

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

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### FILER

#### CRITICAL THERAPEUTICS INC

CIK: **1145404** | IRS No.: **043523569** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **000-50767** | Film No.: **061002403**  
SIC: **2834** Pharmaceutical preparations

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 3, 2006

Critical Therapeutics, Inc.  
(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)	000-50767 (Commission File Number)	04-3523569 (IRS Employer Identification No.)
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60 Westview Street, Lexington, Massachusetts (Address of Principal Executive Offices)	02421 (Zip Code)
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Registrant's telephone number, including area code: (781) 402-5700

Not applicable  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On August 3, 2006, Critical Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2006. The Company also provided guidance regarding net cash expenditures for the third quarter of 2006 and operating expenses and stock-based compensation expense for the second half of 2006. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K and the Exhibit attached hereto shall be deemed incorporated by reference in any registration statement previously or subsequently filed by the Company under the Securities Act of 1933, as amended, except to the extent that such information is superseded by information as of a subsequent date that is included or incorporated by reference into such registration statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

See Exhibit Index attached hereto.

SIGNATURE

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

Date: August 3, 2006

CRITICAL THERAPEUTICS, INC.

By: /s/ Frank E. Thomas

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Frank E. Thomas  
President

EXHIBIT INDEX

Exhibit No.

Description

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99.1

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Press release dated August 3, 2006.

## Critical Therapeutics Reports Second Quarter 2006 Financial Results

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 3, 2006--Critical Therapeutics, Inc. (Nasdaq: CRTX), a biopharmaceutical company focused on the discovery, development and commercialization of products for respiratory, inflammatory and critical care diseases, today reported financial results for the quarter ended June 30, 2006.

For the three months ended June 30, 2006, the Company posted a net loss of \$14.4 million, or \$0.42 per share, based on approximately 34.2 million weighted average shares outstanding. This compares with a net loss of \$9.3 million, or \$0.37 per share, for the same period in 2005, based on approximately 25.0 million weighted average shares outstanding. Financial results for 2006 reflect the adoption of Statement of Financial Accounting Standards No. 123(R) (SFAS 123(R)), related to employee stock-based compensation expense.

Product sales of ZYFLO(R) (zileuton tablets), net of returns, increased 77 percent over the first quarter of 2006, accounting for approximately \$1.8 million of total revenue during the second quarter of 2006, compared with \$1.0 million during the first quarter of 2006. Total revenue for the second quarter of 2006 was \$3.5 million, compared with \$2.3 million in the first quarter of 2006.

Cash and short-term investments as of June 30, 2006 totaled \$52.2 million, compared with \$64.6 million at March 31, 2006. Net cash expenditures during the second quarter of 2006 were \$12.4 million, less than the Company's previous guidance of \$13 million to \$16 million primarily as a result of cost cutting actions that were announced and implemented during the second quarter of 2006.

"During the second half of 2006, we will concentrate on building the momentum of our zileuton program," said Frank Thomas, president of Critical Therapeutics. "With the New Drug Application (NDA) for the twice-daily, controlled-release formulation of zileuton (zileuton CR) submitted to the U.S. Food and Drug Administration (FDA), we are now focused on successfully completing the regulatory review process and finding a strategic partner to expand the market for this more convenient dosing formulation.

"In preparation for the commercial launch of zileuton CR, pending regulatory approval, we plan to initiate one or more Phase IIIb clinical trials to assist physicians in identifying specific patient types or subgroups that could benefit from treatment with zileuton CR beyond current standard-of-care," added Thomas.

#### Recent Highlights

Since the end of the first quarter of 2006, Critical Therapeutics announced that:

- It has submitted an NDA for zileuton CR to the FDA for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. Zileuton CR's dosing regimen allows patients to take two tablets twice daily. The Company anticipates launching zileuton CR during the second half of 2007, pending regulatory approval.
- Its Board of Directors appointed lead independent director Robert Zeiger to serve as Executive Chairman and promoted Frank Thomas to president of the Company.
- The Phase I/II clinical trial of the intravenous formulation of zileuton (zileuton IV) has been completed and top line results are expected to be announced later in the third quarter of 2006. This trial is designed to assess the safety, tolerability and pharmacokinetics of zileuton IV in 60 patients with asthma.
- U.S. Patent No. 7,060,504, "Antagonists of HMGB1 for Treating Inflammatory Conditions" issued for methods of diagnosing and monitoring the severity of several inflammatory conditions, including arthritis and lupus, by measuring the concentration of HMGB1 present in a patient's bloodstream.
- The Centers for Medicare and Medicaid Services created a unique Formulary Key Drug Type category for ZYFLO under guidelines developed specifically for the Medicare Prescription Drug Benefit (Part D).

