 million in aggregate payments that we received upon signing the agreement and upon receiving approval by the FDA of the NDA for ZYFLO CR. We are amortizing these payments over the term of the agreement, along with any future milestone payments received from DEY. The amortization of the upfront and milestone payments will offset some or all of the co-promotion fees paid to DEY for promoting ZYFLO CR and ZYFLO in future periods under the agreement. We expect to record all ZYFLO CR and ZYFLO sales generated by the combined sales force and record any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments in sales and marketing.

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

Critical Accounting Policies

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

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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 our financial condition or operating performance is material.

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

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

As of September 30, 2007, our allowances for ZYFLO CR and ZYFLO product returns were $112,000 and $174,000, respectively. Prior to the first quarter of 2007, we deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as we were unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, based on our product return experience since we launched ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties and sufficient history exists to make such estimates. In connection with this change in estimate, we recorded an increase in net product sales in the nine months ended September 30, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000 and was reported in our results for the first quarter of 2007. We recorded $870,000 in net product sales of ZYFLO CR in the third quarter of 2007 as a result of the commercial launch. We anticipate that the rate of return for ZYFLO CR will be comparable to the rate of return used for ZYFLO. As a result, we recognize revenue for sales of ZYFLO CR upon shipment to third parties and record a reserve for potential returns from these third parties based on our product returns experience with ZYFLO and other factors.

Under our collaboration agreements with MedImmune and Beckman Coulter, we are entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in our statements of operations when earned. We must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared

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by our collaborators with us. We recognize these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. Because MedImmune and Beckman Coulter can each cancel its agreement with us, we do not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of our operations because, in each case, the adjustment is limited to the cash received.

Under our license agreement with IMI, we received an initial license fee of $500,000 in cash and IMI preferred stock valued at $500,000. However, under our license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute), or the Feinstein Institute, we were obligated to pay the Feinstein Institute $100,000 of this cash payment and IMI preferred stock valued at $100,000. We included in revenue from collaboration and license agreements in the second quarter of 2007 the $1.0 million total initial license fee that we received from IMI and included the $100,000 cash payment and IMI preferred stock payment valued at $100,000 that the Company made to the Feinstein Institute in research and development expenses. Under the license agreement, IMI also has agreed to pay us $1.0 million in cash upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on net sales of licensed products and methods by IMI and its affiliates.

Product Returns. Consistent with industry practice, we offer customers the ability to return products during the six months prior to, and the twelve months after, the product expires. At the time of commercial launch in October 2005, we began shipping ZYFLO with an expiration date of 12 months. Since our launch of ZYFLO, we have extended ZYFLO s expiration date from 12 months to 24 months as of September 30, 2007. In September 2007, we launched ZYFLO CR, which currently has an expiration date of 18 months. We anticipate that the rate of return for ZYFLO CR will be comparable to the rate of return for ZYFLO. We may adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. We evaluate this reserve on a quarterly basis, assessing each of the factors described above, and adjust the reserve accordingly. As a result of this ongoing evaluation, our product return reserve is $286,000 at September 30, 2007, which is comprised of a product return reserve of approximately $174,000 for ZYFLO and $112,000 for ZYFLO CR.

Inventory. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. We determine the estimated useful life of our inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of September 30, 2007, inventory consists of zileuton active pharmaceutical ingredient, or API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. On a quarterly basis, we analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of our expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At September 30, 2007, we had an inventory reserve of $596,000. The inventory reserve includes $398,000, recorded in the second quarter of 2007, relating to certain batches of ZYFLO CR tablets that did not meet certain Company specification and $193,000, recorded in the third quarter of 2007, relating to excess ZYFLO finished tablets that we believe will not be sold as a result of our recent launch of ZYFLO CR. In the third quarter of 2007, we received a credit for the $398,000 related to the batches of ZYFLO CR tablets that were reserved for in the second quarter of 2007.

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

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

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

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

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

We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued,

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whichever is more reliably measured, in accordance with SFAS 123(R). We use the Black-Scholes option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

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

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of September 30, 2007, we had federal and state tax net operating loss carryforwards of approximately $146 million, which expire beginning in 2021 and 2007, respectively. We also have research and experimentation credit carryforwards of approximately $2.6 million as of September 30, 2007, which expire beginning in 2021. We have recorded a full valuation allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. As of the date of adoption, the total amount of net unrecognized tax benefit is $202,000, which has been recorded as a reduction to the deferred tax asset with an offsetting adjustment to our valuation allowance. Accordingly, there was no adjustment to accumulated deficit at the date of adoption.

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

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Results of Operations

Three Months Ended September 30, 2007 and 2006

Revenues

Revenue from Product Sales. We recognized $3.1 million of revenue from product sales of ZYFLO and ZYFLO CR in the three months ended September 30, 2007 compared to $1.9 million in the three months ended September 30, 2006. The increase in product revenue is primarily attributable to a $870,000 increase in net product sales as a result of our ZYFLO CR launch in September 2007, a 1.7% increase in ZYFLO prescription volume and an 11% price increase in ZYFLO s wholesale acquisition price over the corresponding period in 2006. On January 1, 2007, based on our product return experience since our launch of ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as we are now able to estimate product returns. Prior to this change, we recognized revenue from product shipments when we determined the right to return the product had lapsed or when we could reasonably estimate returns relating to the shipments to third parties under SFAS No. 48. We anticipate that the rate of return for ZYFLO CR will be comparable to the rate of return for ZYFLO.

Revenue under Collaboration and License Agreements. We recognized collaboration and license revenues of $93,000 in the three months ended September 30, 2007, compared to $2.5 million in the three months ended September 30, 2006, a decrease of approximately $2.4 million. This decrease was primarily due to a $2.5 million decrease in collaboration revenue recognized from MedImmune, offset, in part, by $61,000 in license revenue related to our agreement with IMI. We did not receive any license revenue in the three months ended September 30, 2006.

Since we entered into the agreement with MedImmune in 2003, we have billed a total of $17.8 million to MedImmune, consisting of the $12.5 million initial payment, a $1.3 million milestone payment and $4.0 million of development support. As of September 30, 2007, we have recognized this entire amount as collaboration revenue. At September 30, 2007, we had no deferred collaboration revenue and have completed the research term of our agreement with MedImmune. Our revenue recognized from existing collaborations in 2007 may decline substantially because we have now recognized all of the revenue that we previously deferred. Going forward, our revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under our existing agreements or entering into new collaboration agreements.

Costs and Expenses

Cost of Products Sold. Cost of products sold in the three months ended September 30, 2007 was $1.2 million, compared to $267,000 in the three months ended September 30, 2006. Gross margin for the three months ended September 30, 2007 and 2006 was 61% and 86%, respectively. Cost of products sold in the three months ended September 30, 2007 consisted of expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalties to Abbott and SkyePharma related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. We recorded $219,000 of inventory write-offs in the three months ended September 30, 2007. The write-offs in the third quarter of 2007 resulted from excess or obsolete inventory related to ZYFLO that we believe will no longer be used for commercial sale as a result of our launch of ZYFLO CR in the third quarter of 2007. Cost of products sold in the three months ended September 30, 2006 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. We did not record any write-off in the three months ended September 30, 2006. Excluding the impact of write-offs, our gross margins from product sales was 68% in the three months ended September 30, 2007, compared to 83% in the three months ended September 30, 2006. This decrease in gross margins resulted from our increase in cost of products sold related to ZYFLO CR as a result of a more complex manufacturing process and additional royalty obligations to Abbott and SkyePharma for

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utilization of its controlled-release technology. This decrease was offset, in part, by an increase in our wholesale acquisition price of ZYFLO and our ability to spread some of our fixed costs associated with managing our supply chain over a larger revenue base in 2007.

Research and Development Expenses. Research and development expenses in the three months ended September 30, 2007 were $3.9 million, compared to $6.7 million in the three months ended September 30, 2006, a decrease of approximately $2.8 million, or 42%. This decrease was primarily due to lower expenses in the three months ended September 30, 2007 associated with a reduction in the number of employees performing research and development functions following our 2006 restructurings and non-recurring milestone payments that we made in the third quarter of 2006, offset, in part, by additional clinical costs related to our Phase IV clinical trial for ZYFLO CR.

