

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 17, 2007

**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 April 2007

Commission File Number 0-16174



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**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

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

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](http://www.tevapharm.com)

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**DATA PUBLISHED IN *NEUROLOGY* SHOWED THAT HIGHER DOSE OF COPAXONE<sup>&reg</sup> INCREASED EFFICACY IN RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS)**

**Doubled Dose of COPAXONE<sup>&reg</sup> Maintained Proven Safety Profile and Further Reduced Relapses and Lesions**

Jerusalem, Israel, April 17, 2007 - A 9-month, randomized, double-blind, parallel-group Phase II study of 90 patients comparing a 40 mg dose of COPAXONE<sup>&reg</sup> given daily to the currently approved COPAXONE<sup>&reg</sup> 20 mg dose showed a 38 percent greater reduction in inflammatory disease activity as measured by magnetic resonance images (MRI) of the brain. In addition, patients taking COPAXONE<sup>&reg</sup> 40 mg experienced a reduced mean on-trial relapse rate of 77 percent when compared to annual relapse rate prior to entry, as compared to 62 percent with

COPAXONE<sup>®</sup> 20 mg.

The results of this study, entitled "Randomized, double-blind, dose-comparison of glatiramer acetate in relapsing-remitting MS," were published in a recent issue of *Neurology*. The study can be accessed at: <http://www.neurology.org/cgi/content/abstract/68/12/939>.

"COPAXONE<sup>®</sup> is an established RRMS therapy with more than 12 years of clinical research and experience supporting its efficacy and safety. The recently published data demonstrated that a 40

mg dose was well tolerated, with a safety profile similar to the currently available 20 mg dose," said Jeffrey A. Cohen, M.D., Director of the Experimental Therapeutics Program at Cleveland Clinic's Mellen Center for MS Treatment and Research and Coordinating Principal Investigator of the study. "In addition, the results suggested that a 40 mg dose of COPAXONE<sup>®</sup> may provide better control of disease activity, and justify additional research on the therapeutic effect of higher dosages of this drug."

Based upon the results of this study, a large-scale Phase III study designed to confirm the higher efficacy of COPAXONE<sup>®</sup> with the increased dose has been initiated. The study, entitled FORTE (FORTy mg Efficacy of glatiramer acetate), was launched July, 2006, in 137 centers across North America, Europe, Argentina and Israel. Recruitment of approximately 1,000 patients is expected to be completed in May 2007. These dossiers, including these data, are expected to be submitted to the U.S. Food and Drug Administration in 2008.

## Phase II Study Design and Results

The study was a randomized, double-blind, parallel-group study conducted at 18 centers in the U.S. in 90 patients with RRMS. The study evaluated the effect of 40 mg of COPAXONE<sup>®</sup> (glatiramer acetate injection) given daily versus 20 mg of COPAXONE<sup>®</sup> on disease activity as measured by MRI and clinical relapses, as well as the safety and tolerability of the 40 mg dose over a period of 9 months. Patients that qualified for this study had clinically-definite MS, had experienced a relapse in the previous year, had at least one Gd-enhancing lesion at screening visit, and had a Kurtzke Expanded Disability Status Scale (EDSS) score of 0-5. Patients were randomized in equal numbers to receive either 40 mg or 20 mg of COPAXONE<sup>®</sup>. All patients underwent an MRI at baseline, and then at months 3, 7, 8 and 9. Neurological examinations were performed at screening, baseline, and again at months 3, 6 and 9, and suspected on-trial relapses were confirmed at an unscheduled visit within 7 days.

COPAXONE<sup>®</sup> 40 mg showed a 38 percent greater reduction of inflammatory disease activity as measured by mean cumulative number of Gd-enhancing T1 MRI lesions versus COPAXONE<sup>®</sup> 20 mg (p=0.0898). The benefit of the 40 mg dose was observed in as soon as 3 months (p=0.005) through MRI measurement. When compared to baseline numbers, the risk of having MRI activity (Gd-enhancement) in the 40 mg group at months 7, 8 and 9 was reduced by 75 percent (p<0.0001), compared to 65 percent in patients receiving the 20 mg dose (p<0.0001).

Relapse rates were also lower in patients who received the 40 mg dose of COPAXONE<sup>&reg</sup>, when compared to those who received 20 mg dose (0.34 versus 0.57, respectively). Patients on 40 mg dose of COPAXONE<sup>&reg</sup> experienced a reduced on-trial mean relapse rate of 77 percent when compared to the annual relapse rate prior to entry, versus patients who received the 20 mg dose (62 percent reduction). The time to the first relapse was significantly delayed from 80 days in the 20 mg group to 213 days in the 40 mg group (p = 0.0367). The overall safety profile was similar to that of the 20 mg dose. Some features of injection site reactions and immediate post-injection reactions were more common.

### **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<sup>&reg</sup>**

COPAXONE<sup>&reg</sup> is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE<sup>&reg</sup> are redness, pain, swelling, itching, a lump or an indentation at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>&reg</sup> is now approved in 47 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In North America, COPAXONE<sup>&reg</sup> is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA). In Europe, COPAXONE<sup>&reg</sup> is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. COPAXONE<sup>&reg</sup> is a registered trademark of Teva Pharmaceutical Industries Ltd.

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. Close to 90 percent of Teva's sales are in North America and Europe. Teva's innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

See additional important information at <http://www.copaxone.com/pi/index.html> or call 1-800-887-8100 for electronic releases. For hardcopy releases, please see enclosed full prescribing information.

**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 successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which Teva may obtain U.S. market exclusivity for certain of its new generic products and regulatory changes that may prevent Teva from utilizing exclusivity periods, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra<sup>&reg</sup> and Neurontin<sup>&reg</sup>, the effects of competition on our innovative products, especially Copaxone<sup>&reg</sup> sales, 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, our ability to achieve expected results through our innovative R&D efforts, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, 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 or revise any forward-looking statement, whether as a result of new information, future events or otherwise.*

Jeffrey Cohen, M.D., is a member of Teva's Scientific Advisory Board.

Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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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, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind  
Title: Chief Financial Officer

Date: April 17, 2007



