CRITICAL THERAPEUTICS INC
Form 10-Q
May 12, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For The Quarterly Period Ended March 31, 2005

or

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

For the Transition Period from _____ to _____

Commission File Number: 000-50767

Critical Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

Registrant s telephone number, including area code: **(781) 402-5700**

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of May 2, 2005, the registrant had 24,099,375 shares of Common Stock, $0.001 par value per share, outstanding.

CRITICAL THERAPEUTICS, INC.

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PART I. Financial Information

Item 1. Financial Statements

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

in thousands	March 31, 2005	December 31, 2004
Assets:		
Current assets:		
Cash and cash equivalents	$ 10,698	$ 11,980
Amount due under collaboration agreements	364	16
Short-term investments	56,908	66,849
Prepaid expenses and other	1,393	1,851
Total current assets	69,363	80,696
Fixed assets, net	2,572	2,205
Other assets	213	213
Total assets	$ 72,148	$ 83,114
Liabilities and Stockholders Equity (Deficit):		
Current liabilities:		
Current portion of long-term debt	$ 715	$ 837
Accounts payable	2,933	4,218
Accrued expenses	2,911	2,741
Revenue deferred under collaboration agreements	7,798	8,543
Total current liabilities	14,357	16,339
Long-term debt, less current portion	1,194	1,367
Stockholders equity (deficit):		
Common stock, par value $0.001; authorized 90,000,000 shares; issued and outstanding 24,095,750 and 24,085,481 shares at March 31, 2005 and December 31, 2004, respectively	24	24
Preferred stock, par value $0.001; authorized 5,000,000 shares; no shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively		
Additional paid-in capital	130,201	130,374
Deferred stock-based compensation	(5,590)	(6,101)
Accumulated deficit	(67,646)	(58,527)

Accumulated other comprehensive loss	(392)	(362)
Total stockholders equity (deficit)	56,597	65,408
Total liabilities and stockholders equity (deficit)	$ 72,148	$ 83,114

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

in thousands except share and per share data	Three Months Ended March 31, 2005	2004
Revenue under collaboration agreements	$ 1,359	$ 805
Operating expenses:		
Research and development	6,574	5,613
General and administrative	4,259	1,661
Total operating expenses	10,833	7,274
Operating loss	(9,474)	(6,469)
Other income, net	355	84
Net loss	(9,119)	(6,385)
Accretion of dividends and offering costs on preferred stock		(1,160)
Net loss available to common stockholders	($ 9,119)	($ 7,545)
Net loss per share available to common stockholders	($ 0.38)	($ 6.85)
Basic and diluted weighted-average common shares outstanding	23,862,407	1,100,881

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

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

in thousands	Three Months Ended March 31, 2005	2004
Cash flows from operating activities:		
Net loss	($ 9,119)	($ 6,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	160	395
Amortization of premiums on short-term investments	285	60
Common stock issued in connection with license agreement		485
Stock-based compensation expense	318	2,508
Forgiveness of notes receivable		235
Changes in assets and liabilities:		
Amount due under collaboration agreement	(348)	1,963
Prepaid expenses and other	458	(153)
Accounts payable	(1,285)	186
Accrued license fees and other expenses	170	(4,361)
Revenue deferred under collaboration agreements	(745)	(268)
Net cash provided by (used in) operating activities	(10,106)	(5,335)
Cash flows from investing activities:		
Purchases of fixed assets	(527)	(684)
Proceeds from sales and maturities of short-term investments	19,525	
Purchases of short-term investments	(9,899)	(36,158)
Net cash provided by (used in) investing activities	9,099	(36,842)
Cash flows from financing activities:		
Net proceeds from issuance of convertible preferred stock		28,053
Proceeds from exercise of stock options	20	79
Repayments of long-term debt	(295)	(133)
Net cash (used in) provided by financing activities	(275)	27,999
Net increase (decrease) in cash and cash equivalents	(1,282)	(14,178)
Cash and cash equivalents at beginning of period	11,980	40,078
Cash and cash equivalents at end of period	$ 10,698	$ 25,900

Supplemental disclosures of cash flow information:

Cash paid during the period for interest	$ 42	$ 29
Non-cash investing and financing activities:		
Accretion of dividends and offering costs on preferred stock		$ 1,160
Adjustment to deferred stock-based compensation for services to be performed	$ 193	$ 2,830

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. (Critical or the Company) and its subsidiary, 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 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, 2004.

