TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
July 27, 2006

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a 16 or 15d 16

under the Securities Exchange Act of 1934

For the month of July 2006

Commission File Number 0-16174

- 1 -

Teva Pharmaceutical Industries Limited

(Translation of registrant's name into English)

5 Basel Street, P.O. Box 3190

Petach Tikva 49131 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F X Form 40-F _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes _____ No X

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b): 82-_____

Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

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TEVA INITIATES PHASE III STUDY TO CONFIRM INCREASED EFFICACY OF HIGHER DOSE OF GLATIRAMER ACETATE FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS

Study to Confirm Phase II Results Showing Reduced Relapses and Lesions

Jerusalem, Israel (July 27, 2006) - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today the initiation of a large Phase III study designed to confirm the positive results from the Phase II study which compared a new higher dose of 40 mg/day dose of glatiramer acetate (GA) to the currently approved COPAXONE&reg (GA) 20 mg/day, whose efficacy and safety have been well established by three pivotal trials and over a decade of experience and clinical research. The study, called FORTE - FORTy mg Efficacy of glatiramer acetate - is beginning the enrollment of approximately 1,000 patients in 160 centers across North America, Europe, Argentina and Israel.

The results of the initial nine-month, randomized, double-blind, parallel-group Phase II study were presented at the 58th Annual Meeting of the American Academy of Neurology (AAN) in San Diego, CA, April 1-8, 2006. Patients taking the higher dose of GA had a 38 percent greater reduction in mean cumulative number of gadolinium (Gd)-enhancing lesions as measured by magnetic resonance images (MRI) of the brain compared with those taking the COPAXONE&reg (GA) 20 mg/day dose. In addition, compared to annual relapse rate prior to entry, patients taking GA 40 mg/day experienced a reduced mean on-trial relapse rate of 77 percent whereas patients taking COPAXONE&reg (GA) 20 mg/day experienced a 62 percent reduction. GA 40 mg/day was well-tolerated with a safety profile similar to the currently COPAXONE&reg (GA) 20 mg/day.

"The Phase II study results are very promising and suggest that the established efficacy of COPAXONE&reg can be increased even further with this next generation of GA," said Israel Makov, President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. "The initiation of the FORTE study is part of our commitment to MS patients to develop improved therapies that combine superior efficacy and excellent safety," Makov added.

About the Study

The FORTE study is a 12-month, multinational, multicenter, randomized, parallel-group, double-blind study. Patients will be equally randomized into one of two groups: 40 mg GA once daily or COPAXONE&reg (GA) 20 mg once daily. The study objectives include comparing the efficacy and safety of daily subcutaneous injections of 40 mg/day GA to that of COPAXONE&reg (GA) 20 mg/day in RRMS patients. Confirmed relapses and adverse events will be monitored throughout the study. Patients completing the 12-month phase will continue in the study for an additional 12-month, open-label phase in which all subjects will receive 40 mg/day GA.

Patients and health care providers interested in learning more about the study can visit www.clinicaltrials.gov and enter the trial`s identifier code of NCT00337779 for more information.

About Multiple Sclerosis

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that 400,000 people in the United States are affected by this disease, and that over two million people are affected worldwide. MS is a progressive, demyelinating disease of the central nervous system affecting the brain, spinal cord and optic nerves.

Patients with MS may experience physical symptoms and/or cognitive impairments, including weakness, fatigue, ataxia, physical dysfunction, bladder and bowel problems, sensory effects, and visual impairment. MS also has a significant impact on the sufferers` social functioning and overall quality of life.

About COPAXONE&reg

Current data suggest COPAXONE&reg (glatiramer acetate injection) is a selective MHC class II modulator. COPAXONE&reg is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE&reg are redness, pain, swelling, itching, or a lump at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE&reg is now approved in 44 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In Europe, COPAXONE&reg is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE&reg is marketed by Teva Neuroscience, Inc.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80% of Teva`s sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995**:** *This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management`s current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva`s future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to Teva`s ability to rapidly integrate Ivax Corporation`s operations and achieve expected synergies, Teva`s ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra&reg, Neurontin&reg, Oxycontin&reg and Zithromax&reg, the effects of competition on Copaxone&reg sales, including as a result of the expected reintroduction of Tysabri&reg into the market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva`s Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.*

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, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind
Title: Chief Financial Officer

Date: July 27, 2006