

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 17, 2010

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 2010

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):

Website: www.tevapharm.com

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For immediate release

Teva Announces Tentative Approval of Generic Sensipar®

Jerusalem, May 14, 2010 - 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 Abbreviated New Drug Application (ANDA) for Cinacalcet HCl Tablets 30, 60 & 90 mg.

Upon final approval, Teva's Cinacalcet HCl Tablets will be the AB-rated generic equivalent of Amgen's Sensipar®, indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

The brand product had annual sales of approximately \$458 million in the United States, based on IMS sales data.

Teva is currently involved in patent litigation concerning this product in the U.S. District Court for the District of Delaware. A trial date has not been set.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 15 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

Teva's 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 our 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: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin®^{reg}, Lotrel®^{reg} and Protonix®^{reg}, the extent to which any manufacturing or quality control problems damage our reputation for high

quality production, the effects of competition on sales of our innovative products, especially Copaxone^{®} (including potential generic and oral competition for Copaxone^{®}), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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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/ Eyal Desheh

Name: Eyal Desheh

Title: Chief Financial Officer

Date May 14, 2010