Operating results for the three-month periods ended March 31, 2005 and 2004 are not necessarily indicative of the results for the full year. For the three months ended March 31, 2004 the Company reclassified its investments in auction rate securities from cash equivalents to short term investments to conform with the presentation for the three months ended March 31, 2005.

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, accrued expenses and valuation of stock-based compensation.

(2) Revenue Recognition

The Company recognizes revenue in accordance with the Securities and Exchange Commission s (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 its collaboration agreements. These agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties.

Revenue from research and development funding is recognized over the estimated performance period based on a proportional performance model. Under the proportional performance model, performance is measured as the percentage of cost incurred to date compared to the total costs estimated for the performance period. The amount of revenue recognized during each period represents the cumulative performance percentage of amounts received and due to the Company under the agreement less amounts previously recognized. The Company periodically reviews the estimated performance period and total costs and, to the extent such estimates change, the impact of such change is recorded in operations at that time. If the Company s collaborators have the right to cancel the agreement at any time, the Company does not recognize revenues in excess of cumulative cash collections. Revenue from non-refundable, upfront license fees is recognized ratably over the commitment period. Deferred revenue consists of payments

received in advance of revenue recognized under the agreement.

(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.

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(Unaudited)

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 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. During the three-month period ended March 31, 2005, the Company recorded an unrealized loss on investments of $30,000. The cost of the debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period. The Company has determined the unrealized gain (loss) on investments is temporary and therefore no impairment exists during the three-month periods ended March 31, 2005.

(4) Comprehensive Loss

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying condensed consolidated statements of operations for the three-month period ended March 31, 2005 and 2004, and comprehensive loss is the unrealized gain (loss) on short-term investments for the period. Total comprehensive loss was $9.1 and $6.4 million for the three-month periods ended March 31, 2005 and 2004, respectively. The unrealized loss on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet as of March 31, 2005.

(5) Stock-Based Compensation

The Company accounts for stock-based awards to employees using the intrinsic-value method as prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Accordingly, no compensation expense is recorded for options issued to employees in fixed amounts and with fixed exercise prices at least equal to the fair market value of the Company s common stock at the date of grant. Conversely, when the exercise price for accounting purposes is below fair value of the Company s common stock on the date of grant, a non-cash charge to compensation expense is recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. All stock-based awards to non-employees are accounted for at their fair market value in accordance with Statement of Financial Accounts Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, and Emerging Issues Task Force (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.

The Company expenses deferred stock-based compensation as charges to operations over the vesting period of the options and has recorded $318,000 as stock-based compensation expense during the three-month period ended March 31, 2005, relating to these options.

The remaining number of shares of common stock available for award under the Company s 2004 Stock Incentive Plan totaled 960,771 at March 31, 2005.

Had employee compensation expense been determined based on the fair value at the date of grant consistent with SFAS No. 123, the Company s pro forma net loss and pro forma net loss per share would have been as follows:

(in thousands, except loss per share data)	Three Months Ended March 31, 2005	2004
Net loss available to common stockholders as reported	$ (9,119)	$ (7,546)
Add: Stock-based compensation expense included in reported net loss	448	432

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

(in thousands, except loss per share data)	Three Months Ended March 31, 2005	2004
Deduct: Stock-based compensation expense determined under fair value method	(825)	(470)
Net loss pro forma	$ (9,496)	$ (7,584)
Net loss per share (basic and diluted):		
As reported	$ (0.38)	$ (6.85)
Pro forma	$ (0.40)	$ (6.89)

