TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
April 17, 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

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-

[GRAPHIC OMITTED][GRAPHIC OMITTED]

Website: www.tevapharm.com

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

For Immediate Release

EARLY TREATMENT WITH COPAXONE(R) SIGNIFICANTLY DELAYED PROGRESSION TO CLINICALLY DEFINITE MULTIPLE SCLEROSIS

Teva Seeks Approval for the Extension of its Indication to Include the Treatment of Patients with a First Clinical Event Suggestive of MS

Jerusalem, April 16, 2008 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced new results from the PreCISe study, which demonstrated that early treatment with COPAXONE(R) (glatiramer acetate injection) significantly reduced the risk of developing clinically definite multiple sclerosis (CDMS) by 45 percent compared to placebo (hazard ratio 0.55, p=0.0001). These data were presented as late-breaking science at the 60th Annual Meeting of the American Academy of Neurology (AAN) in Chicago.

Based on the PreCISE results, an application for marketing authorization in Europe to the Medicines and Healthcare products Regulatory Agency (MHRA) for the extension of its indication to include the treatment of patients with a first clinical event suggestive of MS, was submitted and is currently under review. A similar application requesting an expanded label for COPAXONE(R) will also be submitted shortly with the U.S. Food and Drug Administration (FDA).

"Clinically isolated syndrome, or CIS, is a first neurologic episode, usually caused by inflammation or demyelination, which is indicative of possible development of multiple sclerosis," said Giancarlo Comi, M.D., University Vita-Salute San Raffaele, Scientific Institute San Raffaele, Milan, Italy, and principal investigator. "The PreCISe study results clearly demonstrate that early treatment with COPAXONE(R), as early as CIS, reduces the risk of developing MS" he added.

COPAXONE(R), currently indicated for RRMS, is a unique disease modifying treatment with a dual mode of action that has over 10 years of prospective clinical trial data demonstrating long-term clinical treatment benefits and good safety profile. The PreCISe results now extend COPAXONE(R) effect to CIS patients, demonstrating a reduced risk of developing Clinically Definite MS (CDMS). Furthermore, the safety profile of COPAXONE(R) in the PreCISe study was consistent with the well-established safety profile of the product based on many years of post-marketing surveillance and over 100,000 patients treated globally with COPAXONE(R).

Moshe Manor, Group Vice President, Global Innovative Resources of Teva Pharmaceutical Industries, Ltd., said, "These impressive results clearly demonstrate the potency of COPAXONE(R) in treating early phases of multiple sclerosis. Along with its lasting efficacy, confirmed over 10 years, it positions COPAXONE(R) as the preferred treatment option for multiple sclerosis patients."

About the Study
The multi-national, multi-center, prospective, double-blind, randomized, Phase III study was conducted in approximately 100 centers located in the U.S.,

Europe, Argentina, Israel, Nordic countries, Australia and New Zealand. It included a total of 481 patients presenting with a

single clinical episode and MRI suggestive of MS. Patients included were those who had a unifocal disease manifestation (i.e., clinical evidence of a single lesion). Patients received either COPAXONE(R) 20mg/day or placebo as a subcutaneous injection and continued treatment for up to 36 months, unless a second attack was experienced and they were diagnosed with CDMS. Patients who converted to CDMS continued the trial on active treatment for an additional two years. The primary efficacy outcome was time to CDMS, based on a second clinical attack.

COPAXONE(R) (glatiramer acetate injection) was also demonstrated to be very well tolerated in the PreCISe study, with only 16 percent overall dropouts during the up to three-year study period, similar to that observed in RRMS patients treated with COPAXONE(R). All patients in the study participated in a follow-up study with COPAXONE(R) to prospectively assess the impact of early versus delayed treatment with COPAXONE(R) on the long-term course of the disease for a total observation time of up to five years.

A pre-planned interim analysis was performed on data accumulated from approximately 80 percent of the three-year placebo-controlled study exposure. Results of the interim analysis, announced in December 2007, demonstrated the proportion of patients developing CDMS was reduced from 43 percent in the placebo group to only 25 percent in the COPAXONE(R) group ($p<0.0001$). The PreCISe study also demonstrated that the 25th percentile of number of days to conversion to CDMS has more than doubled by COPAXONE(R) from 336 days to 722 days (hazard ratio 0.55, $p=0.0005$) compared with placebo.

At the time of this analysis, the data monitoring committee (DMC) stopped the placebo arm of the study, as COPAXONE(R) successfully met the efficacy endpoint of the study.

About COPAXONE(R)
Current data suggest COPAXONE(R) is a selective MHC (Major Histocompatability Complex) class II modulator. COPAXONE(R) is indicated for the reduction of the frequency of relapses in RRMS. COPAXONE(R) is very well tolerated and the most common side effects of COPAXONEv 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(R) is now approved in 51 countries worldwide, including the United States, all European countries, Canada, Mexico, Australia, and Israel. In Europe, COPAXONE(R) is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE(R) 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. 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. 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: 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(R), Neurontin(R), Lotrel(R), Famvir(R) and Protonix(R), 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(R) 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 though 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.

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For Immediate Release

TEVA ANNOUNCES TENTATIVE APPROVAL OF GENERIC MAXALT(R) TABLETS

Jerusalem, Israel, April 17, 2008 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted tentative approval for the Company's Abbreviated New Drug Application (ANDA) to market its generic version of Merck's migraine pain treatment Maxalt(R) (Rizatriptan Benzoate) Tablets, equivalent to 5 mg and 10 mg base. Final approval of this product is anticipated upon expiration of patent protection for the brand product in June 2012.

The brand product had annual sales of approximately $193 million in the United States for the twelve months that ended December 30, 2007, based on IMS sales data.

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.

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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.

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 17, 2008