CRITICAL THERAPEUTICS INC
Form 8-K
March 14, 2007

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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): **March 13, 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):

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 1.01. Entry into a Material Definitive Agreement.

Zileuton Co-Promotion Agreement

On March 13, 2007, Critical Therapeutics, Inc. (the Company) entered into an agreement with DEY, L.P. (DEY), an affiliate of Merck KGaA, under which DEY and Critical Therapeutics agreed to jointly co-promote ZYFLO® (zileuton tablets) and, if approved by the U.S. Food and Drug Administration (the FDA), the controlled release formulation of zileuton (zileuton CR). Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license or sublicense, under patent rights controlled by the Company, to promote and detail ZYFLO and zileuton CR in the United States, together with the Company and its affiliates, for asthma and, subject to FDA approval, other respiratory conditions.

Both the Company and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In addition, DEY has agreed to provide a minimum number of details per month for ZYFLO and zileuton CR in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. The Company has agreed to provide a minimum number of details per month for ZYFLO and zileuton CR in the first position. From 2008 through 2010, the Company and DEY each have agreed to contribute 50 percent of out-of-pocket promotion expenses for zileuton CR that are accrued or paid to third-parties and approved by the joint commercial committee. The Company and DEY each have agreed to contribute a minimum of $3.0 million per year for these promotion expenses. The Company is responsible for third-party promotion costs during 2007. DEY also has agreed to provide the support of its managed care group to negotiate contracts and engage in other activities with third-party payors for favorable managed care access at an initial rate of approximately $70,000 per calendar quarter. This managed care support will include advice and logistical support to the Company regarding managed care strategy.

Under the co-promotion agreement, DEY has agreed to pay the Company a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement. In addition, DEY has agreed to pay the Company milestone payments of $4.0 million following approval by the FDA of the new drug application for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, the Company will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties up to $1.95 million. The Company has agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, after third-party royalties, in excess of $1.95 million. From the date DEY begins detailing ZYFLO through the commercial launch of zileuton CR, the Company has agreed to pay DEY 70% of quarterly net sales of ZYFLO, after third party royalties, in excess of $1.95 million. Following the commercial launch of zileuton CR through December 31, 2010, the Company has agreed to pay DEY 35% of quarterly net sales, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through December 31, 2013, the Company has agreed to pay DEY 20% of quarterly net sales, after third-party royalties, in excess of $1.95 million.

Beginning three years after the commercial launch of zileuton CR, either party may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by the Company. If DEY exercises this termination right, the Company will be obligated to pay DEY $2.0 million. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party.

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DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the active pharmaceutical ingredients for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement and March 15, 2012. However, if an AB-rated generic product to zileuton CR is introduced, DEY would not be subject to these non-competition obligations and DEY will have the exclusive right to market the authorized generic version of zileuton CR. DEY will not be subject to these non-competition obligations if any of the following occur: DEY exercises its right to terminate the co-promotion agreement if zileuton CR net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million; or DEY terminates the agreement upon the occurrence of a material uncured breach by the Company

Under the co-promotion agreement, the Company granted DEY the exclusive right to negotiate with the Company for the development and commercialization, including co-promotion, of additional zileuton products in the United States for the treatment of asthma and, subject to FDA approval, other respiratory conditions. These exclusive negotiation rights are effective until September 1, 2007 with respect to the injectable formulation of zileuton and December 31, 2007 with respect to other zileuton products.

A joint commercial committee with two members from the Company and two members from DEY will oversee co-promotion activities under the agreement. The co-promotion agreement provides that the joint commercial committee will make decisions by unanimous agreement, with disagreements being referred for resolution by the Chief Executive Officer of each party and further disputes being subject to non-binding mediation.

Binding Letter Agreement for COPD Co-Promotion

As contemplated by the terms of the zileuton co-promotion agreement, the Company and DEY entered into a separate binding letter agreement on March 13, 2007 providing for the Company to co-promote DEY s product candidate for chronic obstructive pulmonary disease (COPD), if approved by the FDA. Under the binding letter agreement, DEY agreed to pay the Company a co-promotion fee based on a percentage of net retail sales of DEY s product candidate for the number of units in excess of a specified level of unit sales. The Company agreed to provide a specified minimum number of details per month for DEY s product candidate.

Although the Company and DEY intend to enter into a more detailed written agreement relating to the co-promotion of DEY s product candidate, the terms of the binding letter agreement will govern the co-promotion of DEY s product candidate if the Company and DEY fail to agree upon a more detailed written agreement. The binding letter agreement provides that the Company and DEY anticipate that they will negotiate and execute a more detailed written agreement within 90 days.

Under the binding letter agreement, the term of the co-promotion arrangement for DEY s COPD product candidate will expire upon termination of the zileuton co-promotion agreement. In addition, the Company has the right to terminate the binding letter of intent or any more detailed written agreement after June 30, 2008 with 90-days advance notice.

Item 7.01. Regulation FD Disclosure

As a result of entering into the co-promotion and marketing services agreement with DEY, prior financial guidance provided by the Company should no longer be considered accurate or otherwise to be relied upon. The Company expects to provide updated financial guidance as part of a quarterly earnings conference call in May 2007 at which the Company also expects to first quarter financial results, strategy and upcoming milestones.

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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: March 14, 2007

CRITICAL THERAPEUTICS, INC.

By: /s/ Frank E. Thomas
Frank E. Thomas
President and Chief Executive Officer