

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 10, 2009

**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 September 2009

Commission File Number 0-16174

**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): \_\_\_\_\_

**Website: [www.tevapharm.com](http://www.tevapharm.com)**

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**For Immediate Release**

**COPAXONE<sup>®</sup> Significantly reduced Disease Severity  
in long-term treated Multiple sclerosis Patients**

*Data from Longest, Continuous Study of MS Treatment Presented  
at European Committee for Treatment and Research in MS*

**JERUSALEM, September 10, 2009**- Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today presented data that demonstrated patients treated for 10 and 15 years with COPAXONE<sup>®</sup> (glatiramer acetate injection) had significant reduction in disease severity. These data, generated from the longest continuous prospective study of any disease modifying therapy in relapsing remitting multiple sclerosis (RRMS), were presented today at the 25<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Düsseldorf, Germany.

The long-term analysis utilized the universal MS Severity Score (MSSS) to evaluate the accumulation of disease severity in long-term COPAXONE<sup>®</sup> patients actively on therapy and those who withdrew early from the 15 year ongoing COPAXONE<sup>®</sup> clinical trial<sup>1</sup>. Results demonstrated that 51 percent of long-term COPAXONE<sup>®</sup> treated patients shifted to lower severity grades ( $p < 0.0001$ ). In contrast, 41 percent of patients who withdrew from COPAXONE<sup>®</sup> showed a deterioration in MSSS grades, when compared to their baseline severity grades. Patients remaining on long-term treatment (treatment exposures of 10.12±1.32 years and 13.6±1.3 years), had improved median MSSS scores of 1.84 and 1.69 at 10 and 15 years, compared to MSSS scores at start, 3.62 and 3.50, respectively. Median MSSS score for withdrawn patients worsened to 6.01 at long-term follow-up versus 4.30 at treatment initiation.

"This study, along with other MSSS studies, is paving the way to enable neurologists to predict the progression of disease severity in MS patients," said Joseph Herbert, M.D., associate professor, NYU Department of Neurology and principal investigator of the study. "The demonstrated positive impact of long-term COPAXONE<sup>®</sup> treatment on

slowing disease progression provides hope to MS patients and further emphasizes the importance of early treatment initiation."

### **About the Analysis**

The modified intention-to-treat cohort (mITT, N=232) included all study patients receiving  $\geq 1$  COPAXONE<sup>®</sup> dose. Of mITT, 108 and 100 patients were ongoing in the trial at 10 and 15 years, respectively. Of the 124 patients who withdrew by the 10<sup>th</sup> year of the study, 50 patients returned for a long-term follow-up. MSSS scores were generated at the onset of COPAXONE<sup>®</sup> treatment, at last patient observation for all those who were on COPAXONE<sup>®</sup> and withdrew, at 10 and 15 year visits for ongoing patients and at 10 year long-term follow-up for withdrawn patients who returned.

At the 10 year long-term follow-up, mean disease duration for withdrawn patients was 18.54  $\pm$  5.91 years and mean time since leaving study for the withdrawn patients was 5.44  $\pm$  2.89 years. Median MSSS scores for ongoing patients were 1.84 and 1.69 at 10 and 15 years, compared to MSSS scores at COPAXONE<sup>®</sup> (glatiramer acetate injection) therapy start, 3.62 and 3.50, respectively. For 50 withdrawn patients, median MSSS score was 6.01 at LTFU vs. 4.30 at COPAXONE<sup>®</sup> treatment initiation.

During the study, there was a significant difference between ongoing patients at 10 and 15 years and those who eventually withdrew, in the shift toward lower disease severity categories from COPAXONE<sup>®</sup> start to last patient observation on COPAXONE<sup>®</sup> ( $p < 0.0001$ ). There was a significant difference in disease severity between ongoing patients at 10 years and withdrawn patients at 10 year long-term follow up. Only 11 percent of ongoing, compared with 41 percent of withdrawn patients, had shifted to higher severity scores; while 51 percent of ongoing, compared to only 24 percent of withdrawn, had shifted to lower severity scores ( $p < 0.0001$ ).

The study was supported by Teva Neuroscience.

### **About COPAXONE<sup>®</sup>**

COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. 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.

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., 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.

## **About Teva Neuroscience**

Teva Neuroscience is dedicated to investigating, developing and marketing ground-breaking products and technologies, with emphasis on cutting-edge treatments for patients who are living with neurological conditions, including multiple sclerosis (MS) and Parkinson's disease (PD). Therapies marketed by Teva Neuroscience include COPAXONE<sup>®</sup> (glatiramer acetate injection) for relapsing-remitting multiple sclerosis (RRMS) and AZILECT<sup>®</sup> (rasagiline tablets) for the treatment of PD.

Teva Neuroscience's suite of innovative products continues to demonstrate the company's commitment to fulfilling unmet medical needs and has helped the company evolve into a global leader in RRMS. Teva Neuroscience is a North American division of Teva Pharmaceutical Industries Ltd., the world's largest generic drug company. Teva Neuroscience is proud of the role it plays in providing effective treatment options to patients worldwide. For more information, please visit [www.tevaneuro.com](http://www.tevaneuro.com) or [www.tevaclinicaltrials.com](http://www.tevaclinicaltrials.com).

## **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 our 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: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<sup>®</sup>, the current economic conditions, 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 effects of competition on our innovative products, especially Copaxone® sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").*

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 September 10, 2009