The following table summarizes the primary components of our research and development expenses for the three months ended September 30, 2007 and 2006:

	Three Months Ended September 30,	
	2007	2006
	(in thousands)	
Zileuton (ZYFLO and ZYFLO CR)	$ 1,993	$ 3,395
Zileuton injection	344	354
CTI-01	6	450
Alpha-7	812	1,025
HMGB1	85	481
General research and development expenses	475	532
Stock-based compensation expense	224	499
Total research and development expenses	$ 3,939	$ 6,736

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

Zileuton (ZYFLO and ZYFLO CR). During the three months ended September 30, 2007, we incurred $2.0 million in expenses related to our orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $3.4 million during the three months ended September 30, 2006, a 41% decrease. This decrease was primarily due to the following:

- $1.9 million reduction in milestone fees paid to third parties as a result of our filing of the ZYFLO CR NDA in July 2006;
- $313,000 reduction in clinical, consulting and manufacturing costs for our NDA registration batches for ZYFLO CR;
- $151,000 reduction in salaries and other personnel related costs related to our 2006 restructurings; and
- $66,000 reduction in operating expenses incurred by our medical affairs and medical information functions, related to our scientific support of ZYFLO, as a result of our 2006 restructurings.

The decreases in the costs described above were partially offset by the following:

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$945,000 increase in clinical and manufacturing costs related to our Phase IV clinical trial for ZYFLO CR; and

$212,000 increase in preclinical, clinical and manufacturing costs related to our life cycle extension program for zileuton.

We anticipate that our research and development expenses related to our orally-dosed zileuton programs for the remainder of 2007 will consist primarily of costs related to conducting our Phase IV clinical trial for ZYFLO CR. This clinical trial is designed to examine the utility of ZYFLO CR in a particular population of asthma patients. In addition, we expect to continue to incur research and development expenses to maintain and operate our medical affairs, medical information and pharmacovigilance functions in support of ZYFLO and ZYFLO CR.

Zileuton Injection. During the three months ended September 30, 2007, we incurred $344,000 of expenses related to our zileuton injection program, compared to $354,000 during the three months ended September 30, 2006, a 3% decrease. This decrease was primarily due to reduction in clinical trial expense related to our Phase I/II clinical trial, which concluded in the first half of 2006, offset by costs related to the preparation for our Phase II clinical trial. We expect that our costs associated with the development of zileuton injection will increase during the fourth quarter of 2007 as a result of our Phase II clinical trial, which we initiated in October 2007 and continued formulation development.

CTI-01. During the three months ended September 30, 2007, we incurred $6,000 in expenses related to program clinical trial costs, as compared to expenses of $450,000 in the three months ended September 30, 2006. Effective February 2007, we terminated our license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals related to the development of CTI-01. We do not plan to pursue further development or incur additional costs related to CTI-01.

Alpha-7. During the three months ended September 30, 2007, we incurred $812,000 of expenses related to our alpha-7 program, compared to $1.0 million during the three months ended September 30, 2006, a 21% decrease. This decrease was primarily due to a reduction in the number of employees working on the program following our October 2006 restructuring. We anticipate that the research and development expenses for our alpha-7 program will not grow substantially in 2007, as we expect increased costs related to preclinical studies conducted by third parties to advance our lead molecule to be offset by the reduced number of employees working on this program. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. We currently expect to conduct initial clinical trials with the alpha-7 program on our own and are also seeking a collaborator as well, which we may or may not secure before beginning clinical development. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the product candidate we choose to develop, the clinical indications developed, the development strategy adopted, and the terms of a collaboration, if we are able to enter into one. As a result, we are unable to estimate the costs or the timing of advancing a small molecule from our alpha-7 program through clinical development.

HMGB1. During the three months ended September 30, 2007, we incurred $85,000 of expenses related to our HMGB1 program, compared to $481,000 during the three months ended September 30, 2006, an 82% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for our continued testing under our collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. We anticipate that research and development costs relating to HMGB1 for the remainder of 2007 will be lower than the corresponding period in the prior year, as a result of our October 2006 restructuring. In addition, a larger portion of the expenses in our HMGB1

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program will be assumed by MedImmune as the program advances into later stages of preclinical development. We also anticipate that some of our expenses in the HMGB1 program will be covered by funding and potential milestone payments from MedImmune under our collaboration agreement. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indications developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while any funding received from MedImmune and Beckman Coulter to support our research efforts is included in revenue under collaboration agreements.

Our general research and development expenses, which are not allocated to any specific program, decreased by $57,000 in the three months ended September 30, 2007 as compared to the three months ended September 30, 2006. This decrease was primarily attributable to a reduction in salaries and wages and other employee-related costs as a result of our May 2006 and October 2006 restructurings as well as improved cost allocation methods for our existing research and development personnel and the related laboratory and general expenses for our current research and development programs, offset, in part, by our lease abandonment charge of $360,000, which we recorded in the third quarter of 2007.

In addition, our stock-based compensation expense decreased $275,000 in the three months ended September 30, 2007, compared to the three months ended September 30, 2006. This decrease was primarily due to the reduction in the number of employees performing research and development functions following our May 2006 and October 2006 restructurings and to the effects of the change in the market price of our common stock on unvested non-employee options. The adjustment to stock-based compensation expense on unvested non-employee options 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 September 30, 2007 and the three months ended September 30, 2006, which resulted in a reduction to our stock-based compensation expense to non-employees of $10,000 and $85,000, respectively.

Sales and Marketing Expenses. Sales and marketing expenses for the three months ended September 30, 2007 were $3.6 million, compared to $3.9 million for the three months ended September 30, 2006. The $332,000 decrease was primarily attributable to a decrease in the number of employees performing sales and marketing functions, offset by expenses related to our third quarter of 2007 ZYFLO CR product launch and promotional and other marketing expenses as a result of our obligations under our co-promotion and marketing agreement with DEY. The number of employees performing sales and marketing functions decreased to 53 employees at September 30, 2007 from 64 employees at September 30, 2006. We expect that our sales and marketing costs will increase during the fourth quarter of 2007 as a result of our recent launch of ZYFLO CR and our co-promotion and marketing agreement with DEY.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2007 were $2.7 million, compared to $2.9 million for the three months ended September 30, 2006. The decrease in the three months ended September 30, 2007 was primarily due to a reduction in salaries and wages and other personnel cost as a result of our 2006 restructurings. The number of employees performing general and administrative functions decreased to 14 employees at September 30, 2007 from 23 employees at September 30, 2006.

Other Income. Interest income for the three months ended September 30, 2007 was $474,000 compared to $612,000 for the three months ended September 30, 2006. The decrease in the three months ended September 30, 2007 was primarily attributable to lower average cash and investment balances, offset, in part, by higher interest rates. Interest expense amounted to $81,000 and $54,000 for the three months ended September 30, 2007 and September 30, 2006, respectively. For the three months ended

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September 30, 2007, the interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures and the accretion of the discount related to the present value of the obligations related to the milestones due on the first and second anniversary of the FDA s approval of ZYFLO CR. For the three months ended September 30, 2006, the interest expense relates primarily to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Nine months Ended September 30, 2007 and 2006

Revenues

Revenue from Product Sales. We recognized revenue from product sales of ZYFLO and ZYFLO CR of $8.3 million in the nine months ended September 30, 2007, compared to $4.7 million in the nine months ended September 30, 2006. The increase in product revenue is primarily attributable to a 19.4% increase in ZYFLO prescription volume, an 11% increase in ZYFLO s wholesale acquisition price as well as an $870,000 increase in net product sales as a result of our ZYFLO CR launch in September 2007. In addition, in the first quarter of 2007 we recorded a $953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. On January 1, 2007, based on our product return experience since our launch of ZYFLO in October 2005, we began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties. Prior to this change in the first quarter of 2007, we recognized revenue from product shipments when we determined the right to return the product had lapsed or when we could reasonably estimate returns relating to the shipments to third parties under SFAS No. 48. We anticipate that the rate of return for ZYFLO CR will be comparable to the rate of return for ZYFLO.

