

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 25, 2011

**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 2011

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)

**New STUDY Demonstrated SIGNIFICANT REDUCTION IN ANNUALIZED RELAPSE RATE AND HALTING OF DISABILITY PROGRESSION in mS patients switching to Copaxone<sup>®</sup>**

*Additional Study Data Showed 70 Percent of Patients had Improved or Stabilized Cognition Following Treatment with Copaxone<sup>®</sup>*

- Data presented at the 63rd Annual Meeting of the American Academy of Neurology (AAN) in Honolulu, HI

**Jerusalem, Israel, April 14, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced preliminary data from two studies, Coptimize and QualiCop.

The global Coptimize study, which followed 688 patients from 19 countries, demonstrated that patients who switched to Copaxone<sup>®</sup> (glatiramer acetate injection) from other approved disease modifying therapies experienced a significant reduction of 61 percent ( $p < 0.0001$ ; signed rank test) in ARR. Switching to Copaxone<sup>®</sup> treatment also halted the progression of disability of patients in the trial. A majority of patients reported better overall wellbeing and less adverse events after switching to Copaxone<sup>®</sup>.

The QualiCop study indicated a significant improvement of cognitive function and depressive symptoms over 24 months. Additionally, patients on Copaxone<sup>®</sup> experienced improved overall multiple sclerosis functional composite (MSFC) scores; the MSFC measures leg function/ambulation, arm/hand function and cognitive function. The study followed 734 patients who were either treatment naïve or previously-treated with other approved injectable

and infused disease modifying therapies for relapsing-remitting multiple sclerosis. In both studies, patients treated with Copaxone also demonstrated stable EDSS (no disease progression) during the study periods.

"These data provide evidence that multiple sclerosis (MS) patients who are not responding optimally to other therapies may benefit from treatment with glatiramer acetate (GA)," said Professor Tjalf Ziemssen, MD, Head of MS center Dresden, Germany and principal investigator on both the Coptimize and QualiCop studies. "These data demonstrated beneficial effects of Copaxone<sup>®</sup> treatment beyond the already established effect on clinical disease activity and safety profile. Improvements in factors that impact patients` quality of life measures such as mobility, depression and cognitive performance, may lead to improved compliance and adherence to therapy."

The results of both the Coptimize and QualiCop studies were presented this week at the 63<sup>rd</sup> Annual Meeting of the American Academy of Neurology (AAN) in Honolulu, Hawaii

### **About the Coptimize Study**

The Coptimize study is an international, non-interventional, longitudinal study, recruiting relapsing-remitting multiple sclerosis (RRMS) patients switching to Copaxone<sup>®</sup> from other injectable and infused disease modifying therapies approved for RRMS within three to six months of screening. The 150 clinics in 19 countries participating in the Coptimize study collected data from about 688 enrolled patients, and leveraged a web-based database to document patients` switch rationale and outcomes, including relapse rate, expanded disability status scale (EDSS), magnetic resonance imaging (MRI), QoL, fatigue and depression, as well as safety and tolerability measures.

The median disease duration of patients in the study was one year, and the median EDSS score at the time of switch was 2.5. The analysis included 648 patients, most of whom reported better efficacy and safety profiles following a switch to Copaxone<sup>®</sup> treatment ( $p < 0.0001$ ; binomial test).

Among 428 patients who had at least one visit post month 0, there was a significant reduction of 61 percent in ARR from 0.85 pre-switch to 0.33 post-switch to COPAXONE<sup>®</sup> ( $p < 0.0001$ ; signed rank test). Disability progressions as measured by EDSS were stable during the 12 months.

### **About the QualiCop Study**

The QualiCop study is a prospective, observational, open label, multicenter non-interventional study of treatment-naïve and previously treated RRMS patients. Over the course of the two-year study, a series of 11 examinations were conducted using various assessments and questionnaires to evaluate QoL (functional assessment of multiple sclerosis, FAMS), fatigue (fatigue scale for motor and cognitive functions, FSMC) and cognition (Paced Auditory Serial Addition Test, PASAT) and Multiple Sclerosis Inventory Cognition, MUSIC tests).

Compared to baseline findings indicate that treatment with Copaxone<sup>®</sup> resulted in improved overall MSFC scores. A robust improvement in cognitive function in patients treated with Copaxone<sup>®</sup> was observed as measured by the PASAT and MUSIC test (p<0.001).

#### **ABOUT COPAXONE<sup>®</sup>**

Copaxone<sup>®</sup> is indicated for the reduction of the frequency of relapses in relapsing-remitting multiple sclerosis, 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, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain.

Copaxone<sup>®</sup> (glatiramer acetate injection) is now approved in more than 50 countries worldwide, including the United States, Russia, 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. 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.sharesolutions.com/pdfs/PrescribingInformation.aspx> or call 1-800-887-8100 for electronic releases.

#### **ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,450 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone<sup>®</sup>, is the number one prescribed treatment for relapsing-remitting multiple sclerosis. Teva employs approximately 40,000 people around the world and reached \$16.1 billion in net sales in 2010.

#### **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® , Lotrel® , Protonix® and Gemzar® , the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone® (including potential generic and oral competition for Copaxone®), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, 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, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, 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").*

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

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 April 14, 2011