Option valuation models require the input of highly subjective assumptions. Because changes in subjective input assumptions can materially affect the fair value estimate, in management s opinion, the calculated fair value may not necessarily be indicative of the actual fair value of the stock options. The Company has computed the pro forma disclosures required under SFAS No. 123 for options granted using the Black-Scholes option-pricing model prescribed by SFAS No. 123. The Company reduced its assumption for the three months ended March 31, 2005 regarding expected volatility to 54%. The reduced rate is based on the Company s actual historical volatility since its initial public offering. The assumptions used and weighted-average information are as follows:

	Three Months Ended March 31, 2005	2004
Risk free interest rate	4.1%	2.2%
Expected dividend yield	0%	0%
Expected lives convertible preferred stock	4 years	4 years
Expected volatility	54%	100%
Weighted-average fair value of options granted equal to fair value	$ 3.38	
Weighted-average fair value of options granted below fair value		$ 3.61

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, or SFAS No. 123R. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. The Statement requires entities to recognize stock compensation expense for awards (with limited exceptions). SFAS No.

123R is effective for the Company commencing January 1, 2006. The Company is currently evaluating the impact of the adoption of SFAS No. 123R and has not yet determined how the financial statements will be effected.

(6) Basic and Diluted Loss per Share

Basic and diluted net loss per common share is calculated by dividing the net loss available to common stockholders 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 5,035,439 and 62,779,676 as of March 31, 2005 and 2004, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of March 31, 2005, and outstanding redeemable convertible preferred stock, stock options, warrants, and unvested restricted common stock as of March 31, 2004.

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(Unaudited)

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

	Three Months Ended March 31,	
	2005	2004
Weighted-average common shares outstanding	24,095,750	1,678,864
Less: weighted-average restricted common shares outstanding	233,342	577,983
Basic and diluted weighted-average common shares outstanding	23,862,407	1,100,881

(7) Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and license agreements that represent the Company s fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company s products in various countries. These agreements include costs related to manufacturing, clinical trials and pre-clinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately $15.9 million as of March 31, 2005. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in and timing of the development of the Company s product candidates.

The Company is party to a number of agreements that require it to make milestone payments, royalties on net sales of the Company s products and payments on sublicense income received by the Company.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending material litigation or other material legal proceedings.

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CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

(8) Relocation of Headquarters

During 2004, the Company relocated its headquarters to Lexington, Massachusetts and consolidated its research facilities from two to one. Under SFAS No. 146, Costs Associated with an Exit or Disposal Activity, the Company recorded a liability of $441,000 in the period ended June 30, 2004 related to the remaining obligations under an operating lease that expires in October 2005 at its previous headquarters. The liability is included in accrued expenses in the accompanying consolidated balance sheet as of March 31, 2005.

The following table summarizes the activity related to the remaining lease obligation recorded under SFAS No. 146 (in thousands):

Balance December 31, 2004	$ 213
Payments	(78)
Rental income under sublease agreement	29
Balance March 31, 2005	$ 164

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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 of Form 10-K for the year ended December 31, 2004 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 including, but not limited to, those set forth under Factors That May Affect Future Results below.

Financial Operations Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases through the regulation of the body s inflammatory response. The inflammatory response occurs within the body s immune system following a stimulus such as infection or trauma. Our most advanced product is ZYFLO® Filmtab®, a tablet formulation of zileuton, which the U.S. Food and Drug Administration, or FDA, approved in 1996 for the prevention and chronic treatment of asthma. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO and other formulations of zileuton for multiple diseases and conditions. We have completed the process of changing manufacturing sites for ZYFLO and submitted a supplemental new drug application, or sNDA, to the FDA on March 31, 2005. Subject to FDA approval, we expect to begin selling ZYFLO in the United States in the fourth quarter of 2005. In addition, we believe that zileuton has potential therapeutic benefits in a range of diseases and conditions, such as acne, chronic obstructive pulmonary disease, or COPD, nasal polyposis and acute asthma exacerbations. We are currently incurring costs to expand our applications of zileuton through development of additional formulations, including controlled-release and intravenous formulations.

