TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 27, 2002

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 November 2002

Commission File Number <u>0-16174</u>

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
indicate by check mark whether the registrant mes of will me aimata reports under cover of Form 20 F of Form 70 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
Yes NoX

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

Dorit Meltzer Director, Investor Relations Teva Pharmaceutical Industries Ltd. (011) 972-3-926-7554

TEVA CONFIRMS EXERCISE OF OPTION UNDER COLLABORATION WITH IMPAX LABORATORIES, INC.

Jerusalem, Israel, November 26, 2002 - Teva Pharmaceutical Industries Limited (Nasdaq: TEVA) confirmed today that an option relating to an additional product under the strategic alliance between a Teva subsidiary and IMPAX Laboratories, Inc. (Nasdaq: IPXL) has been exercised by Teva.

The agreement, signed in June 2001, granted Teva exclusive United States marketing rights and an option to acquire exclusive marketing rights in Canada and various other Western countries for eleven products, allocated among three tiers which reflected the extent of their development at the time of the agreement, plus an option to acquire exclusive marketing rights to one additional IMPAX product pending approval.

The so called "Tier 1 Products", which were products as to which IMPAX had pending ANDAs at the U.S. Food and Drug Administration (FDA), included: Loratadine/Pseudoephedrine Sulfate 12 hour Extended Release Tablets (generic of Claritin^(R) D12), Loratadine/Pseudoephedrine Sulfate 24 hour Extended Release Tablets (generic of Claritin^(R) D24), Loratadine Orally Disintegrating Tablets (generic of Claritin^(R) Reditabs), Bupropion Extended Release Tablets (generic of Wellbutrin^(R) SR Tablets), Bupropion Extended Release Tablets (generic of Zyban^(R) Tablets) and Omeprazole Delayed Release Capsules (generic of Prilosec^(R) Capsules).

The recent tentative and final approvals received by IMPAX from the FDA for its Omeprazole Delayed Release Capsules ANDA triggered the option.

Mr. Israel Makov, President and CEO of Teva said: "We are pleased with our strategic alliance with IMPAX, and our exercise of this option is part of our ongoing relationship with them under our existing contract. Under this option, we have rights to IMPAX's ANDA for Omeprazole Delayed Release Capsules. However, given the pending lawsuit between IMPAX and AstraZeneca regarding this product, we do not anticipate launching this product until the lawsuit is resolved."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 35 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Over 80% of Teva's sales are in North America and Europe. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and niche generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and intends to market its branded products through the IMPAX Pharmaceuticals division. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities.

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, 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 ("FDA") 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 ("SEC"). 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: November 27, 2002