

CRITICAL THERAPEUTICS INC

Form 10-Q

August 13, 2004

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

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

For The Quarterly Period Ended June 30, 2004

or

**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
(State or Other Jurisdiction of
Incorporation or Organization)

04-3523569
(I.R.S. Employer
Identification No.)

60 Westview Street
Lexington, Massachusetts
(Address of Principal Executive Offices)

02421
(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 No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 9, 2004, the registrant had 24,037,652 shares of Common Stock, \$0.001 par value per share, outstanding.

CRITICAL THERAPEUTICS, INC.

FORM 10-Q
TABLE OF CONTENTS

	<u>Page</u>
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2004 and December 31, 2003 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations for the Three- and Six-Months Ended June 30, 2004 and 2003 (Unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Six-Months Ended June 30, 2004 and 2003 (Unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	42
<u>Item 4. Controls and Procedures</u>	42
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	43
<u>Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	43
<u>Item 3. Defaults Upon Senior Securities</u>	44
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	44
<u>Item 5. Other Information</u>	44
<u>Item 6. Exhibits and Reports on Form 8-K</u>	44
<u>SIGNATURES</u>	45
<u>EXHIBIT INDEX</u>	46
<u>EX-3.1 AMENDED & RESTATED CERTIFICATE OF INCORPORATION</u>	
<u>EX-3.2 AMENDED AND RESTATED BYLAWS</u>	
<u>EX-10.1 LOAN AND SECURITY AGREEMENT</u>	
<u>EX-10.3 SUBLEASE TERMINATION AGREEMENT</u>	
<u>EX-10.5 FORM OF INCENTIVE STOCK OPTION AGREEMENT</u>	
<u>EX-10.6 FORM OF NON-STATUTORY STOCK OPTION AGREEMENT</u>	
<u>EX-10.7 FORM OF RESTRICTED STOCK AGREEMENT</u>	
<u>EX-31.1 SECTION 302 CERTIFICATION OF C.E.O.</u>	
<u>EX-31.2 SECTION 302 CERTIFICATION OF C.F.O.</u>	
<u>EX-32.1 SECTION 906 CERTIFICATION OF C.E.O.</u>	
<u>EX-32.2 SECTION 906 CERTIFICATION OF C.F.O.</u>	

Table of Contents**PART I. Financial Information****Item 1. Financial Statements****CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)**

in thousands	June 30, 2004	December 31, 2003
Assets:		
Current assets:		
Cash and cash equivalents	\$ 62,689	\$ 40,078
Amount due under collaboration agreement	1,032	2,500
Short-term investments	29,560	0
Prepaid expenses and other	1,413	430
	<hr/>	<hr/>
Total current assets	94,694	43,008
	<hr/>	<hr/>
Fixed assets, net	2,009	1,556
Other assets	380	490
	<hr/>	<hr/>
Total assets	\$ 97,083	\$ 45,054
	<hr/>	<hr/>
Liabilities and Stockholders Equity (Deficit):		
Current liabilities:		
Current portion of long-term debt	\$ 543	\$ 552
Accounts payable	1,098	323
Accrued license fees	0	4,460
Accrued expenses	2,683	977
Revenue deferred under collaboration agreement	10,924	11,478
	<hr/>	<hr/>
Total current liabilities	15,248	17,790
	<hr/>	<hr/>
Long-term debt, less current portion	458	720
Redeemable convertible preferred stock	0	51,395
Stockholders' equity (deficit):		
Common stock	24	2

Edgar Filing: CRITICAL THERAPEUTICS INC - Form 10-Q

Additional paid-in capital	129,815	11,156
Deferred stock-based compensation	(7,321)	(8,536)
Due from stockholders	0	(40)
Accumulated deficit	(40,764)	(27,433)
Accumulated other comprehensive loss	(377)	0
	<u> </u>	<u> </u>
Total stockholders' equity (deficit)	<u>81,377</u>	<u>(24,851)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 97,083</u>	<u>\$ 45,054</u>

