

Edgar Filing: CRITICAL THERAPEUTICS INC - Form 8-K

CRITICAL THERAPEUTICS INC

Form 8-K

May 31, 2007

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): May 31, 2007

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):

- ☐ 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 8.01. Other Events.

On May 31, 2007, Critical Therapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has approved the Company's New Drug Application for twice-daily ZYFLO CR(TM) (zileuton) extended-release tablets for the prevention and chronic treatment of asthma in adults and

Edgar Filing: CRITICAL THERAPEUTICS INC - Form 8-K

children 12 years of age and older. ZYFLO CR is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with ZYFLO CR can be continued during acute exacerbations of asthma. The Company, together with its co-promotion partner Dey, L.P. ("DEY"), expects to begin marketing ZYFLO CR in the United States in the fall of 2007.

In March 2007, the Company and DEY, an affiliate of Germany-based Merck KGaA, entered into an agreement for the co-promotion of ZYFLO CR and ZYFLO(R) (zileuton tablets), the immediate-release formulation of zileuton. DEY's 200-person sales force began promoting ZYFLO on April 30, 2007. Upon the launch of ZYFLO CR, the Company's and DEY's combined sales force of 240 representatives will begin promoting ZYFLO CR to approximately 15,000 allergists, pulmonologists and primary care physicians across the United States.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K 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 CR; the anticipated success of the co-promotion arrangement with DEY; the progress, timing and success of the product launch for ZYFLO CR; 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: our ability to successfully market and sell ZYFLO CR, including the success of our co-promotion arrangement with DEY; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO CR; patient, physician and third-party payor acceptance of ZYFLO CR as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO CR; our heavy dependence on the commercial success of ZYFLO CR; our ability to maintain regulatory approvals to market and sell ZYFLO CR; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; conducting clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; 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, ZYFLO CR, our discoveries and our drug candidates. 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. 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 Form 8-K reflect the Company's expectations and beliefs as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause the Company's 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 Form 8-K.

Edgar Filing: CRITICAL THERAPEUTICS INC - Form 8-K

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: May 31, 2007

CRITICAL THERAPEUTICS, INC.

By: /s/ Frank E. Thomas

Frank E. Thomas
President and Chief Executive Officer