TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 06, 2005

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 September 2005

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): _____

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-_____

400 Chestnut Ridge Road

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N E W S R E L E A S E

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Teva and Barr Announce Launch of Generic Allegra&reg Tablets By Teva Under Agreement With Barr

Woodcliff Lake, NJ - September 6, 2005... Barr Pharmaceuticals, Inc. (NYSE: BRL) and Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that they have entered into an agreement for the launch of Fexofenadine Hydrochloride 30 mg, 60 mg and 180 mg Tablets, the generic versions of Aventis Pharmaceuticals` Allegra&reg Tablets. Allegra tablets had annual sales of approximately $1.4 billion, based on IMS data for the twelve months ended June 2005.

Under the agreement, Barr has taken the regulatory steps necessary to permit Teva to obtain final U.S. Food and Drug Administration approval of Teva`s Fexofenadine Hydrochloride Tablets and to sell the product within Barr`s 180-day exclusivity. In return, Barr will receive a negotiated percentage of the gross profit of Teva`s product, both during and after the exclusivity period. Teva will record the revenues resulting from sales of the product and remit the negotiated percentage of its gross profit to Barr.

In June 2004 Barr and Teva were granted summary judgment of non-infringement with respect to three patents, and were granted summary judgment of invalidity on an additional patent in the case in April 2005. Several patents remain in the litigation. Although no trial date has been set, the companies expect that a trial will occur sometime in 2006.

"This agreement and launch represent an extraordinary opportunity for consumers and for both companies," said Bruce L. Downey, Barr`s Chairman and Chief Executive Officer. "However, the courts have yet to resolve the pending patent litigation concerning our generic products. The agreement with Teva enables us to maximize the opportunity, while sharing the risk of the ongoing litigation."

Israel Makov, Teva`s President and Chief Executive Officer commented, "The launch of Fexofenadine represents the culmination of many months of work between Teva and Barr. It allows us to accelerate the availability of this important generic product and expands the already large portfolio of generic pharmaceutical products that we offer to American consumers."

Barr was the first generic applicant to file an Abbreviated New Drug Application (ANDA) containing a paragraph IV patent challenge on the patents related to the Allegra tablet product and consequently was granted 180 days exclusivity, which it has now transferred to Teva. Allegra (Fexofenadine Hydrochloride) is indicated for the relief of symptoms associated with seasonal allergic rhinitis and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

About Barr

Barr Pharmaceuticals, Inc. (NYSE: BRL) is a holding company whose principal subsidiaries, Barr Laboratories, Inc. and Duramed Pharmaceuticals, Inc., develop, manufacture and market generic and proprietary pharmaceuticals.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 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.

Barr Pharmaceuticals, Inc. Forward-Looking Statements

Except for the historical information contained herein, the statements made in this press release constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements can be identified by their use of words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates" and other words of similar meaning. Because such statements inherently involve risks and uncertainties that cannot be predicted or quantified, actual results may differ materially from those expressed or implied by such forward-looking statements depending upon a number of factors affecting the Company's business. These factors include, among others: the difficulty in predicting the timing and outcome of legal proceedings, including patent-related matters such as patent challenge settlements and patent infringement cases; the outcome of litigation arising from challenging the validity or non-infringement of patents covering our products; the difficulty of predicting the timing of FDA approvals; court and FDA decisions on exclusivity periods; the ability of competitors to extend exclusivity periods for their products; our ability to complete product development activities in the timeframes and for the costs we expect; market and customer acceptance and demand for our pharmaceutical products; our dependence on revenues from significant customers; reimbursement policies of third party payors; our dependence on revenues from significant products; the use of estimates in the preparation of our financial statements; the impact of competitive products and pricing on products, including the launch of authorized generics; the ability to launch new products in the timeframes we expect; the availability of raw materials; the availability of any product we purchase and sell as a distributor; the regulatory environment; our exposure to product liability and other lawsuits and contingencies; the increasing cost of insurance and the availability of product liability insurance coverage; our timely and successful completion of strategic initiatives, including integrating companies and products we acquire and implementing our new enterprise resource planning system; fluctuations in operating results, including the effects on such results from spending for research and development, sales and marketing activities and patent challenge activities; the inherent uncertainty associated with financial projections; changes in generally accepted accounting principles; and other risks detailed from time-to-time in our filings with the Securities and Exchange Commission, including in our Annual Report on Form 10-K for the fiscal year ended June 30, 2004.

The forward-looking statements contained in this press release speak only as of the date the statement was made. The Company undertakes no obligation (nor does it intend) to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required under applicable law.

Teva Pharmaceutical Industries Ltd. Safe Harbor Statement Under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which express the 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 whether and when the proposed acquisition with Ivax Corporation will be consummated and the terms of any conditions imposed in connection with such closing, the terms and conditions of the financing utilized by Teva for the Ivax acquisition, Teva's ability to rapidly integrate Ivax's operations and achieve expected synergies, 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 under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic products, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final court decision, including that relating to the generic version of Neurontin&reg, the effects of competition on Copaxone&reg sales, 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.

[EDITOR'S ADVISORY: Barr Pharmaceuticals, Inc. news releases are available free of charge through PR Newswire`s News On-Call site at http://www.prnewswire.com/comp/089750.html. Barr news releases and corporate information are also available on Barr`s website (www.barrlabs.com). For complete indications, warnings and contraindications, contact Barr Laboratories' Product Information Department at 1-800-Barr Lab. All trademarks referenced herein are the property of their respective owners.]

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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: September 6, 2005