TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
March 26, 2003

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 March 2003

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 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): _____

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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-_____

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Teva Pharmaceutical Industries Ltd. Web Site www.tevapharm.com

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FOR IMMEDIATE RELEASE

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TEVA & LUNDBECK ANNOUNCE SUCCESSFUL COMPLETION OF

RASAGILINE PHASE III CLINICAL PROGRAM IN PARKINSON`S DISEASE

U.S. and European submissions expected in the second half of 2003

Jerusalem, Israel, March 26, 2003 - Teva Pharmaceutical Industries, Ltd. (Nasdaq: TEVA) and H. Lundbeck A/S(CSE: LUN.CO) are pleased to announce the successful completion of two phase III clinical trials of rasagiline in patients with advanced Parkinson's disease. In both trials, statistically significant results for the primary endpoint were achieved. Each of the studies, which compared once-daily dosages of rasagiline to placebo as an adjunct treatment to levodopa, demonstrated significant reductions in the duration of the "Off" time (a state in which patients are unable to function normally). The results of these two trials follow the successful results of an earlier phase III trial which demonstrated the efficacy of rasagiline as monotherapy in early-stage Parkinson's disease.

With these successful results, rasagiline is now expected to be submitted for regulatory approval in North America and Europe during the second half of 2003.

Israel Makov, President and CEO of Teva said: "The robust results of these trials have met our expectations with regard to the efficacy of rasagiline. We are extremely pleased with the clinical development of this product which holds promise for patients with both early and advanced stages of Parkinson's disease. These results also encourage us to move forward with investigating rasagiline in other neurological disorders."

It is estimated that over one-third of patients diagnosed with advanced Parkinson`s disease experience many hours of "Off" time daily, in which they are unable to function normally. The majority of these patients develop complications which respond poorly to current standard levodopa treatments.

The two double blind placebo controlled phase III clinical trials were PRESTO and LARGO. The PRESTO trial, conducted in North America (treatment duration of 26 weeks), compared the effects of two different dosages of rasagiline, 0.5mg and 1mg once-daily, to placebo in 472 patients. The LARGO trial was conducted in Europe, Israel and Argentina (treatment duration of 18 weeks) with 687 patients and compared the effects of rasagiline, 1mg once daily, to placebo and also included an active comparator arm of patients treated with entacapone - 200mg with each levodopa dose. All patients were optimized on levodopa/decarboxylase inhibitor (DCI) treatment but were still experiencing the response fluctuations typical of advanced stage disease. The tolerability of rasagiline as determined by the percent of patients successfully completing these studies was comparable to placebo. The trials also showed that, in addition to the primary endpoints, highly statistically significant positive effects were obtained for additional endpoints dealing with patient's clinical status and function while both in an "Off" and "On" state.

Rasagiline was developed by Teva based on the original research of Prof. M. Youdim and Prof. J. Finberg from the Haifa Technion School of Medicine in Israel.

The development of rasagiline is part of a long-term strategic alliance for global co-development and European marketing between Teva and Lundbeck. Under the terms of the agreement, Lundbeck will market rasagiline in Europe and in a number of overseas markets, in a joint effort with Teva, while Teva retains exclusive marketing rights in the rest of the world, including North America.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 35 pharmaceutical companies in the world. Close to 90% of Teva`s sales are in North America and Europe. The company develops, manufactures, and markets generic and branded human pharmaceuticals and active pharmaceutical ingredients. Teva`s innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders.

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 current 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 Teva`s ability to successfully develop and commercialize additional

pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell their own generic products or successfully extend the exclusivity period of their branded products, Teva`s ability to rapidly integrate the operations of acquired businesses, the availability of product liability coverage in the current insurance 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 ("FDA") and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, 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 ("SEC"). 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 ANNOUNCES TENTATIVE APPROVAL OF METFORMIN HCl EXTENDED-RELEASE TABLETS

Jerusalem, Israel, March 26, 2003 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U. S. Food and Drug Administration has granted tentative approval of the company`s ANDA for Metformin HCl Extended-Release Tablets, 500 mg. The brand product's annual sales are approximately $410 million.

Metformin HCl Extended-Release Tablets are the AB-rated generic equivalent of Bristol-Myers Squibb`s antihyperglycemic drug, Glucophage&reg XR Tablets, which is indicated as an adjunct to diet to lower blood glucose levels in patients with type 2 diabetes.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 35 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Close to 90% of Teva`s sales are in North America and Europe. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients

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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: March 26, 2003

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