We are also developing product candidates to regulate the excessive inflammatory response that can damage vital internal organs and, in the most severe cases, result in multiple organ failure and death.

CTI-01. We are developing a small molecule product candidate, CTI-01, that we believe may be effective in regulating the inflammatory response. Results from preclinical studies suggest that CTI-01 inhibits the release of protein molecules called cytokines that are responsible for communication between cells in the body and are associated with conditions such as post-operative ileus, which is the loss of normal intestine movement following surgery, and the damage to vital organs that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery.

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

Alpha-7. We are developing small molecules designed to inhibit the body s inflammatory response by acting on the nicotinic alpha-7 cholinergic target, which is a cell receptor associated with the production of the cytokines that play a fundamental role in the inflammatory response. We believe that successful development of a product candidate targeting the nicotinic alpha-7 cholinergic receptor could lead to an oral anti-cytokine therapy for acute and chronic diseases. We are also exploring the development of a medical device, similar to those already marketed for the treatment of epileptic seizures, to stimulate the vagus nerve, a nerve that links the brain with the major organs of the body, and induce an anti-inflammatory response by acting on the alpha-7 receptor.

Since our inception, we have incurred significant losses each year. As of March 31, 2005, we had an accumulated deficit of $67.6 million. We expect to incur significant and growing losses for the foreseeable future. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue to increase over the next several years as we continue to fund our development

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programs and prepare for the potential commercial launch of our product candidates. We do not expect to achieve profitability in the foreseeable future; and we cannot assure you that we will achieve profitability at all. Since inception, we have raised proceeds to fund our operations through our initial public offering of common stock, private placements of equity securities, debt financings, the receipt of interest income and payments from our collaborators MedImmune and Beckman Coulter.

In January 2005, we entered into a license agreement with Beckman Coulter relating to the development of diagnostic products for measuring HMGB1. Under the terms of the agreement, we granted to Beckman Coulter and its affiliates an exclusive worldwide license to evaluate, develop, make, use and sell a kit or assemblage of reagents for measuring HMGB1. In consideration for the license, Beckman Coulter paid us $250,000 and agreed to pay potential additional aggregate license fees of up to $850,000. Beckman Coulter also agreed to pay us royalties based on net sales of licensed products.

Revenue. We have not generated any operating revenues from product sales since our inception on July 14, 2000, and do not expect to generate any operating revenues from product sales until, at the earliest, the fourth quarter of 2005. All of our revenues to date have been derived from license fees, research and development payments and milestone payments that we have received from our collaboration agreements with MedImmune and Beckman Coulter. In the future, we expect to generate revenues from a combination of product sales and payments under corporate collaborations.

Research and Development Expenses. Research and development expenses consist of expenses 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, costs related to the development of our new drug application, or NDA, for controlled-release formulation of zileuton**,** costs of contract research and manufacturing and the cost of facilities. After FDA approval of a product candidate, manufacturing expenses associated with a product will be recorded as cost of sales rather than research and development expenses. We expense research and development costs and patent related costs as incurred. Because of our ability to utilize resources across several projects, many of our research and development costs are not tied to any particular project and are allocated among multiple projects. We record direct costs on a project-by-project basis. We record indirect costs in the aggregate in support of all research and development. Development costs for later stage programs such as zileuton and CTI-01 tend to be higher than earlier stage programs such as our HMGB1 program, due to the costs associated with conducting clinical trials.

We expect that research and development expenses relating to our development portfolio will continue to increase for the foreseeable future. In particular, we expect to incur increased expenses over the next several years for clinical trials of our product development candidates, including the controlled-release and intravenous formulations of zileuton and CTI-01. We also expect manufacturing expenses included in research and development expenses to increase as we complete the technology transfer relating to the manufacturing of ZYFLO and the controlled-release formulation of zileuton and produce inventory in preparation for the commercial launch of ZYFLO.

