

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

February 08, 2010

**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 February 2010

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):

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**For Immediate Release**

**Teva Acquires Marketing Rights for Oral Laquinimod  
in the Nordic and Baltic Regions**

***-- Teva Now Holds Worldwide Commercial Rights for Laquinimod --***

**JERUSALEM, ISRAEL, LUND, Sweden, February 8, 2010** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) announced today that they have amended the marketing and distribution agreement for oral laquinimod, an investigational treatment for relapsing-remitting multiple sclerosis (RRMS). Under the new agreement, Teva extended its marketing and distribution rights to include the Nordic and Baltic regions, previously held by Active Biotech. Active Biotech will receive a higher royalty rate for sales in these territories compared to the royalty rate set under the original licensing agreement signed in 2004 for

sales in the rest of the world.

"We are very excited about the market potential of laquinimod. We believe that laquinimod can be a leading oral therapy for MS as it has the potential to best combine the convenience of an oral formulation with a favorable efficacy, safety and tolerability profile. " said **Moshe Manor, Teva's Group VP, Global Branded Products**. "Licensing a promising new therapeutic option - as we did with laquinimod - is an excellent example of how we plan to execute our branded strategy and expand our innovative pipeline."

"After working with Teva since 2004 on developing laquinimod we believe that Teva is the optimal marketing and distribution partner in our territory," said **Tomas Leanderson, President & CEO Active Biotech**. "We are also very satisfied with the commercial opportunity this offers to Active Biotech", .

Two global Phase III clinical trials to evaluate the efficacy, safety and tolerability of laquinimod - ALLEGRO and BRAVO - have completed enrollment in November 2008 and June 2009, respectively, and are currently ongoing. In February 2009, laquinimod received Fast Track designation from the U.S. Food and Drug Administration (FDA), which may allow the drug to enter the market as soon as late 2011.

### **About Laquinimod**

Laquinimod is a novel once-daily, orally administered immunomodulatory compound that is being developed as a disease-modifying treatment for RRMS. Active Biotech developed laquinimod and licensed it to Teva Pharmaceutical Industries, Ltd. in June 2004. A Phase IIb study in 306 patients was published in *The Lancet* (June 2008) and demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by a median of 60 percent (51 percent mean reduction) versus placebo in RRMS patients. In addition, the study showed a favorable trend toward reducing annual relapse rates and the number of relapse-free patients compared with placebo. Treatment was well tolerated, with only some transient and dose-dependent increases in liver enzymes reported.

Laquinimod is currently in two Phase III clinical trials; ALLEGRO (assessment of oral laquinimod in preventing progression of MS) which is a pivotal, global, 24/30-month, double-blind, Phase III study designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of RRMS, and BRAVO (benefit-risk assessment of Avonex<sup>®</sup> and laquinimod) which is a pivotal, multinational, multi-center, randomized, double-blind, parallel-group, placebo-controlled study designed to compare the safety and efficacy of laquinimod with placebo and to provide risk-benefit data for laquinimod versus a currently available injectable treatment.

### **About Multiple Sclerosis**

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 over two million people may be affected

worldwide. MS is a progressive, demyelinating disease of the central nervous system affecting the brain, spinal cord and optic nerves. Demyelination is the destructive breakdown of the fatty tissue that protects nerve endings.

### **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 pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

### **About Active Biotech**

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in pivotal phase 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 targeted therapy, primarily of renal cancer. Further key projects in clinical development comprise the three orally administered compounds TASQ for prostate cancer, 57-57 for SLE and RhuDex(TM) for RA. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

*Active Biotech is obligated to publish the information contained in this press release in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on January 8, 2010 at 8:00 a.m.ET.*

### **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 versions of Neurontin®reg, Lotrel®reg, Protonix®reg and Eloxatin®reg, the current economic conditions, 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 effects of competition on our innovative products, especially Copaxone®reg sales, including potential oral and generic competition for Copaxone®reg, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, 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, the uncertainty

surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://www.tevapharm.com)

## **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 February 8, 2010

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