Revenue under Collaboration and License Agreements. We recognized collaboration and license revenues of $1.8 million in the nine months ended September 30, 2007, compared to $5.4 million in the nine months ended September 30, 2006, a decrease of approximately $3.6 million or 66%. This decrease was primarily due to a $5.0 million decrease in collaboration revenue from our collaboration with MedImmune, offset by $1.1 million in license revenue related to our agreement with IMI. We did not recognize any license revenue in the nine months ended September 30, 2006. For the nine months ended September 30, 2007, we recognized collaboration revenue of $768,000. Our collaboration revenue included $400,000 of deferred revenue recognized under our collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with our HMGB1 program and approximately $368,000 related to a portion of the $12.5 million of initial fees MedImmune paid to us that we recognized over the duration of the contract and the $5.3 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through September 30, 2007. Collaboration revenue in the nine months ended September 30, 2006 was primarily comprised of the portion of the initial fees MedImmune paid to us that we recognized in each period, and the portion of milestone payments and development support billed to MedImmune in the first quarter of 2006, in 2005 and in 2004 that we recognized in the nine months ended September 30, 2006.

Since we entered into the agreement with MedImmune in 2003, we have billed a total of $17.8 million to MedImmune, consisting of the $12.5 million initial payment, a $1.3 million milestone payment and $4.0 million of development support. As of September 30, 2007, we have recognized this entire amount as collaboration revenue. At September 30, 2007 we had no deferred collaboration revenue and had completed the research term of our agreement with MedImmune. Our revenue recognized from existing collaborations in 2007 may decline substantially because we have now recognized all of the revenue that we previously deferred. Going forward, our revenue from collaboration agreements will fluctuate each

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

Costs and Expenses

Cost of Products Sold. Cost of products sold was $2.7 million in the nine months ended September 30, 2007 and $1.7 million in the nine months ended September 30, 2006. Gross margin for the nine months ended September 30, 2007 and 2006 was 68% and 65%, respectively. Cost of products sold in the nine months ended September 30, 2007 consisted of the expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalties to Abbott and SkyePharma related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. As a result of our change in estimates relating to recognition of ZYFLO sales, we recorded $166,000 in costs of product sold in the nine months ended September 30, 2007. Cost of products sold in the nine months ended September 30, 2006 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. We recorded inventory write-offs of $219,000 in the nine months ended September 30, 2007 and $286,000 in the nine months ended September 30, 2006. The write-offs in the first nine months of 2007 and 2006 resulted from excess or obsolete inventory that could no longer be used for commercial sale. Excluding the impact of write-offs, our gross margins from product sales were 70.7% in both the nine months ended September 30, 2007 and in the nine months ended September 30, 2006. Following the commercial launch of ZYFLO CR in September 2007, our gross margins will likely decrease as a result of additional royalty obligations to Abbott and SkyePharma for utilization of its controlled-release technology.

Research and Development Expenses. Research and development expenses in the nine months ended September 30, 2007 were $17.0 million, compared to $23.1 million in the nine months ended September 30, 2006, a decrease of approximately $6.1 million, or 26%. This decrease was primarily due to lower expenses associated with clinical trials, as well as the reduction in the number of employees performing research and development functions following our 2006 restructurings, offset, in part, by $6.6 million in milestone payments paid and accrued in the nine months ended September 30, 2007 as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007.

The following table summarizes the primary components of our research and development expenses for the nine months ended September 30, 2007 and 2006:

	Nine months Ended September 30,	
	2007	2006
	(in thousands)	
Zileuton (ZYFLO and ZYFLO CR)	$ 11,867	$ 10,245
Zileuton injection	658	2,222
CTI-01	(78)	2,823
Alpha-7	2,659	3,157
HMGB1	294	1,506
General research and development expenses	799	2,011
Stock-based compensation expense	762	1,099
Total research and development expenses	$ 16,961	$ 23,063

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

Zileuton (ZYFLO and ZYFLO CR). During the nine months ended September 30, 2007, we incurred $11.9 million in expenses related to our orally-dosed zileuton programs, including ZYFLO and

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ZYFLO CR, compared to $10.2 million during the nine months ended September 30, 2006, a 16% increase. This increase was primarily due to the following:

- $3.1 million in milestone fees paid to third parties as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007;
- $3.5 million in accrued milestone payments to third parties as a result of the FDA s approval on the NDA for ZYFLO CR in May 2007, which are due on the first and second year anniversary of the FDA s approval;
- $1.5 million increase in clinical and manufacturing costs related to our Phase IV clinical trial for ZYFLO CR; and
- $610,000 increase in clinical and manufacturing costs related to our life cycle extension program for zileuton.

The increases in the costs described above were partially offset by the following:

- $2.8 million reduction in clinical and manufacturing costs for ZYFLO and our NDA registration batches for ZYFLO CR;
- $1.9 million reduction in milestone fees paid to third parties as a result of the filing of the ZYFLO CR NDA in July 2006;
- $610,000 reduction in consulting and scientific advisor fees related to the ZYFLO CR NDA registration batches and ZYFLO product launch;
- $857,000 reduction in operating expenses incurred by our medical affairs and medical information functions, related to our scientific support of ZYFLO, as a result of our 2006 restructurings; and
- $1.3 million reduction in salaries, other personnel related costs and overhead related to our 2006 restructurings.

We anticipate that our research and development expenses related to our orally-dosed zileuton programs for the remainder of 2007 will consist primarily of costs related to conducting our Phase IV clinical trial for ZYFLO CR. This clinical trial is designed to examine the utility of ZYFLO CR in particular groups of asthma patients. In addition, we expect to continue to incur research and development expenses to maintain and operate our medical affairs, medical information and pharmacovigilance functions in support of ZYFLO and ZYFLO CR.

Zileuton Injection. During the nine months ended September 30, 2007, we incurred $658,000 in expenses related to our zileuton injection program, compared to $2.2 million during the nine months ended September 30, 2006, a 70% decrease. This decrease was primarily due to a reduction in clinical trial expenses related to our Phase I/II clinical trial, which concluded in the first half of 2006, offset by costs related to the preparation of our Phase II clinical trial. We expect that our costs associated with the development of zileuton injection will increase during the fourth quarter of 2007 as a result of our Phase II clinical trial, which we initiated in October 2007 and continued formulation development.

CTI-01. During the nine months ended September 30, 2007, we received a net credit of $78,000 related to our CTI-01 program clinical trial costs, as compared to expenses of $2.8 million in the nine

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months ended September 30, 2006. Effective February 2007, we terminated our license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals related to the development of CTI-01. We do not plan to pursue further development of CTI-01 or to incur additional costs related to CTI-01.

Alpha-7. During the nine months ended September 30, 2007, we incurred $2.7 million of expenses related to our alpha-7 program, compared to $3.2 million during the nine months ended September 30, 2006, a 16% decrease. This decrease was primarily due to a reduction in the number of employees working on the program following our October 2006 restructuring, offset by payments made to the Feinstein Institute as a result of our license agreement with IMI and consisting of $100,000 in cash and IMI preferred stock valued at $100,000. We anticipate that the research and development expenses for our alpha-7 program will not grow substantially in 2007, as we expect increased costs related to preclinical studies conducted by third parties to advance our lead molecule to be offset by the reduced headcount of employees working on this program. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. We currently expect to conduct initial clinical trials with the alpha-7 program on our own and are also seeking a collaborator as well, which we may or may not secure before beginning clinical development. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the product candidate we choose to develop, the clinical indications developed, the development strategy adopted, and the terms of a collaboration, if we are able to enter into one. As a result, we are unable to estimate the costs or the timing of advancing a small molecule from our alpha-7 program through clinical development.

HMGB1. During the nine months ended September 30, 2007, we incurred $294,000 of expenses for our HMGB1 program, compared to $1.5 million during the nine months ended September 30, 2006, an 81% decrease. This decrease was primarily due to lower sponsored research costs and laboratory supplies for our continued testing under our collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. We anticipate that research and development costs relating to HMGB1 for the remainder of 2007 will be lower as a result of our October 2006 restructuring. In addition, a larger portion of the expenses in our HMGB1 program have been assumed by MedImmune as the program advances into later stages of preclinical development. We also anticipate that some of our expenses in the HMGB1 program will be covered by funding and potential milestone payments from MedImmune under our collaboration agreement. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indications developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while funding received from MedImmune and Beckman Coulter to support our research efforts is included in revenue under collaboration agreements.

