TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 05, 2006

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 2006

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

Active Biotech AB

Web Site: www.activebiotech.com

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FOR IMMEDIATE RELEASE

Laquinimod Phase IIb Trial confirms efficacy and favorable safety profile and shows significant reduction in the rate of inflammatory disease activity

The once-daily novel oral agent for relapsing remitting multiple sclerosis (MS) patient met its primary end-point.

Jerusalem, Israel and Lund, Sweden, September 5, 2006. - Teva Pharmaceutical Industries Ltd (Nasdaq: TEVA) and Active Biotech AB (ACTI.ST) today announced that a Phase IIb study designed to evaluate the safety and efficacy of laquinimod, a once-daily novel oral agent, in relapsing remitting multiple sclerosis (MS) patients, met its primary end-point.

Laquinimod treatment significantly reduced the rate of inflammatory disease activity, as measured by the cumulative number of Gadolinium enhancing lesions on brain MRI scans after 36 weeks of treatment. Laquinimod treatment also demonstrated a considerable reduction in the number of clinical relapses compared to placebo. This Phase IIb multi-center, randomized, double-blind, placebo-controlled study enrolled approximately 300 patients in 8 European countries and in Israel.

The evaluation of the safety and side-effect data confirmed the favourable safety profile that was seen in earlier phase II clinical trials. The majority of the patients who participated in the study are currently continuing treatment with laquinimod in an ongoing, blinded extension study.

"The study results with once daily oral laquinimod are very encouraging and further demonstrate our ongoing commitment to developing new classes of therapies for MS, including oral therapies, to treat the disease, as well as to improve the patients' quality of life**,**" said Israel Makov, President and CEO of Teva Pharmaceutical Industries Ltd**.**

"As of today, nearly 400 patients have received laquinimod in various clinical trials over the last years. The data from the completed studies together with preclinical documentation, confirm laquinimod`s efficacy and favorable safety profile in MS patients," said Sven Andréasson, President and CEO of Active Biotech AB**.**

The positive result of the clinical trial triggers a milestone payment to Active Biotech.

Further details about the study will be given at Teva's Innovative R&D Day in New York City on September 26th, 2006. A complete presentation of the Phase IIb data will be given at upcoming relevant scientific meetings.

Teva is discussing laquinimod's development plan with regulatory authorities in order to accelerate the clinical program into Phase III.

About Laquinimod

Laquinimod is a novel once-daily, orally administered immunomodulatory compound developed as a disease modifying treatment for multiple sclerosis (MS). Active Biotech developed laquinimod and licensed it to Teva Pharmaceutical Industries Ltd. in June 2004.

About MS

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that 400,000 people in the United States are affected by this disease, and that over one million people are affected worldwide. MS is a progressive, demyelinating disease of the central nervous system affecting the brain, spinal cord and optic nerves.

Patients with MS may experience physical symptoms and/or cognitive impairments, including weakness, fatigue, ataxia, physical dysfunction, bladder and bowel problems, sensory effects, and visual impairment. MS also has a significant impact on the sufferers' social functioning and overall quality of life.

About Active Biotech

Active Biotech AB is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio with pipeline products focused on autoimmune/inflammatory diseases and cancer. Most advanced projects are Laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, as well as ANYARA for use in cancer immunotherapy with the primary indications renal cell cancer and non-small cell lung cancer. Further key projects in clinical development comprise the three orally administered compounds TASQ for prostate cancer 57-57 for SLE and RhuDex&reg for RA.

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, as well as animal health pharmaceutical products. Over 80% of Teva`s sales are in North America and Europe. Teva`s innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

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 risks relating to Teva`s ability to rapidly integrate Ivax Corporation`s operations and achieve expected synergies, Teva`s ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra&reg, Neurontin&reg, Oxycontin&reg and Zithromax&reg, the effects of competition on Copaxone&reg sales, including as a result of the reintroduction of Tysabri&reg into the 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, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, potential exposure to product

liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, 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: September 5, 2006