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

Table of Contents**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

in thousands except share and per share data	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenue under collaboration agreement	\$ 781	\$ 0	\$ 1,586	\$ 0
Operating expenses:				
Research and development	5,027	2,796	10,640	4,993
General and administrative	2,924	789	4,585	1,472
Total operating expenses	7,951	3,585	15,225	6,465
Operating loss	(7,170)	(3,585)	(13,639)	(6,465)
Other income, net	225	13	308	35
Net loss	(6,945)	(3,572)	(13,331)	(6,430)
Accretion of dividends and offering costs on preferred stock	(1,049)	(426)	(2,209)	(847)
Net loss available to common stockholders	(\$ 7,994)	(\$ 3,998)	(\$ 15,540)	(\$ 7,277)
Net loss per share available to common stockholders	(\$ 0.81)	(\$ 6.63)	(\$ 2.81)	(\$ 12.98)
Basic and diluted weighted-average common shares outstanding	9,829,702	603,130	5,524,352	560,827

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

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

in thousands	Six Months Ended June 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	(\$ 13,331)	(\$ 6,430)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	806	102
Loss on disposal of fixed assets	278	0
Stock-based compensation expense	1,802	1,724
Forgiveness of notes receivable	185	0
Changes in assets and liabilities:		
Amount due under collaboration agreement	1,468	0
Prepaid expenses and other	(983)	(76)
Other assets	110	0
Accounts payable	775	(128)
Accrued license fees and other expenses	(2,567)	179
Revenue deferred under collaboration agreement	(554)	0
	<u> </u>	<u> </u>
Net cash used in operating activities	<u>(12,011)</u>	<u>(4,629)</u>
Cash flows from investing activities:		
Purchases of fixed assets	(1,537)	(1,241)
Purchases of short-term investments	(29,937)	0
	<u> </u>	<u> </u>
Net cash used in investing activities	<u>(31,474)</u>	<u>(1,241)</u>
Cash flows from financing activities:		
Net proceeds from issuance of convertible preferred stock	28,050	0
Net proceeds from the initial public offering of common stock	38,174	0
Proceeds from exercise of stock options	143	0
Repurchase of restricted common stock	0	(1)
Proceeds from notes receivable	0	145
Proceeds from long-term debt	0	1,389
Repayments of long-term debt	(271)	(129)
	<u> </u>	<u> </u>

Edgar Filing: CRITICAL THERAPEUTICS INC - Form 10-Q

Net cash provided by financing activities	<u>66,096</u>	<u>1,404</u>
Net increase (decrease) in cash and cash equivalents	22,611	(4,466)
Cash and cash equivalents at beginning of period	<u>40,078</u>	<u>13,539</u>
Cash and cash equivalents at end of period	<u>\$ 62,689</u>	<u>\$ 9,073</u>
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	<u>\$ 54</u>	<u>\$ 28</u>
Non-cash investing and financing activities:		
Conversion of redeemable convertible preferred stock into common stock	<u>\$ 81,802</u>	<u>\$ 0</u>
Accretion of dividends and offering costs on preferred stock	<u>\$ 2,209</u>	<u>\$ 847</u>
Dividends forfeited on preferred stock conversion into common stock	<u>\$ 5,313</u>	<u>\$ 0</u>
Deferred stock-based compensation for services to be performed	<u>\$ 587</u>	<u>\$ 2,993</u>
Settlement of accrued licensing fee with common stock	<u>\$ 485</u>	<u>\$ 0</u>
Initial public offering expenses included in accrued expenses	<u>\$ 298</u>	<u>\$ 0</u>
Unrealized loss on investments	<u>(\$ 377)</u>	<u>\$ 0</u>

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

Table of Contents

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 Registration Statement on Form S-1 dated May 26, 2004.

Operating results for the three- and six-month periods ended June 30, 2004 and 2003 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 accrued expenses and valuation of stock-based compensation.

