CRITICAL THERAPEUTICS INC
Form 8-K
August 23, 2006

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

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 23, 2006**

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

Delaware	**000-50767**	**04-3523569**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS 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**

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 (see General Instruction A.2. below):

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

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Item 8.01. Other Events.
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Item 8.01. Other Events.

On August 23, 2006, Critical Therapeutics, Inc. (the Company) issued a press release announcing results from the Company s Phase I/II clinical trial designed to evaluate safety, tolerability and pharmacokinetics of the intravenous formulation of zileuton (zileuton IV) in patients with asthma. The trial included measurements to detect evidence of improvement in lung function. The double-blind, placebo-controlled trial enrolled 60 patients at 10 clinical sites in the United States. Patients enrolled in the trial had a mean FEV_1 (forced expiratory volume in one second) of 63 percent of predicted normal at baseline and a mean age of 40 years. Patients enrolled in the trial were randomized into four escalating dose groups (75 mg, 150 mg, 300 mg, and 600 mg), each receiving one infusion of either zileuton IV or placebo. Each of the four dose groups enrolled 15 patients, of whom 12 received zileuton IV and three received placebo. All 60 patients who were randomized completed the trial.

Patients in each of the four zileuton IV cohorts showed a greater mean percentage improvement in FEV_1 than patients in the placebo group when measured at 10, 30 and 60-minute intervals after dosing. The 300 mg dose was predicted to approximate the currently approved oral dose of ZYFLO® (zileuton tablets). In this trial, the 300 mg dose group showed a mean improvement in FEV_1 from baseline of 13.7 percent at 60 minutes after dosing. In addition, zileuton IV was well tolerated at all doses tested with no serious adverse events reported in the trial.

Critical Therapeutics is developing zileuton IV initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. According to the Centers for Disease Control and Prevention s National Center for Health Statistics, asthma resulted in approximately 1.8 million emergency room visits in the United States in 2003.

The Company plans to examine the pharmacokinetic data from the trial when it becomes available in September 2006. Following completion of the analysis of the data, the Company expects to determine the next development step for its zileuton IV program, including the appropriate doses for further examination.

Forward-Looking Statements

Any statements in this report about future expectations, plans and prospects for the Company, including, without limitation, statements regarding the Company s plans for the clinical development of zileuton IV 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 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: conducting clinical trials, including difficulties or delays in the completion of data collection or data analysis; the results of preclinical studies and clinical trials with respect to the Company s products under development, such as the results referred to above, 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; and the Company s ability to obtain the substantial additional funding required to conduct its research, development and commercialization activities. These and other risks are described in greater detail in the Risk Factors section of the Company s most recent Quarterly Report on Form 10-Q filed on August 9, 2006 and other filings that the Company makes with the Securities and Exchange Commission. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, the Company s actual

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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 forward-looking statements in this report reflect the Company s expectations and beliefs as of the date of this report. The Company anticipates that subsequent events and developments will cause its expectations and beliefs to change. However, while the Company may elect to update these forward-looking statements publicly at some point in the future, the Company specifically disclaims 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 the Company s views as of any date subsequent to the date of this report.

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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 23, 2006

CRITICAL THERAPEUTICS, INC.

By: /s/ Frank E. Thomas
Frank E. Thomas
President