TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 16, 2008

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 2008

Commission File Number 0-16174

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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-_____

www.tevapharm.com

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For Immediate Release

Teva Receives EU Marketing Authorization for TevaGrastim&reg

First Biosimilar G-CSF Product to Receive Marketing Authorization in the EU

Jerusalem, Israel, September 16, 2008 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that the European Commission`s Directorate General for Enterprise and Industry granted Teva a Marketing Authorization for its human granulocyte colony stimulating factor (G-CSF) product.

This Marketing Authorization follows the positive opinion issued by the CHMP, the scientific committee of the European Medicines Evaluation Agency (EMEA). Teva's product is the first biosimilar G-CSF to receive a Marketing Authorization in the European Union and will be marketed under the brand name TevaGrastim&reg. Teva will progressively begin marketing the product throughout Europe in 2009.

G-CSF, mainly indicated for the treatment of chemotherapy-induced neutropenia, was developed by Teva in collaboration with a partner. The brand product, Neupogen&reg Filgrastim had worldwide sales of approximately $1.3 billion and approximately $300 million in the EU for the twelve months that ended June 30, 2008, based on IMS sales data.

Gerard van Odijk, President and CEO of Teva Europe, said: "As the EU Commission defined the regulatory pathway for the approval of biosimilars in Europe, Teva drew on its extensive resources to develop this product, receive approval and bring it to the market. Our accomplishment - receiving the first Marketing Authorization in the EU for a biosimilar G-CSF product - demonstrates the strength of Teva's biotechnology R&D capabilities and our commitment to bringing high quality and affordable biopharmaceutical products to the market. Gaining this early experience is important for us to further enhance our capabilities in this field".

Teva currently markets a portfolio of biopharmaceutical products including human growth hormone ("hGH") in the United States, as well as interferon alpha 2b, G-CSF and hGH outside the United States. Teva's biogeneric pipeline includes many other products to be launched in the US and the EU, as well as in other markets.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Over 80 percent 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 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, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra&reg , Neurontin&reg, Lotrel&reg and Protonix&reg, the effects of competition on our innovative products, especially 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 Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results though our innovative R&D efforts, our ability to successfully identify, consummate and integrate acquisitions, including the pending acquisition of Barr Pharmaceuticals Inc., potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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: September 16, 2008