TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
December 16, 2004

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 December 2004

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 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

---

Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

(011) 972-2-589-2840

Bill Fletcher

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-8800

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

(011) 972-3-926-7554

TEVA LAUNCHES QUINAPRIL HCL TABLETS;

PURSUANT TO AGREEMENT WITH RANBAXY

Jerusalem, Israel, December 16, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) and Ranbaxy Pharmaceuticals Inc. announced today that Teva has begun commercially shipping Quinapril HCl Tablets, 5 mg, 10 mg, 20 mg and 40 mg, manufactured pursuant to Ranbaxy`s ANDA No. 076607, which received final FDA approval. The product will be sold under the Teva label and marketed by Teva USA.

Quinapril HCl Tablets are the AB-rated generic equivalent of Parke Davis` antihypertensive agent Accupril&reg Tablets. The brand product has annual sales of approximately $555 million.

Teva is distributing the product as part of a supply and distribution agreement entered into by the two companies whereby Ranbaxy will manufacture and supply the product to Teva. Under the terms of this agreement, Teva and Ranbaxy will share in the profits. The launch follows Teva`s relinquishment of its right to a 180-day period of marketing exclusivity for Quinapril HCl Tablets.

In 2003, the FDA granted final approval for Teva`s ANDA for Quinapril HCl Tablets. As the first company to file an ANDA with a Paragraph IV patent certification, Teva was awarded 180 days marketing exclusivity for this product. Teva is currently enjoined from selling Quinapril HCl Tablets under its own ANDA, following a court decision holding that Teva`s product would infringe Pfizer`s 4,743,450 patent. That decision is currently on appeal to the US Court of Appeals for the Federal Circuit.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva`s sales are in North America and Europe.

Ranbaxy Pharmaceuticals Inc. ("RPI") based in Jacksonville, Florida, is a wholly owned subsidiary of Ranbaxy Laboratories Limited ("RLL"), India`s largest pharmaceutical company. RPI is engaged in the sale and distribution of generic and branded prescription products in the U.S. healthcare system.

Ranbaxy Laboratories Limited, India's largest pharmaceutical company, manufactures and markets brand and generic pharmaceuticals and Active Pharmaceutical Ingredients. Ranbaxy's continued focus on R&D has resulted in several approvals in developed markets and significant progress in New Drug Discovery Research. Ranbaxy's foray into Novel Drug Delivery Systems has led to proprietary "platform technologies" resulting in a number of products under development. The Company is selling its products in over 100 countries and has an expanding international portfolio of affiliates, joint ventures and alliances, ground operations in 34 countries and manufacturing operations in 7 countries.

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 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 or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone&reg sales, including potential competition from the expected launch of Tysabri&reg/Antegren&reg, Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that

may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, 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 Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, 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: December 16, 2004