

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 28, 2006

**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 2006

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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**New data confirmEd Antibodies to COPAXONE<sup>&reg</sup> DO Not impact ITS ESTABLISHED and SUSTAINED  
LONG-TERM EFFicacy IN multiple sclerosis**

*COPAXONE<sup>&reg</sup> Treatment Favorably Effected Natural History of Disease Throughout Study*

**Jerusalem, Israel, September 28, 2006** - New data presented today at the 22<sup>nd</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Madrid, Spain, showed that antibodies to COPAXONE<sup>&reg</sup> (glatiramer acetate injection) developed in all patients with multiple sclerosis (MS) treated with COPAXONE<sup>&reg</sup>, but did not interfere with the efficacy of the drug. Over a mean treatment period of more than six years, patients in this cross-sectional study who were continuously treated with COPAXONE<sup>&reg</sup> experienced only a minimal increase in their EDSS score, indicating that the long-term efficacy of the drug was not compromised by treatment-related antibodies.

Studies have shown that neutralizing antibodies (Nabs) develop in 5 percent to 45 percent of all MS patients treated with interferon beta (IFN- ). The presence of Nabs to IFN- may negatively alter the therapeutic effectiveness of this

class of disease modifying drugs which includes IFN-  $\beta$  1a SC (Rebif<sup>®</sup>), IFN-  $\beta$  1b SC (Betaseron<sup>®</sup>), and IFN-  $\beta$  1a IM (Avonex<sup>®</sup>). Patients who test positive for NABs are more likely to have reduced therapeutic benefits from their interferon beta treatment (measured by the reduction in relapse rate, the reduction in disability progression and the disease activity as evidenced by brain magnetic resonance imaging (MRI)).

"Neutralizing antibodies against IFNs are therefore an important issue for MS management, as their development appear to diminish their clinical efficacy," said Professor Dimitrios Karussis, Department of Neurology, Hadassah University Hospital, Ein-Karem, Jerusalem. "Our data confirms that antibodies to COPAXONE<sup>®</sup> which develop in all patients do not neutralize the drug's biological activity and do not compromise its established sustained long term effectiveness." he added.

Recent guidelines on Nabs to beta interferons, produced by the European Federation of Neurological Societies (EFNS), recommend that all people with MS being treated with IFN-  $\beta$  be screened after 12 and 24 months of treatment to determine the existence of anti-IFN-  $\beta$  Abs, and that those who have persistently high levels of NABs after re-testing 3-6 months after the first results, should have their interferon beta treatment discontinued. Furthermore, it is recommended that since NABs are cross-reactive, switch from one IFN preparation to another is of no clinical benefit.

### **About the Study**

Patients in this study (n=126) who had received COPAXONE<sup>®</sup> (glatiramer acetate injection) from 2 years to 15 years were surveyed to determine levels and types of antibodies to COPAXONE<sup>®</sup> and to correlate these parameters with treatment outcomes. Serum samples were collected from study participants, and were analyzed for the presence of antibodies to COPAXONE<sup>®</sup> using ELISA E (enzyme-linked immunosorbent assay) methodology. Clinical data, including the current and previous Expanded Disability Status Scale (EDSS) scores, and the relapse rates, were also collected at the time the serum samples were taken.

Over the mean COPAXONE<sup>®</sup> treatment period of 6.65 years, sera from only six patients demonstrated minimal in vitro neutralizing activity. In addition, patients were clinically stable for the whole COPAXONE<sup>®</sup> treatment period, showing a minimal mean increase in EDSS score of 0.65 (mean annual increase = 0.10 per patient). Despite mean disease duration of 10.75 years, the majority of patients (77 percent) surveyed had an EDSS score of less than 4.0, a stage at which they were still fully ambulatory.

In order to further study the subject of NABs to IFNs, Teva Neuroscience, Inc., recently initiated the first-ever study designed to examine how the implementation of regularly scheduled IFN-  $\beta$  NABs tests in MS patients receiving high-dose IFN-  $\beta$  therapy ultimately affects treatment patterns, versus the usual care of IFN-  $\beta$  patients. The study, called the NABs Count Study, began enrolment in July, 2006, in approximately 130 centers across the United States.

### **About COPAXONE<sup>®</sup>**

Current data suggest COPAXONE<sup>®</sup> (glatiramer acetate injection) is a selective MHC class II modulator. 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, or a lump at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>®</sup> is now approved in 44 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. 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.

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. Over 80% 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 rapidly integrate Ivax Corporation's operations and achieve expected synergies, Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra<sup>®</sup>, Neurontin<sup>®</sup>, Oxycontin<sup>®</sup> and Zithromax<sup>®</sup>, the effects of competition on Copaxone<sup>®</sup> sales, including as a result of the reintroduction of Tysabri<sup>®</sup> into the market, 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, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results 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 publicly or revise any forward-looking statement, whether as a result of new information, future developments 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: September 28, 2006



