TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 20, 2007

## 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 2007

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 <u>X</u> 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
V. V.
Yes NoX
If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):
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Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

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#### FOR IMMEDIATE RELEASE

#### TEVA PROVIDES UPDATE ON EDRATIDE FOR SYSTEMIC LUPUS ERYTHEMATOSUS

**Jerusalem, Israel, September 19, 2007** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that the Company's synthetic peptide, edratide (TV-4710), did not meet its primary endpoint in the PRELUDE trial, a Phase 2 clinical trial in patients with systemic lupus erythematosus (SLE). The drug candidate, administered as a subcutaneous weekly injection, was shown to be safe and well-tolerated.

PRELUDE, a randomized, double-blind, placebo-controlled, parallel assignment Phase 2 study, enrolled 340 patients from 12 countries across North America, Latin America, the European Union, Russia, and Israel. The study was designed to assess the efficacy and safety of edratide, with the primary endpoint being the reduction of lupus disease activity over a 26-week treatment period, as measured by the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score.

Analyses of edratide's performance in other secondary clinical endpoints measured in the trial are still ongoing, and any potential further development plans for this product candidate will not be determined until these additional analyses have been completed.

### **About Edratide**

Edratide (TV-4710) is a synthetic peptide composed of 19 amino-acid residues developed by Teva Pharmaceutical Industries Ltd. based on research done by Prof. Edna Mozes of the Weizmann Institute of Science, Rehovot, Israel. The sequence of the peptide is based on the complementarity determining region 1 (CDR1) of a pathogenic human anti-DNA monoclonal antibody (mAb) that bears the 16/6 idiotype (16/6 Id). This idiotype was found to have clinical relevance in SLE patients. Edratide was tested and found active in several relevant in-vitro and in-vivo models for lupus and was previously found to be safe for administration to humans in two phase I studies.

#### **About Teva**

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), 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 76 percent of Teva's sales are in North America and Europe. Teva's innovative R&D focuses on developing novel drugs, primarily for diseases of the central nervous system and auto-immune diseases.

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 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, 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&reg, Neurontin&reg, Lotrel&reg, and Famvir&reg, the effects of competition on our innovative products, especially Copaxone&reg 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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Teva Pharmaceutical Industries Ltd. Web Site: <a href="https://www.tevapharm.com">www.tevapharm.com</a>
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 1 9, 2007