

CRITICAL THERAPEUTICS INC
Form 8-K
June 28, 2005

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):

June 28, 2005

CRITICAL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

000-50767

04-3523569

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. 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:

- 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))

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Item 1.01 Entry into a Material Definitive Agreement.

On June 28, 2005, Critical Therapeutics, Inc. (the "Company") entered into a commercial manufacturing agreement with Patheon Pharmaceuticals Inc. ("Patheon") for the manufacture of commercial supplies of ZYFLO® Filmtab® immediate release tablets (zileuton tablets). The Company had previously contracted with Patheon for the manufacture of ZYFLO for clinical trials and regulatory review. Under the commercial manufacturing agreement, the Company is responsible for supplying the active pharmaceutical ingredient for ZYFLO to Patheon. Patheon is responsible for manufacturing the ZYFLO immediate release tablets and conducting stability testing, as outlined in the supplemental new drug application for ZYFLO filed by the Company with the U.S. Food and Drug Administration. The Company has agreed to purchase at least 50% of its commercial supplies of ZYFLO immediate release tablets for sale in the United States from Patheon each year for the term of the commercial manufacturing agreement.

The commercial manufacturing agreement has an initial term of three years beginning on the date commercial manufacturing of the ZYFLO immediate release tablets commences and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon 12-months' prior written notice of termination or Patheon provides the Company 18-months' prior written notice of termination. In addition, the Company has the right to terminate the commercial manufacturing agreement upon 30-days' prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents the Company from importing, exporting, purchasing or selling ZYFLO immediate release tablets. If the Company provides six-months' advance notice that it intends to discontinue commercializing ZYFLO, the Company will not be required to purchase any additional quantities of ZYFLO immediate release tablets, provided that the Company pays Patheon for a portion of specified fees and expenses associated with orders previously placed by the Company. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. If the commercial manufacturing agreement expires or is terminated for any reason, the Company has agreed to take delivery of and pay for undelivered quantities of ZYFLO that the Company previously ordered, purchase at Patheon's cost Patheon's inventory of ZYFLO maintained in contemplation of filling orders previously placed by the Company and pay the purchase price for components of the ZYFLO immediate release tablets ordered by Patheon from suppliers in reliance on orders previously placed by the Company.

ZYFLO® is a registered trademark of Critical Therapeutics, Inc. Filmtab® is a registered trademark of the Abbott Group of Companies.

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SIGNATURES

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.

CRITICAL THERAPEUTICS, INC.

June 28, 2005

By: */s/ Frank E. Thomas*

Name: Frank E. Thomas

*Title: Chief Financial Officer, Senior Vice President of
Finance and Treasurer*