

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
June 14, 2004

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 June 2004

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

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

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.

Active Biotech AB

Web Site: www.tevapharm.com

Web Site: www.activebiotech.com

FOR IMMEDIATE RELEASE

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TEVA AND ACTIVE BIOTECH ANNOUNCE AGREEMENT FOR LAQUINIMOD POTENTIAL ORAL THERAPY FOR MULTIPLE SCLEROSIS

Jerusalem, Israel, and Lund, Sweden, June 14, 2004 - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) and Active Biotech AB (Stockholm: ACTLST) announced today that they have signed an agreement to develop and commercialize laquinimod, Active Biotech's novel immunomodulatory compound, which has the potential to be an orally available disease modifying treatment of multiple sclerosis (MS).

Under the terms of the agreement, which is subject to Hart-Scott-Rodino review and the applicable waiting period, Teva will acquire the exclusive rights to develop, register, manufacture and commercialize laquinimod worldwide, with the exception of the Nordic and Baltic countries, where Active Biotech will retain all commercial rights.

Active Biotech has successfully completed a Phase II trial and presented its results at the 2004 American Academy of Neurology (AAN) Annual Meeting held in San Francisco this past April. These results showed that oral laquinimod, in a dosage of 0.3 mg daily, is well tolerated and effective in suppressing the development of active lesions in relapsing MS. Teva intends to complete the clinical development program and will conduct Phase III studies.

"As a leader in the global MS Market, the addition of laquinimod to Teva's innovative pipeline further demonstrates our commitment to developing new classes of therapies for MS patients to treat their disease and improve their quality of life, while expanding our company's presence in the field of neurology," said Israel Makov, President & CEO of Teva Pharmaceutical Industries. "We are pleased to collaborate with a growing biotechnology company such as Active Biotech, who shares our dedication to sound science and innovation."

"Teva is our partner of choice as they are a market leader in the MS field and have a proven experience in clinical development in neurology. If laquinimod reaches the market, it will contribute to a better life for MS patients. A success of the laquinimod project would mean significant royalty streams to Active Biotech", said Sven Andréasson, President & CEO of Active Biotech.

Teva has agreed to make an upfront payment of 5 million USD to Active Biotech and to conduct and fund the further clinical development of laquinimod. The contract between the two companies also calls for Teva to make payments to Active Biotech upon the achievement of various milestones, which include sales targets. If such milestones were all to be met, payments to Active Biotech would aggregate to 92 million USD. Active Biotech will also receive tiered double digit royalties on sales of the product, once marketed.

About Laquinimod

Laquinimod is a novel immunomodulatory substance developed as an orally available disease modifying treatment of MS. The conclusion from a recently concluded Phase II study is that oral laquinimod in a dosage of 0.3 mg daily is

well tolerated and effective in suppressing development of active brain MRI lesions in relapsing MS. Treatment over six months with 0.3 mg of laquinimod daily resulted in a 30-percent decrease in MRI disease activity. Patients with disease activity at the start of the study showed a decrease of more than 40 percent. The study also confirmed laquinimod's advantageous safety profile.

About Multiple Sclerosis (MS)

Multiple sclerosis (MS) is a chronic, progressive disease of the central nervous system. It is the most common neurological disease causing disability in young adults. It has been described as an autoimmune disease because it is one of many diseases in which the immune system attacks healthy areas of the body as if they were foreign. In MS, these attacks are aimed at the central nervous system. The central nervous system is made up of nerves covered by a substance called *myelin*, which is similar to insulation protecting electrical wires because it surrounds and protects nerve fibers. When myelin or the nerve fiber is destroyed or damaged, the nerves cannot send electrical impulses to and from the brain, causing the onset of MS symptoms.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 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 percent 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.

About Active Biotech

Active Biotech is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio and pipeline products with focus primarily on autoimmune/ inflammatory diseases and cancer. Most advanced projects include orally administered small molecules with unique immunomodulatory properties that can be used to treat autoimmune and inflammatory diseases, as well as a novel concept for use in cancer immunotherapy.

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 current 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 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 their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, including its recent acquisition of Sicor Inc., the availability of product liability coverage in the current insurance 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 and other regulatory authority approvals, the

regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, 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: June 14, 2004

