TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
October 19, 2011

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 October, 2011

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):_____

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Investigational Laquinimod Demonstrates Its Potential as a New Oral Treatment For RRMS

- ***Late-breaking presentation of BRAVO results and additional analyses from ALLEGRO study reinforce novel clinical profile of laquinimod***
- ***Pre-clinical evidence supports that laquinimod targets peripheral inflammation and key neurodegenerative processes occurring directly in the CNS***

JERUSALEM & LUND, Sweden--(BUSINESS WIRE)--October 18, 2011--Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced the presentation of Phase III clinical and pre-clinical data, which collectively demonstrate that once-daily oral laquinimod modulates the pathological processes of multiple sclerosis to impact disease activity, disability progression and brain volume loss. The data will be featured in more than 20 scientific posters and presentations this week at the 5th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS) in Amsterdam, The Netherlands.

Findings from the second Phase III study, BRAVO, being highlighted as late-breaking research, showed that at 24-months, the primary endpoint of reduction in annualized relapse rates (ARR) did not reach statistical significance (0 = 0.075); however, after applying a pre-specified sensitivity analysis to correct for meaningful imbalances in baseline characteristics (MRI) between treatment groups, laquinimod significantly reduced ARR (21.3%, p = 0.026). Laquinimod also demonstrated a significant reduction in the risk of disability progression as measured by the Expanded Disability Status Scale (EDSS) (33.5%, p = 0.044) and in MRI-measured brain volume loss (27.5%, p =< 0.0001). The safety and tolerability profile of laquinimod was favorable.

New exploratory analyses from ALLEGRO, the first Phase III study in the laquinimod clinical development program, demonstrated that laquinimod had an effect on the rate of severe relapses, showing a 38 percent reduction in the annualized rate of relapses requiring hospitalization and a 27 percent reduction in those requiring intravenous steroids. Treatment with laquinimod was also associated with a 36 percent reduction in the risk for three month confirmed EDSS progression (p=0.0122) and a 48 percent reduction in the risk for six month confirmed EDSS progression (p= 0.0023). Additionally, laquinimod had a positive impact on patient-reported fatigue and cognitive functioning, as assessed by the Modified Fatigue Impact Scale (MFIS) and the short-form (SF)-36 general health survey.

“The life-long, debilitating nature of multiple sclerosis and well-recognized clinical variability, underscore the need for therapies that can slow disease progression and improve patient treatment experience,” said **Professor Giancarlo Comi**, Director of the Department of Neurology and Institute of Experimental Neurology at the San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Italy. "Both the ALLEGRO and BRAVO studies provide consistent evidence of a clear impact of laquinimod on progression of disability and brain atrophy, measures of the neurodegenerative process of MS. These effects on disease burden, together with the effects on relapse management, the convenience of oral administration and the excellent safety and tolerability profile represent a unique approach to the treatment of MS.”

“Several supportive pre-clinical studies being presented further elucidate the potential novel mechanisms of action of laquinimod, which target both neurodegeneration occurring directly in the CNS and peripheral inflammation,” said **Wolfgang Brück, M.D**., Director of Neuropathology at Georg-August-University in Goettingen, Germany. “The cuprizone and EAE mouse model studies showed that laquinimod reduced demyelination, axonal damage and resulted in dose-dependent decreases in pro-inflammatory cytokines, further demonstrating that the compound acts directly on resident CNS cells to decrease neurodegeneration and brain volume loss.”

“The data presented at ECTRIMS contribute to the growing body of scientific evidence supporting the novel clinical profile of laquinimod,” said **Jon Congleton**, Teva’s Vice President, Global Strategic Marketing. “We are excited by the prospect of laquinimod providing a treatment option that addresses important attributes of RRMS therapy, namely reduction of disability progression and irreversible tissue loss, without compromising convenience, safety or

tolerability."

ABOUT LAQUINIMOD

Laquinimod is an oral, once-daily CNS-active immunomodulator with a novel mechanism of action being developed for the treatment of MS. Laquinimod crosses the blood brain barrier to potentially have a direct effect on resident CNS inflammation and neurodegeneration. The global Phase III clinical development program evaluating oral laquinimod in MS consists of two pivotal studies, ALLEGRO and BRAVO. In the ALLEGRO study, laquinimod demonstrated a positive impact on disease activity and disability progression, while maintaining a favorable safety and tolerability profile. In addition to the MS clinical studies, laquinimod is currently in Phase II development for Crohn's disease and Lupus, and is being studied in other autoimmune diseases.

ABOUT MULTIPLE SCLEROSIS

MS is the leading cause of neurological disability in young adults. It is estimated that more than 400,000 people in the United States are affected by the disease and that two million people may be affected worldwide. Multiple sclerosis is a degenerative disease of the central nervous system in which inflammation and axonal damage and loss result in the development of progressive disability.

ABOUT TEVA

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,300 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 45,000 people around the world and reached $16.1 billion in net sales in 2010.

ABOUT ACTIVE BIOTECH

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in or entering pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, TASQ for prostate cancer as well as ANYARA for use in cancer targeted therapy, primarily of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn's and Lupus. Further projects in clinical development comprise the two orally administered compounds, 57-57 for SLE & Systemic Sclerosis and RhuDex™ for RA. Please visit www.activebiotech.com for more information.

Teva's 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, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic version of Protonix®, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone® (including potential generic and oral competition for Copaxone®), the impact of continuing consolidation of our distributors and

customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of Cephalon), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in our Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission.

Active Biotech's Safe Harbor Statement in Accordance with the Swedish Securities Market Act:

This press release contains certain forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of the company, or industry results, to differ materially from any future results, performance or achievement implied by the forward-looking statements. The company does not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the date of this press release.

Active Biotech is obligated to publish the information contained in this press release in accordance with the Swedish Securities Market Act.

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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/ Eyal Desheh
Name: Eyal Desheh
Title: Chief Financial Officer

Date: October 19, 2011