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, human resource and sales and marketing functions. Other costs reflected in general and administrative expenses include facility costs not otherwise included in research and development expenses and professional fees for legal and accounting services.

We anticipate that our general and administrative expenses will also increase as we expand our operations, facilities and other activities now that we are operating as a publicly traded company. In addition, we expect to incur significant sales and marketing costs as we hire a sales force to commercialize ZYFLO.

Deferred Stock-Based Compensation Expense. As discussed more fully in Note 5 to our condensed consolidated financial statements included herein and in Notes 7 and 8 to our consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2004, in lieu of cash payments we granted 120,000 and 66,666 shares of common stock, restricted shares of our common stock and options to purchase common stock to non-employees during the three-months ended March 31, 2005 and 2004, respectively. We

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recorded these grants at fair value when granted. We periodically remeasure the fair value of the unvested portion of these grants, resulting in charges or credits to operations in periods when such remeasurement results in differences between the fair value of the underlying common stock and the exercise price of the options that is greater than or less than the differences, if any, between the fair value of the underlying common stock and the exercise price of the options at their respective previous measurement dates.

As discussed more fully in Note 5 to our condensed consolidated financial statements included herein and Notes 7 and 8 to our consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2004, we granted 238,500 and 43,789 stock options to employees during the three-months ended March 31, 2005 and 2004, respectively. Certain of the employee options granted during 2004 and prior years were deemed for accounting purposes to have been granted with exercise prices below their then-current market value. We recorded the value of these differences as deferred stock-based compensation. We amortize the deferred amounts as charges to operations over the vesting periods of the grants, resulting in stock-based compensation expense. We anticipate recording stock-based compensation expense of $1.3 million in the last nine months of 2005, $1.8 million in 2006, $1.6 million in 2007 and $18,000 in 2008, less adjustment for forfeitures, relating to the amortization of employee deferred stock-based compensation recorded as of March 31, 2005.

Critical Accounting Policies

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

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

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

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

Our significant accounting policies are more fully described in the Notes to Consolidated Financial Statements and Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies in our annual report on Form 10-K for the year ended December 31, 2004. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, accrued expenses, stock-based compensation and income taxes described under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies in our annual report on Form 10-K for the year ended December 31, 2004, fit the definition of critical accounting estimates.

Revenue Recognition. Under our collaboration agreements with MedImmune and Beckman Coulter, we are entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in our statement of operations when earned. We must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by our collaborators with us. We recognize these revenues over the estimated performance period as set forth in the contracts based on proportional performance and

adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by our collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with us, we do not recognize revenues in excess of cumulative cash collections. It is

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difficult to estimate the impact of the adjustments on the results of our operations because, in each case, the amount of cash received would be a limiting factor in determining the adjustment.

Accrued Expenses. As part of the process of preparing our consolidated financial statements, we are required to estimate certain expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for that we accrue include professional service fees, such as fees paid to lawyers and accountants, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, and fees paid to contract manufacturers in connection with the production of clinical materials. In connection with 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. Many 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 have begun to be incurred 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 judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-Based Compensation. To date, we have elected to follow Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees,* or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation Accounting Principles Board Opinion,* or SFAS 123. Accordingly, we have not recorded stock-based compensation expense for stock options issued to employees in fixed amounts with exercise prices at least equal to the fair value of the underlying common stock on the date of grant. In the notes to our consolidated financial statements included herein, we provide pro forma disclosures in accordance with SFAS 123 and related pronouncements. We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123 and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The two factors which most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted or sold by us under APB 25, SFAS 123 and EITF 96-18 requires fair value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, we use the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees or non-employees, we estimate the fair value of the equity instruments based upon consideration of factors which we deem to be relevant at the time using cost, market or income approaches to such valuations. Because shares of our common stock have only recently become publicly traded, market factors historically considered in valuing stock and stock option grants include comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing, pricing of private sales of our convertible preferred stock, prior valuations of stock grants and the effect of events that have occurred between the time of such grants, economic trends, perspective provided by investment banks and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

