

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
July 07, 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 July 2008

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-\_\_\_\_\_



Contact:     **Elana Holzman**     Teva Pharmaceutical Industries Ltd.     972 (3) 926-7554  
              **Kevin Mannix**     Teva North America     (215) 591-8912

**For Immediate Release**

**TEVA PROVIDES UPDATE ON FORTE TRIAL**

Jerusalem, Israel July 7, 2008 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced top-line results from a Phase III study designed to assess the efficacy, safety and tolerability of glatiramer acetate (GA) 40mg as compared to the approved COPAXONE<sup>®</sup> 20mg in the treatment of relapsing-remitting multiple sclerosis (RRMS). The 40mg dose did not demonstrate increased efficacy in reducing the relapse rate; however, the higher dose maintained the favorable safety and tolerability profile of COPAXONE<sup>®</sup> 20mg.

Seventy-eight percent (78%) of COPAXONE<sup>®</sup> 20mg treated patients remained relapse-free throughout the study. Moreover, patients that completed one year of treatment with COPAXONE<sup>®</sup> 20mg experienced a very low annualized relapse rate of 0.27. This robust effect was also reflected in a remarkable reduction of inflammatory activity as measured by MRI.

"While the trial did not demonstrate an enhanced efficacy at the higher dose level, the study reaffirms that COPAXONE<sup>®</sup> 20mg, the leading multiple sclerosis therapy, remains the optimal treatment dose with unmatched long term efficacy confirmed over 10 years," said Moshe Manor, Group Vice President - Global Innovative Resources. "Teva is committed to ongoing research in the field of multiple sclerosis and will continue to move forward towards providing additional treatment options to multiple sclerosis patients".

Teva will continue to analyze the study results to better understand the effect of GA 40mg on patients. The Company is also evaluating the use of GA for additional indications.

### **About the Study**

A randomized, double-blind study, designed to assess the efficacy, safety and tolerability of 40mg glatiramer acetate, as compared to the currently approved COPAXONE<sup>®</sup> (glatiramer acetate) 20mg dose.

The study was conducted in 136 centers in North America, Argentina, Europe and Israel, and included 1,155 patients with RRMS. The trial's primary clinical outcome measure was rate of confirmed relapses.

### **About COPAXONE<sup>®</sup>**

Current data suggest COPAXONE<sup>®</sup> (glatiramer acetate injection) is a selective MHC (Major Histocompatibility Complex) class II modulator. COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS. COPAXONE<sup>®</sup> is very well tolerated and the most common side effects of COPAXONE<sup>®</sup> are redness, pain, swelling, itching, or 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, all European countries, Canada, Mexico, Australia and Israel. In Europe, COPAXONE<sup>®</sup> is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE<sup>®</sup> is marketed by Teva Neuroscience, Inc.

See additional important information at <http://www.COPAXONE.com/pi/index.html> or call 1-800-887-8100 for electronic releases.

### **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 one 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 Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's 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 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.

### **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 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 (including the pending acquisition of Bentley Pharmaceuticals, Inc.), 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)

---

**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/ Eyal Desheh

Name: Eyal Desheh  
Title: Chief Financial Officer

Date: July 7, 2008