(2) Initial Public Offering of Common Stock

On June 2, 2004, the Company sold 6,000,000 shares of its common stock in its initial public offering at a price to the public of \$7.00 per share. On June 30, 2004, the Company sold an additional 110,000 shares at a price to the public of \$7.00 per share pursuant to the partial exercise of the underwriters' over-allotment option. The Company received gross proceeds of \$42.8 million, of which \$3.0 million was paid as an underwriting discount. Expenses related to the offering totaled approximately \$1.9 million, of which \$298,000 remains in accrued expenses as of June 30, 2004. The Company has invested the net proceeds in highly liquid, interest-bearing, investment grade securities.

In connection with the Company's initial public offering of common stock, all of the issued and outstanding redeemable convertible preferred stock converted to common stock at a ratio of one share of common stock for each 3.75 shares of preferred stock then outstanding. As of June 2, 2004, there were 60,410,237 shares of preferred stock that converted into 16,109,403 shares of common stock. The par value and additional paid-in capital related to the redeemable convertible preferred stock totaling \$81.8 million was reclassified to common stock in the Company's balance sheet as of June 30, 2004. Accrued dividends totaling \$5.3 million were forfeited in connection with this conversion to common stock.

As of June 30, 2004, the Company has authorized capital stock of 90,000,000 shares of common stock with a par value of \$0.001 per share and 5,000,000 shares of preferred stock with a par value of \$0.001 per share. The rights and

preferences of the preferred stock may be established from time to time by the Company's board of directors.

(3) Reverse Stock Split

The Company effected a 1-for-3.75 reverse stock split of all outstanding common stock and stock options as of May 20, 2004. All references to the number of common shares and per share amounts have been retroactively restated for all periods presented to reflect this reverse stock split including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Table of Contents

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(4) 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.

Revenue under the Company's collaboration agreement with MedImmune, Inc. 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, to the extent such estimate changes, the impact of such change is recorded in operations at that time. Because the Company's collaborator has the right to cancel the agreement at any time, the Company does not recognize revenues in excess of cumulative cash collections. Deferred revenue consists of payments received in advance of revenue recognized under the agreement.

(5) 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 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. During the three- and six-month periods ended June 30, 2004, the Company recorded an unrealized loss on investments of \$377,000. There was no unrealized gain or loss in 2003 as all holdings were classified as cash equivalents. 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.

(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 six-month periods end June 30, 2004, and comprehensive loss is the unrealized loss on short-term investments for the period. There were no items affecting comprehensive loss for the three- or six-month periods ended June 30, 2003. Total comprehensive loss was \$7.3 million and \$3.6 million for the three-month periods ended June 30, 2004 and 2003, respectively, and \$13.7 million and \$6.4 million, for the six-month periods ended June 30, 2004 and 2003, respectively. The unrealized loss on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet as of June 30, 2004.

(7) 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

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

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.

Stock option activity for the six-month period ended June 30, 2004 is as follows:

		Number of Shares	Weighted-Average Exercise Price Per Share
		<hr/>	<hr/>
Outstanding	December 31, 2003	1,862,229	\$ 0.87
Granted		43,789	2.90
Exercised		(164,966)	0.48
Cancelled		(266)	0.38
		<hr/>	<hr/>
Outstanding	March 31, 2004	1,740,786	\$ 0.96
Granted		361,336	5.78
Exercised		(20,676)	3.10
Cancelled		(13,336)	5.63
		<hr/>	<hr/>
Outstanding	June 30, 2004	2,068,110	\$ 1.75
		<hr/>	<hr/>
Exercisable	June 30, 2004	424,387	\$ 1.09
		<hr/>	<hr/>

Certain of the employee stock options granted to employees in the three- and six-months ended June 30, 2004 were deemed for accounting purposes to have been granted at exercise prices below fair value. The Company has recorded the \$523,000 difference between the exercise price and the fair value as deferred stock-based compensation for the six-month period ended June 30, 2004. The Company expenses deferred stock-based compensation as charges to operations over the vesting period of the options. The remaining number of shares of common stock available for award under the Company's equity incentive plans totaled 3,784,149 at June 30, 2004.