Our general research and development expenses, which are not allocated to any specific program, decreased by $1.2 million in the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006. This decrease was primarily attributable to a reduction in salaries and wages and other employee-related costs as a result of our 2006 restructurings and improved cost allocation methods for our existing research and development personnel and the related laboratory and general expenses for our current research and development programs, offset, in part, by the lease abandonment charge of $360,000 we recorded in the third quarter of 2007.

In addition, our stock-based compensation expense decreased $337,000 in the nine months ended September 30, 2007, compared to the nine months ended September 30, 2006. This decrease was primarily due to the reduction in the number of employees performing research and development functions following our 2006 restructurings and the effects of the change in the market price of our

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common stock on unvested non-employee options. The adjustment to stock-based compensation expense on unvested non-employee stock options is calculated based on the change in fair value of our common stock during the period. The fair value of our common stock decreased during both the nine months ended September 30, 2007 and the nine months ended September 30, 2006, which resulted in a reduction to our stock-based compensation expense to non-employees of $7,000 and $370,000, respectively.

Sales and Marketing Expenses. Sales and marketing expenses for the nine months ended September 30, 2007 were $8.2 million, compared to $16.5 million for the nine months ended September 30, 2006. The $8.3 million decrease was primarily attributable to a decrease in the number of employees performing sales and marketing functions, offset, in part, by expenses related to our ZYFLO CR product launch in the third quarter of 2007. For the nine months ended September 30, 2007, the co-promotion fee owed to DEY for promoting ZYFLO and ZYFLO CR has been offset by the amortization of the upfront and milestone payments.

The number of employees performing sales and marketing functions decreased to 53 employees at September 30, 2007 from 64 employees at September 30, 2006. We expect that our sales and marketing costs will increase in the fourth quarter of 2007 as a result of our co-promotion and marketing agreement with DEY and the recent commercial launch of ZYFLO CR.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2007 were $9.2 million, compared to $10.9 million for the nine months ended September 30, 2006. The decrease in the nine months ended September 30, 2007 was primarily due to a reduction in salaries and wages and other personnel costs as a result of our 2006 restructurings, offset, in part, by increased consulting and advisory fees associated with our co-promotion and marketing agreement with DEY. The number of employees performing general and administrative functions decreased to 14 employees at September 30, 2007 from 23 employees at September 30, 2006.

Other Income. Interest income for the nine months ended September 30, 2007 was $1.6 million, compared to $2.1 million for the nine months ended September 30, 2006. The decrease in the nine months ended September 30, 2007 was primarily attributable to lower average cash and investment balances, offset, in part, by higher interest rates. Interest expense amounted to $150,000 and $169,000 for the nine months ended September 30, 2007 and September 30, 2006, respectively. For the nine months ended September 30, 2007, the interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures and the accretion of the discount related to the present value of the obligations related to the milestones due on the first and second anniversary of the FDA s approval of ZYFLO CR. For the nine months ended September 30, 2006, the interest expense relates primarily to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have raised proceeds to fund our operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from our collaboration, license and co-promotion agreements, the exercise of stock options, and, beginning in the fourth quarter of 2005 and the third quarter of 2007, revenues from sales of ZYFLO and ZYFLO CR, respectively. As of September 30, 2007, we had $34.0 million in cash, cash equivalents and short-term investments. We have invested our remaining cash balance in highly liquid, interest-bearing, investment grade securities in accordance with our established corporate investment policy.

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In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid us initial fees of $12.5 million and an additional $5.3 million through September 30, 2007 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program. We invoiced MedImmune for an additional $31,000 for work performed in the third quarter of 2007. As of September 30, 2007, we had completed the research term of our agreement with MedImmune.

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

Under our co-promotion agreement with DEY, we received a non-refundable upfront payment of $3.0 million in March 2007 and a milestone payment of $4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007. In addition, DEY has agreed to pay us a milestone payment of $5.0 million following commercial launch of ZYFLO CR. We expect this milestone payment to become payable in the fourth quarter of 2007.

Credit Agreement with Silicon Valley Bank. We have financed the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment, software licenses and the completion of leasehold improvements through advances under a credit agreement with Silicon Valley Bank, which was most recently modified as of January 6, 2006. As of September 30, 2007, we had no borrowing capacity available under the modified credit agreement or any other credit agreement. We are currently considering financing alternatives to fund capital expenditures in the future.

We have granted Silicon Valley Bank a first priority security interest in substantially all of our assets, excluding intellectual property, to secure our obligations under the credit agreement. As of September 30, 2007, we had $592,000 in debt outstanding under this credit agreement related to equipment advances. As a result of our October 2006 restructuring, we incurred restructuring charges for the impairment of a number of our assets. As a result of these charges, we have paid to Silicon Valley Bank certain proceeds received from the sale of a portion of these impaired assets and may pay to Silicon Valley Bank certain proceeds received from future sales of any remaining impaired assets.

Advances made under the modified credit agreement after September 30, 2004 accrue interest at a rate equal to the prime rate plus 2% per year. As of September 30, 2007, outstanding equipment advances under the modified credit agreement had a weighted-average effective interest rate of approximately 9.75% per year. Advances made under the modified credit agreement are required to be repaid in equal monthly installments of principal plus interest accrued through the repayment term, which range from 36 to 42 months. Repayment begins the first day of the month following the advance. No advances were made in the nine months ended September 30, 2007 under the modified credit agreement.

Cash Flows

Operating Activities. Net cash used in operating activities was $14.7 million for the nine months ended September 30, 2007, as compared to $41.6 million for the nine months ended September 30, 2006. Net cash used in operations for the nine months ended September 30, 2007 consisted of a net loss of $25.4 million, depreciation and amortization expense, accretion of premiums on short-term investments and other, the loss on the disposal of fixed assets and non-cash restructuring charges of $868,000, a net change in the reserve for inventory of $476,000, stock-based compensation expense of $2.9 million and an increase in working capital accounts of $6.9 million offset by IMI preferred stock valued at $400,000

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that we received as part of a license agreement. The increase in working capital accounts was primarily due to $7.0 million in aggregate payments that we received from DEY upon the signing of the co-promotion agreement and receiving approval by the FDA of the NDA for ZYFLO CR and a $3.5 million increase in accrued license expenses offset, in part, by a $1.2 million reduction in deferred product revenue, a $675,000 reduction in deferred collaboration revenue and fees, a $1.3 million increase in accounts receivable, a $671,000 increase in prepaid and other expenses and a $663,000 increase in inventory.

Investing Activities. Investing activities provided $509,000 of net cash in the nine months ended September 30, 2007, compared to $20.7 million in the nine months ended September 30, 2006. During the nine months ended September 30, 2007, we made capital expenditures of $7,000. In addition, as interest rates have gradually increased, we have maintained more of our proceeds from recent financings as cash equivalents rather than short-term investments.

Financing Activities. In the nine months ended September 30, 2007, we used $537,000 of net cash in financing activities, compared to $778,000 in the nine months ended September 30, 2006. Net cash used in financing activities for the nine months ended September 30, 2007 principally related to repayment of our long-term debt offset in part by proceeds from stock option exercises and our employee stock purchase plan.

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 September 30, 2007. If not utilized, federal net operating loss carryforwards will begin to expire in 2021. State net operating loss carryforwards began to expire in 2006. The federal tax credits expire beginning in 2021. To date, we have not recognized the potential tax benefit of our net operating loss carryforwards or credits on our balance sheet or statements of operations. The future utilization of our net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code.