Income Taxes. As part of the process of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of March 31, 2005, we had federal and state tax net operating loss carryforwards of approximately $48.0 million, which expire beginning in 2021 and 2006, respectively. We also have research and experimentation credit carryforwards of approximately $696,000, which expire beginning in 2021. We have recorded a full valuation

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allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

Results of Operations

Three Months Ended March 31, 2005 and 2004

Revenue Under Collaboration Agreements. We recognized revenues of $1.4 million three months ended March 31, 2005 compared to $0.8 million three months ended March 31, 2004. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid us that we recognized in each period and a portion of the $1.5 million and $364,000 billed to MedImmune in 2004 and for the three months ended March 31, 2005, respectively, for development support. We have reported the balance of the payments as deferred revenue and will recognize such amount over the estimated 41-month research term of our agreement with MedImmune based on the proportion of cumulative costs incurred as a percentage of the total costs estimated for the performance period. As of March 31, 2005, we had $7.8 million in deferred revenue remaining to be recognized under our collaboration agreements with MedImmune and Beckman Coulter.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2005 were $6.6 million compared to $5.6 million for the three months ended March 31, 2004, an increase of approximately $1.0 million. This increase was primarily due to higher expenses associated with the growth in the number of employees performing research and development functions and increased facilities, equipment and laboratory charges associated with our increased research and development activities during the three months ended March 31, 2005. In the first quarter of 2005 we incurred $3.4 million in expenses related to our zileuton program as compared to $1.1 million during the first quarter of 2004. This increase was primarily due to initiation of the ZYFLO open-label study with patients with asthma and mastocytosis, the ongoing Phase II clinical trials of ZYFLO for inflammatory acne and the manufacturing costs related to the product registration. In addition, we incurred $0.7 million of expenses in the first quarter of 2005 in connection with our CTI-01 program as compared to $0.6 million during the first quarter of 2004. These increases were partially offset by a decrease of $2.1 million in stock-based compensation expense from first quarter of 2005 compared to the first quarter of 2004, primarily due 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 is calculated based on the change in fair value of our common stock during the period. The fair value of our common stock increased during the three months ended March 31, 2004, which resulted in higher stock-based compensation expense while the fair value of our common stock decreased during the three months ended March 31, 2005, which resulted in a credit to stock-based compensation expense.

The following table summarizes the primary components of our direct research and development expenses for the three months ended March 31, 2005 and 2004:

	Three Months Ended March 31,	
	2005	2004
	(in thousands)	

Zileuton	$ 3,404	$ 1,124
CTI-01	695	598
HMGB1	507	443
Alpha-7	487	311
General research and development expenses	1,480	1,027
Stock-based compensation expense	1	2,110
Total research and development expenses	$ 6,574	$ 5,613

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Our general research and development expenses, which are not allocated to any specific program, increased by $453,000 in the three months ended March 31, 2005 compared to the corresponding period in 2004 primarily due to a $432,000 increase in rent expense resulting from our move into a larger research facility.

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

Zileuton. During the three months ended March 31, 2005, we incurred costs for the development of the controlled-release formulation of zileuton, including costs associated with the technology transfer of the manufacture of zileuton, including the active pharmaceutical ingredient, or API, the controlled-release tablets and NDA for the controlled-release formulation of zileuton. Continuing throughout 2005, we expect our research and development expenses for zileuton will principally relate to the transfer of Abbott s manufacturing technology relating to the controlled-release formulation of zileuton and the anticipated clinical trials of the controlled-release and intravenous formulations of zileuton. In October 2004, we also initiated a Phase II clinical trial with ZYFLO in patients with moderate to severe inflammatory acne. The costs associated with this trial are being incurred over an approximate nine-month period. The actual costs and timing for the development and commercialization of our zileuton products are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. As a result, we are unable to estimate the costs or the timing of advancing our zileuton products through clinical development and commercialization.

