

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
April 28, 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 April 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

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

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FOR IMMEDIATE RELEASE

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TEVA AND ALPHARMA ENTER INTO AGREEMENT RELATING TO GABAPENTIN

Jerusalem, Israel, April 28, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has entered into an agreement with Alpharma Inc. (NYSE:ALO) pertaining to pending Abbreviated New Drug Applications (ANDAs) for gabapentin 600 mg and 800 mg tablets, and gabapentin 100 mg, 300 mg and 400 mg capsules, the bioequivalent versions of Pfizer's Neurontin[®] Tablets and Neurontin[®] Capsules. Neurontin[®] Tablets and Neurontin[®] Capsules had U.S. sales of over \$2 billion for the twelve-month period ended December 31, 2003 according to IMS.

Alpharma holds a final ANDA approval for its gabapentin capsules and is awaiting final ANDA approval for the tablets. Teva Pharmaceuticals USA, Inc. ("Teva USA") currently holds tentative approvals for both the tablets and the capsules. The parties believe that the Alpharma ANDAs for the products are entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity, although another generic manufacturer has challenged these rights in litigation pending in a U.S. District Court. Patent litigation is pending with Pfizer on these products.

Under the terms of the agreement, Alpharma will permit Teva USA to launch its gabapentin within Alpharma's exclusivity period, and Teva will make certain payments, based on Teva USA's sales, to Alpharma relating to the period of exclusivity. In addition, the parties have agreed to certain risk sharing arrangements relating to patent litigation risks regarding a gabapentin launch.

Mr. Israel Makov, President and CEO of Teva, commented: "We are pleased to enter into this agreement with Alpharma. We believe that this agreement will facilitate the introduction of the generic version of this important product and thereby significantly reduce its cost to the U.S. consumer."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 30 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.

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, including its recent acquisition of Sicor Inc., 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 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. 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: April 28, 2004