Funding Requirements

We expect to devote substantial resources to support the commercial launch of ZYFLO CR, to fund our Phase IV clinical trial of ZYFLO CR and to fund the development of our product candidates. We also expect to make less than $50,000 in capital expenditures in the remainder of 2007 for the purchase of software and computer equipment. We expect to fund our capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Our funding requirements will depend on numerous factors, including:

- the ongoing costs of the commercial launch of ZYFLO CR;
- the scope, costs and results of our clinical trials on ZYFLO CR and zileuton injection;
- the amount and timing of sales and returns of ZYFLO CR and ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO CR and ZYFLO;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;

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

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

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

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

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

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

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

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

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

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to successfully commercialize ZYFLO CR and to sell ZYFLO. Based on our operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under existing collaboration agreements will be sufficient to fund anticipated levels of operations into the fourth quarter of 2008.

For the nine months ended September 30, 2007, our net cash used in operating activities was $14.7 million, and we had no capital expenditures. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional products or 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. Such equity securities may have rights and preferences superior to those of the holders of our common stock. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

Contractual Obligations

We have summarized in the table below our fixed contractual obligations as of September 30, 2007:

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	Payments Due by Period				
Contractual Obligations	Total	Less Than One Year	One to Three Years	Three to Five Years	More than Five Years
			(In thousands)		
Short- and long-term debt	$ 620	$ 570	$ 50	$	$
Research and license agreements	10,197	2,032	2,556	764	4,845
Consulting agreements	548	548			
Severance agreements	17	17			
Manufacturing and clinical trial agreements	36,938	19,007	16,353	1,578	
Lease obligations	2,044	1,500	544		
Total contractual cash obligations	$ 50,364	$ 23,674	$ 19,503	$ 2,342	$ 4,845

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 September 30, 2007, we have made aggregate milestone payments of $7.8 million to Abbott under our license agreements related to ZYFLO and ZYFLO CR.

In addition, under our license agreement with SkyePharma, through its subsidiary Jagotec, for ZYFLO CR, we agreed to make aggregate milestone payments of up to $6.6 million upon the achievement of various development and commercialization milestones. Through September 30, 2007, we have made aggregate milestone payments of $3.0 million to SkyePharma under our agreement.

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

The amounts listed for consulting agreements are for fixed payments due to our scientific and business consultants. The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. On August 20, 2007, we entered into an agreement with Jagotec, under which Jagotec agreed to manufacture and supply bulk ZYFLO CR tablet cores for commercial sale. We have agreed to purchase minimum quantities of ZYFLO CR tablet cores during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, we have agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless we provide Jagotec with 24-months prior written notice of termination or Jagotec provides us with 36-months prior written

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notice of termination. In addition, we have the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting or selling ZYFLO CR. We also may terminate the agreement upon six-months advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and we determine to permanently cease commercialization of ZYFLO CR. Likewise, we may terminate the agreement upon 12-months advance notice if it intends to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, we have agreed to purchase quantities of ZYFLO CR tablets that are subject to binding forecasts. In addition, as discussed in our annual report on Form 10-K for the year ended December 31, 2006, we entered into a manufacturing and supply agreement with Rhodia Pharma Solutions Ltd. for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. On September 30, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions Ltd., sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions Ltd., or Shasun. Under this agreement, we committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and in the first quarter of 2008. The API purchased from Shasun currently has a minimum shelf-life of 36 months. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While our purchase commitment for API from Shasun exceeds our current forecasted demand in 2007, we expect that any excess API purchased in 2006 and 2007 under our agreement with Shasun will be used in commercial production batches in 2007, 2008 and 2009 and sold before it requires retesting. Therefore, no reserve for this purchase commitment has been recorded as of September 30, 2007.

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

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

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 September 30, 2007, we estimate that the fair value of our investment portfolio would decline by approximately $3,000. In addition, we could be exposed to losses related to these securities should one of our counterparties default.

We attempt to

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mitigate this risk through credit monitoring procedures. Although we consider our investments to be available-for-sale securities in order to fund operations, if necessary, we have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness in our internal control over financial reporting described below.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated whether any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2007 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on the evaluation we conducted, management has concluded that the material weakness in our internal control over financial reporting described below continued to impact our internal control over financial reporting.

In connection with the preparation of our financial statements for the quarter ended June 30, 2007, we identified a material weakness in our internal control over financial reporting. This material weakness related to the operation of controls over accounting for non-routine transactions, specifically the accrual of milestone obligations due under certain of our contractual arrangements in accordance with generally accepted accounting principles, or GAAP. As a result of this material weakness, a material adjustment was recorded to our draft interim financial statements after the financial close of our prior quarter ended June 30, 2007. While our internal disclosure controls and procedures detected the need to accrue for the milestone obligations, we did not initially reach the appropriate conclusion relative to the timing of the accrual recognition. As a result of the foregoing, our management determined that our operation of controls related to accounting for non-routine transactions was inadequate and ineffective as of June 30, 2007.

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To remediate the material weakness described above and to enhance our internal control over financial reporting, we have implemented or are in the process of implementing the following improvements to our internal controls process:

- improvements to our procedures for the review of non-routine transactions;
- assessments of the expertise and training of our employees responsible for finance and accounting who perform and review non-routine transactions and providing additional training to such employees addressing any identified training deficiencies; and
- review of our controls and procedures relating to the financial close process to determine if any further improvements need to be implemented.

Because some these improvements are still in the process of being implemented or have only recently been implemented, our management also determined that our operation of controls related to accounting for non-routine transactions remained inadequate and ineffective as of September 30, 2007. However, we believe that we have taken or are taking the appropriate steps that will be intended to remediate the material weakness described above and to ensure our disclosure controls and procedures will be effective at a reasonable assurance level in future periods. We will continue to implement and test our remediation activities.

Except as noted above, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Not applicable.

Item 1A. Risk Factors.

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

Risks Relating to Our Business

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

ZYFLO CR and ZYFLO are currently our only commercially marketed products. We only recently commercially launched ZYFLO CR on September 27, 2007. We commercially launched ZYFLO in October 2005 and ZYFLO has not achieved broad market acceptance. If we are able to successfully commercialize ZYFLO CR, we expect it will account for a significant portion of our revenues for the foreseeable future and that sales of ZYFLO will decline as patients convert to ZYFLO CR. However, we cannot assure you that ZYFLO CR will not suffer the same lack of broad market acceptance that has affected ZYFLO. Our product candidates are in early clinical and preclinical stages of development and are a number of years away from commercialization.

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

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

The commercial success of ZYFLO CR will depend upon its acceptance by the medical community, third-party payors and patients. Physicians will prescribe ZYFLO CR only if they determine, based on experience, clinical data,

side effect profiles or other factors, that this product either alone or in combination with other products is appropriate for managing their patient s asthma. We believe that the primary advantage of ZYFLO CR over ZYFLO is ZYFLO CR s more convenient dosing schedule, but this advantage may not result in broad market acceptance of ZYFLO CR, and we may experience the same types of difficulties with ZYFLO CR that we have experienced with ZYFLO.

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Despite being approved by the FDA since 1996, ZYFLO, our first marketed zileuton product, has not achieved broad market acceptance. During the period between our commercial launch of ZYFLO in October 2005 through August 2007, prescription data for ZYFLO indicates that approximately 4,949 physicians prescribed the product. We recorded revenue from the sale of ZYFLO of only $6.6 million for the year ended December 31, 2006. We recorded revenue from the sale of ZYFLO and ZYFLO CR of $8.3 million for the nine months ended September 30, 2007. We have had difficulty expanding the prescriber and patient base for ZYFLO, in part, we believe, because some physicians view ZYFLO as less effective than other products on the market or view its clinical data as outdated and because it requires dosing of one pill four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two pills twice daily or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, our sales of ZYFLO CR will be limited and our revenues will be adversely affected.

Market perceptions about the safety of ZYFLO may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO. These periodic liver function tests also are recommended for patients taking ZYFLO CR, based upon its product label, which was approved by the FDA in May 2007. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO and other zileuton product candidates, including ZYFLO CR. As a result, many physicians may have negative perceptions about the safety of ZYFLO and other zileuton product candidates, including ZYFLO CR, which could limit their commercial acceptance. The absence of ZYFLO from the market prior to our commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues. These negative perceptions could carry over to ZYFLO CR.

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

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

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We are considering alternatives to our current business strategy that could significantly impact our future operations and financial position.