CTI-01. Expenses for CTI-01 increased slightly in the three months ended March 31, 2005 primarily due to costs associated with the initiation of a Phase II clinical trial during the three months ended March 31, 2005. We expect our costs for this program will continue to increase for the remainder of 2005 as we continue this Phase II clinical trial of CTI-01. This trial and the other development work required for this program will require significant expenditures before we can seek regulatory approval. We estimate that the total direct costs that we will need to incur to advance CTI-01 through clinical development will be at least $25.0 million. However, the actual costs and timing of clinical trials and associated activities to enable a regulatory submission are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. As a result, we believe that these estimated direct costs may change significantly as the product advances through clinical development.

HMGB1. Expenses for HMGB1 remained relatively unchanged in the three months ended March 31, 2005 as compared to the three months ended March 31, 2004. Our expenses for this program may vary from period to period depending on the resources required for activities being performed by us and those performed by our collaborator, MedImmune. We currently anticipate that most research and development costs relating to HMGB1 in 2005 will be covered by MedImmune under our collaboration with MedImmune. However, we expect to undertake some internal research and preclinical testing and we cannot be certain that the research payments received from MedImmune will fully cover the costs associated with these activities. Because our HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. As a result, we are not able to estimate the costs or the timing of advancing an HMGB1-inhibiting product or products through clinical development. The expenses for HMGB1 are reflected in the accompanying statement of operations as part of research and development expenses while the funding received from MedImmune to fund our research efforts is included in revenue under collaboration agreement.

Alpha-7. Expenses for our alpha-7 program increased in the three months ended March 31, 2005 primarily due to costs associated with our efforts to develop small molecule product candidates. We anticipate that significant additional expenditures will be required to advance any product candidate or device through

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preclinical and 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 project we choose to develop, the clinical indication developed and the development strategy adopted. As a result, we are unable to estimate the costs or the timing of advancing a small molecule or medical device to stimulate the vagus nerve from our alpha-7 program through clinical development.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2005 were $4.3 million compared to $1.7 for the three months ended March 31, 2004. The $2.6 million increase in the three months ended March 31, 2005 was primarily attributable to the following:

Personnel costs increased $1.0 million as a result of the increase in the number of employees performing general and administrative functions from 9 employees at March 31, 2004 to 23 employees at March 31, 2005.

Personnel and related travel costs increased $423,000 as a result of the increase in the number of employees performing medical affairs and sales and marketing functions which increased from 2 employees at March 31, 2004 to 19 employees at March 31, 2005.

Facility and equipment costs increased $286,000 as a result of our move to a larger facility.

Directors and officers insurance costs increased $171,000 due to an increase in premiums following our initial public offering.

Other Income, Net. Other income, net for the three months ended March 31, 2005 was $355,000 compared to $84,000 for the three months ended March 31, 2004. The increase in the three months ended March 31, 2005 was primarily attributable to interest earned on the $56.2 million in gross proceeds from our series B preferred stock financing in October 2003 and March 2004 and the $37.8 million in net proceeds from our initial public offering in June 2004. Interest income and interest expense amounted to $398,000 and $42,000, respectively, for the three months ended March 31, 2005 compared to $112,000 and $29,000, respectively, in the corresponding period in 2004.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have financed our operations through the sale of common and preferred stock, debt financings, the receipt of interest income, and payments from our collaborators MedImmune and Beckman Coulter. As of March 31, 2005, we had $67.6 million in cash, cash equivalents and short-term investments. We have invested the net proceeds from our financings in highly liquid, interest-bearing, investment grade securities in accordance with our established corporate investment policy.

In July 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid us initial fees of $12.5 million and an additional $1.9 million through March 31, 2005 to fund certain research expenses incurred by us for the HMGB1 program. In addition, in connection with entering into this collaboration, an affiliate of MedImmune purchased $15.0 million of our series B convertible preferred stock, which converted into 2,857,142 shares of common stock in June 2004 in connection with our initial public offering.

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 North Shore-Long Island Jewish Research Institute on milestone payments we receive from MedImmune. We anticipate that by the end of 2005, in addition to payments already