

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 30, 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 May 2006

Commission File Number 0-16174

- 1 -

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

Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

(011) 972-2-589-2840

George Barrett

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-3030

Liraz Kalif / Kevin Mannix

Investor Relations

(011) 972-3-926-7554 / (215) 591-8912

**TEVA ANNOUNCES TENTATIVE APPROVAL OF SIMVASTATIN TABLETS; PROVIDES UPDATE ON
180-DAY EXCLUSIVITY**

Jerusalem, Israel, May 25, 2006 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration ("FDA") has granted tentative approval for the Company's Ivax Abbreviated New Drug Application ("ANDA") for Simvastatin Tablets USP, 5 mg, 10 mg, 20 mg, 40 mg and 80 mg.

Upon final approval, the Company's Simvastatin Tablets will be the AB-rated generic equivalent of Merck's Zocor® Tablets, a product indicated for the treatment of high cholesterol. Total annual sales of the brand product are approximately \$4.6 billion.

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

As the first company to file an ANDA containing a paragraph IV certification for the 5 mg, 10 mg, 20 mg, and 40 mg strengths, Teva is eligible to receive 180-day Hatch-Waxman statutory exclusivity to market these products.

Further, today the FDA filed an appeal to the United States Court of Appeals concerning Teva's 180-day exclusivity. The FDA is challenging a May 1, 2006 decision by the District Court, which found unlawful the FDA's October 24, 2005 decision denying the Company's citizen's petition on the exclusivity issue. The FDA is seeking expedited review and has proposed a schedule whereby the appeal will be fully briefed over the summer, with arguments to be heard at the Court's earliest convenience thereafter. Teva has agreed to an expedited schedule.

Teva expects to receive final approval for the 5 mg, 10 mg, 20 mg, and 40 mg strengths with exclusivity on June 23, 2006, when the product patent expires.

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. Close to 90% of Teva's sales are in North America and Europe.

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[®], Neurontin[®], Oxycontin[®] and Zithromax[®], the effects of competition on Copaxone[®] sales, including as a result of the expected reintroduction of Tysabri[®] 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

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: May 25, 2006