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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss available to common stockholders as reported	(\$7,994)	(\$3,998)	(\$15,540)	(\$7,277)
Add: Stock-based compensation expense included in reported net loss	455	3	887	3
Deduct: Stock-based compensation expense determined under fair value method convertible preferred stock	<u>(569)</u>	<u>(8)</u>	<u>(1,040)</u>	<u>(15)</u>
Net loss pro forma	<u>(\$8,108)</u>	<u>(\$4,003)</u>	<u>(\$15,693)</u>	<u>(\$7,289)</u>
Net loss per share (basic and diluted):				
As reported	<u>(\$ 0.81)</u>	<u>(\$ 6.63)</u>	<u>(\$ 2.81)</u>	<u>(\$12.98)</u>
Pro forma	<u>(\$ 0.82)</u>	<u>(\$ 6.64)</u>	<u>(\$ 2.84)</u>	<u>(\$13.00)</u>

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

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 assumptions used and weighted-average information are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk free interest rate	3.6%	2.0%	3.4%	2.1%
Expected dividend yield	0%	0%	0%	0%
Expected lives convertible preferred stock	4 years	4 years	4 years	4 years
Expected volatility	100%	100%	100%	100%
Weighted-average fair value of options granted equal to fair value	\$4.91	\$0.26	\$4.91	\$0.26
Weighted-average fair value of options granted below fair value	\$4.65	\$1.77	\$5.03	\$1.72

(8) Basic and Diluted Loss per Share

Basic and diluted net loss per common share is calculated by dividing the net loss applicable 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 2,536,783 and 21,728,696 as of June 30, 2004 and 2003, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of June 30, 2004, and outstanding redeemable convertible preferred stock, stock options, warrants, and unvested restricted common stock as of June 30, 2003.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Weighted-average common shares outstanding	10,319,621	1,549,436	6,058,303	1,550,509
	489,919	946,306	533,951	989,682

Less: weighted-average
restricted common shares
outstanding

Basic and diluted
weighted-average common
shares outstanding

_____	_____	_____	_____
9,829,702	603,130	5,524,352	560,827
_____	_____	_____	_____

Accretion of Dividends and Offering Costs on Preferred Stock

Prior to the Company's initial public offering, holders of preferred stock had a right to receive dividends at a stated rate per share. The Company recorded accretion of these dividends as well as offering costs in order to arrive at the net loss available to common stockholders in the periods prior to the initial public offering. Upon conversion of the preferred stock into common stock, the holders of preferred stock, pursuant to the terms of the preferred stock,

Table of Contents

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

forgave all cumulative accrued dividends. As of May 26, 2004, cumulative accrued dividends on the Company's preferred stock totaled \$5.3 million.

(9) Long Term Debt

Effective June 30, 2004, the Company entered into a modification to its existing loan and security agreement. The modification gives the Company the ability to borrow up to an additional \$3.0 million under a credit agreement from July 1, 2004 to December 31, 2004. From January 1, 2005 to December 31, 2005, the Company has additional borrowing capacity up to an amount equal to the lesser of (i) \$3.0 million minus the principal amount of advances made in 2004 and (ii) \$1.3 million. Advances made during 2004 and 2005 accrue interest at a rate equal to the prime rate plus 2% per year. Advances made in 2004 and 2005 are required to be repaid in equal monthly installments of principal plus interest accrued through the date of repayment. The repayment term for advances made in 2004 is 42 months. The repayment term for advances made in 2005 is 36 months. In connection with the original loan and security agreement, the Company granted the lender a first priority security interest in substantially all of the Company's assets, excluding intellectual property, to secure the Company's obligations under the credit agreement.

(10) 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 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 \$9.0 million as of June 30, 2004. 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. In particular, under the Company's license agreement with Abbott Laboratories for zileuton, it agreed to make aggregate milestone payments of up to \$13.0 million to Abbott upon the achievement of various development and commercialization milestones relating to zileuton. In addition, under the Company's manufacturing agreement with SkyePharma, through its subsidiary Jagotec, for the controlled-release version of zileuton, it agreed to make aggregate milestone payments of up to \$6.6 million upon the achievement of various development and commercialization milestones.

These milestone amounts also do not include royalties on net sales of the Company's products and payments on sublicense income that the Company may owe as a result of receiving payments under the collaboration agreement with MedImmune.