"In addition to the management changes that we announced during the quarter, we undertook a series of steps to intensify our focus and improve our execution," said Thomas. "In the second quarter of 2006, we reduced our cash burn rate by 32 percent compared with the first quarter of 2006, reduced our headcount, streamlined our sales territories, deferred certain manufacturing expenses and reduced spending on early-stage discovery and research programs to concentrate on our most promising later-stage programs."

#### Financial Results for the Three Months Ended June 30, 2006 and 2005

Total revenue for the three months ended June 30, 2006 was \$3.5 million, compared with \$1.4 million for the same period in 2005. Critical Therapeutics' HMGB1 collaboration with MedImmune, Inc. and its license agreement with Beckman Coulter, Inc. to develop diagnostic assays accounted for \$1.7 million in revenue during the second quarter of 2006 and all of the Company's revenue during the second quarter of 2005. Critical Therapeutics began selling ZYFLO in the U.S. in October 2005. Product sales of ZYFLO, net of returns, increased 77 percent to \$1.8 million of total revenue during the second quarter of 2006, compared with \$1.0 million during the first quarter of 2006.

For the quarter ended June 30, 2006, net shipments of ZYFLO to wholesalers, third-party distributors and pharmacies totaled approximately \$2.2 million. Revenue from sales of ZYFLO is recognized when prescriptions are filled, net of any discounts or rebates, rather than when the product is shipped to third parties. The Company currently estimates prescriptions filled based on distribution channel data provided by external sources. This accounting treatment resulted in approximately \$1.8 million being recorded as net product sales in the second quarter of 2006, with \$1.3 million remaining as deferred product revenue on the Company's balance sheet at June 30, 2006. During the second quarter of 2006, the Company obtained additional distribution channel data from mail order pharmacies and non-retail facilities, such as clinics and hospitals, allowing the Company to better estimate total prescriptions filled. This resulted in the recognition of \$173,000 of additional revenue from 792 prescriptions in the second quarter of 2006 that related to the period from launch in October 2005 to the end of the first quarter of 2006. The number of total prescriptions recorded during the second quarter of 2006 increased nearly 68 percent to 8,921, including the 792 prescriptions, compared with 5,317 prescriptions recorded in the first quarter of 2006. The increase in product sales would have been 37 percent over the first quarter of 2006 had the additional revenue of \$173,000 been recorded during the first quarter of 2006.

Total operating expenses for the three months ended June 30, 2006 increased \$7.4 million to \$18.6 million, compared with \$11.1 million for the same period in 2005. The increase over the prior year was primarily due to costs associated with the launch of the Company's first marketed product, ZYFLO, and severance and other related charges associated with the Company's restructuring and change in management that occurred during the second quarter of 2006. Specifically, increases in operating expenses over the prior year resulted principally from changes in the following areas:

- Cost of products sold in the second quarter of 2006 totaled \$890,000. Included in the cost of products sold was approximately \$187,000 related to the write-down of certain ZYFLO inventory that was nearing its expiration date.
- Research and development (R&D) expenses increased \$283,000 to \$6.9 million in the second quarter of 2006, compared with \$6.7 million for the second quarter of 2005. This increase primarily related to clinical costs associated with the intravenous and controlled-release formulations of zileuton.
- Sales and marketing expenses totaled \$5.7 million in the second quarter of 2006, compared with \$1.8 million in the second quarter of 2005. This increase primarily is related to the commercial launch of ZYFLO, including costs associated with the increased number of employees performing sales and marketing functions, product samples and marketing and promotional materials. Sales and marketing expenses in the

second quarter of 2006 also include \$302,000 of severance and \$525,000 of stock-based compensation expense related to the departure of the Company's senior vice president of sales and marketing.

- General and administrative expenses totaled \$5.1 million in the second quarter of 2006, compared with \$2.7 million in the second quarter of 2005. This increase primarily is related to \$671,000 of severance and \$1.3 million of stock-based compensation expense related to the departure of the Company's president and chief executive officer and \$79,000 of severance associated with the restructuring that occurred during the second quarter of 2006.
- Stock-based compensation expense totaled \$3.1 million in the second quarter of 2006, which includes \$1.8 million related to the changes in management that occurred during the second quarter of 2006. In the second quarter of 2005, stock-based compensation expense totaled \$633,000. Stock-based compensation expense for 2006 is calculated under SFAS 123(R). Stock-based compensation expense for 2005 was calculated under Accounting Principles Board Opinion No. 25.

