

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 10, 2008

**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 2008

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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**For Immediate Release**

**COPAXONE<sup>®</sup> SIGNIFICANTLY REDUCED ANNUAL RELAPSE RATES AND STABILIZED DISEASE PROGRESSION IN RELAPSING REMITTING MULTIPLE SCLEROSIS PATIENTS FAILING INTERFERON TREATMENT**

**Jerusalem, April 10, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from a three-year study evaluating relapsing-remitting multiple sclerosis (RRMS) patients who failed first-line monotherapy and switched treatments. The results demonstrated that patients who switched from interferon (IFN) to COPAXONE<sup>®</sup> (glatiramer acetate injection) experienced a 77 percent reduction in annualized relapse rates (0.63 to 0.14). In addition, these patients did not progress significantly in their disability as measured by Expanded Disability Status Scale (EDSS). The results of this study, entitled "Therapeutic outcome 3 years after switching of immunomodulatory therapies in patients with RRMS in Argentina," were published in the April issue of the *European Journal of Neurology*.

The study evaluated the clinical efficacy of switching patients who responded inadequately to first-line immunomodulatory therapy. All patients who switched among the immunomodulatory treatments benefited in terms of relapse rate reduction, however, those who switched from IFN to COPAXONE<sup>®</sup> experienced no significant

disability progression, while patient disability continued to increase in patients who switched from COPAXONE<sup>&reg</sup> to IFN  $\beta$  or from one IFN  $\beta$  to another IFN  $\beta$ . These observations may be due to the emergence of neutralizing antibodies (NABs) in patients taking IFN  $\beta$ . In addition, proportion of patients who did not experience a relapse over the entire 3-year treatment period, increased from 16% to 68% following switch to COPAXONE<sup>&reg</sup>. Whereas the proportion of relapse-free patients switching from one IFN  $\beta$  to another IFN  $\beta$  remained similar before and after switch.

"RRMS patients who respond inadequately to first-line immunomodulatory therapy, generally benefit from switching to another class of immunomodulatory therapy", said Adriana Carrá, M.D., Department of Neurology, Hospital Británico de Buenos Aires, Buenos Aires, Argentina, principal investigator. "For patients switching from IFN  $\beta$  to Glatiramer Acetate, the results obtained are consistent with those of previous studies demonstrating a robust reduction in mean annualised relapse rate and a stabilisation of disease progression".

### About the Study

The prospective observational study included 114 RRMS patients and was conducted at eight multiple sclerosis (MS) centers in Argentina. The study evaluated the clinical efficacy of switching patients who responded inadequately to first-line immunomodulatory therapy, as measured by annualized relapse rates, as well as the mean change in EDSS over a six-year period. The study included a three-year initial treatment phase (*Before Switch* period) and a three-year *After Switch* treatment phase.

Patients included in the study were drawn from a large patient registry in Argentina of over 1,500 patients. Treatment was initiated with one of four immunomodulatory therapies: IFN  $\beta$ -1a i.m., IFN  $\beta$ -1a s.c. (22 or 44  $\mu$ g), IFN $\beta$ -1b or COPAXONE<sup>&reg</sup>. Clinical outcome was assessed after 3 years of treatment. Patients fulfilling criteria for treatment failure, defined as inadequate efficacy or the occurrence of adverse events, switched treatments either from low-dose to high-dose IFN  $\beta$  (n=31), from IFN  $\beta$  to COPAXONE<sup>&reg</sup> (n=47) or mitoxantrone (n=13), or from COPAXONE<sup>&reg</sup> to IFN  $\beta$  (n=16) and followed for an additional three years. The choice for subsequent treatment was made by the neurologist after discussion with the patient.

In the group of patients who switched from IFN  $\beta$  to COPAXONE<sup>&reg</sup> the annual relapse rate was reduced by 0.63 to 0.14, a decrease of 77 percent ( $p < 0.0001$ ). In those who switched to mitoxantrone, the annualized decreased rate was reduced by 71 percent (0.53 to 0.15) ( $p = 0.64$ ). In contrast, the decrease in annualized relapse rates in patients switching between different IFN  $\beta$  preparations was modest, declining from 0.37 to 0.16 (57 percent), ( $p = 0.03$ ).

For all patients switching because of inadequate efficacy, the EDSS score increased significantly over the original treatment period prior to the switch. Following the switch, EDSS scores continued to increase in patients switching from one IFN  $\beta$  to another ( $P = 0.028$ ) or from COPAXONE<sup>&reg</sup> to an IFN  $\beta$  ( $P = 0.0059$ ). In contrast, in patients who switched from IFN  $\beta$  to either COPAXONE<sup>&reg</sup> or mitoxantrone, no significant progression was observed during the switch. Least improved scores were observed in patients switching between IFN  $\beta$  treatments.

In patients switching because of adverse events, no significant change in EDSS scores was observed during the initial period of treatment with either IFN or COPAXONE<sup>®</sup>. EDSS scores remained stable following a switch from IFN to COPAXONE<sup>®</sup> and from COPAXONE to IFN .

### **About 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>®</sup>**

COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE<sup>®</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>®</sup> is now approved in 51 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In North America, COPAXONE<sup>®</sup> is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA). In Europe, COPAXONE<sup>®</sup> is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. COPAXONE<sup>®</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.

## About Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), 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.

### **Teva's 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: when and whether the proposed acquisition will be consummated, Teva's ability to rapidly integrate Bentley's' operations with its own operations and achieve expected synergies, the diversion of management time on merger-related issues, Teva's ability to accurately predict future market conditions, 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>®</sup>, Neurontin<sup>®</sup>, Lotrel<sup>®</sup>, Famvir<sup>®</sup> and Protonix<sup>®</sup>, 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, the effects of competition on our innovative products, especially Copaxone<sup>®</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.

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 10 , 2008

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