We are in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. As part of this process, we are considering alternatives to our current business strategy designed to maximize the value of our commercial organization and product development programs, and we have engaged an investment bank to advise us in considering our potential strategic alternatives. After concluding this review, it is possible that we could determine to pursue one or more of the strategic alternatives that we are considering or a variation of one of these alternatives. For example, we could determine to engage in one or more potential transactions, such as the sale or divestiture of certain of our assets, the sale or merger of our company, or other strategic transactions, or to continue to operate our business in accordance with our existing business strategy. Pending any decision to change strategic direction, we are continuing our commercial and development activities in accordance with our existing business strategy with an increased focus on our cash position. There can be no assurance that our evaluation of strategic alternatives will lead to a change in our current business strategy, or result in one or more transactions. If we determine to pursue an alternative strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the potential impact of a potential change in our existing business strategy.

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

After reducing the size of our sales force as part of the cost reduction programs that we announced in 2006, we then increased the size of our sales force in connection with the commercial launch of ZYFLO CR to approximately 42 sales representatives as of September 30, 2007. Rebuilding our sales force involved significant time and expense. If we are not successful in our efforts to retain an adequate sales force, our ability to market and sell ZYFLO CR would be impaired.

In March 2007, we entered into a co-promotion agreement with Dey, L.P., a wholly-owned subsidiary of Mylan Inc., or DEY, for the co-promotion of ZYFLO CR and ZYFLO. We cannot predict whether the co-promotion arrangement will lead to increased sales for ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR on September 27, 2007 and for ZYFLO on April 30, 2007. Given the recent initiation of DEY s efforts, the potential success of the co-promotion arrangement is uncertain. Under the co-promotion agreement, we agreed to provide a minimum number of promotional details per month by our sales representatives to a specified group of office-based physicians and other health care professionals for ZYFLO CR. If we are not successful in our efforts to provide the required level of promotional detailing, DEY s co-promotion fee may be increased and DEY may have a right to terminate the co-promotion agreement for ZYFLO CR. For example, if we experience greater than expected turnover of sales representatives, we may have difficulty satisfying our minimum detailing obligations.

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

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minimum number of promotional details per month by our sales representatives to a specified group of office-based physicians and other health care professionals. If we are not successful in our efforts to provide the required level of promotional detailing for PERFOROMIST, our co-promotion fee may be reduced and DEY may have a right to terminate the PERFOROMIST co-promotion agreement. Promoting both ZYFLO CR and PERFOROMIST may be challenging for our sales representatives and may reduce their efficiency, which could negatively impact our revenues.

In addition, the amount of any co-promotion fee that DEY pays to us under the PERFOROMIST co-promotion agreement will be limited if PERFOROMIST does not achieve market acceptance. For example, safety concerns relating to PERFOROMIST may harm potential sales. PERFOROMIST belongs to a class of medications known as long-acting $beta_2$-adrenergic agonists, or LABAs, which may increase the risk of asthma-related death. Data from a large placebo-controlled study in the United States comparing the safety of the LABA salmeterol or placebo plus usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding also may apply to formoterol, the active ingredient in PERFOROMIST.

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

We are subject to minimum purchase obligations under our supply agreements with our third-party manufacturers, which require us to buy inventory of the zileuton active pharmaceutical ingredient, or API, and tablet cores for ZYFLO CR. If ZYFLO CR does not achieve the level of demand we anticipate, we may not be able to use the inventory we are required to purchase. Significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If we are required to recognize charges for excess inventories, it could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory.

In November 2007, we have not released for commercial supply one batch of ZYFLO CR tablet cores due to issues associated with the manufacture. If we are unable to manufacture or release ZYFLO CR on a timely and consistent basis, if we fail to maintain an adequate inventory of zileuton API or ZYFLO CR core tablets, or if our inventory were to be destroyed or damaged or reached its expiration date, patients might not have access to ZYFLO CR, our reputation and our brand could be harmed and physicians may be less likely to prescribe ZYFLO CR in the future. Conversely, if we are unable to sell our inventory in a timely manner, we could experience cash flow difficulties and additional financial losses.

We would be exposed to similar risks if we fail to maintain an adequate inventory of ZYFLO or zileuton API or if our inventory were to be destroyed or damaged or reach its expiration date.

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

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

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

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the therapeutic benefit or other improvement over existing comparable products;

pricing and cost effectiveness;

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

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

the extent and success of our sales and marketing efforts.

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

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

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

internal preclinical programs;

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

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

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

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

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

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

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

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

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

The development and commercialization of new drugs is highly competitive. We will face competition with respect to the development of product candidates and for ZYFLO CR, 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 CR and ZYFLO. Many established therapies currently command large market shares in the asthma market, including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products.

In the severe asthma market, competition results primarily from the therapies developed for mild to moderate asthma, such as Singulair®, Advair® and inhaled corticosteroids that are used in combination or as add-on therapies, along with oral and injectable steroid treatments. One product, Xolair®, developed jointly by Novartis AG, Genentech, Inc. and Tanox, Inc., was approved in 2004 for severe allergic asthma and had U.S. sales of $427 million in 2006. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in June 2007, AstraZeneca commercially launched in the United States Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a long-acting beta2-agonist, which is expected to compete in the moderate and severe asthma markets.

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

Many therapies for COPD are already well established in the respiratory marketplace, including GlaxoSmithKline s Advair® and Serevent® and Spiriva®, a once daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer. In April 2007, Sepracor, Inc. commercially launched Brovana® for COPD. Other novel approaches are also in development.

In April 2007, Sepracor commercially launched a direct competitor to PERFOROMIST called Brovana®. Brovana is an isomer of formoterol that is delivered in a nebulized formulation. DEY has sued Sepracor for infringement of DEY s patents and Sepracor has counterclaimed.

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

If our therapeutic programs directed toward the body s inflammatory response result in commercial

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products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc. s Enbrel®, Johnson & Johnson s Remicade®, Bristol-Myers Squibb Company s Orencia®, Abbott Laboratories Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company s Xigris®.

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

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

We will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products obsolete or noncompetitive. If our product candidates are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those product candidates.

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

We depend on the principal members of our management and scientific staff, including Frank E. Thomas, our President and Chief Executive Officer, Trevor Phillips, Ph.D., our Chief Operating Officer and Senior Vice President of Operations, and Thomas P. Kelly, our Chief Financial Officer and Senior Vice President of Finance and Corporate Development. 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. Dana Hilt, M.D., our former Chief Medical Officer and Senior Vice President of Clinical Development, resigned effective September 25, 2007. Dr. Hilt s resignation may have a negative effect on our product development efforts if we are unable to find a suitable replacement within a reasonable period of time.

Our success depends in large part on our ability to attract and retain qualified scientific, commercial and management personnel. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, will place additional requirements on our management, operational and financial resources. These demands may

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require us to hire additional management and scientific personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the research, development, regulatory approval and commercialization of our product candidates.

We have also experienced turnover on our board of directors. For example, we have had six directors leave our board and two directors join our board since June 30, 2006. We currently have five directors serving on our board. If we are unable to attract and retain qualified directors, the achievement of our corporate objectives could be significantly delayed or may not occur.

We identified a material weakness in our internal control over financial reporting for the second quarter of 2007 that has not yet been effectively remediated. If we fail to achieve and maintain effective internal control over financial reporting, we could face difficulties in preparing timely and accurate financial reports, which could result in a loss of investor confidence in our reported results and a decline in our stock price.

In connection with the preparation of our financial statements for the second quarter of 2007, we identified a material weakness in our internal control over financial reporting as discussed in Item 4 of this quarterly report on Form 10-Q and as previously reported in our quarterly report on Form 10-Q for the quarter ended June 30, 2007. While we have implemented or are in the process of implementing steps to remedy the material weakness, we may not be successful in promptly and effectively remediating the material weakness. Any failure or difficulties in implementing and maintaining these procedures and controls could cause us to fail to meet our periodic reporting obligations or result in our inability to prevent or detect material misstatements in our financial statements. As a result of this material weakness, our management was not able to provide an unqualified assessment of our internal control over financial reporting as of either June 30, 2007 or September 30, 2007. Our management may not be able to provide an unqualified assessment of our internal control over financial reporting for the year ending December 31, 2007 or beyond, or be able to provide quarterly certifications that our disclosure controls and procedures are effective. In addition, our independent registered public accounting firm may not be able to provide an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2007 or beyond. It is also possible that we or our independent registered public accounting firm may identify additional significant deficiencies or material weaknesses in our internal control over financial reporting in the future. Any material weakness, or any remediation thereof that is ultimately unsuccessful, could cause investors to lose confidence in the accuracy and completeness of our financial statements, which in turn could harm our business, lead to a decline in our stock price and restrict our ability to raise additional funds needed for the growth of our business.