#### Financial Results for the Six Months Ended June 30, 2006

Total revenue for the six months ended June 30, 2006 increased \$3.0 million to \$5.8 million, compared with \$2.8 million for the same period in 2005. Critical Therapeutics' HMGB1 collaboration with MedImmune and its license agreement with Beckman Coulter to develop diagnostic assays accounted for \$2.9 million in revenue during the first half of 2006, and all of the Company's revenue during the first half of 2005. Product sales of ZYFLO accounted for \$2.8 million of revenue during the first half of 2006.

Total operating expenses for the six months ended June 30, 2006 were \$38.3 million, compared with \$22.0 million for the same period in 2005. This increase was primarily due to costs associated with the commercialization of ZYFLO. The net loss for the six months ended June 30, 2006 was \$31.2 million, or \$0.91 per share, based on approximately 34.2 million weighted average common shares outstanding. This compares with a net loss of \$18.4 million, or \$0.75 per share, for the six months ended June 30, 2005, based on approximately 24.5 million weighted average common shares outstanding. The increase in common shares outstanding resulted primarily from the private placement of approximately 9.9 million common shares in June 2005.

Stock-based compensation expense for the six months ended June 30, 2006 totaled \$4.5 million, as calculated under SFAS 123(R). Stock-based compensation expense for the same period in 2005 totaled \$952,000, as calculated under Accounting Principles Board Opinion No. 25.

#### Financial Guidance

Critical Therapeutics expects that net cash expenditures will be between \$13 million and \$15 million in the third quarter of 2006. This anticipated increase over actual second quarter 2006 net cash expenditures of \$12.4 million primarily is related to milestone payments owed to two third parties as a result of the Company's NDA submission to the FDA for zileuton CR. In the third quarter, revenue from sales of ZYFLO will continue to be recognized based on prescriptions filled, net of any discounts or rebates.

For the second half of 2006, the Company expects research and development expenses to be between \$15 million and \$18 million, sales and marketing expenses to be between \$8 million and \$10 million, and general and administrative expenses to be between \$4 million and \$6 million. These estimates for 2006 include the impact of expensing stock options to employees under SFAS 123(R). The non-cash charges related to stock-based compensation expense for employees and non-employees are projected to be between \$3 million and \$4 million for the second half of 2006.

#### Conference Call Information

Critical Therapeutics will hold an audio webcast and conference call to discuss the Company's second quarter 2006 financial results, strategy, upcoming milestones and financial guidance. Investors and other interested parties can access the call as follows:

Date: Thursday, August 3, 2006  
Time: 5:00 p.m. ET  
Dial-in: (800) 289-0730 (domestic)  
(913) 981-5509 (international)

Conference ID: 4240445

Webcast Information: [www.crtx.com](http://www.crtx.com)

A live and archived audio webcast of the conference call also will be available on the "Investors" section of the Critical Therapeutics website. From the home page, click on "Investors" and then on "Webcasts & Presentations."

#### About ZYFLO

ZYFLO is indicated for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO, which contains the active ingredient zileuton, blocks the formation of leukotrienes that may contribute to asthma symptoms. Zileuton is an orally active inhibitor of 5-lipoxygenase, the enzyme that catalyzes the formation of leukotrienes from arachidonic acid. The recommended dose is one 600 mg tablet four times a day. ZYFLO is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Therapy with ZYFLO can be continued during acute

exacerbations of asthma. ZYFLO should be taken regularly, even during symptom-free periods.

Zileuton CR is an investigational drug product and is not currently approved for marketing.

Mild to moderate side effects associated with the use of ZYFLO are abdominal pain, upset stomach and nausea. A small percentage of patients treated with ZYFLO show an increased release of a liver enzyme known as ALT. As a result, the level of liver enzymes in patients treated with ZYFLO should be measured by a simple blood test. It is recommended that physicians perform this test before administering ZYFLO and repeat the test on a regular basis while patients are on the medication. ZYFLO is contraindicated in patients with active liver disease or transaminase elevations greater than or equal to three times the upper limit of normal.

For full prescribing information, please visit [www.crtx.com/pat\\_pi.html](http://www.crtx.com/pat_pi.html) or call the Company's toll free telephone number 1-866-835-8216 to request medical information.