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.

(11) Relocation of Headquarters

During the three-month period ended June 30, 2004, the Company relocated its headquarters to Lexington, MA 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 three-month period ended June 30, 2004 related to the remaining obligations under an operating lease that expires in October 2005 at its previous headquarters. This liability represents the expected future payments under the operating lease assuming the Company is unable to sublease the space given the current local office vacancy rate and the short remaining term under the lease agreement. The Company paid \$52,000 for the three-month period ended June 30, 2004 related to these lease payments leaving a balance in accrued expenses of \$389,000 at June 30, 2004. The expense associated with this liability has been included in general and administrative expenses in the accompanying statement of operations.

In connection with the consolidation of facilities, the Company recorded a loss of \$278,000 in the three months ended June 30, 2004 to retire certain assets left at one of its leased facilities. This amount was included in general and administrative expenses in the accompanying statement of operations.

Table of Contents

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(12) Recently Issued Accounting Pronouncements

In March 2004, the EITF reached consensus on the guidance provided in EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* (EITF 03-1) as applicable to debt and equity securities that are within the scope of SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities* and equity securities that are accounted for using the cost method specified in APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. An investment is impaired if the fair value of the investment is less than its cost including adjustments for amortization, accretion, foreign exchange, and hedging. EITF 03-1 outlines that an impairment would be considered other-than-temporary unless a) the investor has the ability and intent to hold an investment for a reasonable period of time sufficient for the recovery of the fair value up to (or beyond) the cost of the investment and b) evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The investor should consider its cash or working capital needs to assess its intent and ability to hold an investment for a reasonable period of time for the recovery of fair value up to or beyond the cost of the investment. In addition, the severity and duration of the impairment should also be considered in determining whether the impairment is other-than-temporary. This new guidance is effective for reporting periods beginning after June 15, 2004. The Company is currently evaluating the impact of the new accounting guidance, but does not expect it to have a material impact on its results of operations or financial condition.

Table of Contents

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 Registration Statement on Form S-1 (No. 333-113727) 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.

Nature of Business

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 Zylflo® 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 Zylflo and other formulations of zileuton for multiple diseases and conditions. We are currently in the process of changing manufacturing sites for Zylflo, and subject to FDA approval of these sites, we expect to begin selling Zylflo in the United States in the middle of 2005.

We are also developing products 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 protein B1, may be an important target for the development of products to treat inflammatory 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 our monoclonal antibodies directed towards HMGB1 in a number of animal models.

Cholinergic Anti-inflammatory Program. We are developing small molecules designed to inhibit the body's inflammatory response by acting on the nicotinic α -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 α -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, which links the brain with the major organs of the body, and induce an anti-inflammatory response by acting on the α -7 receptor.

Overview

Since our inception, we have incurred significant losses each year. As of June 30, 2004, we had an accumulated deficit of \$40.8 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 programs and prepare for

potential commercial launch of our product candidates. We do not expect to achieve profitability in the foreseeable future, if at all. Since inception, we have funded our operations through the sale of

Table of Contents

common and preferred stock, debt financings, the receipt of interest income and payments from our collaborator MedImmune.

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 formulation 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 purchase inventory in preparation for the commercial launch of Zyflo.

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 commercialize Zyflo and the controlled-release formulation of zileuton.

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 Note 2 of the Notes to Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates in our Registration Statement on Form S-1 (File No. 333-113727). 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 and Estimates in our Registration Statement on Form S-1 (File No. 333-113727), fit the definition of critical accounting estimates.

Revenue Recognition. Under our collaboration agreement with MedImmune, 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 our collaboration agreement can be canceled by MedImmune, we do not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the

Table of Contents

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 which 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. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs which 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. 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 Note 7 to our condensed 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, or EITF, Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18. 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 nonemployees, 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 only recently became 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, we have federal and state tax net operating loss carryforwards, which expire beginning in 2021 and 2006, respectively. We also have research and development credit carryforwards. We have recorded a valuation allowance as an offset

Table of Contents

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 availabl