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

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

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

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

the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities

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who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

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

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

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

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

state and foreign law equivalents of the foregoing;

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

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

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

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

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provisions are open to a variety of interpretations, and additional legal or regulatory change.

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

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

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

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

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

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

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

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

The development, manufacturing, pricing, marketing, sales and reimbursement of ZYFLO CR, ZYFLO and our other product candidates, together with our general operations, are subject to extensive regulation by Federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company and had approximately 81 employees as of September 30, 2007. We rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented and changing regulatory requirements, it is possible that we may not be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

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

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

Our sales of ZYFLO CR and ZYFLO are, and any future sales of our product candidates will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and Federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and we expect there will continue to be, state and Federal legislative and administrative proposals that could limit the amount that state or Federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and

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Modernization Act of 2003, or the MMA, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as MCOs, may adopt their own reimbursement reductions in response to legislation. Any reduction in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new drug product is approved, governmental and private reimbursement for that product, and the amount for which that product will be reimbursed, are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, including ZYFLO CR, and current reimbursement policies for marketed products may change at any time.

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

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

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

Our business exposes us to significant potential product liability risks that are inherent in the

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

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

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

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

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

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

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

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

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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 any of our product candidates under development, our ability to generate product revenue and achieve profitability, our reputation and our ability to raise additional capital will be materially impaired.

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

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

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

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

Adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in a submission or approval for a narrower indication. If clinical trials fail, our product candidates would not become commercially viable. In particular, if our Phase IV clinical trial for ZYFLO CR that we initiated in July 2007 fails or produces results that are adverse or inconclusive, sales of ZYFLO CR and our financial results could be materially and adversely affected.

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

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

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients and volunteers into clinical trials;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in ongoing or past clinical trials for the same or a different indication;
- serious and unexpected drug-related side effects observed during ongoing or past preclinical studies; or
- the placement of a clinical hold on a trial.

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

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

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

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for regulatory approval or clearance or conduct additional clinical trials on the schedule we currently anticipate.

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

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

Our products and product candidates are subject to continuing regulatory review after approval, including the review of spontaneous adverse drug experiences and clinical results from any post-market testing required as a condition of approval that are reported after our product candidates become commercially available. The manufacturer and the manufacturing facilities we use to make 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.

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

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

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

product seizures;

voluntary or mandatory recalls;

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

We are relying on DEY to jointly promote and market ZYFLO CR and ZYFLO. ZYFLO CR and ZYFLO are our only commercially marketed products. Our sales force has not been successful to date in significantly expanding the market for ZYFLO. As a result, our ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of our co-promotion arrangement with DEY. DEY initiated promotional detailing activities for ZYFLO CR on September 27, 2007 and for ZYFLO on April 30, 2007.

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

If DEY were to terminate or breach the co-promotion agreement, and we were unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promoting and marketing ZYFLO CR, our sales of ZYFLO CR would be limited and we would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. Any decision not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement would limit our ability to generate significant revenues from product sales.

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DEY is a subsidiary of Mylan Inc. Mylan acquired DEY as part of its acquisition of Merck KGaA s generic business, of which DEY was a part, in October 2007. We cannot predict what impact Mylan s acquisition of DEY may have on our co-promotion arrangement with DEY.

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

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

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

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

In addition, our collaborations with MedImmune and Beckman Coulter and any future collaborative

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arrangements that we enter into with third parties may not be scientifically or commercially successful. Factors that may affect the success of our collaborations include the following:

- our collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product on which they are collaborating with us or that could affect our collaborators commitment to us;
- reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our collaborators would reduce our revenues, which we expect will be based on a percentage of net sales by collaborators;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;
- our collaborators may not devote sufficient time and resources to any collaboration with us, which could prevent us from realizing the potential commercial benefits of that collaboration; and
- our collaborators may pursue higher priority programs or change the focus of their development programs, which could affect their commitments to us.

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

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

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

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

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

We have contracted with Shasun Pharma Solutions Ltd. for commercial production of the zileuton

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API, subject to specified limitations, through December 31, 2010. Zileuton API is used in our two FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in our zileuton injectable product candidate. Our only source of supply for zileuton API is Shasun, which manufactures the zileuton API in the United Kingdom. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged, or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture ZYFLO and ZYFLO CR.

We have contracted with SkyePharma PLC, through its subsidiary Jagotec AG, for the manufacture of core tablets for ZYFLO CR for commercial sale. Our only source of supply for the core tablets of ZYFLO CR is SkyePharma, which manufactures the core tablets in France. The manufacture of the core tablets for ZYFLO CR could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed. In January 2007, following a decision to concentrate on oral and pulmonary products, SkyePharma announced that it had reached an agreement for the sale of its injectable business. If SkyePharma sells all or a part of its remaining business or the manufacturing site for the core tablets of ZYFLO CR, our ability to produce ZYFLO CR may be impaired.

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

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

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

If Shasun, Patheon or SkyePharma experiences any significant difficulties in their respective manufacturing processes for our products including the zileuton API, ZYFLO CR core tablets or finished product for ZYFLO or ZYFLO CR, we could experience significant interruptions in the supply of ZYFLO and ZYFLO CR. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity or the scheduling of manufacturing sufficient for our needs at our third party manufacturing partners, could impair our ability to supply ZYFLO CR and ZYFLO at required levels.

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Such an interruption could cause us to incur substantial costs and impair our ability to generate revenue from ZYFLO and ZYFLO CR may be adversely affected. In particular, our ability to commercially launch ZYFLO CR depends on having a sufficient supply of ZYFLO CR on hand.

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

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

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

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

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

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at least 75% of our annual billings for ZYFLO during 2006. The loss of any of these wholesaler customers accounts or a material reduction in their purchases could harm our business, financial condition and results of operations.

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

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

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

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. We may seek to enter into additional collaboration agreements with pharmaceutical companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, we expect to seek to enter into collaboration agreements with respect to the development of our Alpha-7 product candidates and zileuton injection. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. We may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to us. If we are not successful in efforts to enter into a collaboration arrangement with respect to a product candidate, we may not have sufficient funds to develop any of our product candidates internally. If we do not have sufficient funds to develop our product candidates, we will not be able to bring these product candidates to market and generate revenue. In addition, our inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on our financial condition and results of operations because:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If any parties should successfully claim that our creation or use of proprietary technologies infringes

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

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

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

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

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

Risks Relating to Our Financial Results and Need for Additional Financing

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

We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $25.4 million in the nine months ended September 30, 2007 and net losses of $48.8 million in the year ended December 31, 2006. As of September 30, 2007, we had an accumulated deficit of approximately $179.8 million. For the quarter ended September 30, 2007, we recorded $3.1 million of revenue from the sale of ZYFLO and ZYFLO CR and have not recorded revenue from any other product. We expect that we will continue to incur substantial losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts. We expect that the losses that we incur will fluctuate from quarter to quarter and that these fluctuations may be substantial. We will need to generate significant revenues to achieve profitability. Until we are able to generate such revenues, we will not be profitable and will need to raise substantial additional capital to fund our operations.

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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 activities.

We expect to devote substantial resources to support the commercial launch of ZYFLO CR, to fund our Phase IV clinical trial on ZYFLO CR and to fund the development of our other product candidates. Our funding requirements will depend on numerous factors, including:

the ongoing costs of the commercial launch of ZYFLO CR;

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

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

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

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

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

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

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

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

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

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

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

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

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

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to successfully commercialize ZYFLO CR. Based on our current operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the fourth quarter of 2008.