### About Critical Therapeutics

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of products for respiratory, inflammatory and critical care diseases. The Company owns worldwide rights to the asthma drug ZYFLO(R) (zileuton tablets), as well as other formulations of zileuton. ZYFLO is the only 5-lipoxygenase inhibitor approved for marketing by the U.S. Food and Drug Administration. The Company's commercialization efforts for ZYFLO are carried out by its specialty sales force. Critical Therapeutics also is developing treatments directed toward the severe inflammatory response in acute diseases and conditions that lead to admission to the emergency room or intensive care unit, and acute exacerbations of other chronic diseases that frequently lead to hospitalization. For more information, please visit [www.crtx.com](http://www.crtx.com).

### Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Critical Therapeutics, Inc., including, without limitation, statements regarding possible therapeutic benefits, market acceptance and future sales of ZYFLO and, if approved, zileuton CR; the progress, timing and success of our regulatory filings, regulatory approvals and product launches, including for zileuton CR; the timing and magnitude of potential cost savings; the progress and timing of our drug development programs and related trials; the efficacy or safety of our drug candidates; our strategy, future operations, financial position, future revenues, and projected costs, including our net cash expenditures for the third quarter of 2006 and projected expenses for the second half of 2006; prospects, plans and objectives of management; and all other statements that are not purely historical in nature, constitute "forward-looking statements" within the meaning of the Private

Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "will," "would" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties relating to: the extent of market acceptance of ZYFLO and, if approved, zileuton CR; our ability to successfully market and sell ZYFLO; our ability to transition our management team effectively; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO; patient, physician and third-payer acceptance of ZYFLO as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO and, if approved, zileuton CR; conducting clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our products under development and whether such results will be indicative of results obtained in later clinical trials; the timing and success of submission, acceptance and approval of our regulatory filings, including, without limitation, the NDA submission for zileuton CR; our heavy dependence on the commercial success of ZYFLO and, if approved, zileuton CR; our ability to obtain the substantial additional funding required to conduct our research, development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc.; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO, our drug candidates and our discoveries. These and other risks are described in greater detail in the "Risk Factors" section of our most recent Quarterly Report on Form 10-Q and other filings that we make with the Securities and Exchange Commission (SEC). If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements.

In addition, the statements in this release reflect our expectations and beliefs as of the date of this release. We anticipate that subsequent events and developments will cause our expectations and beliefs to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this release.

ZYFLO(R) is a registered trademark of Critical Therapeutics, Inc.

Financial Tables Follow

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

CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited)

	June 30, 2006	December 31, 2005
in thousands, except share data		
<hr/>		
Assets:		
Current assets:		
Cash and cash equivalents	\$37,292	\$57,257
Accounts receivable, net	957	1,024
Amount due under collaboration agreements	250	205
Short-term investments	14,869	25,554
Inventory, net	2,786	1,869
Prepaid expenses and other	1,563	2,179
<hr/>		
Total current assets	57,717	88,088
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Fixed assets, net	3,333	3,563
Other assets	168	168
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Total assets	\$61,218	\$91,819
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Liabilities and Stockholders' Equity:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	\$1,151	\$1,179
Accounts payable	4,292	4,615
Accrued expenses	4,568	4,876
Revenue deferred under collaboration agreements	3,259	5,706
Deferred product revenue	1,272	1,707
<hr/>		
Total current liabilities	14,542	18,083
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Long-term debt and capital lease obligations, less current portion	930	1,489
Stockholders' equity:		
Preferred stock, par value \$0.001; authorized 5,000,000 shares; no shares issued and outstanding	-	-
Common stock, par value \$0.001; authorized 90,000,000 shares; issued and outstanding 34,237,790 and 34,126,977 shares at June 30, 2006 and December 31, 2005, respectively	34	34
Additional paid-in capital	182,806	181,718
Deferred stock-based compensation	(296)	(3,794)
Accumulated deficit	(136,767)	(105,617)
Accumulated other comprehensive loss	(31)	(94)
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Total stockholders' equity	45,746	72,247
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Total liabilities and stockholders' equity	\$61,218	\$91,819
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The accompanying notes are an integral part of these condensed consolidated financial statements.

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

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

Repayments of long-term debt and capital lease obligations	(587)	(505)
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Net cash provided by (used in) financing activities	(524)	51,469
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Net decrease in cash and cash equivalents	(19,965)	44,236
Cash and cash equivalents at beginning of period	57,257	11,980
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Cash and cash equivalents at end of period	\$37,292	\$56,216
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CONTACT: Critical Therapeutics, Inc.  
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