TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 08, 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 September 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): _____

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-_____

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

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FOR IMMEDIATE RELEASE

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tEVA ANNOUNCEs nda sUBMISSION OF RASAGILINE AS A TREATMENT FOR PARKINSON`S DISEASE

Jerusalem, Israel, September 8, 2003 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has submitted to the US Food and Drug Administration (FDA) a New Drug Application (NDA) for rasagiline for the treatment of Parkinson`s disease (PD). The submission is based on data from three Phase III clinical trials in early and advanced PD patients.

Rasagiline is a novel, potent, second-generation irreversible monoamine oxidase type B (MAO-B) inhibitor. It differs from earlier propargylamine MAO-B inhibitors in its chemical structure, its greater potency, lack of amphetamine metabolites, and once-a-day dosing.

Over 1600 patients with PD participated in clinical trials worldwide, during the development of rasagiline.

"This is another milestone for Teva's developing franchise in the CNS arena." said Israel Makov, President and CEO of Teva. "This development is further substantiated through our collaboration with Eisai, which will enable us to expand the scope of rasagaline's use into other indications. More importantly, we are very pleased to be in a position to offer patients with early and advanced stage PD what may become a new and an important treatment for this disease."

Teva Neuroscience, Inc. and Eisai Inc. will co-promote rasagiline in the United States once approved by the FDA, as part of a long-term strategic alliance between Teva Pharmaceutical Industries Ltd. and Eisai Co., Ltd. Rasagiline will become Teva Neuroscience`s second branded neurology product**.** Eisai Inc. also currently markets two neurology products in the U.S.

Teva Pharmaceutical Industries Ltd. anticipates submitting an application to market rasagiline as a treatment for PD in the European Union later this year. Upon approval, rasagiline will be co-marketed in Europe by Teva and H. Lundbeck A/S as part of a long term strategic alliance between the two companies.

Rasagiline is a joint development of Teva and the Technion - Israel institute of Technology.

Teva Pharmaceutical Industries Ltd, headquartered in Israel, is among the top 30 pharmaceutical companies in the world. The company develops, manufactures, and markets generic and branded human pharmaceuticals and active pharmaceutical ingredients. Close to 90 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 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

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 8, 2003