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For the nine months ended September 30, 2007, our net cash used for operating activities was $14.7 million, and we had minimal capital expenditures. For the year ended December 31, 2006, our net cash used for operating activities was $51.4 million, and we had capital expenditures of approximately $370,000. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional products or product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

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

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 CR and ZYFLO;

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the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;

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

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

the amount and timing of product returns for ZYFLO CR or ZYFLO;

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

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

production problems occurring at our third party manufacturers;

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

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

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

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

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

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

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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 October 31, 2007, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 23% of our outstanding common stock. As a result, our directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

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

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

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

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

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

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

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

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

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

Not applicable.

Item 5. Other Information.

On November 5, 2007, we entered into amended and restated employment agreements with Frank E. Thomas, our President and Chief Executive Officer, and Jeffrey E. Young, our Vice President of Finance, Chief Accounting Officer and Treasurer. On November 6, 2007, we entered into amended and restated employment agreements with Trevor Phillips, Ph.D., our Chief Operating Officer and Senior Vice President of Operations, and Scott B. Townsend, our Senior Vice President of Legal Affairs, General Counsel and Secretary.

The employment agreements with Mr. Thomas and Mr. Young have an initial term commencing on November 5, 2007 and the employment agreements with Dr. Phillips and Mr. Townsend have an initial term commencing on November 6, 2007. Each of the employments agreements continues through December 31, 2009 and automatically extends for an additional one-year term after such time on each subsequent anniversary of the commencement date unless either we or the executive officer gives 90-days prior notice.

Under the employment agreements, each executive officer is paid a base salary and is eligible for an annual cash bonus of a specified percentage of his annual base salary and an annual equity award. The employment agreements provide for an annual base salary of $345,000 for Mr. Thomas, $300,000 for Dr. Phillips, $245,000 for Mr. Townsend and $195,000 for Mr. Young. The employment agreements provide for an annual target cash bonus as a percentage of base salary of 40% for Mr. Thomas, 35% for Dr. Phillips, 30% for Mr. Townsend and 30% for Mr. Young.

The actual amount of any cash bonus or equity award is determined by the compensation committee of our board of directors. The compensation committee may make actual cash bonus awards that may be greater or less than the annual target cash bonus based on overall corporate performance and individual performance. Although generally none of the executive officers is guaranteed either an annual cash bonus or an annual equity award, each of the executive officers is entitled to a minimum cash bonus for the year ended December 31, 2007 if he remains employed with us through December 31, 2007. The employment agreements provide for a cash bonus for 2007 of $138,000 for Mr. Thomas, $157,500 for Dr. Phillips, $73,500 for Mr. Townsend and $43,875 for Mr. Young.

In addition, on November 5, 2007, based on the recommendation of the compensation committee, our independent directors established increases in the base salaries for our executive officers effective January 1, 2008. The independent directors approved a 2008 annual base salary of $358,800 for Mr. Thomas, $279,500 for Thomas P. Kelly, our Chief Financial Officer and Senior Vice President of Finance and Corporate Development, $312,000 for Dr. Phillips, $275,000 for Mr. Townsend and $202,800 for Mr. Young.

Each employment agreement with Mr. Thomas, Dr. Phillips, Mr. Townsend and Mr. Young provides that if we terminate the executive officer s employment other than for cause or if the executive officer terminates his employment for good reason, in each case as those terms are defined in his employment agreement, then we are obligated to provide the following to the executive officer, provided he executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

- a lump sum payment in an amount equal to the annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment in an amount equal to 1.25 times the annual base salary in effect at that time for Dr. Phillips;

- monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents and 100% of the amount of the monthly premiums paid by us for life insurance and disability insurance for the executive officer until the earlier of one year after termination or the last day of the first month when such officer is eligible for benefits through other employment;

a lump sum payment in an amount equal to the pro rata portion of the target cash bonus in effect in the year of termination; and

accelerated vesting of 50% of outstanding unvested stock options and restricted stock.

Immediately upon a change of control of Critical Therapeutics, as defined in his employment agreement, each executive officer is entitled to accelerated vesting of 50% of all his outstanding unvested stock options and restricted stock. In addition, Dr. Phillips is entitled to receive a one-time lump sum payment of $175,000 upon a change of control.

If we terminate the employment of Mr. Thomas, Dr. Phillips, Mr. Townsend or Mr. Young other than for cause or if the executive officer terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control, then we are obligated to provide the following to the executive officer, provided he executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

a lump sum payment in an amount equal to the annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment in an amount equal to 1.5 times the annual base salary in effect at that time for Dr. Phillips;

monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents and 100% of the amount of the monthly premiums paid by us for life insurance and disability insurance for the executive officer until the earlier of one year after termination or the last day of the first month when such officer is eligible for benefits through other employment;

a lump sum payment in an amount equal to a pro rata portion of the target cash bonus in effect in the year of termination;

accelerated vesting of 100% of outstanding unvested stock options and restricted stock; and

up to three months of outplacement services.

Upon voluntary resignation, each executive officer is entitled to a lump sum payment in an amount equal to a pro rata portion of his annual bonus from the previous year provided that the executive officer gives 90 days prior written notice of resignation and executes a release of Critical Therapeutics. Upon termination of employment as a result of death or disability, as defined in his employment agreement, the vesting of each executive officer s outstanding unvested stock options and restricted stock will accelerate by one year. In addition, if the executive s employment terminates as a result of his death, we will pay to the executive s estate an amount equal to a pro rata portion of the bonus, if any, paid to the executive in the year prior to his death.

Under Mr. Thomas s employment agreement, he is entitled to an additional one-time special cash bonus of $625,000 if he remains employed with us through January 31, 2008. If Mr. Thomas s employment is terminated on or before January 31, 2008 by us other than for cause, by him for good reason, or as a result of his death or disability, then Mr. Thomas will be entitled to receive his annual target cash bonus for 2007 plus this one-time special cash bonus. The one-time special cash bonus is payable to Mr. Thomas in lieu of the cash compensation and benefits that he would otherwise be entitled to if his employment is terminated on or before July 31, 2008, although he would remain entitled to accelerated vesting of his outstanding unvested stock options and restricted stock as specified in his employment agreement depending on the circumstances under which his employment terminated.

Each executive officer has agreed not to compete with us during his employment with us and for a one-year period after termination of employment by us for any reason or after a change of control of Critical Therapeutics. Each executive officer has also agreed not to disclose any confidential information obtained during his employment.

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: November 8, 2007	/s/ Frank E. Thomas Frank E. Thomas *President and Chief Executive Officer* (*Principal Executive Officer*)
Date: November 8, 2007	/s/ Thomas P. Kelly Thomas P. Kelly *Chief Financial Officer and Senior Vice President of Finance and Corporate Development* (*Principal Financial Officer*)
Date: November 8, 2007	/s/ Jeffrey E. Young Jeffrey E. Young *Vice President of Finance, Chief Accounting Officer and Treasurer* (*Principal Accounting Officer*)

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Third Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K dated October 5, 2007 (SEC File No. 000-50767)).
10.1 +	Manufacturing and Supply Agreement dated as of August 20, 2007 by and among the Company, Jagotec AG and SkyePharma PLC.
10.2 +	First Amendment dated November 5, 2007 to the Manufacturing Services Agreement by and between Patheon Pharmaceuticals Inc. and the Company dated May 9, 2007.
10.3	Employment Agreement dated August 21, 2007 by and between the Company and Thomas P. Kelly (Incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K dated August 21, 2007 (SEC File No. 000-50767)).
10.4	Amended and Restated Employment Agreement dated November 5, 2007 by and between the Company and Frank E. Thomas.
10.5	Amended and Restated Employment Agreement dated November 6, 2007 by and between the Company and Trevor Phillips.
10.6	Amended and Restated Employment Agreement dated November 6, 2007 by and between the Company and Scott B. Townsend.
10.7	Amended and Restated Employment Agreement dated November 5, 2007 by and between the Company and Jeffrey E. Young.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Confidential treatment requested as to certain portions, which portions have been

omitted and filed separately with the Securities and Exchange Commission.